Public Interest Patent Law Institute

ACLU

COMMENTS OF THE PUBLIC INTEREST PATENT LAW INSTITUTE AND THE AMERICAN CIVIL LIBERTIES UNION ON THE CURRENT PATENT SUBJECT MATTER ELIGIBILITY GUIDANCE

Docket Number: PTO-P-2022-0026

The Public Interest Patent Law Institute ("PIPLI") and the American Civil Liberties Union ("ACLU") are grateful for the opportunity to provide comments regarding the United States Patent and Trademark Office's ("USPTO") subject matter eligibility guidance, Docket No. PTO-P-2022-0026.

PIPLI is a nonprofit, nonpartisan public interest organization dedicated to ensuring the patent system promotes innovation and access for the benefit of all members of the public. Patents concretely affect the lives and livelihoods of virtually every American. Yet, most of them do not own, acquire, or apply for patents, including those who contribute to or depend on technological advances—for example, research scientists, open source technology developers, small businesses, medical patients, and health care providers. Because they do not interact directly with the USPTO as patent applicants do, these constituencies' needs are underrepresented in proceedings where patent policy decisions are made. As a result, those decisions too often overlook their needs and impede their ability to contribute to or access scientific advances. Giving due consideration to the needs of the diverse individuals and communities affected by the patent system is essential to fulfilling its goals of promoting progress and public access to knowledge. PIPLI's mission is to improve the patent system's ability to fulfill these goals by enhancing public representation and consideration in the institutions that shape patent law. In service of this mission, PIPLI conducts policy research; engages in educational outreach; provides free legal counseling to those affected by the patent system, advocates for greater transparency, ethics, and equity; and submits amicus briefs and comments to courts, government agencies, and standard-setting organizations.

The ACLU is a national, nonprofit, nonpartisan organization dedicated to the principles of liberty found in the U.S. Constitution. The ACLU recognizes that patent regulation can significantly affect civil liberties, including rights guaranteed under the First Amendment. Section 101 of the Patent Act and the long-standing prohibitions on patenting natural phenomena, laws of nature, and abstract ideas have played a vital role in securing intellectual freedom and fostering scientific innovation. The ACLU represented over 20 pathology and genetics organizations, geneticists, breast and ovarian cancer patients, and patient advocacy groups to challenge the practice of granting patents on isolated DNA, resulting in a unanimous 2013 U.S. Supreme Court decision striking down such patents in *Association for Molecular Pathology v. Myriad Genetics*. Preventing patents on natural phenomena and abstract ideas has broadened healthcare options available to patients, including women with family histories of cancer, people with disabilities, and children with rare diseases. The ACLU also has regularly filed amicus briefs with the Supreme Court and engaged in advocacy with the PTO and Congress to support Section 101's prohibitions on patenting laws of nature and abstract ideas. The ACLU therefore has a significant interest in PTO actions and guidance that govern how the agency deals with patent eligibility determinations.

I. OVERVIEW

As the Supreme Court has emphasized, Congress was given the authority to grant patents "in the hope that the productive effort thereby fostered will have a positive effect on society through the introduction of new products and processes of manufacture into the economy, and the emanations by way of increased employment and better lives for our citizens."[1] In other words, the patent system was designed to benefit the public.

Section 101's patent eligibility requirements are particularly important to the patent system's ability to fulfill this goal by striking a "balance between creating incentives that lead to creation, invention, and discovery and impeding the flow of information that might permit, indeed spur, invention."[2] Because examiners rely on the USPTO's guidance to evaluate patent applications, the public has a powerful interest in ensuring that guidance describes patent eligibility law accurately and helps examiners apply it faithfully.

Unfortunately, the current guidance does the opposite. Instead of helping examiners apply controlling law, the guidance encourages them to ignore, contradict, or circumvent it. In so doing, the guidance practically guarantees that examiners issue patents that would be deemed ineligible if the law were correctly applied. Guidance such as this diminishes patent quality, erodes the public's confidence in granted patents, creates confusion and uncertainty, increases the expense of district court litigation, and deprives the public of access to knowledge that would otherwise be available to fuel innovation and improve people's lives.

These avoidable harms will persist as long as the current guidance does. For that reason, we urge the USPTO in the strongest possible terms to revise the guidance so that it is consistent with the Supreme Court and Federal Circuit precedents governing patent eligibility today. These revisions are necessary for the guidance to conform to controlling law, but they are also necessary for the public to access the building blocks of scientific research on which future innovation, quality of life, and economic vitality in this country depend.

