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**Professor Joshua D. Sarnoff submits the following comments in regard to the U.S. Patent and Trademark Office (PTO) request for information "on the current state of patent eligibility jurisprudence in the United States," Docket Number PTO–P–2021–0032.**  Professor Sarnoff teaches patent and administrative law at DePaul University College of Law, has filed amicus briefs in the Supreme Court and lower courts in important eligibility cases, has written extensively about patent eligible subject matter, and was a Thomas A. Edison Distinguished Scholar at the PTO.  On June 4, 2019, he testified before the Senate Committee on the Judiciary, Subcommittee on Intellectual Property in its Hearing on The State of Patent Eligibility in America (Attachment A, hereafter referred to as "Sarnoff Testimony").

Introduction

"Something is rotten in the state of" eligibility jurisprudence, based (mostly) on how the US Court of Appeals for the Federal Circuit ("CAFC" or "Federal Circuit") and the PTO have interpreted and applied the law, rather than on the current Supreme Court articulation of the law.  (Apologies to Shakespeare, Hamlet, Act. I, sc. iv., ln. 67.)  Specifically, what is rotten is the inability of the CAFC and the PTO to accurately state what judicial precedents actually hold, and for the Supreme Court to expressly admit that it has repealed past precedents (which is not discussed further here).  As a result, the CAFC and the PTO cannot properly apply analogical reasoning to reach correct results and they do not follow the CAFC's own rules that earlier panel precedents are controlling in the event of a conflict.[1]  This basic problem is described in the Sarnoff Testimony, as well as in the testimony of former Chief Judge of the CAFC Paul Michel (Attachment B).  In large part, this inconsistency results either from a failure to properly understand the ***purpose*** of eligibility law or, if properly understood, from a rejection by administrative and judicial actors of the idea that current eligibility law ***should*** fulfill that function, and thus these decisionmakers seek to undermine the current law rather than engage (or while also engaging) through the proper channels to change it.

Because of this inconsistency in the law and in its application, any actual empirical data (rather than anecdotes which should largely be ignored) that the PTO may develop or receive in regard to its study about the effects of the current jurisprudence are highly suspect and should not be relied upon to make any recommendations.  This is particularly true given that the PTO and the public cannot know what consequences would result if the current law were properly

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[1] *See Robert Bosch, LLC v. Pylon Mfg. Corp.,* 719 F.3d 1305, 1316 (Fed. Cir. 2013) (en banc) ("Panel opinions are, of course, opinions of the court and may only be changed by the court sitting en banc."); *Deckers Corp. v. United States,* 752 F.3d 949, 964 (Fed. Cir. 2014); *UMC Elecs. Co. v. United States,* 816 F.3d 647, 652 n.6 (Fed. Cir. 1987); *Kimberly-Clark Corp. v. Fort Howard Paper Co.,* 772 F.2d 860, 863 (Fed. Cir. 1985); *Mother's Rest., Inc. v. Mama's Pizza, Inc.,* 723 F.2d 1566, 1573 (Fed. Cir. 1983)).

interpreted applied and what opportunity costs would result from different legal alternatives (properly achieved by legislative change or proper hierarchical interpretation).

Accordingly, I will not address in these comments the **effects** of the current state of the jurisprudence on particularly industries, on research and development, or on innovation more generally, except to state that clarifying the jurisprudence and applying it properly could result in either greater eligibility or lesser eligibility overall, depending on how one resolves what the "current law" is and assuming its proper application and that there are no legislative changes or Supreme Court reinterpretations of the current law.  Before recommending any actual changes to the current law (as opposed to properly determining and applying it), moreover, the PTO should not assume that the submitted **anecdata** regarding the effects of recent eligibility doctrine have any meaningful bearing on the question of what the law **should** be.

Instead, the PTO should:

1. focus its efforts on better training its examiners in how to perform analogical reasoning when CAFC decisions conflict, by following the CAFC's own rule that the first-in-time panel precedent controls in the event of a conflict of interpretation of or in the application of the law, and should make clear that examiners must perform the research on the current state of the law (or be provided with correct, timely guidance that they can then rely upon) and must engage in such difficult-to-perform analogical reasoning; and
2. either follow that law properly or assert substantive rulemaking authority in post-grant reviews or more generally to interpret and apply the law as the PTO thinks is best and is most reflective of (past) legislative intent, even if those interpretations and applications are contrary to Supreme Court and CAFC precedent.[2]

In contrast, in any recommendations to Congress to change eligibility law, the PTO should:

3. encourage Congress to impose measures to assure consistent judicial interpretations and applications, including adopting mandatory interpretive rules for any legislative language regarding eligibility that Congress may retain or revise, by specifying more clearly the purpose of eligibility law that the Courts are supposed to apply, and by providing greater opportunities for private parties to force en banc CAFC reviews to address inconsistent interpretations and applications of the CAFC's precedents; and
4. explicitly seek legislative authorization of substantive rulemaking power over patent validity provisions; or (if Congress is unwilling to do so)

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[2] The holdings of the District Court and CAFC panel that the PTO lacks such substantive rulemaking authority in *Tafas v. Dudas* and *Tafas v. Doll* were vacated by the CAFC, *Tafas v. Doll,* 328 Fed.Appx. 658 (Fed. Cir. 2009) (en banc), and there is no *en banc* holding of the CAFC nor of the Supreme Court holding that the PTO lacks such rulemaking power as an incident to its general rulemaking authority or to the legislative authorization to examine patents and to perform post-grant reviews).  *But cf.* Merck & Co., Inc. v. Kessler, 80 F.3d 1543, 1550 (Fed.Cir.1996); Animal Legal Def. Fund v. Quigg, 932 F.2d 920, 930 (Fed.Cir.1991).

