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Recent PTO Guidance Charts a New Course Through the Patent Eligibility Quagmire

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38 Biotechnology Law Report 341
Number 6, 2019

DOI: 10.1089/blr.2019.29152.cmh

Recent PTO Guidance Charts a New Course Through the Patent Eligibility Quagmire

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In a span of four years, 2010–2014, the U.S. Supreme Court issued four decisions that have dramatically altered patent eligibility jurisprudence: *Bilski*, *Mayo*, *Myriad*, and *Alice*.[1] Prior to *Bilski*, the perceived scope of patentable subject matter in the U.S., as set forth in decisions of the Court of Appeals of the Federal Circuit, appeared to encompass nearly any innovation that could be claimed as a product or process, so long as it provided some "useful, concrete, and tangible result."[2] *Bilski* announced a substantial heightening of the bar, rendering patent eligibility a substantial hurdle to be overcome by those seeking to patent some innovations that prior to *Bilski* had easily satisfied the standard, particularly with respect to business methods and information technology. The *Myriad* and *Mayo* decisions explicitly expanded the heightened stringency into the realm of biotechnology, rendering patent eligibility a significant, if not insurmountable, bar to the patenting of important innovations in the life sciences, particularly those involving diagnostics and natural products.

Alice represented the culmination of this jurisprudential shift, establishing the current framework for assessing patent eligibility, commonly referred to as the *Alice/Mayo* test or framework (I will refer to it as simply the *Alice* test). This test consists of two steps. Step 1 asks whether the claim as a whole is "directed to" one of the judicial exceptions to patent eligibility established in earlier Supreme Court precedent, *i.e.*, an abstract idea, law of nature, or natural phenomena. If the answer is yes, the inquiry proceeds to Step 2, which asks whether the claimed invention incorporates enough "more," beyond the judicial exception, to justify patent eligibility. Step 2 is often referred to as a search for an "inventive concept," which generally requires the exclusion of elements that would not be considered "well-understood, routine, and conventional" at the time of invention. If the answer to Step 2 is no, *i.e.*, the claim lacks sufficient inventive concept, the claim recites patent ineligible subject matter, and is unpatentable irrespective of how useful and non-obvious the subject matter might be.

The *Alice* test arose out of decisions involving process claims, and is of questionable use in assessing the patent eligibility of products. Some Federal Circuit decisions have explicitly found that the *Alice* test is not the appropriate test for a claim directed towards a natural product, and that instead *Myriad* should be applied to natural products. *Myriad* is the only decision out of the four to address the patent eligibility of product claims, and it held that a product is only patent eligible if it possesses "markedly different characteristics" than any naturally occurring counterpart. These characteristics can be structural and/or functional. The U.S. Patent and Trademark Office (PTO), on the other hand, instructs its examiners to apply the *Alice* test to both product and process claims. In the case of product claims, the PTO incorporates *Myriad*'s "markedly different characteristics" test into Step 1 of the *Alice* test.

Ever since *Bilski* was decided, the PTO has struggled to apply the new patent eligibility jurisprudence

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[1] *Bilski v. Kappos*, 561 U.S. 593 (2010), *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66 (2012), *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576 (2013), *Alice Corp. Pty. v. CLS Bank Int'l*, 573 U.S. 208 (2014).

[2] *See, e.g.*, *State Street Bank & Trust Co. v. Signature Financial Group, Inc.*, 149 F.3d 1368, 1373 (Fed. Cir. 1998), *and AT&T Corp. v. Excel Communications, Inc.*, 172 F.3d 1352, 1357 (Fed. Cir. 1999).

in a consistent and predictable manner. The *Alice* test is stated at a high level of abstraction, and the Supreme Court has given little concrete guidance as to how it is to be applied beyond the specific claims at issue in its precedent. At times, the Supreme Court's explanation of patent eligibility seems internally inconsistent, for example with respect to method of treatment claims. Judges on the Federal Circuit have complained that Supreme Court precedent, particularly the *Mayo* decision, denies patent eligibility to some of the most important innovation occurring in medicine, particularly in the realm of diagnostics and personalized medicine, which could not have been what the Supreme Court intended.[3] There have been increasing calls for the Supreme Court or Congress to intervene and straighten out what many consider to be a mess, including many of the judges on the Federal Circuit.[4]

