

U.S. Patent Office Releases New Guidelines for Determining Subject Matter Eligibility

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By: P. Brian Giles and Anthony J. Zucchero

On December 15, 2014, the U.S. Patent and Trademark Office (PTO) released its *2014 Interim Guidance on Patent Subject Matter Eligibility* (the “*Interim Guidance*”).¹ The new *Interim Guidance* establishes a streamlined approach for determining subject matter eligibility along with some examples applying this approach to nature-based product claims. The PTO is accepting comments on the *Interim Guidance* until March 16, 2015, and plans to release additional examples and refinements in the future. We will likely have to wait for future court decisions to sufficiently resolve much of the ambiguity surrounding subject matter eligibility. In the meantime, the *Interim Guidance* provides useful direction that should allow practitioners to obtain commercially valuable claims for previously contentious subject matter, including nature-based products, diagnostics, and computer-implemented methods.

Some discoveries are not eligible for patent protection. This subject matter eligibility threshold emerges from the statutory requirement codified in 35 U.S.C. § 101 that a claimed invention be directed to a process, machine, manufacture, or composition of matter. The courts have further established a judicial requirement (exception) that the claimed invention not be wholly directed to a law of nature, physical phenomenon (product of nature), or abstract idea.²

Since the landmark 1980 Supreme Court decision in *Diamond v. Chakrabarty*, which noted that “Congress intended statutory subject matter to include anything under the sun that is made by man,”³ patent practitioners have generally viewed the subject matter eligibility requirement as a “coarse filter” that seldom restricts patentability. This understanding was turned on its head when the U.S. Supreme Court held in *Mayo Collaborative Serv. v. Prometheus Labs.* (“*Mayo*”) that the correlation between drug metabolite levels and the toxicity/efficacy of the drug is a law of nature or natural phenomenon that is not by itself patent eligible.⁴ Shortly thereafter, the U.S. Supreme Court further held in the *Association for Molecular Pathology v. Myriad Genetics* (“*Myriad*”) that a naturally occurring DNA segment is a product of nature and not patent eligible merely because it has been isolated.⁵ These decisions have created significant ambiguity for patent practitioners and patent Examiners alike.

On March 4, 2014, the PTO released a memorandum (“*Guidance Memorandum*”) that attempted to guide Examiners on how to determine subject matter eligibility in view of the *Myriad* and *Mayo* decisions.⁶ This *Guidance Memorandum* was heavily criticized, especially for its treatment of natural products in view of *Myriad*. Many attorneys and industry groups argued that the *Guidance Memorandum* went too far in its interpretation of the Court’s analysis in

Myriad. In particular, critics argued that the *Guidance Memorandum* erred by requiring that naturally derived products, such as biologics, small molecules, and vaccines, possess significant structural differences from their naturally occurring counterparts in order to be patent eligible, while not adequately weighing functional differences that may exist between naturally derived products and their naturally occurring counterparts.

As an example, the *Guidance Memorandum* implied that gunpowder would be patent ineligible because the term ‘gunpowder’ encompasses a mixture of naturally occurring components (potassium nitrate, sulfur and charcoal) that are “not markedly different” in structure from their naturally occurring counterparts.⁷ However, this analysis ignored the obvious functional differences between gunpowder and naturally occurring potassium nitrate, sulfur and charcoal. Likewise, the *Guidance Memorandum* concluded that a claim to a beverage composition comprising naturally occurring pomelo juice and a preservative would not be patent-eligible, because such a claim would encompass a mixture of two naturally occurring substances (e.g., pomelo juice and vitamin E) that do not combine together in a way that creates a structural difference from what exists in nature.⁸ However, this analysis ignored potential differences between the properties of the beverage composition and naturally occurring pomelo juice and vitamin E. Based on the reasoning presented in the pomelo juice example, a pharmaceutical composition including a natural product and a pharmaceutically acceptable excipient would likely be determined to be patent ineligible. Needless to say, the *Guidance Memorandum* provoked significant criticism from many attorneys and industry groups.