5.  encourage Congress to provide greater opportunities for any interested party (consistent with Article III of the Constitution) to challenge PTO interpretations issued by guidance documents that are inconsistent with the law as articulated by the courts.

The remainder of these comments focuses on (1) the kinds of inconsistencies demonstrated by the PTO in its eligibility guidance documents, (2) the purposes of eligibility doctrine as articulated by the Supreme Court for current law, and (3) the kinds of inconsistencies demonstrated by the CAFC in interpreting a Supreme Court and earlier panel precedents and in performing analogical reasoning.  In part, these inconsistencies reflect the deeply polarized views of the proper **purposes** of eligibility doctrine held by particular PTO administrators at particular times and by CAFC judges deciding the cases in front of them.  But rather than properly applying the law as it is while seeking to change it (such as by affirmatively seeking Supreme Court review, by drafting legislation, or by holding en-banc reviews), the PTO's guidance and the CAFC decisions depart from the law as articulated by the Supreme Court **and** by the CAFC.  This generates errors both of legal interpretation and of application, and creates inconsistency throughout the body of jurisprudence that makes proper analogical reasoning by judges much more difficult.  The inconsistency of PTO guidance and of CAFC precedents in turn makes it virtually impossible for examiners to "properly" apply the law.  Instead, examiners will be forced (if only by internal evaluation and supervision requirements) to apply improper guidance or simply (but wrongly) to apply the most current CAFC decision, even if the guidance or decision is inconsistent with Supreme Court precedent or with an earlier (and therefore binding) CAFC panel precedent.  But the PTO guidance does not instruct examiners to, nor are examiner trained as lawyers to, research and apply superior Supreme Court precedents and earlier CAFC panel precedents inconsistent with the later CAFC panel precedents.  Instead, PTO examiners normally will default to applying improper guidance or the wrong precedential interpretations of the law, which invariably will lead in application to many wrong results.  By explicitly identifying these inconsistencies, in contrast, the PTO in litigation could productively seek to shame the CAFC judges into doing a better job of acting consistently or of going en banc to resolve those inconsistencies.[3]  And by identifying the kinds of errors that the PTO guidance documents make, hopefully the PTO the can make better recommendations to Congress by properly articulating existing law and can be better informed when deciding whether to recommend any changes to the law.

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[3] *Cf. Atl. Thermoplastics Co. v. Faytex Corp.,* 974 F.2d 1279, 1281 (Fed. Cir. 1992) (en banc) (Rich, J., dissenting from the denial of rehearing en banc) ("The *Atlantic* panel[, which had refused to follow the earlier precedent in the *Scripps Clinic & Research Foundation v. Genentech, Inc.,* 927 F.2d 1565 (Fed. Cir. 1991),] continued [to explain that]: 'A[n earlier panel] decision that fails to consider Supreme Court precedent does not control if the court [i.e. the *Atlantic* panel] determines that the prior panel [in the earlier *Scripps* case] would have reached a different conclusion if it had considered controlling precedent.'  This is not only insulting to the [prior] *Scripps* panel (Chief Judge Markey, Judge Newman and a visiting judge), it is mutiny. It is heresy. It is illegal.").

1.  <u>PTO Eligibility Guidance and Inconsistency With Judicial Case Law</u>

The PTO issued eligibility guidance in January of 2019, Attachment C, and issued an update to that guidance in October of 2019, Attachment D.  The January 2019 guidance showed how the PTO then viewed the applicable law and how it instructed examiners to evaluate eligible subject matter.  If the guidance described the applicable law in error, and it did, then literally thousands of patent applications were improperly evaluated until the error was eventually corrected by an update to the guidance in October of 2019.  If patents were granted in error based on that improper articulation of the law, and they were, those errors can now only be corrected by very expensive post-grant reviews (because there is no legislated third-party right to challenge the grant of a patent directly by appeal on the administrative record).  In contrast, if patents were improperly denied, the applicants could at least appeal to the CAFC (and likely futilely to the Supreme Court) to properly interpret and correctly apply the current law.

It is important to note why the PTO issued this guidance before explaining why it was obviously and clearly wrong.  As the guidance noted, 84 Fed. Reg. at 52 (emphasis added):

> Since the Alice case, courts have been ''compare[ing] claims at issue to those claims already found to be directed to an abstract idea in previous cases.'' Likewise, the USPTO has issued guidance to the patent examining corps about Federal Circuit decisions applying the Alice/Mayo test, for instance describing the subject matter claimed in the patent in suit and noting whether or not certain subject matter has been identified as an abstract idea.
> While that approach was effective soon after Alice was decided, ***it has since become impractical. The Federal Circuit*** has now issued numerous decisions identifying subject matter as abstract or non-abstract in the context of specific cases, and that number is continuously growing. In addition, ***similar subject matter has been described both as abstract and not abstract in different cases. The growing body of precedent has become increasingly more difficult for examiners to apply in a predictable manner,*** and concerns have been raised that different examiners within and between technology centers may reach inconsistent results.
> ***The USPTO, therefore, aims to clarify the analysis.  In accordance with judicial precedent and in an effort to improve consistency and predictability***, the 2019 Revised Patent Subject Matter Eligibility Guidance extracts and synthesizes key concepts identified by the courts as abstract ideas to explain that the abstract idea exception includes the following groupings of subject matter, when recited as such in a claim limitation(s) (that is, when recited on their own or per se)….