Former chief judge of the Federal Circuit Paul Michel filed an *amicus curiae* brief with the Supreme Court on his own behalf urging the Court to grant *certiorari* in a recent Federal Circuit decision that found an important medical diagnostic innovation patent ineligible under *Mayo*, and to revise its patent eligibility jurisprudence in a manner that allows for the patentability of diagnostic methods of the type at issue in the case, and other important innovations in biotechnology. In the words of Judge Michel, the "Federal Circuit's menagerie of patent-eligibility decisions over the past decade are devoid of any semblance of consistency [, and] have created an unbounded and detrimental uncertainty in biotechnology innovation. ... [T]he utter doctrinal confusion has created a legal quagmire that impedes technological progress and the societal benefits that flow from groundbreaking innovation."[5]

The PTO in particular has struggled to implement the Supreme Court's recent patent eligibility jurisprudence.[6] The PTO has no authority to make substantive law, and is required to do its best to apply the patent law as it has been interpreted by the courts. The PTO employs thousands of patent examiners, many of whom are non-attorneys, and it is important to provide guidance that allows these examiners to apply the new test for patent eligibility in a fair, predictable, and consistent manner. This became an incredibly difficult undertaking in the wake of *Bilski* and its progeny.

The PTO has responded to the challenge by issuing a series of guidance documents for use by its examiners in assessing patent eligibility, along with examples applying the guidance to specific hypothetical claims, mostly involving information technology and biotechnology. This guidance has been revised with each Supreme Court decision, and continues to evolve as the Federal Circuit issues precedential opinions applying the new patent eligibility standard in a variety of contexts. After *Alice* was decided in 2014, for example, the PTO issued its *2014 Interim Guidance on Patent Subject Matter Eligibility* (2014 IEG).[7] This was followed by the *July 2015 Update On Subject Matter Eligibility*, the *May 2016 Subject Matter Eligibility Update*, the *2016 Memoranda On Subject Matter Eligibility Decisions*, the *December 2016 Business Method Example Update*, and the *2018 Memoranda and Notice on Subject Matter Eligibility Decisions*.[8]

All of the guidance documents issued prior to January 2018 have been incorporated into the latest edition of the Manual of Patent Examining Procedure (MPEP).[9] The PTO has stated that any guidance issued prior to January 2018 should not be relied upon.

On January 7, 2019, the PTO issued its *2019 Revised Patent Subject Matter Eligibility Guidance* (2019 PEG),[10] which refines and clarifies some aspects of the guidance provided in the MPEP, most particularly with respect to the assessment of whether a claim or claim element is "directed to" a judicial exception. The public was invited to comment on the 2019 PEG, and in October the PTO released its *October 2019 Update: Subject Matter Eligibility*,[11] which responds to comments received with further explanation and examples, with the focus on clarifying practice for patent examiners. This Report offers an assessment of where things stand after the *October 2019 Update* with respect to examination for patent eligibility at the PTO.

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[3] *See, e.g., Athena Diagnostics, Inc. v. Mayo Collaborative Servs.*, 927 F.3d 1333 (Fed. Cir. 2019).

[4] *Id.*

[5] Brief of the Hon. Paul R. Michel (Ret.) as *Amicus Curiae* in Support of Petitioners, *Athena Diagnostics, Inc. v. Mayo Collaborative Servs.*, U.S. Supreme Court Docket No. 19-430 (Nov. 1, 2019).

[6] 84 Fed. Reg. 50 (Jan. 7, 2019).

[7] 79 Fed. Reg. 74618 (Dec. 16, 2014).

[8] *Subject Matter Eligibility (Examination Guidance by Date of Issuance)*, USPTO.GOV, https://www.uspto.gov/patent/laws-and-regulations/examination-policy/subject-matter-eligibility-examination-guidance-date

[9] MANUAL OF PATENT EXAMINING PROCEDURE (MPEP) § 2601 (9th ed., revision 08.2017, revised January 2018).

[10] 84 Fed. Reg. 50 (Jan. 7, 2019).

[11] 84 Fed. Reg. 55942 (Oct. 18, 2019).