Following the U.S. Supreme Court’s ruling in *Alice Corp. Pty. Ltd. v. CLS Bank Int’l*, which related to the subject matter eligibility of claims directed to an abstract idea,⁹ the PTO issued new guidelines in view of *Alice Corp.* (the “*Alice Guidance*”) on June 25, 2014. The *Interim Guidance* supplements the *Alice Guidance* and supersedes the *Guidance Memorandum*. The *Interim Guidance* seeks to provide a comprehensive view of subject matter eligibility in view of *Mayo*, *Myriad*, and *Alice Corp.*

The *Interim Guidance* begins with a two-step analysis for subject matter eligibility. The first step (“Step 1”) is to determine whether the claim satisfies the statutory requirement of being directed to a process, machine, manufacture, or composition of matter.¹⁰ If the answer is yes, then the second step (“Step 2”) is to determine whether the claim is “wholly directed to subject matter encompassing a judicially recognized exception.”¹¹ To accomplish this second step, the *Interim Guidance* applies the two-part framework from *Alice Corp.* and *Mayo* (referred to as the “*Mayo test*”). The first part of the *Mayo test* (“Step 2A” in the *Interim Guidance*) is to determine whether the claim is “directed to” a law of nature, natural phenomenon, or abstract idea, which occurs when one of these judicial exceptions are “recited (i.e., set forth or described)” in the claim.¹² According to the *Interim Guidance*, “Such a claim requires closer scrutiny for eligibility because of the risk that it will ‘tie up’ the excepted subject matter and pre-empt others from using the law of nature, natural phenomenon, or abstract idea.”¹³ Therefore, if the answer is yes, the second part of the *Mayo test* (“Step 2B” in the *Interim Guidance*) is to evaluate

whether the claim recites additional elements that amount to significantly more than the judicial exception.

In regard to Step 2A, the *Interim Guidance* is largely silent on how to evaluate whether a claim is “directed to” a law of nature or an abstract idea. The *Interim Guidance* does, however, provide an additional test to determine whether a claim to a nature-based product is “directed to” a natural phenomenon. To determine whether a claim recites a “product of nature” exception, the claimed product should be compared to its naturally occurring counterpart to determine if there are “markedly different” characteristics based on structure, function, and/or properties. Note that the prior *Guidance Memorandum* focused exclusively on structural differences. As a consequence, the *Interim Guidance* recognizes the patent eligibility of gunpowder based on its markedly different functional properties¹⁴, and a beverage composition comprising pomelo juice and a natural preservative based on its markedly different property of slower spoiling.¹⁵

Once a claim is found to be “directed to” a judicial exception, Step 2B requires analysis of whether the claim contains additional elements that amount to “significantly more” than the judicial exception itself. The *Interim Guidance* provides the following examples of limitations that would qualify as “significantly more”: improvements to another technology or technical field;¹⁶ improvements to the functioning of a computer itself;¹⁷ applying the judicial exception with, or by use of, a particular machine;¹⁸ effecting a transformation or reduction of a particular article to a different state or thing;¹⁹ adding a specific limitation other than what is well-understood, routine and conventional in the field, or adding unconventional steps that confine the claim to a particular useful application;²⁰ or other meaningful limitations beyond generally linking the use of the judicial exception to a particular technological environment.²¹

In order to demonstrate consistency of the framework with existing case law, the *Interim Guidance* applies its framework to claims from prior Supreme Court and Federal Circuit decisions.²² As with the prior *Guidance Memorandum*, the PTO also provided additional hypothetical examples for nature-based products to aid Examiners in assessing subject matter eligibility during examination. The conclusions reached in these examples are reasonable and more consistent with current case law; however, as with prior guidelines, the PTO largely refrained from addressing scenarios not yet considered by the courts.