Stated differently, even the PTO recognized that the Federal Circuit's precedents were so inconsistent that the PTO could not properly train its examiners in performing analogic reasoning, by distinguishing among those inconsistent precedents.[4]  More importantly, the PTO purported to seek to "clarify the

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[4] In contrast, the PTO could have followed the Federal Circuit's own rule and thus could have applied only the earliest in time of any inconsistent precedents, as that is the binding law under the Federal Circuit's own rules.  But

analysis," *id.* at 52, rather than follow the law as actually articulated by the Supreme Court.  To the extent that the PTO guidance was actually intended to depart from the law as articulated, then the PTO should simply have said so.  To the extent the PTO sought only to discern and articulate those principles from the conflicting CAFC cases (that also conflict with the Supreme Court precedents), it clearly did a poor job of it.  The PTO ultimately had to reverse course to correct its error in the October 2019 update.  I suspect that the January 2019 Guidance had more to do with an intent to change the law, given the publicly expressed views of the then-Director of the PTO, than with what would otherwise appear to be incompetence of the PTO's lawyers who reviewed the guidance document before issuing it.

Significantly, the January 2019 guidance, at 84 Fed. Reg. 53-54 (emphasis added), articulated as a core principle of *Alice* Step One that a claim is patent eligible unless it "recites" (as a claim limitation) the ineligible discovery that it applies.

> In accordance with judicial precedent, and to increase consistency in examination practice, the 2019 Revised Patent Subject Matter Eligibility Guidance sets forth a procedure to determine whether a claim is ''directed to'' a judicial exception under USPTO Step 2A. ***Under the procedure, if a claim recites a judicial exception (a law of nature, a natural phenomenon, or an abstract idea as grouped in Section I, above), it must then be analyzed to determine whether the recited judicial exception is integrated into a practical application of that exception.*** A claim is not ''directed to'' a judicial exception, and thus is patent eligible, if the claim as a whole integrates the recited judicial exception into a practical application of that exception….
> ***If the claim does not recite a judicial exception*** (a law of nature, natural phenomenon, or subject matter within the enumerated groupings of abstract ideas in Section I*), **then the claim is eligible at Prong One of revised Step 2A*** [*Alice* step one]. This concludes the eligibility analysis, except in the rare circumstance described below [addressing abstract ideas not falling into any of those abstract idea groupings].

However, even a simple comparison of the PTO's approach to the holdings of the Supreme Court in *Alice* and in *Bilski* should have revealed to the drafters of the guidance that the PTO's statement of "principles" was incorrect.  In *Alice,* the Supreme Court identified as the "abstract idea" underlying the claims (the creativity that the claims applied) the ineligible concept of "intermediated settlement."  Note that "intermediated settlement" was nowhere "recited "in the claims at issue, which were held ineligible as "directed to" that abstract idea at Step One and as not adding anything that would have converted the claims into an eligible invention at Step Two, even though the claims practically applied the concept of intermediated settlement

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as noted, that either (1) would require examiners to research and interpret the law to determine when judicial precedents are in conflict, and most examiners are not lawyers, or (2) would require the PTO to issue guidance indicating how the CAFC is not following its own rules and that the PTO will follow the earlier precedents that the guidance identified as inconsistent with the later cases (because the CAFC refused to go en banc to overturn the earlier precedents).  Needless to say, such explicit and embarrassing political confrontation with judicial overseers is not likely to occur.  We academics can, however, get away with "speaking truth to power."

in a novel and specific manner.  *Alice Corp. Pty. Ltd. v. CLS Bank, Intern.,* 573 U.S. 208, 217, 221 (2014).  *See id.* at 218 ("These claims are drawn to the abstract idea of intermediated settlement.").  Although *Alice* does use the term "recite" at various places, it does so in describing the **nature** of the claims, and not as a requirement for the claims to explicitly recite the abstract ideas in claim language in order for the claims to be "directed to" an abstract idea.[5] But as with the claims in *Alice,* the claims in *Bilski* nowhere "recite" the abstract idea of "hedging risk," but rather "recite" a series of steps that practically and concretely applied that abstract idea (an intangible concept) of hedging risk that underlay and was reflected by the claim limitations.

Following the PTO Guidance at PTO Step 2A (Alice Step One) to require that an "abstract idea" must be "recited" in the claim thus would necessarily lead to the wrong results in many cases, including the very cases that articulated and applied the legal standard.  The PTO should have known that was the case from a cursory inspection of the decisions in *Bilski* and *Alice*, not by their busy examiners but by the PTO lawyers and administrators issuing the guidance.  Yet the PTO required that examiners determine whether the claims "recite" an abstract idea, and if not to find claims to be eligible without any further analysis.  By October of 2019 (ten months after applying the January 2019 guidelines to who knows how many patents), and only after receiving comments on the January 2019 Guidance, the PTO "clarified" its January 2019 statements by impliedly acknowledging the readily apparent inconsistency with *Alice.*  But rather than acknowledge that its earlier Guidance was issued in error, the PTO sought to minimize the appearance of confusion and the extent of the error that its own guidance had caused.  The PTO thus claimed in the October 2019 update that the January 2019 Guidance had not actually changed how the PTO examined applications, even though it clearly had done so. And the PTO did so by saying that its use of the term "recites" in the January 2019 Guidance did not actually mean "recites," but rather meant recites or does not recite.  *See* Attachment E at 1 (emphasis added):

