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PTO Issues New Draft Guidance for Determining Patent-Eligible Subject Matter

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The United States Patent and Trademark Office (PTO) issued interim guidance for use by its personnel when determining patent-eligible subject matter under 35 U.S.C. § 101 (“Section 101”). The new guidance will alter the way patent examiners assess patent applications for subject matter eligibility, and may provide some relief to patent applicants and holders in the life sciences. The new guidance attempts to create a uniform approach to analyzing subject matter eligibility by incorporating the Supreme Court’s decisions in *Mayo*,¹ *Myriad*,² and *Alice*,³ which collectively addressed the law regarding subject matter eligibility for life sciences, software, and business methods.

The PTO also issued a series of updated examples that illustrate the latest guidance for natural products, and announced plans to issue additional examples for abstract ideas and software-related patents in the coming weeks.

The new guidance offers patent applicants new opportunities for pursuing patent protection. Patent applicants can begin referring to the new guidance immediately when drafting new applications and responding to rejections under Section 101. Where possible, applicants may also wish to file claim amendments or additional continuing patent applications to recoup subject matter ceded in view of the previous PTO guidelines. Applicants should also consider whether to file or maintain any appeals in view of this new guidance.

BACKGROUND

35 U.S.C. § 101 states that “[w]hoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor...” The Supreme Court has long held that this section of the Patent Act contains important exceptions: “laws of nature, natural phenomena, and abstract ideas” are not patent eligible.⁴ The Supreme Court has been very active in this area of law in the past few years, and its recent decisions have attempted to further refine what constitutes patent-eligible subject matter.⁵

¹ *Mayo Collaborative Serv. v. Prometheus Labs., Inc.*, 566 U.S. ___, 132 S. Ct. 1289 (2012).

² *Association for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. ___, 133 S. Ct. 2107 (2013).

³ *Alice Corp. Pty. Ltd. v. CLS Bank, Int'l*, 573 U.S. ___, 143 S. Ct. 2347 (2014).

⁴ See *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980); *O'Reilly v. Morse*, 56 U.S. 62 (1853); *Diamond v. Diehr*, 450 U.S. 175, 185 (1981); *Bilski v. Kappos*, 561 U.S. 593, 594 (2010).

⁵ See Client Alerts for *Mayo*, *Myriad*, and *Alice*.

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The PTO issued the new guidelines, entitled “2014 Interim Guidance on Patent Subject Matter Eligibility,” to provide patent examiners with specific procedures for determining subject matter eligibility in view of the latest judicial decisions. The new guidance supplements the June 25, 2014 “Preliminary Examination Instructions in view of the Supreme Court decision in *Alice Corp*” and supersedes the March 4, 2014 “Procedure For Subject Matter Eligibility Analysis Of Claims Reciting Or Involving Laws Of Nature/Natural Principles, Natural Phenomena, And/Or Natural Products.” The PTO noted that many of the changes presented in the new guidelines were made in response to public comments concerning the original March 2014 procedure.

The PTO published the new guidance, which is effective immediately, in the *Federal Register* on December 16, 2014.⁶

THE NEW PROCEDURE

The new guidance alters the process of determining subject matter eligibility previously established in March 2014. As with the previous procedure, an examiner must begin by determining a claim’s broadest reasonable interpretation. The examiner can then proceed to the first step in the analysis, which asks whether the claim is directed to one of the four categories recited in Section 101: processes, machines, manufactures, or compositions of matter. A claim that is not directed to one of these categories is not patent eligible under the statute, and the examiner can stop the analysis here.

If the claim is directed to one of these categories, the examiner next proceeds to analyze the claim’s eligibility using the two-part test announced in *Alice* (also called the *Mayo* test).⁷ In the first part, the examiner determines whether the claim is directed to a judicially recognized exception.⁸ Judicially recognized exceptions include abstract ideas, laws of nature, natural phenomena, and natural products. A claim that does not include a judicially recognized exception is patent eligible and the analysis is complete.

