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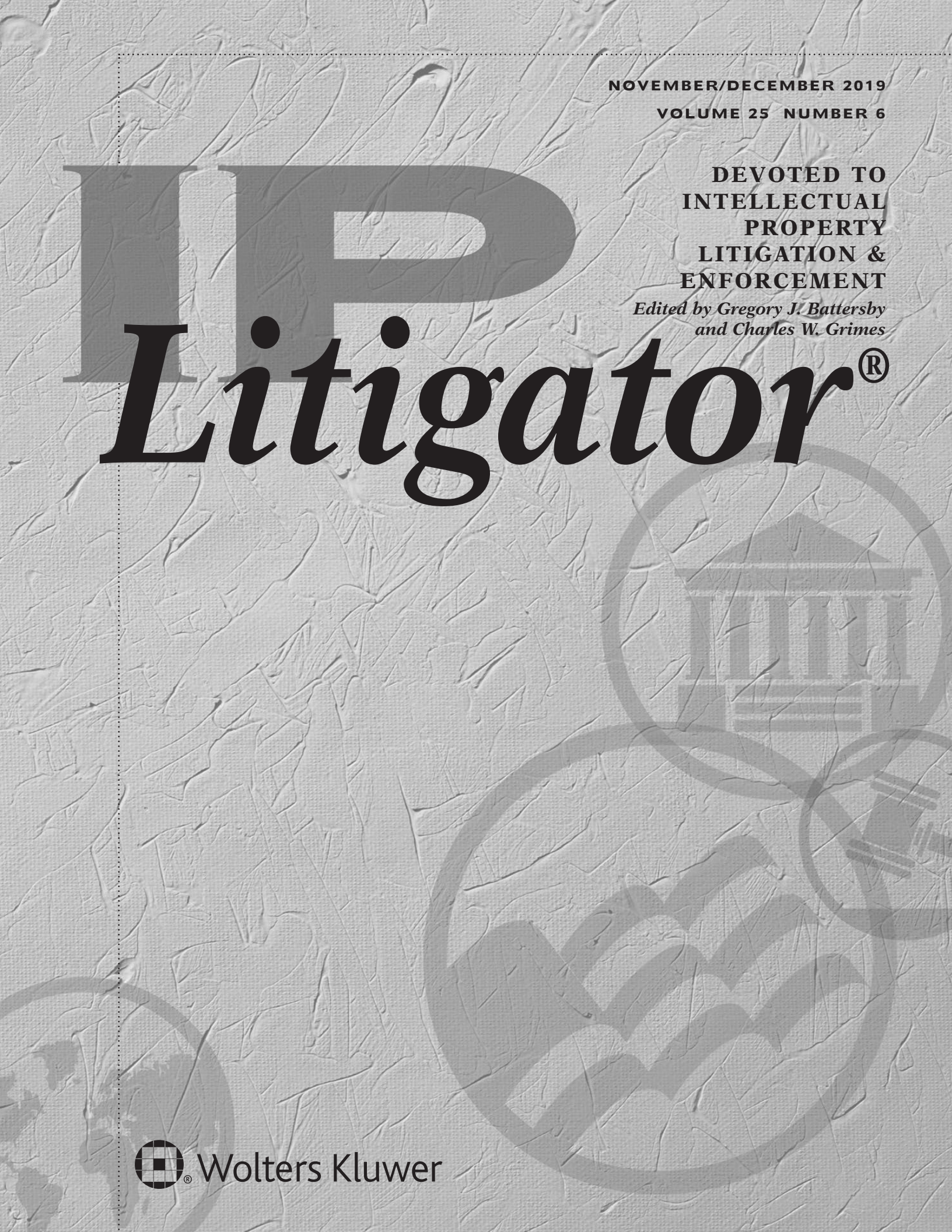

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How to Think About and Successfully Navigate Patent Eligibility After Alice, Myriad, *and* Mayo

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More than five years after the Supreme Court laid out the principles of patent eligibility in *Mayo*, *Myriad*, and *Alice*, judges, industry, and counsel continue to express difficulty in accepting and applying them. Recently, in *Athena v. Mayo*, a divided Federal Circuit denied a petition to rehear a panel decision that had excluded a diagnostic invention from patent protection, with eight concurring and dissenting opinions.[1] Since *Alice*, over 40 petitions have been filed asking the Supreme Court to revisit its rulings.[2] Congress is now looking into the issue, seeking stakeholder views on how to reform patent eligibility.[3]

None of these efforts will succeed to the extent they seek black letter rules. Patent eligibility is a gray area of the patent law, dependent on applying principles to a set of facts relating to what the invention purports to be and how it is claimed in a particular case. History has shown that searching for a rigid rule has always failed. Although the absence of a bright line test can be unsettling, a firm understanding of patent eligibility principles and relevant precedent, applied after a thorough understanding of a particular claimed invention at issue, can improve advocacy and provide reasonable predictability. Just as copyright law lives with the idea versus expression dichotomy, so should patent law be able to live with the abstract idea/law of nature/natural phenomenon versus application dichotomy.[4] This article aims to navigate this subtle area of law and explore potential approaches to address the current state of patent eligibility issues.