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[5] *See, e.g., id.* at 218-19 ("Claim 1 [in *Bilski*] **recited a series of steps <u>for hedging risk</u>**, including: (1) initiating a series of financial transactions between providers and consumers of a commodity; (2) identifying market participants that have a counterrisk for the same commodity; and (3) initiating a series of transactions between those market participants and the commodity provider to balance the risk position of the first series of consumer transactions) (emphasis added); *id.* at 219 (""[A]ll members of the Court agree[d]" that the patent at issue in *Bilski* **claimed an "abstract idea**." … Specifically, the claims **described** "the basic concept of hedging, or protecting against risk."") (emphasis added); *id.* (""The concept of hedging" **as recited** by the claims in suit was therefore a patent-ineligible "abstract idea, just like the algorithms at issue in *Benson* and *Flook*"") (emphasis added); *id.* ("It follows from our prior cases, and *Bilski* in particular, that the claims at issue here are directed to an abstract idea…. Petitioner acknowledges that its claims **describe** intermediated settlement, see Brief for Petitioner 4, but rejects the conclusion that its claims recite an "abstract idea."… *Bilski* belies petitioner's assertion. The concept of risk hedging we identified as an abstract idea in that case cannot be described as a "preexisting, fundamental truth." The patent in *Bilski* simply involved a "series of steps **instructing how to** hedge risk.") (emphasis added); *id.* at 221 (""A claim that **recites** an abstract idea must include "additional features" to ensure "that the [claim] is more than a drafting effort designed to monopolize the [abstract idea]."… Simply appending conventional steps, specified at a high level of generality," was not "*enough* " to supply an " '**inventive concept.**'"") (emphasis added).

> The 2019 PEG **did not change the meaning of "recites"** from how this term is used in the Manual of Patent Examining Procedure (MPEP). That is, a claim recites a judicial exception when the judicial exception is "set forth" or "described" in the claim. While the terms "set forth" and "describe" are thus both equated with "recite," their different language is intended to indicate that there are two ways in which an exception can be recited in a claim. For instance, the claims in *Diamond v. Diehr* **clearly stated** a mathematical equation **in the repetitively calculating step, such that the claims "set forth"** an identifiable judicial exception, **but** the claims in *Alice Corp. v. CLS Bank,* **"described" the concept of intermediated settlement without ever explicitly using the words** "intermediated" or "settlement."

*Alice* in Wonderland comes to mind here.[6]

To summarize, the reason I have spent so many pages here explaining just this one (but critical) error in the PTO's guidance document is not to berate the PTO and its lawyers and administrators for failing to properly understand the applicable law. This is particularly the case given that the Supreme Court uncarefully used the term "recites" when it clearly did not mean to use that term but instead meant something more like "reflects." Rather, the point is to make clear that there are serious consequences for not following the law as construed by the courts, or having the courts not following the law consistently. Other examples of the PTO uncritically adopting improper CAFC precedents as guidance are provided below. Who knows how many applications were improperly granted as patents in the interim even though they claimed ineligible subject matter? The same is true for judicial decisions that improperly fail to follow superior jurisdiction or earlier panel precedents, as described further below.

More importantly, as discussed next, this example helps to explain the purpose of the eligibility doctrine under current law. Understanding that purpose is critical to any evaluation of the current state of eligibility doctrine, as it is the failure to understand (or to agree upon) the purpose of eligibility law that likely leads to its inconsistent application of the law, intentionally or unwittingly. Without clearly understanding the proper purpose of eligibility law, it is virtually impossible to properly apply the law through analogical reasoning (particularly given inconsistent precedents). And that demonstrates that the current state of the law is rotten. Whether it is also bad for society in regard to lost innovation and adverse social consequences or the opposite simply cannot be measured, although no doubt the PTO will receive lots of anecdotes on both sides of that issue.

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[6] *See* Lewis Carroll, The Annotated Alice: Alice's Adventures in Wonderland & Through the Looking Glass 269 (Gardner ed. 1960) ("'When I use a word,' Humpty Dumpty said in rather a scornful tone, 'it means just what I choose it to mean--neither more nor less.' 'The question is,' said Alice, 'whether you can make words mean so many different things.' 'The question is,' said Humpty Dumpty, 'which is to be master--that's all.'").

2. <u>The Proper Purpose of Eligibility Doctrine (Under Current Law)</u>

The **purpose** of the Supreme Court's eligibility analysis, which reflects the purpose of eligibility doctrine, is to determine the underlying **concept** being applied by the claim elements (whether defined structurally or functionally), in order to assure that **the right kind of creativity** is being claimed as an invention using peripheral claiming language.  That inquiry must proceed without regard to whether a claim explicitly "recites" the underlying creative concept being practically applied (which creative concept is an intangible idea).  To have an eligible invention, the underlying concept being practically applied by the claim must be a **creative, technological** advance **in that application**, and must not merely be a "useful, concrete, and tangible" **practical application** of an ineligible scientific, natural, or abstract discovery or of aesthetic or other non-technological creativity.[7]

Determining the underlying concept being applied so as to determine if the claim **reflects** (rather than "recites") a **sufficiently creative** technological advance over any ineligible subject matter and not merely a practical application of that ineligible subject matter is what the *Mayo-Alice* framework requires.[8]  This is also why the Supreme Court in *Parker v. Flook* -- in language that was not impliedly repealed by *Diamond v. Diehr*[9] -- required both that the "claim as a whole" must be evaluated to determine the **nature** of the underlying **creativity** that the claim as a whole reflects, and that if some of the underlying creativity is based on an ineligible discovery then there must be some "other inventive concept" in the arrangement of the claimed elements practically applying the ineligible discovery than its mere application to