Furthermore, for any claim that includes one or more nature-based product limitations, the examiner must determine whether the nature-based product limitation(s) exhibit “markedly different characteristics” from their closest naturally occurring counterpart(s).⁹ The markedly-different-characteristics analysis should be applied only to the nature-based product limitations themselves. While the previous guidance relied on structural differences for this analysis,¹⁰ examiners can now also consider functional differences or other properties when determining whether a product is markedly different.¹¹

⁶ 2014 Interim Guidance on Patent Subject Matter Eligibility, 79 Fed. Reg. 74618 (Dec. 16, 2014).

⁷ *Alice Corp.*, 134 S. Ct. at 2355.

⁸ Guidance, 79 Fed. Reg. at 74621.

⁹ *Id.* at 74623.

¹⁰ 2014 Procedure For Subject Matter Eligibility Analysis Of Claims Reciting Or Involving Laws Of Nature/Natural Principles, Natural Phenomena, And/Or Natural Products, THE UNITED STATES PATENT AND TRADEMARK OFFICE (Mar. 4, 2014), http://www.uspto.gov/patents/law/exam/myriad-mayo_guidance.pdf, at 4-5.

¹¹ Guidance, 79 Fed. Reg at 74623.

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Examiners must conduct the markedly-different-characteristics analysis on a case-by-case basis, as even a small change can qualify.¹² For example, a composition of matter that combines two or more nature-based products is patent eligible if the combination exhibits markedly different characteristics from the individual components as they exist in nature. The PTO uses a claim directed to gunpowder to illustrate a patent-eligible combination of two or more nature-based products. Gunpowder's constituent components—namely potassium nitrate, charcoal, and sulfur—are not explosive when isolated from each other. Yet these components become highly explosive when mixed together in a specific manner. The PTO says this mixture constitutes patent-eligible subject matter because the components do not occur together in nature, and the explosive characteristics of the mixture are markedly different properties from those of the individual components.¹³

Likewise, a purified or isolated product will be eligible when there is a resultant change in characteristics sufficient to show a marked difference from the product's naturally occurring counterpart.¹⁴ In the PTO's earlier guidance, certain compositions of matter, such as proteins or minerals, automatically failed this prong of the test and had to undergo further analysis. The new guidance provides that a claim directed to a purified or isolated composition of matter is patent eligible when the purification or isolation changes the composition's characteristics sufficiently to show a marked difference from the product's naturally occurring counterpart.¹⁵

A determination that a claim has markedly different characteristics means that the claim does not fall into the product of nature exception and is therefore patent eligible.¹⁶ The subject-matter-eligibility analysis is thus complete. However, if the claim recites a product that does not include markedly different characteristics from the product's naturally occurring counterpart, the claim is directed to a judicial exception and the examiner must proceed to the second part of the *Mayo* analysis.

Here, the examiner determines whether the claim as a whole includes an "inventive concept."¹⁷ The inventive-concept analysis requires the examiner to determine whether an element or combination of elements is "sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the [ineligible concept] itself."¹⁸ The PTO guidance instructs examiners to determine whether a claim as a whole recites additional features that represent "more than a drafting effort designed to monopolize the [judicial] exception."¹⁹ The guidance lists several examples of such drafting efforts from case law, including the method claim at issue in *Mayo*. The Supreme Court determined the claims at issue in *Mayo* were merely directed to applying the judicial exception²⁰ or included insignificant extra-solution activity, such as data gathering in conjunction with the law of

¹² *Id.*

¹³ *Nature-Based Products*, THE UNITED STATES PATENT AND TRADEMARK OFFICE (Mar. 4, 2014), http://www.uspto.gov/patents/law/exam/mdc_examples_nature-based_products.pdf, at 1.

¹⁴ Guidance, 79 Fed. Reg. 74623.

¹⁵ *Id.*

¹⁶ *Id.* at 74623-74624.

¹⁷ *Mayo*, 132 S. Ct. at 1294.