Core Principles Driving Patent Eligibility Determinations

Although Section 101 of the Patent Act provides that patents may be awarded for the invention or discovery of "any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof," over 150 years of US jurisprudence has established that patent protection cannot extend to abstract ideas, laws of nature, or natural phenomena.[5] Only useful applications thereof are patent eligible.[6]

This gatekeeping function of patent law ensures that (a) patents are awarded only when an inventor ***applies*** a concept or natural phenomenon for a useful result; and (b) inventors indeed claim that application, rather than seeking aggressively to monopolize the basic tools of scientific and technological work which would impede innovation rather than promote it.[7]

The gatekeeping function of patent eligibility also serves to ensure that what passes through the eligibility threshold on to the remaining elements of patent law is subject matter that the patent law is equipped to judge under the other requirements for patentability, including novelty, adequacy of disclosure, and nonobviousness.[8] The late Chief Judge Archer of the Court of the Appeals for the Federal Circuit explained this concept in his prescient dissent in *In re Alappat*, where he foreshadowed that the majority's simplistic rule (eventually eviscerated by *Alice*), enabling patent eligibility so long as a claim recited any structure, would lead to disastrous consequences (a prediction that came true with the *State Street* progeny of banking method patents).[9] He used the hypothetical of a patent claiming a compact disc wherein the new structure consisted of the specific arrangement of pits in the plastic material that encodes a particular new song identified in the patent claim.[10] The patent claims in such a case expressly recite a structure (rather than just the idea of the new song) and the claimed structure of the patent is novel (because the arrangement of pits defined by the song is a new combination).[11] Yet, the invention clearly resides in the discovery of new music.[12] Because examiners have the burden of making rejections, and because patent law is not equipped to adjudge novelty and obviousness of arrangements of chords, lyrics, and notes versus prior songs, the result of allowing that "invention" through the eligibility gate is a patent on music, which all agree is not the stuff of patent law.[13] This thought experiment shows that the determination

of whether an invention or discovery passes through the § 101 gate ensures that the remaining provisions of patent law, including novelty and nonobviousness over the prior art, can be meaningfully applied to the subject matter purporting to be the invention.[14]

As Chief Judge Archer explained in *Alappat*'s dissent over 20 years ago, and as the Supreme Court's cases consistently hold, in determining patent eligibility, one should first ask the question: What does the patent claim (and the specification show) the invention is for?[15] The patent should be taken at face value. If a claimed invention includes an ineligible concept, inquiry must be made into whether the claim is seeking patent protection for the ineligible concept, or whether the claim considered as a whole is for a patent eligible application.[16] The dispositive issue is not just whether the claim recites on its face something physical (such as a machine), though of course the presence of structure in a claim is an element of the claimed invention to be considered.[17] The body of Supreme Court cases, including those before *Mayo*, *Myriad*, and *Alice*, offer guidance in how to think about whether a claim is adequately applying, for example, a mathematical formula or a natural biological phenomenon.[18]

Mayo, Myriad, and *Alice*

In *Mayo*, *Myriad*, and *Alice*, the Supreme Court continued to build out the patent eligibility framework established in its earlier decisions.[19] The Court articulated a two-step test (*Mayo*/*Alice* test) for distinguishing eligible and ineligible patent claims: (1) whether the claim at issue is directed to a patent-ineligible abstract idea, law of nature, or natural phenomenon; and (2) if so, whether additional claim elements both individually and as an ordered combination transform the nature of the claim as a whole into a patent-eligible application.[20] The Court described step two as a search for an "inventive concept"—that is, 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.[21]

In *Mayo*, the Court addressed patent eligibility of a diagnostic invention claimed in a very broad way. The inventors discovered the relationship between the precise concentrations of certain metabolites in the blood and the likelihood that a dosage of a class of drugs will prove ineffective or cause harm.[22] The claims recited a method comprising two physical steps and two "wherein" clauses.[23] The physical steps included (1) administering a drug to a patient; and (2) determining the metabolite concentration in the patient's blood.[24] The "wherein" clauses recited what the results indicated, that is, that a patient's metabolite concentration above or below the predetermined levels (the precise concentrations discovered by the inventors) indicated a need to increase or decrease the amount of the drug.[25]

The Court found that the *Mayo* claims set forth the law of nature discovered by the inventors.[26] The Court then considered whether the claims do significantly more than simply describe the natural relationship.[27] The Court found that the "administering" step simply refers to the relevant, pre-existing audience (doctors), the "wherein" clauses simply tell the doctors about the relevant natural law, and the "determining" step, set forth in highly general language, simply tells the doctors to measure and use the natural law.[28] The Court then considered all of the steps together as an ordered combination, and found that this added nothing to the law of nature that was not already present when the steps were considered separately.[29]

In *Myriad*, the inventors discovered the precise locations of two human genes and determined their generic codes.[30] The Court found that claims to an isolated portion of the naturally occurring human genetic code (*i.e.*, DNA) was an ineligible product of nature (law of nature exception), while a claim to a synthetically modified form of DNA (*i.e.*, cDNA) was eligible.[31]