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[7] *See, e.g., In re Bilski,* 545 F.3d 943, 959-60 (Fed. Cir. 2008) (en banc) ("we also conclude that the "useful, concrete and tangible result" inquiry is inadequate and reaffirm that the machine-or-transformation test outlined by the Supreme Court is the proper test to apply.") (citing In re Alappat, 33 F.3d 1526, 1544 (Fed. Cir. 1994) (en banc)); Alappat, 33 F.3d at 1551 (C.J. Archer dissenting) ("'In this inquiry it is necessary to commence with the process of exclusion; for although, in their widest acceptation, the terms "invention" and "discovery" include the whole vast variety of objects on which the human intellect may be exercised, so that in poetry, in painting, in music, in astronomy, in metaphysics, and in every department of human thought, men constantly invent or discover, in the highest and the strictest sense, their inventions and discoveries in these departments are not the subjects of the patent law....'") (quoting G. Curtis, *A Treatise on the Law of Patents for Useful Inventions* at xxiii-xxv (4th ed. 1873); *id.* at 1553 ("The requirement of the patent law that an invention or discovery reside in the *application* of an abstract idea, law of nature, principle, or natural phenomenon is embodied in the language of 35 U.S.C. § 101.") (emphasis in original); *id.* at 1554 ("Through the expedient of putting his music on known structure, can a composer now claim as his invention the structure of a compact disc or player piano roll containing the melody he discovered and obtain a patent therefor? The answer must be no. The composer admittedly has invented or discovered nothing but music. The discovery of music does not become patentable subject matter simply because there is an arbitrary claim to some structure.").

[8] Although the Supreme Court used the different terminology of "'markedly different **characteristics** from any found in nature,'" Association for Molecular Pathology v. Myriad similarly requires finding such a sufficiently creative technological advance over a discovered product of nature and its discovered characteristics. 569 U.S. 576, 590-91 (2013) (quoting *Diamond v. Chakrabarty,* 447 U.S. 303, 310 (1980)) (emphasis added).

[9] Even had that aspect of *Flook* been impliedly repealed in *Diehr,* it would then have impliedly been restored by *Alice* and other Supreme Court cases decided subsequent to *Flook.*  Unlike the CAFC's rule for precedents, the later-in-time Supreme Court decision controls in the event of a conflict.

achieve a useful result.[10]  Otherwise, the claim would "monopolize" the abstract idea, albeit only in part (with regard to the particular, uncreative, specific application of the abstract idea that was claimed).  Stated differently, such an understanding of eligibility doctrine would allow discoverers to swallow the public domain of uncreative applications of ineligible subject matter piecemeal, rather than in one large bite by claiming the discovery as a whole.

Although the *Mayo-Alice* two-step framework can mislead examiners or judges into improperly ignoring some claim elements (rather than focusing on the claim as a whole) when determining the nature of the underly concept(s) being applied by a claim, little harm is done by first deciding if there is an underlying ineligible discovery being applied and then asking whether the claim elements individually or as an "ordered combination"[11] add sufficient technological creativity in the application of that ineligible discovery.  But the PTO's January 2019 Guidance also can mislead examiners into thinking that they should simply compare the claims to prior categories of "abstract ideas," without having to carefully *identify* the underlying concept(s) being applied by the claims at issue, when determining whether the creativity reflected in the claim is due to an ineligible discovery or to a sufficiently novel, technological advance.  Nothing in the PTO Guidance asks the examiners to address that central question.  Similarly, failing to recognize and to address that central question is why the courts have remained confused as to whether and when to find claims ineligible or eligible under Alice Step One or Alice Step Two.[12]

It would help for the PTO, the courts, and (if necessary) Congress to articulate a clear statement of the purpose and nature of the evaluation to be performed to determine patent eligibility.  Under existing law as interpreted by the Supreme Court, this purpose should be stated as: **to determine whether the creative concept *reflected by* the claim *as a whole* is *due to* an ineligible discovery or to a *sufficiently* creative, technological application of an ineligible**

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[10] Parker v. Flook, 437 U.S. 584, 594 (1978) (Our approach to respondent's application is, however, not at all inconsistent with the view *that a patent claim must be considered as a whole*. Respondent's process is unpatentable under § 101, not because it contains a mathematical algorithm as one component, but because *once that algorithm is assumed to be within the prior art,* the application, *considered as a whole, contains no patentable invention.* Even though a phenomenon of nature or mathematical formula may be well known, an inventive application of the principle may be patented. Conversely, the discovery of such a phenomenon cannot support a patent unless there is some other inventive concept in its application.") (emphasis added).  *See Alice,* 573 U.S. at 225 ("***Viewed as a whole,*** petitioner's method claims simply recite the concept of intermediated settlement as performed by a generic computer.") (emphasis added).  *Cf. id.* at 217-18 ("We have described step two of this analysis as a search for an "'inventive concept'"—*i.e.,* an element or combination of elements that is "sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the [ineligible concept] itself.").

[11] *See Alice,* at 217 ("To answer that [Step Two] question, we consider the elements of each claim both individually and "as an ordered combination" to determine whether the additional elements "transform **the nature of the claim**" into a patent-eligible application.") (citations omitted) (emphasis added).

[12] *See, e.g., CosmoKey Solutions GmbH & Co. KB v. Duo Security LLC,* 2021 WL 4515279, at *7 (Fed. Cir. Oct. 4, 2021) (Reyna, J., concurring) ("the majority skips step one of the *Alice* inquiry and bases its decision on what it claims is step two. I believe this approach is extraordinary and contrary to Supreme Court precedent. It turns the *Alice* inquiry on its head.").  *Cf.* Dennis Crouch, En Banc Petition: Counting to Two Alice Style, Attachment F; Dennis Crouch, Alice Corp. v. CLS Bank: When Two Become One, Attachment G ("As you'll see, the court's conclusions in Alice Step One (conventional actions in a generic way) fully answer Alice Step Two as well.").