MPEP § 2106

The MPEP sets forth a two-step process for examiners to assess whether a patent claim qualifies as eligible subject matter under 35 U.S.C. § 101, illustrated by a flow chart.[12] Beginning with Step 1, the examiner is to assess whether the claim is directed towards one of the four categories of statutory patent eligible subject matter explicitly set forth in Section 101, *i.e.*, a process, machine, manufacture, or composition of matter. If not, the claim is not patent eligible. If the answer to Step 1 is yes, the examiner is directed to consider whether the patent eligibility of the claim is self-evident; if that is the case, the examiner can decide that the claim qualifies as patent eligible subject matter without engaging in any further analysis. The MPEP refers to this as "streamlined" analysis.[13] If the analysis cannot be streamlined in this way, the examiner is directed to proceed to Step 2, which is broken down into two parts. Step 2A asks whether the claim is "directed to" a judicial exception, *i.e.*, a law of nature, a natural phenomenon (product of nature), or an abstract idea. If not, the claim is patent eligible. If the claim is found to be directed to a judicial exception, the examiner is to proceed to Step 2B, which asks whether the claim recites additional elements that amount to "significantly more" than the judicial exception, *i.e.*, an inventive concept. If the answer is yes, the claim is patent eligible, if not, the claim is directed towards subject matter that is not patent eligible.

Step 2A begs the question of what it means for a patent claim to be "directed to" a judicial exception. This is the language used by the Supreme Court in *Mayo* and *Alice*, but the Court has provided little in the way of guidance as to what it means for a patent claim to be "directed to" a judicial exception. The MPEP states that a "claim is directed to a judicial exception when a law of nature, a natural phenomenon, or an abstract idea is recited (*i.e.*, set forth or described) in the claim."[14] The MPEP goes on to clarify that a claim can "recite" a judicial exception in one of two ways, either by "setting forth" the exception, or by "describing" the exception. A claim "sets forth" an exception when it contains discrete language identifiable as a judicial exception. Examples include the mathematical equation set forth in the repetitively calculating step in the claims at issue in *Diehr*, and the law of nature set forth in the "wherein clause" in the *Mayo* claims.[15] The MPEP points to the claims at issue in *Alice* as an example in which the patent ineligible concept of intermediated settlement was "described" despite the fact that the claims do not explicitly use the words "intermediated" or "settlement."[16]

While the language cited above suggests that "directed to" equates with "recites," elsewhere the MPEP states that "[s]ome claims reciting an abstract idea are not directed to the abstract idea because they also recite additional elements (such as an improvement) demonstrating that the claims as a whole clearly do not seek to type the abstract idea. In such claims, the improvement, or other additional elements, shifts the focus of the claimed invention from the abstract idea that is incidentally recited."[17] Taken in whole, the MPEP appears to be saying that a claim is "directed to" a judicial exception if it recites that judicial exception, unless the judicial exception is only "incidentally recited." For guidance as to what it means for a judicial exception to be only "incidentally recited," the MPEP points to MPEP §§ 2106.05(a) and 2106.06(b) for examples of the "types of improvements that the courts have identified as indicative of eligibility in the first step of the *Alice/Mayo* test (Step 2A)."[18] These sections of the MPEP provide examples of Federal Circuit decisions in which the Federal Circuit found that a patent claim reciting a judicial exception was nonetheless not directed towards that exception because the claim provided a technological solution to a technological problem, such as improved computer functionality.

2019 REVISED PATENT SUBJECT MATTER ELIGIBILITY GUIDANCE

On January 7, 2019, the PTO issued its *2019 Revised Patent Subject Matter Eligibility Guidance* (2019 PEG), refining and clarifying its guidance with respect to Step 2A in the eligibility analysis, which asks whether the claim is "directed to" a judicial exception.[19] The 2019 PEG explicitly supersedes MPEP § 2106.04(II), the section of the MPEP that addresses the PTO's Step 2A. The 2019 PEG applies to all applications, and to all patents resulting from applications, filed before, on, or after January 7, 2019, *i.e.*, it is being applied retroactively.[20] The 2019 PEG is intended to provide