In *Alice*, the Court addressed patent eligibility of claims directed to a trading platform for minimizing risk in financial transactions by using a trusted third party to settle obligations between two other parties.[32] The Court found that the claims were drawn to the abstract idea of intermediated settlement.[33] The Court then considered whether the claims do significantly more than simply describe the abstract idea.[34] The Court found that the additional claim process steps did nothing more than providing an instruction to apply the abstract idea of intermediated settlement using an unspecified, generic computer.[35]

Federal Circuit Precedent after *Mayo, Myriad*, and *Alice*

Life Sciences Cases

In the life sciences field, the Federal Circuit has held several diagnostic claims ineligible under the *Mayo*/*Alice* test.[36] These cases involved a range of different diagnostic inventions.[37] The Federal Circuit compared these diagnostic claims with the *Mayo* claims and found that their similarities compelled the conclusion that the diagnostic claims at issue were directed to natural laws.[38] Although some of the claims recited the use of specific diagnostic techniques or assays, the patent specifications described

them as well-understood and conventional.[39] The Federal Circuit held that, under *Mayo*, using conventional techniques to detect newly discovered natural laws did not supply an inventive concept that would transform the claims into patent-eligible applications.[40]

Several Federal Circuit judges noted how the court had interpreted *Mayo* so broadly that the judicially created exceptions have become more aggressive in reach than they should be.[41] For example, Judge Stoll criticized what she argued to be the court's inflexible application of *Mayo*, which created decisions inconsistent with the precepts of *Mayo* and the patent system as a whole.[42] The judges disagreed over the interpretation of *Mayo* on various issues, including (1) whether concreteness and specificity of the claims may move a claim from being directed to a law of nature to an application of the natural law and (2) whether discovery of previously unknown natural laws satisfies the inventive concept requirement.[43]

In addressing these issues, several judges critically relied on comparisons between the claims at issue in *Athena* (a recent diagnostic case before the Federal Circuit) with those in *Mayo*.[44] Below is a comparison of the claim language.

Judge Newman found that the multi-step diagnostic claims in *Athena*, performed by a combination of specific chemical and biological steps, were not directed to a law of nature, and that *Mayo* did not exclude such claims from being eligible for patenting.[47] She noted that in reaching the opposition conclusion, the *Athena* panel majority had incorrectly eliminated from the claims any steps that are performed by conventional procedures and failed to consider the claims "as a whole."[48]

Judge Moore also found that the *Athena* claims differed significantly from the *Mayo* claims and should be patent eligible.[49] She noted that the claimed steps in *Mayo* were set forth in highly general language covering all processes that make use of the natural law, and the breadth and

Representative claim in *Mayo*[45]	**Representative claim in *Athena*[46]**
1. A method of optimizing therapeutic efficacy for treatment of an immune-mediated gastrointestinal disorder, comprising:	7. A method [for diagnosing neurotransmission or developmental disorders related to muscle specific tyrosine kinase (MuSK) in a mammal comprising the step of
(a) *administering* a drug providing 6-thioguanine to a subject having said immune-mediated gastrointestinal disorder; and	*detecting* in a bodily fluid of said mammal autoantibodies to an epitope of muscle specific tyrosine kinase (MuSK)], comprising
(b) *determining* the level of 6-thioguanine in said subject having said immune-mediated gastrointestinal disorder,	*contacting* MuSK or an epitope or antigenic determinant thereof having a suitable label thereon, with said bodily fluid,
	immunoprecipitating any antibody/MuSK complex or antibody/MuSK epitope or antigenic determinant complex from said bodily fluid and
	monitoring for said label on any of said antibody/MuSK complex or antibody/MuSK epitope or antigen determinant complex,
wherein the level of 6–thioguanine less than about 230 pmol per 8×10^8 red blood cells indicates a need to increase the amount of said drug subsequently administered to said subject and wherein the level of 6–thioguanine greater than about 400 pmol per 8×10^8 red blood cells indicates a need to decrease the amount of said drug subsequently administered to said subject.	wherein the presence of said label is indicative of said mammal is suffering from said neurotransmission or developmental disorder related to (MuSK).

generality of the *Mayo* claims led to their demise.[50] In contrast, she found that the *Athena* claims were directed to a new and useful process of specific, concrete steps to apply the law of nature.[51] Judge Moore also noted that the inventiveness of the discovery should be considered when assessing patent eligibility.[52] Unlike the *Mayo* claims that recited a generic determining step, she found that the *Athena* claims recited the use of antibody–antigen complexes that had never been used by prior art diagnostic tests.[53]

On the other hand, the Federal Circuit has distinguished *Mayo* to uphold claims directed to new methods of treating diseases and laboratory techniques.[54] With regard to treatment claims, the Federal Circuit found that specific methods of treatment for specific patients, using specific compounds at specific doses to achieve specific outcomes, were not directed to a natural law.[55] The Federal Circuit also found a new and improved method of producing hepatocytes patent eligible.[56] The claims at issue recited various concrete steps (freezing, thawing, and separating) for producing a tangible and useful result and were found to fall squarely outside of patent-ineligible concepts.[57]

Petitions for the Supreme Court to revisit the patent eligibility issue continue to be filed and remain pending.[58] Whether the Supreme Court will take up these cases, and whether such review is needed for the Federal Circuit to reduce its expressed internal conflict, remain to be seen.