**discovery.**[13]  Of course, nothing in the statute currently provides "how sufficiently creative" the technological concept reflected by the application of ineligible subject matter must be. Accordingly, courts and examiners will have to proceed by analogical reasoning once they understand what is the purpose of their evaluations.  The sufficiency (or not) of the creative technical application, moreover, must be evaluated *in light of the ineligible discovery,* which *Flook* and *Bilski* **treat as prior art** against the applicant (even if the ineligible subject matter was newly discovered by the applicant and was first disclosed in the application).[14]  In this way, the ineligible discovery or its discovered characteristics or applications in nature **cannot contribute** to any evaluation of the sufficiency of the creativity of the claimed technical application at issue.  In contrast, if we wish to reward natural, scientific, and abstract discoveries with private property rights, we can create "patents" on scientific principles, products of nature, and abstract ideas directly, without having to parse applications for technological creative sufficiency and with much less confusion and effort.  Of course, that would not be a good idea, for the reasons articulated in *Gottschalk v. Benson* and *Mayo.*[15]

3. <u>The Failure of the CAFC to Follow Supreme Court Precedent and Inconsistent CAFC Panel Precedents</u>

I will provide only two examples of how I believe the CAFC has failed to properly follow Supreme Court precedents.  The first is a case called *Vanda Pharmacueticals, Inc.  v. West-Ward Pharmeceuticals Int'l Ltd.,* 887 F.3d 1117 (Fed. Cir. 2018) (*Hikma v. Vanda* on petition for certioriari to the Supreme Court, which was denied).  The Federal Circuit panel majority sought to distinguish the Supreme Court's *Mayo* decision and found method of treatment claims to be patent eligible.  Apparently, the majority of the divided panel believed that claiming a **treatment** step **necessarily** assures that a claim is not "directed to" an ineligible discovery under *Mayo-Alice* Step One, but to a patent eligible, technological application.[16]  In

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[13] *See, e.g., Mayo Collaborative Services v. Prometheus Labs., Inc.,* 566 U.S. 66, 73 (2012) (the relevant cases "insist that a process that focuses upon the use of a natural law also contain other elements or a combination of elements, sometimes referred to as an "inventive concept," sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the natural law itself.") (quoting *Flook,* 437 U.S. at 594).

[14] *See* at *Flook,* 437 U.S. at 592 ("'*We think the case must be considered as if the principle being well known, the plaintiff had first invented a mode of applying it . . . .'* "… We think this case must also be considered as if the principle or mathematical formula were well known.") (quoting O'Reilly v. Morse, 56 U.S. (15 How.) 62, 115 (1853)) (emphasis in original).  *Bilski,* 561 U.S. 593, 610 (2010) ("The Court [in *Flook*] concluded that the process at issue there was "unpatentable under § 101, not because it contain[ed] a mathematical algorithm as one component, but because once that algorithm *[wa]s assumed to be within the prior art,* the application, considered as a whole, contain[ed] no patentable invention.") (quoting *Flook,* 437 U.S. at 594) (emphasis added).

[15] *See* Gottschalk v. Benson, 409 U.S. 63, 67 (1972) ("Phenomena of nature, though just discovered, mental processes, and abstract intellectual concepts are not patentable, as they are the basic tools of scientific and technological work."); *Mayo,* 566 U.S. at 86 ("even though rewarding with patents those who discover new laws of nature and the like might well encourage their discovery, those laws and principles, considered generally, are "the basic tools of scientific and technological work." … And so there is a danger that the grant of patents that tie up their use will inhibit future innovation premised upon them, a danger that becomes acute when a patented process amounts to no more than an instruction to "apply the natural law," or otherwise forecloses more future invention than the underlying discovery could reasonably justify.").

[16] *Vanda Pharms.,* 887 F.3d at 1134-35 ("This case, however, is not *Mayo.*  First, the claims in *Mayo* were not directed to a novel method of treating a disease. Instead, the claims were directed to a diagnostic method based on the

contrast, the panel dissenter would have found *Mayo* to be applicable and the claim ineligible, notwithstanding that this was a method of treatment claim. I believe the panel majority's analysis of the Supreme Court precedents is wrong, and more importantly that its analogical reasoning in applying the precedent is flawed (as articulated by the dissent).[17] If the CAFC judges themselves can't properly perform the required analogical reasoning, then we are in deep trouble. (At least one and maybe two judges on this panel must have been wrong in their analogical decision as to whether or not *Mayo* determined the outcome.) And the likely reason that the judges cannot properly perform the analogical applications is that their decisions reflect motivated reasoning regarding what they believe the purposes of eligibility law **should be** rather than what the law actually **is.**

Based on *Vanda,* The PTO subsequently issued a guidance document for examiners confirming this interpretation for examination (as otherwise examiners might not be aware of the precedent), resulting in **all** method-of-treatment claims **not** being subjected to further evaluation under the *Mayo-Alice* framework. Thus, none of the examiners have evaluated such claims to assess the nature of the underlying concept being applied and whether that concept is sufficiently creative in light of an ineligible natural discovery that is to be treated as if prior art.[18] The consequence is that **thousands** of method-of-treatment patents may have been improperly granted since *Vanda*, as they have never been properly evaluated under the Supreme Court's *Mayo-Alice* framework (assuming that the panel minority was correct that superior Supreme Court precedent in *Mayo* should have controlled the outcome in *Vanda).*

Significantly, in reaching its categorical holding, the panel majority in *Vanda* did not explain how adding a treatment step **necessarily** provides another "inventive concept" that is **sufficiently creative** so that the claim as a whole amounts to more than just the application of a discovered natural correlation, albeit limited to specific "post-solution activity" and a particular "field-of-use."[19] In contrast, as the panel majority implicitly recognized, a diagnostic claim based on the