While not comprehensive, the *Interim Guidance* does provide some useful examples illustrating how to apply its framework to nature-based product claims. The PTO has not yet provided examples applying its framework to claims involving abstract ideas or natural laws; however, they plan to do so in the future. Even so, it is unlikely that any future examples provided by the PTO will resolve all of the ambiguity surrounding subject matter eligibility. Until further clarity is provided by additional court decisions, we expect significant diversity in the way Examiners evaluate subject matter eligibility during examination.

On a positive note, the new *Interim Guidance* provides a more concise and tempered approach for determining subject matter eligibility than the much maligned *Guidance Memorandum*. With the *Interim Guidance* in hand, practitioners should now be able to pursue a variety of strategies to obtain commercially valuable claims for previously contentious subject matter, including nature-based products, diagnostics, and computer-implemented methods. We recommend that practitioners employ several of these strategies in parallel to protect against any future changes in the subject matter eligibility landscape.

For more information, please contact:



P. Brian Giles, Ph.D., J.D.
Associate

bgiles@mcciplaw.com



**Anthony J. 'A.J.' Zuccherro,
Ph.D.**
Patent Agent

azuccherro@mcciplaw.com

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¹ 2014 Interim Guidance on Patent Subject Matter Eligibility, 79 Fed. Reg. 74618 (Dec. 16, 2014).

² See *Bilski v. Kappos*, 130 S. Ct. 3218, 3225 (2010); *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980).

³ *Chakrabarty*, 447 U.S. at 308 (internal citations and quotations omitted).

⁴ *Mayo Collaborative Serv. v. Prometheus Labs., Inc.*, 132 S.Ct. 1289 (2012).

⁵ *Association for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S.Ct. 2107 (2013).

⁶ Guidance For Determining Subject Matter Eligibility Of Claims Reciting Or Involving Laws of Nature, Natural Phenomena, & Natural Products (March 4, 2014), http://www.uspto.gov/patents/law/exam/myriad-mayo_guidance.pdf.

⁷ *Id.* at 9–10.

⁸ Evaluating Subject Matter Eligibility Under 35 USC § 101: March 2014 Update (March 19, 2014), http://www.uspto.gov/patents/law/exam/myriad-mayo_slides_20140319.pdf.

⁹ *Alice Corp. Pty. Ltd. v. CLS Bank Int'l*, 134 S.Ct. 2347 (2014) (addressing whether claims directed to a computer-implemented, electronic escrow service for facilitating financial transactions concern abstract ideas ineligible for patent protection).

¹⁰ 35 U.S.C. § 101

¹¹ *Interim Eligibility Guidance* at 74621.

¹² 79 Fed. Reg. at 74622.

¹³ *Id.* (internal citations omitted).

¹⁴ Nature-Based Products (December 2014), http://www.uspto.gov/patents/law/exam/mdc_examples_nature-based_products.pdf.

¹⁵ *Id.* at 2

¹⁶ 79 Fed. Reg. at 74624 (citing *Alice Corp.*, 134 S. Ct. at 2359; *Diamond v. Diehr*, 450 U.S. 175, 177–78 (1981)).

¹⁷ *Id.* (citing *Alice Corp.*, 134 S. Ct. at 2359).

¹⁸ *Id.* (citing *Bilski*, 130 S. Ct. at 3227).

¹⁹ *Id.* (citing *Diehr*, 450 U.S. at 184).

²⁰ *Id.* (citing *Mayo*, 132 S. Ct. at 1299, 1302).

²¹ *Id.* (citing *Alice Corp.*, 134 S. Ct. at 2360).

²² Notably, the *Interim Guidance* did not apply its framework to the facts in *Classen Immunotherapies, Inc. v. Biogen IDEC*, 659 F.3d 1057 (Fed. Cir. 2011) (holding that a further step of immunization in accordance with a determined lower-risk schedule moved an abstract scientific principle to a specific application), *cert. denied*, 133 S. Ct. 973 (2013).