[12]MPEP § 2106(III).
[13]*Id.*
[14]MPEP § 2106.04(II).
[15]*Id.* (citing *Diamond v. Diehr*, 450 U.S. 175 (1981)).
[16]*Id.*
[17]MPEP § 2106.04(a)(1)(II).
[18]*Id.*
[19]84 Fed. Reg. 50 (Jan. 7, 2019).
[20]*Id.*

greater clarity and predictability in the procedure for examining patent claims for subject matter eligibility, and it does so primarily by revising the examination procedure with respect to the PTO's Step 2A, which corresponds to the first step of the *Alice* test.[21] In particular, the 2019 PEG introduces two changes into the examination procedure by: (1) providing groupings of subject matter that is considered an abstract idea; and (2) breaking down Step 2A into two distinct Prongs, for the purpose of clarifying that a claim is not "directed to" a judicial exception if the judicial exception is "integrated" into a practical application of that exception.[22] In other words, mere recitation of a judicial exception does not necessarily mean that a claim is "directed to" that judicial exception, it is only "directed to" the exception under circumstances in which it has not been integrated into a practical application.

Groupings of abstract ideas

The 2019 PEG sets forth groupings of abstract ideas that are intended to enable PTO personnel to more readily determine whether a claim recites subject matter that is an abstract idea. The 2019 PEG notes that prior to this the PTO had provided guidance to the patent examining corps in the form of specific examples of subject matter that had been identified as an abstract idea (or not) in Supreme Court and post-*Bilski* Federal Circuit decisions. The 2019 PEG notes that while that approach was effective in the immediate aftermath of *Alice*, it has since become impractical. The number of Federal Circuit decisions addressing the issue has increased, and in some cases subject matter has been described as an abstract idea in one judicial decision, while in another case very similar subject matter has been described as not an abstract idea. In short, it is becoming increasingly difficult to reconcile the growing body of precedent. With the expanding and at times inconsistent case law, the PTO has found it more and more difficult for examiners to apply the judicial precedent in a predictable manner, and this raises the concern that "different examiners within and between technology centers may reach inconsistent results."[23]

The 2019 PEG "extracts and synthesizes key concepts identified by the courts as abstract ideas" to arrive at the following groupings of subject matter that constitute an abstract idea when recited as such in a claim limitation(s): (1) mathematical concepts; (2) certain methods of organizing human activity, such as fundamental economic principles or practices, commercial or legal interactions, and managing personal behavior relationships or interactions between people; and (3) mental processes. Only under "rare circumstances" is a claim that does not recite subject matter falling within one of these enumerated categories to be treated as reciting an abstract idea. Furthermore, a patent examiner is not permitted to conclude that a claim recites an abstract idea if it does not recite subject matter falling within one of these categories, unless the examiner follows a special process applicable to these rare circumstances, which entails approval by the Technology Center Director and justification for why the claim limitation is being treated as reciting an abstract idea.[24]

Revised Step 2A

The 2019 PEG cites to Supreme Court and Federal Circuit precedent for the proposition that a patent claim is not "directed to" a judicial exception if that claim integrates the exception into a practical application, and sets forth a revised Step 2A designed to facilitate the determination of whether a claim that recites a judicial exception integrates that exception into a practical application. A claim is not "directed to" a judicial exception, and is thus patent eligible, if the claim as a whole integrates the recited judicial exception into a practical application of the exception.

The 2019 PEG subdivides Step 2A into two Prongs. In Prong One, the examiner is instructed to evaluate whether the claim recites a judicial exception. For abstract ideas, Prong One represents a change as compared to prior guidance. Previously, examiners were instructed to compare the claimed concept to the PTO's "Eligibility Quick Reference Sheet Identifying Abstract Ideas," which provided specific examples of claim limitations that had been found to constitute abstract ideas. These examples were taken from Supreme Court and Federal Circuit precedent. Under the 2019 PEG, in contrast, examiners are instructed to: (1) identify the specific limitation(s) in the claim under examination (individually or in combination) that the examiner believes recites an abstract idea; and (2) determine whether the identified limitation(s) fall within the subject matter grouping of abstract ideas enumerated in the 2019 PEG, as described above. If the claim is found not to recite a judicial exception, it is patent eligible, and this concludes the analysis.