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"relationships between concentrations of certain metabolites in the blood and the likelihood that a dosage of a thiopurine drug will prove ineffective or cause harm." … This "relation is a consequence of the ways in which thiopurine compounds are metabolized by the body—entirely natural processes. And so a patent that simply describes that relation sets forth a natural law."… Here, the '610 patent claims recite the steps of carrying out a dosage regimen based on the results of genetic testing. The claims require doctors to "internally administer[ ] iloperidone to the patient in an amount of 12 mg/day or less" if the patient has a CYP2D6 poor metabolizer genotype; and "internally administer[ ] iloperidone to the patient in an amount that is greater than 12 mg/day, up to 24 mg/day" if the patient does not have a CYP2D6 poor metabolizer genotype…. These are treatment steps. In contrast, as shown above, the claim in *Mayo* stated that the metabolite level in blood simply "indicates" a need to increase or decrease dosage, without prescribing a specific dosage regimen or other added steps to take as a result of that indication.").

[17] *See id.* at 1140 (Prost, C.J., dissenting) ("The majority finds the claims herein are not directed to a natural law at step one of the § 101 analysis, but its efforts to distinguish *Mayo* cannot withstand scrutiny.").

[18] *See* Bahr Memo to Examining Corps, Attachment I, at 2-3 ("(1) "method of treatment" claims that practically apply natural relationships should be considered **patent eligible** under Step 2A of the USPTO's subject matter eligibility guidance; and (2) it is not necessary for "method of treatment" claims that practically apply natural relationships to include nonroutine or unconventional steps to be considered **patent eligible** under 35 U.S.C. § 101.") (emphasis in original).

[19] *See Bilski,* 561 U.S. at 610 ("*Flook* rejected "[t]he notion that post-solution activity, no matter how conventional or obvious in itself, can transform an unpatentable principle into a patentable process.") (quoting *Flook,* 437 U.S. at 590); *id.* at 610-11 ("the prohibition against patenting abstract ideas "cannot be circumvented by attempting to

same ineligible natural discovery may be held ineligible, as it was in *Mayo* (whether or not the claim in *Mayo* was actually a treatment claim).[20]  I have attached an amicus brief that I helped draft seeking to obtain Supreme Court review of the *Vanda* decision, Attachment H, as the panel majority's analysis in *Vanda* seems to entirely fail to address the nature of the underlying creativity in the claim and whether a claimed treatment application is sufficiently creative **in light of** the ineligible discovered natural correlation (which is to be treated as if it were prior art). Further, it seems inconsistent with the direction from *Alice* that the **form** of the claim (rather than the creativity it reflects) should not be determinative of eligibility, and thus the system claims in Alice were held to be no more eligible than the process claims.[21]

Similarly, in *Illumina, Inc. v. Ariosa Diagnostics, Inc.,* another divided panel majority of the CAFC held that a **preparing materials** step (for use in diagnosis and treatment) to be categorically patent eligible as not being "directed to" naturally discovered materials (cell free fetal DNA that is shorter than maternal DNA).  As the panel majority stated, "This is not a diagnostic case. And it is not a method of treatment case. It is a method of preparation case."[22]  In other words, the

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limit the use of the formula to a particular technological environment" or adding "insignificant postsolution activity."") (quoting Diamond v. Diehr, 450 U.S. 175, 191-92 (1981).

[20] *See Vanda Pharms.,* 887 F.3d at 1135 ("The inventors recognized the relationships between iloperidone, CYP2D6 metabolism, and QTc prolongation, but that is not what they claimed. They claimed an application of that relationship….  The claim [in Mayo] was not a treatment claim…. Thus, the claim in *Mayo* did not involve doctors *using* the natural relationship between the metabolite level and lessening "the likelihood that a dosage of a thiopurine drug will prove ineffective or cause harm."… Here … [t]hese are treatment steps."). (emphasis in original). *Cf.* Athena Diagnostics Inc. v. Mayo Collaborative Services, L.L.C., 915 F.3d 743, 752-53 (2019) ("We consider it important at this point to note the difference between the claims before us here, which recite a natural law and conventional means for detecting it, and applications of natural laws, which are patent-eligible. *See Vanda* … (holding that method of treatment by administering drug at certain dosage ranges based on a patient's genotype was not directed to a natural law). Claiming a natural cause of an ailment and well-known means of observing it is not eligible for patent because such a claim in effect only encompasses the natural law itself. But claiming a new treatment for an ailment, albeit using a natural law, is not claiming the natural law."). But that distinction only makes sense if one is *not* seeking to determine whether the claimed invention reflects any sufficient creativity beyond merely applying a new, but ineligible, natural discovery, which is the purpose of the eligibility analysis.

[21] *Alice,* 573 U.S. at 226 ("Petitioner's claims to a computer system and a computer-readable medium fail for substantially the same reasons…. Put another way, the system claims are no different from the method claims in substance. The method claims recite the abstract idea implemented on a generic computer; the system claims recite a handful of generic computer components configured to implement the same idea. This Court has long "warn[ed] ... against" interpreting § 101 "in ways that make patent eligibility 'depend simply on the draftsman's art.' "") (citations omitted).