Computer Technology Cases

In computer technology cases, the current state of patent eligibility law has likewise received criticism. Judge Plager, for example, recently stated in a dissent in *Interval Licensing* that the current law "renders it near impossible to know with any certainty whether the invention is or is not patent eligible" and that this body of law was "incoherent."[59]

That being said, Judge Plager also authored the Federal Circuit's opinion in *Amdocs* recognizing that the absence of "a single, universal definition of 'abstract idea'" did not leave courts and practitioners without any recourse.[60] Rather, the "decisional mechanism" used by courts is to examine earlier, similar cases to compare and contrast with the present facts.[61] This is the "classic common law methodology" that is more flexible than a single governing definition and is the approach followed by both the Supreme Court and the Federal Circuit.[62] Under such a system, there may not be the certainty of a bright line rule, but practitioners well-versed in recent Federal Circuit precedent nonetheless can predict the likelihood of a particular eligibility outcome.

Thus, the Supreme Court and the Federal Circuit thereunder have developed a body of precedent, which practitioners and industry must rely upon for arguments in specific cases, and in thinking about how best to draft patents. In the meantime, the Federal Circuit presumably will, as it does in other areas, monitor panel precedent to determine when *en banc* review is needed to resolve conflict. There is already an ample body of post-*Alice* Federal Circuit precedent. For example, if the patent is directed to storing and retrieving data from a database, at least one of the parties should be discussing *Enfish*.[63] If the patent is directed to an improvement to hardware systems, briefing would be incomplete without a discussion of *Visual Memory*.[64] If the patent involves graphical user interface elements, there should be a discussion of *Data Engine*.[65] If the case involves encoding and decoding data, at least one of the parties should quote the line from *RecogniCorp*: "Morse code, ordering food at a fast food restaurant via a numbering system, and Paul Revere's 'one if by land, two if by sea' signaling system all exemplify encoding at one end and decoding at the other end."[66] Thus, the knowledgeable practitioner has a body of precedent with which to frame arguments.

Furthermore, a practitioner should have not only a wide knowledge base of Federal Circuit cases since *Alice*, but also a deep and up-to-date knowledge base. For example, a cursory reading of the Federal Circuit's recent *Chamberlain* opinion instructs that "the broad concept of communicating information wirelessly, without more, is an abstract idea."[67] The truly knowledgeable practitioner, however, will also know that just about a month later, Judge Chen also authored the court's opinion in *SIPCO*, where he specifically distinguished *Chamberlain*.[68] The point is that, far from being a hopeless morass of unpredictability, the well-versed practitioner should have a good sense of how the Federal Circuit will rule on subject-matter eligibility on a technology patent at the beginning of litigation.

Legislative Reform

With stakeholders and the Federal Circuit itself expressing dissatisfaction with the law, particularly with regard to inventions involving diagnostics and computer software, legislative reform on patent eligibility is potentially on the horizon.[69] The proponents of the present bills seek to define, in a closed list, exclusive categories of statutory subject matter that alone should not be eligible for patent protection.[70] As currently proposed, the closed list of exclusions might include the following categories: fundamental scientific principles, products that exist solely and exclusively in nature, pure mathematical formulas, economic or commercial principles, and mental activities.[71] The reform also aims to create a "practical application" test to ensure that the statutorily ineligible subject matter is construed narrowly.[72]

In May 2019, Senators Tillis and Coons and Representatives Collins, Johnson, and Stivers released a draft bill and the relevant provisions on patent eligibility read as follows[73]:

Section 100:

(k) The term "useful" means any invention or discovery that provides specific and practical utility in any field of technology through human intervention.

Section 101:

(a) Whoever invents or discovers any useful process, machine, manufacture, or composition of matter, or any useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

(b) Eligibility under this section shall be determined only while considering the claimed invention as a whole, without discounting or disregarding any claim limitation.

When compared to the current Patent Act, the draft bill defines the term "useful" in § 101 as providing "specific and practical utility in any field of technology through human intervention." The language "field of technology" may be interpreted to exclude business methods or fine arts from the scope of the patent law. Also, the language "through human intervention" may be interpreted to narrowly exclude only materials or relationships (such as genes or natural relationships) as existed in nature, but not human-made subject matter with some level of human intervention. As such, under the proposed § 101, it may be easier to protect diagnostic technologies utilizing specific conventional assays than the current *Mayo*/*Alice* test from the Supreme Court. In addition, the draft bill removes the term "new" from § 101, which may also be interpreted to reject the requirement to search for an inventive concept in the second step of the *Mayo*/*Alice* test.[74] The draft bill also adds that eligibility "shall be determined only while considering the claimed invention as a whole, without discounting or disregarding any claim limitation."[75] This language is consistent with the law already established by *Mayo*, *Myriad*, *Alice*, and earlier Supreme Court cases.