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[21] *Id.*
[22] *Id.*
[23] *Id.*
[24] *Id.* at 56–57.

However, if the claim recites a limitation (or limitations) falling within one of the enumerated categories, the examiner is instructed to proceed to Prong Two, as described below. In the rare circumstance in which an examiner believes a claim limitation that does not fall within the enumerated groupings nonetheless recites an abstract idea, the claim is to be analyzed according to the special process described above.

The 2019 PEG states that for the other judicial exceptions, laws of nature and natural phenomena, Prong One does not represent a change. Examiners are to continue following existing guidance to identify whether a claim recites one of these exceptions, and if it does, proceed to Prong Two.

In Prong Two, the examiner is instructed to evaluate whether the claim as a whole integrates the recited judicial exception into a practical application of the exception. As set forth in the 2019 PEG, a "claim integrates a judicial exception into a practical application when it applies, relies on, or uses 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 a judicial exception."[25] If the exception is so integrated, then the claim is not directed to a judicial exception and is patent eligible. If the exception is not so integrated, then the claim is directed to the judicial exception, and the analysis proceeds to Step 2B and a determination of whether the claim embodies an inventive concept.

The 2019 PEG instructs examiners to evaluate integration into a practical application by: (1) identifying whether there are any additional elements recited in the claim beyond the judicial exception(s); and (2) evaluating those additional elements individually and in combination to determine whether they integrate the exception into a practical application. The 2019 PEG provides a number examples of considerations that indicate that an additional element (or combination of elements) may have integrated the exception into a practical application. These considerations include any additional element that: (1) reflects an improvement in the functioning of a computer, or improvement to other technology or technical field; (2) applies a judicial exception to effect a particular treatment or prophylaxis for a disease or medical condition; (3) implements a judicial exception with, or uses a judicial exception in conjunction with, a particular machine or manufacturer that is integral to the claim; (4) effects transformation or reduction of a particular article to a different state or thing; or (5) applies or uses the judicial exception and some other meaningful way beyond generally linking the use of the judicial exception to a particular technological environment. Those familiar with the Federal Circuit's decision that was the subject of the appeal in *Bilski* will recognize that considerations (3) and (4) explicitly incorporate the Federal Circuit's "machine or transformation" test, which the Supreme Court in *Bilski* held is not the sole and fundamental test for patent eligibility, although it can serve as useful guidance in assessing patent eligibility.[26]

Some of these considerations were discussed in prior PTO guidance in the context of Step 2B (inventive concept), but the 2019 PEG states that evaluating them in the context of Step 2A promotes early and efficient resolution of patent eligibility, and improves certainty and reliability. The 2019 PEG notes that, unlike Step 2B, Prong Two of revised Step 2A specifically excludes consideration of whether an additional element represents well-understood, routine, conventional activity. Examiners are instructed to ensure that they give weight to all additional elements, regardless of whether or not they are conventional, when evaluating whether a judicial exception has been integrated into a practical application under Prong Two.

The 2019 PEG notes that the list of considerations provided is not exclusive, and there may be other examples of integrating an exception into a patent application that do not fall into any of these categories. The guidance also provides examples in which courts have found that a judicial exception has not been integrated into a practical application, such as when an additional element in the claim: (1) 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) adds insignificant extra-solution activity to the exception; or does no more than generally link the use of a judicial exception to a particular technological environment or field of use.

If the examiner concludes after conducting the Prong Two analysis that the claim is directed to a judicial exception, the analysis proceeds to Step 2B, *i.e.*, an evaluation of whether the claim embodies an inventive concept. Although the 2019 PEG does not revise the analysis under Step 2B, it does specifically point out that there is an overlap between the considerations to be evaluated under

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[25] *Id.* at 53.

[26] *Bilski v. Kappos*, 561 U.S. 593 (2010).

Step 2B and under Prong Two of the revised Step 2A, and that in many cases a consideration need not be reevaluated in Step 2B if it was already evaluated under Prong Two. At the same time, examiners are instructed to consider at Step 2B whether an additional element or combination of elements considered in Prong Two might add a specific limitation or combination of limitations that is not well-understood, routine, conventional activity in the field, which is indicative that inventive concept may be present, even if the judicial exception was not found to be integrated into a practical application at Prong Two.