II. THE USPTO'S CURRENT PATENT-ELIGIBILITY GUIDANCE

A. The Supreme Court's Patent Eligibility Jurisprudence is Clear and Has Been Applied Predictably.

In *Bilski, Mayo, Myriad,* and *Alice*, the Supreme Court set out clear guidelines on enforcing Section 101's prohibition on patenting laws of nature, natural phenomena, and abstract ideas. In *Mayo* and *Alice*, the Court established a two-part test for patent eligibility: (1) determining whether the claims at issue are directed to patent-ineligible subject matter, and (2) examining the elements of the claim to determine whether they, individually or collectively, contain an "inventive concept" sufficient to transform the claim into patent-eligible subject matter.[3] The Federal Circuit has

[1] *Diamond v. Chakrabarty*, 447 U.S. 303, 307 (1980) (internal quotation marks and citation omitted).
[2] *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576, 590 (2013) ("*Myriad"*) (internal quotation marks and citations omitted).
[3] *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66, 81 (2012); *Alice Corporation Pty. v. CLS Bank International*, 573 U.S. 208, 217–18 (2014).

applied this test predictably since *Alice*, repeatedly rejecting arguments based on earlier case law, like the machine or transformation test.[4] Significantly, the Supreme Court has consistently declined to review the Federal Circuit's post-*Alice* patent eligibility decisions.

Federal Circuit judges have explicitly acknowledged the Supreme Court's patent eligibility test is clear and that case law applying it is consistent. For example, Judge Alan D. Lourie recognized in a concurring opinion accompanying the court's *per curiam* order in *Athena Diagnostics, Inc. v. Mayo Collaborative Servs.*, "our cases are consistent."[5] He further recognized that in the context of diagnostic methods, the distinction between eligible and ineligible subject matter is "a clear line."[6] Despite dissenting in that case, Chief Judge Kimberly A. Moore recognized the certainty surrounding patent subject matter eligibility.[7] Other judges have recognized the value of the Supreme Court's clarification of patent subject matter eligibility. For example, Judge Haldane Robert Mayer wrote that "[b]efore the Supreme Court stepped in to resuscitate section 101, a scourge of meritless infringement suits clogged the courtrooms and exacted a heavy tax on scientific innovation and technological change."[8]

Empirical evidence confirms the conclusions of these long-serving judges. For example, in the five years after *Alice* issued, the Federal Circuit affirmed 89% of district court decisions finding patent claims ineligible.[9] From 2013 through 2020, decisions applying § 101 had an affirmance rate of 65% when appealed to the Federal Circuit and decided in precedential opinions, higher than the circuit's overall affirmance rate of 56%.[10] The affirmance rate for § 101 decisions was higher than the overall affirmance rate in most years during this period.[11]

The affirmance rate is even higher when non-precedential affirmances under Federal Circuit Rule 36 are considered. In a 2018 study of all Federal Circuit patent-eligibility decisions since *Alice*, Paul Gugliuzza and Mark Lemley determined the court affirmed 90% of district court

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[4] *See, e.g.*, *Solutran, Inc. v. Elavon, Inc.*, 931 F.3d 1161, 1169 (Fed. Cir. 2019) (explaining that "passing the [machine or transformation] test alone is insufficient to overcome . . . failings under step two [of *Alice*]"); citing *DDR Holdings, LLC v. Hotels.com, L.P.*, 773 F.3d 1245, 1256 (Fed. Cir. 2014) ("[I]n *Mayo*, the Supreme Court emphasized that satisfying the machine-or-transformation test, by itself, is not sufficient to render a claim patent-eligible, as not all transformations or machine implementations infuse an otherwise ineligible claim with an 'inventive concept.'").

[5] *Athena Diagnostics, Inc. v. Mayo Collaborative Servs., LLC*, 927 F.3d 1333, 1336 (Fed. Cir. 2019) (Lourie, J., concurring).

[6] *Id*.

[7] *Id.* at 1363 (Moore, J., dissenting).

[8] *In re Marco Guldenaar*, 911 F.3d 1157, 1165 (Fed. Cir. 2018) (Mayer, J., concurring); *see also Ultramercial, Inc. v. Hulu, LLC*, 772 F.3d 709, 720 (Fed. Cir. 2014) (Mayer, J., concurring) ("The Supreme Court has taken up four subject matter eligibility challenges in as many years, endeavoring to right the ship and return the nation's patent system to its constitutional moorings . . . the PTO has for many years applied an insufficiently rigorous subject matter eligibility standard . . . .").

[9] Robert Sachs, Alice*: Benevolent Despot or Tyrant? Analyzing Five Years of Case Law Since* Alice v. CLS Bank*: Part I*, IPWATCHDOG (Aug. 29, 2019), https://www.ipwatchdog.com/2019/08/29/alice-benevolent-despot-or-tyrantanalyzing-five-years-of-case-law-since-alice-v-cls-bank-part-i/id=112722/.