More extreme provisions are floating around as well, including one that abrogates "all cases establishing or interpreting [judicially created] exceptions to eligibility."[76] Other extreme provisions would remove considerations relating to other patent law provisions from the subject matter eligibility analysis and require that the § 101 provisions be "construed in favor of eligibility."[77]

In June 2019, the Senate Judiciary Subcommittee on Intellectual Property held multiple hearings and sought feedback on the draft bill. At the conclusion of the hearings, Senator Tillis acknowledged the need to further refine the changes to § 101 in the draft bill.[78]

Practical Considerations Going Forward

As *Mayo*, *Myriad*, *Alice*, and subsequent cases continue to show, patent eligibility is not a bright line test. Rather, it is determined based on the underlying principles and the application of relevant precedent to the particular facts surrounding an invention at issue. Due to the diversity in discoveries that are claimed as inventions, and how broadly patent applicants seek to claim subject matter as their inventions, it is important not to simply throw up one's hands in frustration or just look to align claim elements with those in *Mayo*, *Myriad*, *Alice*, or a particular case. Instead, one should carefully consider a particular invention as the patentee purports to describe it in the patent itself, how it is being claimed, and whether the claimed invention is what *Mayo*, *Myriad*, and *Alice* and the principles underlying § 101 aim to exclude from patent protection.

Particularly, it is essential to read a patent fully to understand what the patentee purports to have invented and claimed.[79] In doing so, think about the three components of invention, well established in the patent law: (1) the way the invention operates (*i.e.*, the arrangements of structure, materials, substances, etc.), (2) the principles of operation (*i.e.*, how natural laws or abstract ideas function to operate on the structures, materials, substances, etc.), and (3) the useful results achieved.[80] With each of these three aspects in mind, consider what is claimed and whether it is significant—an application beyond the natural laws or abstract ideas themselves. For a claim to pass the eligibility gate, it is critical that the limitations of the claims, taken as a whole, bring forth a practical application that is of substance, rather than adding trivial gloss to a patent that is actually seeking to protect a natural law or abstract idea itself.

It is critical to remember that when determining patent eligibility, the issue is ***not*** whether the claimed application at issue is in fact inventive. Rather, the sole issue is whether the patent, taken at face value, is purporting to claim as the invention subject matter residing in the application of an idea, natural phenomenon, law of nature, etc. If courts mistakenly examine whether a purported application is in fact inventive in view of the prior art, they would be regressing to how the patent law treated invention prior to 1952 when 35 U.S.C. § 103 was enacted specifically for the purpose of establishing objective ground rules for determining inventiveness.[81] Unfortunately, it seems like

cases where courts are being criticized for examining the fact of inventiveness over prior art in the context of patent eligibility, including considering evidence extrinsic to what the patent itself purports to state as constituting the invention, are seemingly falling victim to the approach courts used to take before 1952 in deciding whether or not subject matter was worthy of being thought of as an invention.

For diagnostic inventions, it is important to recognize that the Supreme Court did not broadly hold any particular category of technology as patent-ineligible. In practice, courts may, at least initially, question the patent eligibility of diagnostic claims due to their seemingly textual similarities to the *Mayo* claims. To overcome such an inclination, merely limiting the claims to the use of specific conventional assays may not be sufficient. Nonetheless, distinguishing the invention and how it was claimed from *Mayo* may persuade a court that the claims at issue fall outside of the ineligible concepts that § 101 is designed to exclude. For example, demonstrating that the use of specific assays has an inventive concept (such as achieving higher diagnostic accuracy when compared to other techniques) may provide a meaningful distinction over *Mayo*, where the inventors merely discovered a natural law and the claims recited highly general steps that must be performed to use the natural law.

As legislators continue to address what subject matter should be excluded from patent protection under § 101, the principles driving this exclusionary rule and its gatekeeping function should remain. If the copyright statute is considered by analogy (where the idea/expression dichotomy is codified), the proposed subsection (b) of the pending bill could conceivably add another sentence along the following lines:

> (b) … In no case does patent protection extend to mathematical relationships, abstract ideas, laws of nature, natural phenomena, or products of nature, but useful applications thereof are eligible for patent protection. Eligibility under this section shall be determined based on the claimed invention as a whole, including the way in which a useful result is achieved, and without discounting or disregarding any claim limitation.

History has shown that patent eligibility has and always will be a challenging area of patent law. Nonetheless, for the patent system to continue to encourage innovations, it is critical to maintain a gatekeeping function, ensuring that patent law promotes and rewards useful innovation. At this point, it is not clear whether the courts can bring some peace to their seemingly internal strife by virtue of extant Supreme Court precedent, or whether they will need either more pronouncements by the Supreme Court or new legislation (that does not itself create new issues). In the meantime, we remain hopeful that the basic principles are sufficiently established that they can serve as a foundation for approaching individual cases.