An additional element or combination of elements that simply appends well-understood, routine, conventional activities previously known in the industry, specified at a high level of generality, to the judicial exception is indicative that an inventive concept may not be present. On the other hand, an examiner could find that an additional element constitutes insignificant extra-solution activity under Prong Two, but that under Step 2B the element is unconventional or otherwise more than what is well-understood, routine, conventional activity in the field. This finding may indicate that an inventive concept is present and that the claim is thus eligible.

OCTOBER 2019 UPDATE

The public was invited to comment on the 2019 PEG, and in October the PTO released its *October 2019 Update: Subject Matter Eligibility*, which responds to comments that were received with further explanation and examples, with the focus on clarifying practice for patent examiners.[27] Among other things, the Update provides additional guidance on identifying abstract ideas using the enumerated groupings provided in the 2019 PEG. For example, it provides more explanation and examples taken from case law with respect to each of the groupings, *i.e.*, mathematical concepts, certain methods of organizing human activity, and mental processes. With respect to mental processes, the Update explains that while a claim limitation that cannot be practically performed in the human mind does not represent a mental process, because it can only be practically performed through the use of a computer or other machine, a claim limitation that can be performed practically in human mind does recite a mental process. Two examples from biotechnology are provided. In *University of Utah Research Foundation v. Ambry Genetics Corp.*, the Federal Circuit held that claims to "comparing BRCA sequences in determining the existence of alterations" can practically be performed in the human mind.[28] Similarly, in *Classen Immunotherapies, Inc. v. Biogen IDEC*, the Federal Circuit held that a claim limitation of collecting and comparing known information can practically be performed in human mind.[29] The Update further states that even a recited process step that is limited to performance on a computer can be classified as a mental process if, under the broadest reasonable interpretation of the claim, the process could be practically performed by the human mind, perhaps with the aid of a pen and paper.

The Update introduces a "treatment/prophylaxis" consideration, pursuant to which a claim can integrate a judicial exception into a practical application by applying or using the judicial exception to effect a particular treatment or prophylaxis for a disease or medical condition. Much of the genesis of this consideration comes from the Federal Circuit's *Vanda* decision.[30] The treatment/prophylaxis consideration applies not only to laws of nature and natural phenomena, the exceptions most often associated with method of treatment claims, but also to abstract ideas, such as the mental comparison of immunization-related information, which was practically applied in *Classen Immunotherapies, Inc. v. Biogen IDEC* by actually immunizing mammals in accordance with a particular immunization schedule.[31] The Update identifies the following factors as relevant in determining whether a claim applies or uses a recited judicial exception to effect a particular treatment or prophylaxis for a disease or medical condition: (1) the particularity or generality of the treatment or prophylaxis, (2) whether the limitation(s) have more than a nominal or insignificant relationship to the exception(s), and (3) whether the limitation(s) are merely extra-solution activity or a field of use.

NEW EXAMPLES

Prior to 2019, the PTO had released 36 examples applying the *Alice* test to a variety of hypothetical inventions and claims, mostly involving

[27] 84 Fed. Reg. 55942 (Oct. 18, 2019).
[28] 774 F.3d 755, 763 (Fed. Cir. 2016).
[29] 659 F.3d 1057, 1067 (Fed. Cir. 2011).
[30] *Vanda Pharm. Inc. v. W.-Ward Pharm. Int'l Ltd.*, 887 F.3d 1117 (Fed. Cir. 2018).
[31] 659 F.3d 1057, 1067 (Fed. Cir. 2011).

information technology or biotechnology, broadly defined.[32] These 36 examples have been retained, but the 2019 PEG introduced six more examples (Examples 37–42), and an additional four examples were introduced in the October Update (Examples 43–46).[33] Only two of the examples, Examples 43 and 44, relate to biotechnology, the others generally relate to information technology and invoke the abstract idea exception, or in some cases no exception at all. Examples 43 and 44 recite a law of nature and a product of nature, respectively, and Example 43 further recites an abstract idea.