[10] ACLU, *Comments on Patent Eligibility Jurisprudence Study, Docket Number: PTO-P-2021-0032*, Sept. 7, 2021, https://www.regulations.gov/comment/PTO-P-2021-0032-0052 ("ACLU Comments"), at 2. These measurements are based on numbers provided by Gibson Dunn's annual Federal Circuit Year in Review reports. *See id.* at 8, n.49.

[11] *Id.*

ineligibility decisions on appeal.[12] That study also revealed a striking contrast: the Federal Circuit issued fifty Rule 36 affirmances of ineligibility decisions compared to zero such affirmances of decisions finding claims eligible. The court wrote an opinion in all of those cases. These data show that perception of patent eligibility jurisprudence may be skewed by which cases the Federal Circuit chooses for written opinions.

Claims of confusion in patent eligibility law are based on policy preferences, not objective evidence. The USPTO can and must provide guidance that is faithful to the Supreme Court and Federal Circuit's patent eligibility jurisprudence.

B. The USPTO's Current Guidance Is Inconsistent with Governing Law.

The current guidance's inconsistency with controlling law is widely recognized, including within the USPTO. According to the Government Accountability Office's (GAO) recent survey of Patent and Trial Appeal Board (PTAB) judges, 30% of responding judges stated that "the 2019 Revised Patent Subject Matter Eligibility Guidance creates new tests for evaluating whether an invention is eligible that are not supported or established by the applicable case law."[13] Some judges specified that the MPEP's unsupported tests have the effect of "broaden[ing] the types of inventions that are patentable beyond the case law."[14] The fact that so many PTAB judges believe the guidance gets the law wrong in ways that ensure ineligible patents issue provides sufficiently compelling reasons to revise it.

Moreover, the Federal Circuit has repeatedly declined to follow the current guidance, overturned decisions based on it, and classified parts of the MPEP as contrary to law.[15] For example, in *Cleveland Clinic*, the Federal Circuit explicitly concluded that a hypothetical claim described in the MPEP as eligible (Example 29-claim 1) would be ineligible under controlling law. As the court explained, the hypothetical claim involves a method that is "strikingly similar" to the claim held ineligible in *Ariosa v. Sequenom*, and, despite the MPEP's contrary classification, "*Ariosa* must control."[16]

When affirming PTAB decisions that "rel[y] on a recitation of the Office Guidance," the Federal Circuit has gone out of its way to explain that the PTAB's "reasoning and conclusions are nevertheless in accord with the relevant case law."[17] The inconsistencies between the current guidance and case law are so well-established that the Federal Circuit has affirmatively explained that the PTAB's conclusions are correct despite relying on that guidance.

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[12] *Id.* (citing Paul Gugliuzza & Mark Lemley, *Can a Court Change the Law By Saying Nothing?*, 71 VANDERBILT L. REV. 765 (2018)).

[13] U.S. GOV'T. ACCOUNTABILITY OFFICE, *Patent and Trial Appeal Board: Preliminary Observations on Oversight of Judicial Decision-making*, July 21, 2022, https://www.gao.gov/assets/gao-22-106121.pdf, at 14.

[14] *Id.*

[15] *See, e.g.*, *cxLoyalty, Inc. v. Maritz Holdings Inc.*, 986 F.3d 1367, 1376 (Fed. Cir. 2021) (rejecting PTAB's finding of claims amended in Covered Business Method Review as eligible based on USPTO guidance); *Cleveland Clinic Found. v. True Health Diagnostics LLC,* 760 F. App'x 1013, 1019 (Fed. Cir. 2019) (rejecting patent owner's argument for eligibility based on MPEP example of patent-eligible claim).

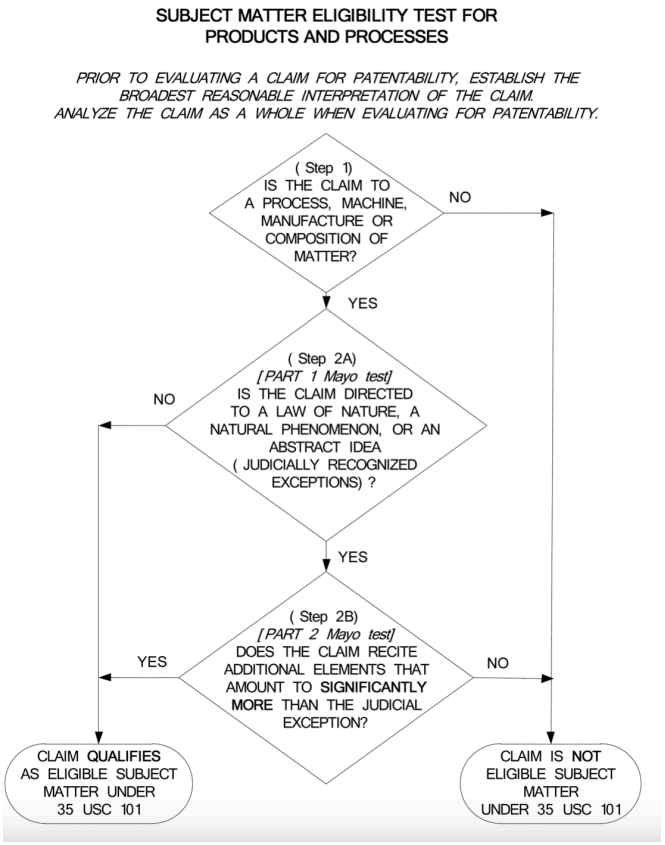
[16] *Cleveland Clinic*, 760 F. App'x at 1021 (discussing *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371 (Fed. Cir. 2015)).