1. *Athena Diagnostics, Inc. v. Mayo Collaborative Servs., LLC*, 927 F.3d 1333 (Fed. Cir. 2019).
2. Press Release, Chris Coons, US Senator for D.E., Coons and Tillis: What We Learned at the Patent Reform Hearing (June 24, 2019), *https://www.coons.senate.gov/news/op-eds/coons-and-tillis-what-we-learned-at-patent-reform-hearings*.
3. *Id.*
4. *See*, *e.g.*, *In re Alappat*, 33 F.3d 1526, 1554 n.15 (Fed. Cir. 1994) (*en banc*) (Archer, C.J., dissenting in relevant part); *Intellectual Ventures I LLC v. Symantec Corp.*, 838 F.3d 1307, 1323–24 (Fed. Cir. 2016) (Mayer, J., concurring).
5. *See*, *e.g.*, *O'Reilly v. Morse*, 56 U.S. (15 How.) 62, 116 (1854) (citing the English case *Neilson v. Harford*, Web. P.C. 295, 371 (1841)); *Mackay Radio & Tel. Co. v. Radio Corp. of Am.*, 306 U.S. 86, 94 (1939); *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 130 (1948); *Gottschalk v. Benson*, 409 U.S. 63, 65 (1972); *Parker v. Flook*, 437 U.S. 584, 589 (1978); *Diamond v. Diehr*, 450 U.S. 175, 185 (1980); *Alice Corp. v. CLS Bank Int'l*, 573 U.S. 208, 216 (2014).
6. *See*, *e.g.*, *Benson*, 409 U.S. at 65; *Flook*, 437 U.S. at 591; *Diehr*, 450 U.S. at 187; *Alice*, 573 U.S. at 217.
7. *Alice*, 573 U.S. at 216; *Mayo Collaborative Servs. v. Prometheus Labs.*, 566 U.S. 66, 72 (2012) ("[Our precedents] warn us against upholding patents that claim process that too broadly preempt the use of a natural law.").
8. The gatekeeper function of Section 101 has been discussed in Supreme Court cases at times in a more subtle way. *See Mayo*, 566 U.S. at 89–91 (rejecting the argument that other statutory provisions—specifically §§ 102, 103, and 112—could adequately perform the screening function served by § 101); *Flook*, 437 U.S. at 593 (The determination of "what type of discovery is sought to be patented must precede the determination of whether that discovery is, in fact, new or obvious."); *Diehr*, 450 U.S. at 189; *see also Alappat*, 33 F.3d at 1553–54 (Archer, C.J., dissenting) (citing, *inter alia*, *Flook*, *Diehr*).
9. *Alappat*, 33 F.3d at 1551–68 (Archer, C.J., dissenting); *see Alice*, 573 U.S. at 216–27.
10. *Alappat*, 33 F.3d at 1553–54 (Archer, C.J., dissenting).
11. *Id.*
12. *Id.*
13. *Id.*
14. *Id.*
15. *Id.* at 1557. *See Mayo*, 566 U.S. at 73–75; *Flook*, 437 U.S. at 593.
16. *Alappat*, 33 F.3d at 1557 (Archer, C.J., dissenting); *see also Diehr*, 450 U.S. at 191–92; *Mayo*, 566 U.S. at 77–80; *Alice*, 573 U.S. at 217–18.
17. *Alappat*, 33 F.3d at 1557 (Archer, C.J., dissenting); *see also Mayo*, 566 U.S. at 84; *Alice*, 573 U.S. at 222.
18. *See*, *e.g.*, *Diehr*, 450 U.S. 175; *Flook*, 437 U.S. 584; *Diamond v. Chakrabarty*, 447 U.S. 303 (1980); *Funk Bros.*, 333 U.S. 127; *see also Alappat*, 33 F.3d at 1551–68 (Archer, C.J., dissenting).
19. *Mayo*, 566 U.S. at 77–80; *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576, 589–96 (2013); *Alice*, 573 U.S. at 217–18.
20. *Alice*, 573 U.S. at 217.
21. *Id.* at 217–18.
22. *Mayo*, 566 U.S. at 73–74.
23. *Id.* at 74–75.
24. *Id.* at 74.
25. *Id.* at 75.
26. *Id.* at 77.
27. *Id.* at 77–82.
28. *Id.*
29. *Id.*
30. *Myriad*, 569 U.S. at 583–84.
31. *Id.* at 584–85, 589–96.
32. *Alice*, 573 U.S. at 219–20.
33. *Id.* at 218.
34. *Id.* at 221–26.
35. *Id.* at 223–24. In *Alappat*, Chief Judge Archer advocated for this same reasoning because, if the court "look[ed] *only* to whether the claim reads on structure and *ignor[ed]* the claimed invention, [it would] result in the awarding of

patents for discoveries well beyond the scope of the patent law." 33 F.3d at 1554 (Archer, C.J., dissenting) (emphasis in original).