¹⁸ *Id.*

¹⁹ Guidance, 79 Fed. Reg. 74624.

²⁰ *Mayo*, 132 S. Ct. at 1301.

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nature.²¹ In this circumstance, the claim is not patent eligible, and the examiner should reject it under Section 101. Conversely, if the claim recites significantly more than the judicial exception itself, the claim is patent eligible.²²

The guidance indicates that claims that recite more than one judicial exception must proceed through the analysis one limitation at a time.²³ Any limitation that fails to recite something significantly different from a judicial exception invalidates the entire claim.²⁴ However, additional elements that satisfy the “inventive-concept” analysis might apply to all judicial exceptions within the same claim.²⁵

The new guidance does not dramatically change how the PTO will evaluate software patents. The guidance largely implements the holding and analysis proffered in *Alice*, while taking into account the Federal Circuit’s recent holdings in *Ultramercial* and *Digitech*.²⁶ The PTO will release examples of what it deems both patent-eligible and ineligible claims in the coming weeks.

A STREAMLINED APPROACH

In addition to the full subject-matter-eligibility analysis described above, the interim guidance now also allows examiners to use a streamlined analysis where a claim’s patent eligibility is “self-evident.”²⁷ Examiners can distinguish between claims that attempt to monopolize a judicial exception from claims that merely involve a judicial exception but when viewed as a whole clearly do not seek to tie up any judicial exception such that others cannot practice it.²⁸ Life science patent applicants and holders criticized the March guidance for requiring an examiner to analyze all products derived from natural sources, including chemicals, nucleic acids, proteins, peptides, bacteria, and antibiotics, regardless of claim scope.²⁹ The streamlined analysis applies to claims that merely recite one of these nature-based product limitations without seeking to monopolize the judicial exception itself, and therefore reduces the number of claims that must undergo the full analysis.

The PTO provides examples of claims eligible for this new approach, including “a robotic arm assembly having a control system that operates using a certain mathematical formula” and “an artificial hip prosthesis coated with a naturally occurring mineral.”³⁰ An examiner does not have to undertake a complete “markedly-different-

²¹ *Id.* at 1297-98.

²² Guidance, 79 Fed. Reg 74624.

²³ *Id.* at 74625.

²⁴ *Id.*

²⁵ *Id.*

²⁶ *Id.* at 74631.

²⁷ *Id.* at 74625.

²⁸ *Id.*

²⁹ 2014 Procedure For Subject Matter Eligibility Analysis Of Claims Reciting Or Involving Laws Of Nature/Natural Principles, Natural Phenomena, And/Or Natural Products, THE UNITED STATES PATENT AND TRADEMARK OFFICE (Mar. 4, 2014), http://www.uspto.gov/patents/law/exam/myriad-mayo_guidance.pdf, at 3.

³⁰ Guidance, 79 Fed. Reg 74625.

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characteristics” analysis in either of these cases because “such claims do not attempt to improperly tie up the nature-based product.”³¹

This guidance provides for a broadening of the law, particularly in the life sciences space. However, Section 101 will likely remain at the forefront of patent law for the foreseeable future. This area of law continues to evolve quickly as the Federal Circuit and lower courts begin to apply recent cases.

OPPORTUNITY TO COMMENT

The PTO is currently soliciting public comments on the new interim guidance. Those wishing to submit comments may do so electronically until March 16, 2015, by following the instruction posted on the PTO website.³² The PTO will also host a public forum to introduce the new guidance and receive feedback from any interested member of the public on January 21, 2015.³³

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Because of the generality of this update, the information provided herein may not be applicable in all situations and should not be acted upon without specific legal advice based on particular situations. Prior results do not guarantee a similar outcome.

³¹ *Id.*

³² 2014 Interim Guidance on Subject Matter Eligibility, THE UNITED STATES PATENT AND TRADEMARK OFFICE (Dec. 15, 2014), http://www.uspto.gov/patents/law/exam/interim_guidance_subject_matter_eligibility.jsp.

³³ *Id.*