[17] *In re Zunshine*, 816 F. App'x 477, 478–79 (Fed. Cir. 2020) (citing *In re Rudy*, 956 F.3d 1379, 1383 (Fed. Cir. 2020))

C. The USPTO Should Issue New Guidance Based on a Clean Slate or the Original Post-*Alice* Guidance.

The current guidance is so voluminous (at 100 pages, it is longer than the *Myriad*, *Mayo*, and *Alice* opinions combined) and replete with mischaracterizations of law that it is not practicable to enumerate each and every aspect of the guidance that must be revised to ensure consistency with Supreme Court and Federal Circuit case law. Rather than suggest the USPTO shoulder this burden, we believe the best way to conform the current patent eligibility guidance to controlling law is to start from a clean slate that centers on the two-part test that the Supreme Court set forth and applied in *Mayo* and *Alice,* accurately captures the Supreme Court's precedents including in *Myriad*, draws on subsequent Federal Circuit case law for examples of how they should be applied to particular types of patent claims, and eliminates changes made by the revised guidance documents of June 2018 and October 2019.

An alternative to starting from a blank slate that would make the guidance consistent with controlling law would be restoring the guidance the USPTO issued after *Alice* in 2014. This guidance was far more faithful to the Supreme Court's patent eligibility test than the current guidance. For example, the 2014 guidance instructed examiners to perform the same two-step analysis the Court applied in *Mayo* and *Alice*, as depicted in the flowchart reproduced below:[18]



[18] USPTO, *2014 Interim Guidance on Subject Matter Eligibility*, 79 Fed. Reg. 74618, 74621, Dec. 16, 2014 ("2014 Guidance"); *compare id. with* USPTO, *October 2019 Update: Subject Matter Eligibility* ("2019 Guidance"), at 10 (depicting flowchart with additional steps, including "streamlined analysis" between steps 1 and 2A).

Even if the USPTO chooses to retain aspects of the current guidance, those that are inconsistent with controlling law must be revised. While these inconsistencies are too numerous to enumerate in full here, highlighted below are revisions of particular importance and urgency. These must be made to restore consistency with controlling law and prevent further harm to the public. Otherwise, the guidance will continue leading examiners to issue ineligible patents that will obstruct rather than enhance the advancement and accessibility of science and technology.

III. REVISIONS NECESSARY TO CONFORM TO CONTROLLING LAW

A. The USPTO's Guidance Must Follow the Supreme Court's Two-Part Test.

First and foremost, the guidance must be revised so that it accurately reflects the Supreme Court's patent eligibility test. That test requires:

(1) determining whether the claim at issue is directed to ineligible subject matter—i.e., a law of nature, natural phenomenon, product of nature, or abstract idea; and if so,

(2) determining whether the claim contains elements that, individually or collectively, represent an inventive concept that is eligible for protection—i.e., something which is significantly more than the ineligible subject matter identified in step one and not routine, conventional, well-understood, generic, or part of the ineligible subject matter itself.

The Supreme Court clearly described and applied this two-part test in *Alice*.[19] Numerous subsequent Federal Circuit decisions have confirmed that, including *In re Killian*, where it stated: "In *Alice* . . . and *Mayo* . . . , the Supreme Court explicated a two-step test for determining whether claimed subject matter falls within one of the judicial exceptions to patent eligibility."[20]

Regrettably, the current guidance strays far from this two-part test, adding a number of additional steps, which find no support in the Patent Act or post-*Alice* case law, yet heavily tilt the scales in favor of eligibility. These steps practically guarantee the issuance of patent claims that will chill innovation and impede access to knowledge until and unless they are challenged in district court litigation. These unauthorized and harmful aspects of the guidance must be removed and replaced with instructions that allow patent examiners and PTAB judges to apply governing law, including judicial precedents. The USPTO should provide guidance that helps them do so correctly instead of directing them to circumvent it.