36. *In re BRCA1 and BRCA2-Based Hereditary Cancer Test Patent Litig.*, 774 F.3d 755 (Fed. Cir. 2014); *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371 (Fed. Cir. 2015), *reh'g denied*, 809 F.3d 1282 (Fed. Cir. 2015), *cert. denied*, 136 S. Ct. 2511 (2016); *Genetic Techs. Ltd. v. Merial L.L.C.*, 818 F.3d 1369 (Fed. Cir. 2016), *cert. denied*, 137 S. Ct. 242 (2016); *Cleveland Clinic Found. v. True Health Diagnostics LLC*, 859 F.3d 1352 (Fed. Cir. 2017) (*Cleveland Clinic I*), *cert. denied*, 138 S. Ct. 2621 (2018); *Roche Molecular Sys., Inc. v. CEPHEID*, 905 F.3d 1363 (Fed. Cir. 2018); *Athena Diagnostics, Inc. v. Mayo Collaborative Serv., LLC*, 915 F.3d 743 (Fed. Cir. 2019), *reh'g denied*, 927 F.3d 1333, *petition for cert. filed*, __ S. Ct. __ (2019); *Cleveland Clinic Found. v. True Health Diagnostics LLC*, 760 F. App'x 1013 (Fed. Cir. 2019) (*Cleveland Clinic II*).
37. *In re BRCA1*, the claimed invention involved a method for screening for genes linked to inherited breast and ovarian cancer by analyzing certain mutations in the DNA. 774 F.3d at 761–62. In *Ariosa*, the claimed invention involved a method for detecting paternally inherited fetal abnormalities by analyzing the blood or serum of a pregnant female. 788 F.3d at 1373–74. In *Genetic Techs.*, the claimed invention involved a method for detecting a coding region of a DNA based on its relationship to non-coding regions. 818 F.3d at 1371–73. In *Cleveland Clinic*, the claimed invention involved a method for diagnosing risk of cardiovascular disease by analyzing for the enzyme myeloperoxidase and detecting the correlation between blood myeloperoxidase levels and cardiovascular disease. *Cleveland Clinic I*, 859 F.3d at 1355–58; *Cleveland Clinic II*, 760 F. App'x at 1015–16. In *Roche*, the claimed invention involved a method for detecting pathogenic bacterium Mycobacterium tuberculosis based on nucleotide content. 905 F.3d at 1365–67. In *Athena*, the claimed invention involved a method for diagnosing *myasthenia gravis* by detecting the presence of muscle-specific tyrosine kinase. 915 F.3d at 747–48.
38. *See*, *e.g.*, *In re BRCA1*, 774 F.3d at 761–62; *Ariosa*, 788 F.3d at 1376; *Genetic Techs.*, 818 F.3d at 1375–76; *Cleveland Clinic I*, 859 F.3d at 1360; *Cleveland Clinic II*, 760 F. App'x at 1018; *Roche*, 905 F.3d at 1371–72; *Athena*, 915 F.3d at 750–53.
39. For example, in *Ariosa*, various claims recited using the polymerase chain reaction to amply DNA and using a sequence specific probe to detect amplified DNA. 788 F.3d at 1374, 1377–78. In *Cleveland Clinic I*, various claims recited using the enzyme-linked immunosorbent assay to detect the protein. 859 F.3d at 1357–58, 1362. In *Athena*, various claims recited specific immunological assays and concrete method steps, such as, mixing the protein complex having a label with bodily fluid and monitoring for the label on the protein complex. 915 F.3d at 751, 753–54.
40. *In re BRCA1*, 774 F.3d at 755, 764–65; *Ariosa*, 788 F.3d at 1377–78; *Genetic Techs.*, 818 F.3d at 1376–77; *Cleveland Clinic I*, 859 F.3d at 1361–63; *Roche*, 905 F.3d at 1372–73; *Athena*, 915 F.3d at 753–55; *Cleveland Clinic II*, 760 F. App'x at 1019–20.
41. *E.g.*, *Athena*, 915 F.3d at 757–64 (Newman, J., dissenting); *Athena*, 927 F.3d at 1352, 1359–63 (Moore, J., dissenting), 1364 (Newman, J., dissenting), 1370–71 (Stoll, J., dissenting), 1371 (O'Malley, J., dissenting).
42. *Id.* at 1371 (Stoll, J., dissenting).
43. *Athena*, 915 F.3d at 757–62 (Newman, J., dissenting); *Athena*, 927 F.3d at 1359–63 (Moore, J., dissenting), 1364–65 (Newman, J., dissenting).
44. *Athena*, 915 F.3d at 757–58 (Newman, J., dissenting); *Athena*, 927 F.3d at 1359–63 (Moore, J., dissenting), 1364–65 (Newman, J., dissenting).
45. *Mayo*, 566 U.S. at 74–75 (emphasis added).
46. *Athena*, 915 F.3d at 747 (emphasis added).
47. *Id.* at 757–64 (Newman, J., dissenting).