Example 43 illustrates the application of revised Step 2A to five method of treatment claims directed towards a personalized medicine invention, wherein a diagnostic test is used to identify a certain category of patients (non-responders), and tailors the treatment to the patient's status as a responder or non-responder. Claim 1, which recites a step of "administering a treatment to the patient," without any restrictions on the nature of the treatment, is found to be patent ineligible, because at Prong Two of Step 2 it is determined that the claim did not integrate a recited judicial exception into a practical application, because the treatment limitation is stated at such a high level of generality and does not meaningfully limit the claim. In contrast, hypothetical Claims 2–4 are deemed patent eligible because they limit the treatment to either "a non-steroidal agent capable of treating [a specified disease]," rapamycin, or a course of plasmapheresis, respectively. Because these elements are deemed to constitute a "particular treatment or prophylaxis" under the 2019 PEG, the claims are found to integrate the exception into a practical application, and therefore not to be directed towards a judicial exception. Claim 5, which recites a treatment method comprising "administering rapamycin to a patient identified as having [a particular disease]," but does not recite a diagnostic test, is found to be patent eligible at Prong One of Step 2A, because a method of treating a disease with the drug does not set forth or describe any recognized exception.

Example 44 analyzes four exemplary claims relating to a hypothetical natural product ("denveric acid") useful in the treatment of diabetes. Claim 1 recites a "dosage unit comprising denveric acid in a container." This claim is found to be directed to an exception in the form of a nature-based product limitation (the denveric acid), and at Prong Two of the analysis the claim is found not to have integrated the judicial exception into a practical application, because the only additional element is the "container." Given that denveric acid must be placed in a container in order to store and use it, the recitation of a container fails to meaningfully limit the claim. At best, the PTO concludes, it is "the equivalent of merely adding the words 'apply it' to the judicial exception."

Claim 2, on the other hand, limits the container to a specific delivery device. Although the background of this example explains that this delivery device is well-understood, and is routinely used to administer other medications, Prong Two analysis excludes consideration of whether a limitation is well-understood, routine, conventional activity. The delivery device was evaluated under the "particular machine" consideration, using the three factors set forth in MPEP 2106.05(b). The delivery device is found: (1) not to be recited at a high level of generality, (2) to constitute an integral part of the claim, and (3) to be more than just a field of use or other insignificant limitation. Thus, the product of nature exception is integrated into a practical application, and accordingly Claim 2 is not directed to a judicial exception.

Claim 3 is limited to non-naturally occurring variants of denveric acid that have been chemically modified so as to be effective for a longer duration than naturally occurring denveric acid, i.e., an "intermediate-acting" denveric acid. At Prong One of the analysis this claim is found to not recite the natural product, because the intermediate-acting product has markedly different functional characteristics than its naturally occurring, "short-acting" counterpart.

Claim 4 recites a dosage unit of denveric acid in combination with protamine. At Prong One of the analysis, the markedly different characteristics analysis is applied to a nature-based product produced by combining multiple naturally occurring components (the denveric acid and protamine), rather than the component parts. Because denveric acid and protamine do not occur together in nature, there is no naturally occurring counterpart mixture for comparison, and so the claimed mixture is compared to its naturally occurring components. Denveric acid by itself has relatively short-acting glycemic control characteristics, and protamine by itself has no glycemic control characteristics. In combination, they provide intermediate-acting glycemic control, which is found to constitute a change in functionality, in that

[32] *Subject Matter Eligibility*, USPTO.GOV, https://www.uspto.gov/patent/laws-and-regulations/examination-policy/subject-matter-eligibility

[33] *Id.*

the glycemic control characteristics of the mixture are different than the mere "sum" of the glycemic control characteristics of the individual components. This distinguishes the example from *Funk Brothers*, in which the Supreme Court held a bacterial mixture to be patent ineligible because each species of bacteria in the mixture continued to have "the same effect as it always had," *i.e.*, it lacked markedly different characteristics.[34]

CONCLUSION

The 2019 PEG should significantly improve the patent examination process, not only in terms of consistency and predictability, but also in more accurately distinguishing between claims that merely recite a judicial exception versus inventions that apply abstract ideas and natural laws to solve practical problems. Former chief judge of the Federal Circuit Paul Michel has stated that the 2019 PEG and October Update represent "impressive progress on providing clearer guidance to the innovation community," and that in his view they are a "very important step forward."[35] I would hope that the Federal Circuit endorses the essence of the PTO's revised approach to assessing whether a patent claim is directed to a judicial exception, as it could help to address the concern that under the Federal Circuit's current interpretation of *Mayo* and *Alice* too many meritorious inventions are being denied patent eligibility.