[19] *Alice*, 573 U.S. at 217–18.
[20] *In re Killian*, 45 F.4th 1373, 1379 (Fed. Cir. 2022) (citations omitted); *see also CareDx, Inc. v. Natera, Inc*., 40 F.4th 1371, 1376 (Fed. Cir. 2022); *Am. Axle & Mfg., Inc. v. Neapco Holdings LLC*, 967 F.3d 1285, 1292 (Fed. Cir. 2020), *cert. denied*, 142 S. Ct. 2902 (2022).

B. The Practical Application Exception Is Contrary to Law and Must Be Removed.

1. The Supreme Court Has Held Practical Applications Are Not Enough for Eligibility.

One of the most problematic parts of the current guidance is the "practical application" exception that authorizes skipping the second part of the Supreme Court's test, and thus ensures the issuance of patents that are directed to ineligible subject matter yet contain no inventive concept.

This aspect of the guidance is neither supported by nor reconcilable with governing law. Indeed, the Supreme Court has consistently rejected the notion that integrating ineligible subject matter into a practical application is enough to establish eligibility without an inventive concept. As it explained in *Alice*: "In holding that the process [in *Parker v. Flook*] was patent ineligible, we rejected the argument that 'implement[ing] a principle in some specific fashion' will 'automatically fal[l] within the patentable subject matter of § 101.'"[21] *Alice* explicitly reaffirmed "the proposition that the prohibition against patenting abstract ideas cannot be circumvented by attempting to limit the use of the idea to a particular technological environment."[22]

2. The Guidance Relies on Federal Circuit Cases that Do Not Support the "Practical Application" Exception.

The guidance describing the practical application exception cites no precedent that undermines the Supreme Court's clear holding in *Alice*. That includes the two Federal Circuit cases the guidance cites as examples of decisions finding claims eligible as practical applications: *SRI v. Cisco* and *Bascom v. AT&T*.[23]

Although the court in *SRI* affirmed a district court decision finding claims eligible, it did not rely or focus on whether ineligible subject matter was integrated into a practical application. (The terms "practical" and "practical application" do not even appear in the opinion.) Rather, the Federal Circuit's decision turned on the specificity of the claimed solution to a similarly specific technological problem. As the court explained: "The claims are directed to using a specific technique—using a plurality of network monitors that each analyze specific types of data on the network and integrating reports from the monitors—to solve a technological problem arising in computer networks: identifying hackers or potential intruders into the network."[24] In other words, the court concluded the claims were not directed to an abstract idea because they recited a sufficiently *specific* technique.

SRI's emphasis on specificity is distinct from the instruction in the current guidance that "if . . . additional limitations reflect an improvement in the functioning of a computer, or an improvement to another technology or technical field, the claim integrates the judicial exception

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[21] *Alice*, 573 U.S. at 218 (quoting *Parker v. Flook,* 437 U.S. 584, 593 (1978)).
[22] *Id.* (citations omitted).
[23] *See* 2019 Guidance at 11–12 (discussing *SRI Int'l, Inc. v. Cisco Systs., Inc.*, 930 F.3d 1295 (Fed. Cir. 2019) and *Bascom Global Internet Servs., Inc. v. AT&T Mobility LLC*, 827 F.3d 1341 (Fed. Cir. 2016)).
[24] *SRI*, 930 F.3d at 1303–04.

into a practical application and . . . [n]o further analysis is required."[25] What the guidance omits is the requirement that the claim limitations reflect a sufficiently *specific* improvement to sufficiently *specific* technology. As the Federal Circuit emphasized in *SRI*: "The 'focus of the claims is on the *specific* asserted improvement in computer capabilities'—that is, providing a network defense system that monitors network traffic in real-time to automatically detect large-scale attacks."[26]

Similarly, in *Enfish*, the Federal Circuit affirmed a district court's finding of eligibility because the claims were "directed to a *specific* improvement to the way computers operate, embodied in the self-referential table."[27] In a subsequent case, the court emphasized the importance of this "specific improvement" in distinguishing eligible from ineligible claims: "In *Enfish*, we applied the distinction to reject the § 101 challenge at stage one because the claims at issue focused not on asserted advances in uses to which existing computer capabilities could be put, but on a specific improvement—a particular database technique—in how computers could carry out one of their basic functions of storage and retrieval of data."[28]

This line reasoning follows directly from the Supreme Court's decision to reject "as unpatentable Samuel Morse's general claim for 'the use of the motive power of the electric or galvanic current ... however developed, for making or printing intelligible characters, letters, or signs, at any distances.'"[29]

The guidance's reliance on *Bascom* to support finding eligibility after step one of the *Alice* test is even more overtly misplaced. Crucially, the Federal Circuit in *Bascom* did not classify the claims as a practical application of an abstract idea or stop its analysis at step one. Rather, it found the claims eligible only after conducting the second step of the *Alice* test and identifying a sufficiently inventive concept. The Federal Circuit said so explicitly: "Here, in contrast [to *Enfish*], the claims and their specific limitations do not readily lend themselves to a step-one finding that they are directed to a nonabstract idea. We therefore defer our consideration of the specific claim limitations' narrowing effect for step two."[30] *Bascom* does not support or reflect the practical application exception described in the guidance in any respect.