48. *Id.* at 759–62.
49. *Athena*, 927 F.3d at 1359–63 (Moore, J., dissenting).
50. *Id.* at 1360–61.
51. *Id.* at 1361–62.
52. *Id.* at 1362–63.
53. *Id.*
54. *Rapid Litig. Mgmt. Ltd. v. CellzDirect, Inc.*, 827 F.3d 1042 (Fed. Cir. 2016); *Vanda Pharms. Inc. v. West-Ward Pharms. Int'l Ltd.*, 887 F.3d 1117 (Fed. Cir. 2018), *petition for cert. filed*, 2018 WL 6819525 (Dec. 20, 2018); *Natural Alternatives Int'l, Inc. v. Creative Compounds, LLC*, 918 F.3d 1338 (Fed. Cir. 2019); *Endo Pharms. Inc. v. Teva Pharms USA, Inc.*, 919 F.3d 1347 (Fed. Cir. 2019).
55. *Vanda*, 887 F.3d at 1134–36; *Natural Alternatives*, 918 F.3d at 1345–46; *Endo Pharms.*, 919 F.3d at 1356.
56. *CellzDirect*, 827 F.3d at 1046.
57. *Id.* at 1050.
58. *Athena*, *petition for cert. filed*, __ S. Ct. __ (Oct. 2, 2019); *Vanda*, *petition for cert. filed*, 2018 WL 6819525 (Dec. 20, 2018).
59. *Interval Licensing LLC v. AOL, Inc.*, 896 F.3d 1335, 1348 (Plager, J., concurring in part and dissenting in part).
60. *Amdocs (Isr.) Ltd. v. Openet Telecom, Inc.*, 841 F.3d 1288, 1294 (Fed. Cir. 2016).
61. *Id.*
62. *Id.*
63. *Enfish, LLC v. Microsoft Corp.*, 822 F.3d 1327 (Fed. Cir. 2016).
64. *Visual Memory LLC v. NVIDIA Corp.*, 867 F.3d 1253 (Fed. Cir. 2017).
65. *Data Engine Techs. LLC v. Google LLC*, 906 F.3d 999 (Fed. Cir. 2018).
66. *RecogniCorps, LLC v. Nintendo Co.*, 855 F.3d 1322, 1326 (Fed. Cir. 2017).
67. *Chamberlain Grp. v. Techtronic Indus. Co.*, 935 F.3d 1341, 1347 (Fed. Cir. 2019).
68. *SIPCO, LLC v. Emerson Elec. Co.*, 2019 U.S. App. LEXIS 28935, at *26 n.3, 2019 WL 4656205, at *8 (Fed. Cir. Sept. 25, 2019).
69. Press Release, Thom Tillis, US Senator for N.C., Sens. Tillis and Coons and Reps. Collins, Johnson, and Stivers Release Draft Bill Text to Reform Section 101 of the Patent Act (May 22, 2019), *https://www.tillis.senate.gov/2019/5/sens-tillis-and-coons-and-reps-collins-johnson-and-stivers-release-draft-bill-text-to-reform-section-101-of-the-patent-act*.
70. Press Release, Thom Tillis, US Senator for N.C., Sens. Tillis and Coons and Reps. Collins, Johnson, and Stivers Release Section 101 Patent Reform Framework (Apr. 17, 2019), *https://www.tillis.senate.gov/2019/4/sens-tillis-and-coons-and-reps-collins-johnson-and-stivers-release-section-101-patent-reform-framework*.
71. *Id.*
72. *Id.*
73. Press Release, Thom Tillis, US Senator for N.C., Sens. Tillis and Coons and Reps. Collins, Johnson, and Stivers Release Draft Bill Text to Reform Section 101 of the Patent Act (May 22, 2019), *https://www.tillis.senate.gov/2019/5/sens-tillis-and-coons-and-reps-collins-johnson-and-stivers-release-draft-bill-text-to-reform-section-101-of-the-patent-act*.
74. *Id.*
75. *Id.*
76. *Id.*
77. *Id.*
78. Press Release, Chris Coons, US Senator for D.E., Coons and Tillis: What We Learned at the Patent Reform Hearing (June 24, 2019), *https://www.coons.senate.gov/news/op-eds/coons-and-tillis-what-we-learned-at-patent-reform-hearings*.
79. *See*, *e.g.*, *Alice*, 573 U.S. at 212–14; *Mayo*, 566 U.S. at 73–75; *Myriad*, 569 U.S. at 582–85; *Flook*, 437 U.S. at 593; *Alappat*, 33 F.3d at 1557 (Archer, C.J., dissenting).
80. *See*, *e.g.*, *Alappat*, 33 F.3d at 1551–52 (Archer, C.J., dissenting) (quoting G. Curtis, *A Treatise on the Law of Patents for Useful Inventions* at xxiii–xxv (4th ed. 1873)); *cf. Graver Tank & Mfg. Co. v. Linde Air Products Co.*, 339 U.S. 605, 609–10 (1950) (a claimed invention is composed of the "way," the physical form; the "function," the principles of operation; and the "result," the effect achieved).
81. *See* P. J. Federico, *Commentary on the New Patent Act*, in 35 U.S.C.A. (1954 ed., discontinued in subsequent volumes) (*reprinted in* 75 J. Pat. & Trademark Off. Soc'y 161, 182–184 (1993)), available at *https://heinonline.org/HOL/P?h=hein.journals/jpatos75&i=196*.

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