Writing in dissent from the *en banc* court's decision to deny rehearing in *Athena Diagnostics* v. *Mayo*, Judge Moore correctly observed that "[n]one of my colleagues defend the conclusion that claims to diagnostic kits and diagnostic techniques, like those at issue [in this case], should be ineligible."[36] Judge Moore, joined by Judges O'Malley, Wallach, and Stoll, argues that a majority of her colleagues on the Federal Circuit have mistakenly interpreted *Mayo* as tying their hands in a manner that compels the conclusion that all medical diagnostic inventions are patent ineligible. She disagrees, and interprets *Mayo* as allowing the lower courts the discretion to uphold the patent eligibility of meritorious diagnostic inventions such as the one at issue in *Athena Diagnostics*, pointing to substantial differences between the *Athena* claims and the claims at issue in *Mayo*.

Probably most important insight reflected in the 2019 PEG is the emphasis on distinguishing between a claim or claim element that merely "recites" a judicial exception, versus a claim or claim element that is "directed to" a judicial exception, as well as the analytical tools for making the distinction, and in particular the two-prong approach to deciding whether a claim is directed to a judicial exception. In some unfortunate cases, both at the PTO and in the courts, a claim that recites a judicial exception has been too quickly characterized as being directed to that exception, with the patent eligibility analysis then proceeding directly to the second step of the *Mayo* test, the search for inventive concept. The inventive concept is typically found to be lacking based on the conventional nature of the additional elements recited in the claim. It is highly significant that under Prong Two of Step 2A of the PTO's revised examination process examiners are specifically instructed to take into account conventional, well-understood, and routine elements in determining whether a claim integrates a recited exception into a practical application.

To see how this might play out with respect to a diagnostic invention, consider the claims at issue in *Athena Diagnostics*.[37] Representative Claim 1 recited a "method for diagnosing neurotransmission or developmental disorders related to [MuSK] in a mammal comprising the step of detecting in a bodily fluid of said mammal autoantibodies to an epitope of [MuSK]."[38] The panel majority found that Claim 1, and the claims that depended from it, recited a natural law, *e.g.*, "the correlation between the presence of naturally-occurring MuSK autoantibodies in bodily fluid and MuSK-related neurological diseases like MG."[39] The court went on to conclude that the claims at issue (which depended from Claim 1) were directed to the natural law because the "additional recited steps only apply conventional techniques to detect that natural law."[40] Under the 2019 PEG's revised examination procedure, in contrast, it would have been improper not to give due consideration to these additional recited steps at Prong Two solely because they involve conventional techniques. If the Federal Circuit had

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[34] *Funk Brothers Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127 (1948).

[35] Brief of the Hon. Paul R. Michel (Ret.) as *Amicus Curiae* in Support of Petitioners, *Athena Diagnostics, Inc. v. Mayo Collaborative Servs.*, U.S. Supreme Court Docket No. 19-430 (Nov. 1, 2019).

[36] *Athena Diagnostics, Inc. v. Mayo Collaborative Servs.*, 927 F.3d 1333 (Fed. Cir. 2019).

[37] *Athena Diagnostics, Inc. v. Mayo Collaborative Servs.*, LLC, 915 F.3d 743 (Fed. Cir. 2019).

[38] *Id.* at 747.

[39] *Id.* at 750.

[40] *Id.* at 751.

taken this approach in *Athena Diagnostics*, which I think would be permissible under *Mayo* and the other relevant Supreme Court precedent, it might have come to the conclusion that the claims were not directed towards a natural law, and thus that the claims are patent eligible. All of the judges on the Federal Circuit seem to agree this would have been the correct outcome, given the overall policy objectives of patent law and the nature of the claimed invention, and I agree with Judge Moore that intervention by the Supreme Court and/or Congress is not required to uphold the patent eligibility of truly meritorious innovations in medical diagnostics and personalized medicine.

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