Moreover, the analyses in *Bascom* and *SRI* were different from those patent examiners perform. As appeals of district court decisions, the courts were obligated to follow the *Philips* claim construction standard rather than the broadest reasonable interpretation (BRI) standard that governs examination. District courts apply a more rigorous claim construction rubric because of the presumption of validity granted patents receive—a presumption that rests on the assumption that examiners will thoroughly scrutinize the claims before allowing them to issue. To justify the presumption of validity, examiners must apply the BRI at all stages of their review, including to questions of patent eligibility. As such, they should interpret claims as broadly as is reasonable, rather than narrowing them based on disclosures in the specification as district courts and, when reviewing their decisions, the Federal Circuit do.

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[25] 2019 Guidance at 11.
[26] *SRI*, 930 F.3d at 1303 (quoting *Enfish LLC v. Microsoft, Corp.*, 822 F.3d 1327, 1335–36 (Fed. Cir. 2016)) (emphasis added).
[27] *Enfish*, 822 F.3d at 1336 (emphasis added).
[28] *Elec. Power Grp., LLC v. Alstom S.A.*, 830 F.3d 1350, 1354 (Fed. Cir. 2016).
[29] *Mayo*, 566 U.S. at 85 (quoting *Morse v. O'Reilly*, 56 U.S. (15 How.) 62, 86 (1853)).
[30] *Bascom*, 827 F.3d at 1349 (Chen, J.).

3. The Guidance Should Encourage Examiners to Conduct the Second Step of the *Alice* Test Because the Resulting Prosecution History Benefits the Public.

To the extent *Bascom* is instructive, it demonstrates that close patent eligibility questions should proceed to the second step of the *Alice* analysis—especially when those questions are before patent examiners. That is so because the public benefits from the record examiners create when determining if claims contain an inventive concept. In some instances, an examiner's analysis may lead the applicant to narrow claims through amendments or clarify them in responsive remarks. Regardless of an applicant's response, the contents of an office action may help the public understand the meaning and scope of the patent's claims, and thereby avoid needless infringement, including by developing new inventions beyond the bounds of the claims. If the patent becomes the subject of litigation, statements in the prosecution history are evidence on which parties and courts can rely—including to resolve cases—at early stages of litigation, preventing the needless expenditure of substantial amounts of time and money.

By giving examiners a reason not to perform the second step of the *Alice* test, the practical application exception deprives the public of these valuable benefits. Because courts do not apply a practical application exception (or anything remotely similar), the record examiners create when following the current guidance offers nothing of any, let alone comparable, value. It only makes prosecution history files less useful to courts and parties, thus increasing the time and cost required to determine if patents are ineligible post-issuance.

C. The Treatment or Prophylaxis Exception Is Contrary to Law and Must Be Removed.

The current guidance instructs examiners to skip the second step of the *Alice* test if claims recite an application or use of ineligible subject matter to "effect a particular treatment or prophylaxis for a disease or medical condition."[31] That is contrary to law and harmful to public health.

For example, the 2019 Guidance describes a hypothetical claim "that recites mentally analyzing information to identify if a patient has a genotype associated with poor metabolism of beta blocker medications," as well as a step of "administering a lower than normal dosage of a beta blocker medication to a patient identified as having the poor metabolizer genotype."[32] According to the guidance, "[t]his administration step is particular, and it integrates the mental analysis step into a practical application," thus establishing eligibility.[33]

That is wrong. In *Mayo*, the claim involved "[a] method of optimizing therapeutic efficacy for treatment of an immune-mediated gastrointestinal disorder"—i.e., a treatment or prophylaxis.[34] To provide such treatment, the claim required administering a drug containing a particular compound—6–thioguanine—to a subject with a particular condition—"immune-mediated gastrointestinal disorder."[35] This "administering" step was not enough to make the claim eligible

[31] 2019 Guidance at 13.
[32] *Id.* at 14.
[33] *Id.*
[34] *Mayo*, 566 U.S. at 74–75.
[35] *Id.*

for patent protection because "the prohibition against patenting abstract ideas cannot be circumvented by attempting to limit the use of the formula to a particular technological environment."[36]

Mayo makes clear that administering a known treatment does not establish patent eligibility without more.[37] If a patient's genotype indicates their metabolism of beta blockers is poor, simply administering additional beta blockers does nothing more than use that biological information (which no human invented) to do what doctors have long done (administer beta blockers). Without more, there is simply no invention to patent.