[22] Illumina, Inc. v. Ariosa Diagnostics, Inc., 967 F.3d 1319, 1325 (Fed. Cir. 2020).  *See id.* at 1325-57 ("We conclude that the claims are *not* directed to that natural phenomenon but rather to a patent-eligible method that *utilizes* it. The claims in this case are directed to methods for preparing a fraction of cell-free DNA that is enriched in fetal DNA…. The claims include physical process steps that change the composition of the mixture, resulting in a DNA fraction that is different from the naturally occurring fraction in the mother's blood. The dependent claims further illustrate the concrete nature of the claimed process steps…. Here, in contrast, the claims are directed to more than just the correlation between a DNA fragment's size and its tendency to be either fetal or maternal, a correlation which is not even mentioned in the claims. The claims do not cover a method for detecting whether a cell-free DNA fragment in a previously-prepared sample is fetal or maternal based on the natural size distribution of cell-free DNA fragments; rather, the claimed methods exploit that natural size distribution *during* the sample preparation steps to remove some maternal DNA from the mother's blood.") (second emphasis added).  *See id.* at

panel majority held the claims to be eligible, without assessing whether there was any sufficient creativity in the preparation steps *in light of* the ineligible discovery of the relative size of the DNA fragments at issue, contrary to Supreme Court precedent, and the majority focused on the "concreteness" of the claim notwithstanding the rejection by the en banc CAFC in *Bilski* of the "useful, concrete, and tangible" test of *Alappat.* In contrast, the dissent focused (properly) on the nature of the creativity reflected in the claimed process, and noted that "[t]he asserted claims are directed to a natural phenomenon, the patents' *sole claimed advance* is the discovery of that natural phenomenon, and the application of the natural phenomenon utilizes routine steps and conventional procedures that are well known in the art."[23] Again, after *Illumina,* the PTO is likely failing to evaluate any method of preparation claims for eligibility, potentially improperly granting **thousands** of patents.

In regard to inconsistency of CAFC panel decisions with earlier panel precedents, these tend to follow a similar pattern that depends on which particular draw of which at-least-two-out-of-three judges the appellants and appellees end up with. And that result of that draw is largely determined by whether at-least-two-out-of-three judges view eligibility in terms of concreteness and specificity of the claimed invention or in terms of the creativity underlying the claimed invention. But more importantly, the panel inconsistency that results ends up with decisions that reach different results but are *not analogically distinguishable* on the facts of those cases. Don't take my word for it. Here is what Professor Dennis Crouch recently stated in regard to the *CosmoKey Solutions v. Duo Security* case, Eligibility: Turning Application On-and-Off for Authentication Patent Eligible, Attachment J: "Patentee wins this one–with the Federal Circuit reversing the district court and finding the claims on patent-eligibility under Alice step-two. This is another case that serves as a data-point, but I struggle to differentiate it from similar cases finding claims ineligible." If a trained law professor with years of practical lawyer experience and who writes the foremost patent law blog can't see the difference between the cases except for the holdings, then patent examiners who don't have legal training and are under time pressures don't stand a chance of performing the required analogical reasoning.

And it's not just trained law professors or examiners. As Chief Judge Michel stated in his testimony to Congress (Attachment B, emphasis added):

> In my view, recent cases are unclear, inconsistent with one another and
> confusing. **I myself cannot reconcile the cases**. That applies equally to Supreme
> Court and Federal Circuit cases. Nor can I predict outcomes in individual cases
> with any confidence since the law keeps changing year after year. If I, as a judge
> with 22 years of experience deciding patent cases on the Federal Circuit's bench,

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1325-26 ("Here, it is undisputed that the inventors of the … patents discovered a natural phenomenon…. For simplicity, we adopt Illumina's articulation of the natural phenomenon, *i.e.*, that cell-free fetal DNA tends to be shorter than cell-free maternal DNA in a mother's bloodstream."). Cf. *id.* ("Under *Mayo,* we have consistently held diagnostic claims unpatentable as directed to ineligible subject matter.").

[23] *Id.* at 1330 (Reyna, J., dissenting) (emphasis added).

cannot predict outcomes based on case law, how can we expect patent examiners, trial judges, inventors and investors to do so?

….

To make matters even less clear, the [Supreme] Court then added layers of additional terms of equally unclear and unbounded meaning, including what a patent claim is "directed to," what is "significantly more" than an exception, whether something extracted from nature and then altered is "markedly different", and whether an invention represents a "practical application" of an exclusion.

Although this criticism is trenchant, Chief Judge Michel is way too polite to actually state the obvious, that the CAFC judges are either *intentionally* not following Supreme Court law (difficult as it may be to apply) or their own rule that the first-in-time panel precedent controls in the event of a conflict (which should not occur, because the second panel should follow the first panel's decision, unless the second panel can get the issue taken en banc).  The alternative understanding of Chief Judge Michel's criticism is even worse – that even CAFC judges (much less patent examiners of administrative patent judges) are *unable* to make the needed analogical distinctions based on the facts, with the result that the cases "cannot [be] reconcile[d]."  Simply put, more honesty about judicial disagreements and more willingness to air those disagreements by en banc (even if temporary) settlement of those disputes would go a long way towards resolving this problem.  But it would then reduce the perceived legitimacy of the courts as neutral interpreters, appliers, and arbiters of the law.

Conclusion

In order to clear up eligibility, we will need to get clarity over the purpose of eligibility doctrine under current law.  This is not too difficult.  As explained above, the purpose has already been made clear by Supreme Court precedents, even if some judges, PTO officials, or the public do not like the purpose of the law as so understood.  If judges, PTO officials, or the public wish to avoid applying the law as so interpreted, they can seek legislative change or can seek to have the Supreme Court reinterpret the current law.  But unless and until that happens, we need judges and PTO officials to *consistently* and *properly* apply the law as articulated by the Supreme Court (and for the Supreme Court to expressly repeal inconsistent prior precedents).  Until that happens, as noted in the introduction, it will be impossible to tell through empirical evidence (rather than through anecdata) whether the law is or is not operating well in any sector, when the law has not been and is not being interpreted and applied consistently.