Establishing patent eligibility based on the sole act of administering a drug – without any requirement for an additional inventive concept –would significantly impede access to effective medical care. That is true of the hypothetical claim the 2019 Guidance approves: if a doctor identifies a patient's genotype, the claim would "tie up the doctor's subsequent treatment decision whether that treatment does, or does not, change in light of the inference he has drawn using the [identification]."[38] In other words, if the doctor determines a patient's genotype is associated with poor metabolism of beta blockers and provides a higher dosage of beta blockers, he may infringe the claim even if he would have provided the higher dosage for other reasons, like the patient's weight, medical history, physical symptoms, or other genetic conditions.

Mayo also recognizes that such claims can "inhibit the development of more refined treatment recommendations . . . that combine [genetic information] with later discovered features of . . . human physiology or individual patient characteristics."[39] For example, researchers interested in refining beta blocker dosage (or more complicated medical regimes) by using information about genes associated with beta blocker metabolism with other patient information, including information about other genes, could be blocked by the hypothetical claim. Even if researchers had the resources to pay for a license, they would have to delay their research to obtain one and there is no guarantee the patent owner would give them one. They might instead do as Myriad: use their exclusive right to prevent the development or commercialization of more comprehensive and cost-effective medical care.

The current guidance cites no case that supports this exemption from the *Alice* test. The case it cites as an example of relevant treatments or prophylaxes, *Classen Immunotherapies, Inc. v. Biogen IDEC*, 659 F.3d 1057 (Fed. Cir. 2011) predates the Supreme Court's decisions in *Mayo*, *Myriad*, and *Alice.*[40]

The Federal Circuit's case law cannot and does not allow what *Mayo* forbids. The court has made that clear. In *Vanda v. West Ward*, the Federal Circuit held a claim eligible that was directed not merely to a particular medical treatment, but to "'a *specific* method of treatment for *specific* patients using a specific compound at *specific* dose to achieve a specific outcome.'"[41] In

[36] *Id.* at 78 (internal quotation marks and citations omitted).
[37] *Id.*
[38] *Id*. at 86–87.
[39] *Id.*
[40] 2019 Guidance at 13
[41] *In re Zunshine*, 816 F. App'x 477, 479 (Fed. Cir. 2020) (quoting *Vanda Pharms. Inc. v. West Ward Pharms. Int'l*, Ltd., 887 F.3d 1117, 1136 (Fed. Cir. 2018)) (emphasis in original).

Zunshine, the Federal Circuit rejected the proposition the 2019 Guidance embraces, stating: "In *Vanda*, we did not hold that all methods of treating a disease are categorically patent eligible."[42]

The law clearly and consistently holds that simply applying a natural law (or abstract idea) to a method of treatment does not by itself establish patent eligibility or justify skipping the search for an inventive concept at step two of the *Alice* test. By directing examiners to skip the inventive concept analysis, this part of the guidance exacerbates the very dangers the Supreme Court sought to prevent in *Mayo.*

D. Eliminate the "Streamlined Analysis" for Claims on Products of Nature and Maintain the "Markedly Different" Characteristics Analysis as Required By Law.

When considering claims that may qualify as ineligible products of nature, the Manual of Patent Examining Procedure instructs examiners to "consider whether the streamlined eligibility analysis discussed in MPEP § 2106.06 is appropriate," and if so, states that "it would not be necessary to conduct a markedly different characteristics analysis."[43] This instruction should be removed because it allows examiners to bypass the legally required analysis and grant patents on ineligible products of nature—the building blocks of science that must remain open for all to access.

To determine whether a patent claim is directed to a product of nature, the law requires determining whether there are marked differences between what an applicant claims as their invention and what exists in nature. The Supreme Court relied on this test to distinguish a patent-eligible synthetic "bacterium [which] was new 'with markedly different characteristics from any found in nature,'" from the ineligible gene sequence which Myriad "separat[ed] . . . from its surrounding genetic material," but "did not create."[44]

The MPEP tells examiners they can bypass the marked differences test if a claim "clearly does not seek to tie up any judicial exception such that others cannot practice it . . . as [its] eligibility will be self-evident."[45] This instruction assumes that eligibility is evident when a claim does not preempt all uses of ineligible subject matter. That is wrong. As the Federal Circuit made clear in *Ariosa v. Sequenom,* "[w]hile preemption may signal patent ineligible subject matter, the absence of complete preemption does not demonstrate patent eligibility."[46] The fact that a claim does not preempt all uses of ineligible subject matter does not establish eligibility; still, they must contain an inventive concept that transforms these "building blocks of human ingenuity . . . into something more."[47]

The MPEP's approach does what *Myriad* prohibits: it opens the door to patents on products that nature created and humans merely discovered or isolated.[48] By providing exclusive rights to natural products that were available without human intervention, patents such as these impede

[42] *Id.*
[43] MPEP § 2106.04(b)(II).
[44] *Myriad*, 569 U.S. at 590–91 (citation omitted).
[45] MPEP § 2106.06.
[46] *Ariosa*, 788 F.3d at 1379.
[47] *Alice*, 573 U.S. at 217 (internal quotation marks and citation omitted).
[48] *See Myriad*, 569 U.S. at 591.

more innovation than they promote, taking material from the public domain without contributing anything in return. The MPEP must be revised to instruct examiners to apply controlling law and reject such claims instead of encouraging them to defy the law and grant exclusive rights to nature's work.

E. Restore Examiners' Ability to Identify Abstract Ideas through Comparisons to Cases and/or Revise the List of Groupings to Include those the Federal Circuit Has Recognized.

The USPTO has historically allowed patent examiners to identify abstract ideas at step one of the *Alice* test by doing what the Supreme Court requires: comparing claims under consideration to those classified as abstract (or not) in the case law.

In *Alice*, the Supreme Court confirmed the correctness of this approach, explaining it would "not labor to delimit the precise contours of the 'abstract ideas' category" because "[i]t is enough to recognize that there is no meaningful distinction between the concept of risk hedging in *Bilski* and the concept of intermediated settlement at issue here. Both are squarely within the realm of 'abstract ideas' as we have used that term."[49] Following *Alice*, the Federal Circuit has likewise looked to its decisions and those of the Supreme Court to determine whether particular claims are directed to abstract ideas.[50]

The USPTO's original post-*Alice* guidance provided a list of "[t]he types of concepts courts have found to be abstract ideas," but it explicitly stated these were "intended to be illustrative and not limiting."[51] It further explained in a subsequent update to the 2014 Guidance that examiners were instructed to identify abstract ideas by comparison because courts had consistently taken that approach instead of defining the term more narrowly: "Because the courts have declined to define abstract ideas, other than by example, the 2014 [Guidance] instructs examiners to refer to the body of case law precedent in order to identify abstract ideas by way of comparison to concepts already found to be abstract."[52]

Even though the Supreme Court has not issued a single patent eligibility decision since *Alice*, the USPTO changed its guidance on this part of the *Alice* test. As the 2019 Guidance asserts: "the Office has shifted its approach from the case-comparison approach in determining whether a claim recites an abstract idea and instead uses enumerated groupings of abstract ideas."[53] By creating an enumerated—and thus constrained—list of abstract idea groupings, the USPTO's guidance does what neither the Supreme Court nor the Federal Circuit have done: constrain the contours of the abstract ideas category by identifying a limited set of categories.

Further, the USPTO's list of groupings is so narrow that it excludes many abstract ideas identified as such in precedential decisions. For example, the Federal Circuit has "treated

[49] *Alice*, 573 U.S. at 221.
[50] *See, e.g.*, *Elec. Power Grp., LLC v. Alstom S.A.*, 830 F.3d 1350, 1353–54 (Fed. Cir. 2016) (collecting cases identifying analogous claims as "within the realm of abstract ideas").
[51] 2014 Guidance at 74622.
[52] USPTO, *July 2015 Update: Subject Matter Eligibility*, at 3.
[53] 2019 Guidance at 2.

collecting information, including when limited to particular content (which does not change its character as information), as within the realm of abstract ideas."[54]

Numerous abstract ideas the Federal Circuit has identified do not fit within the limited set the USPTO's guidance recognizes (*i.e.*, mathematical concepts, certain methods of organizing human activity, and purely mental processes). Examples include: the "abstract idea of extracting and storing data from hard copy documents using generic scanning and processing technology"[55]; "the idea of retaining information in the navigation of online forms"[56]; the "abstract idea of classifying and storing digital images in an organized manner"[57]; and the abstract ideas of "tailoring information based on navigation data" and "tailoring content based on the time of day at which the user viewed the content."[58]

The guidance should be revised to restore the approach of the original post-*Alice* guidance—as well as the Supreme Court and Federal Circuit—where abstract ideas are identified through comparisons to analogous ideas addressed in Federal Circuit and Supreme Court case law. Examiners have a great deal of expertise already; allowing them to identify cases this way will improve the accuracy of their patent eligibility determinations over time.

At a minimum, the list of enumerated groupings should be expanded to include *all* of the types of ideas the Federal Circuit and Supreme Court have identified as abstract in their decisions and acknowledge that others may exist. In particular, the guidance should recognize that methods of collecting, organizing, and storing information can qualify as abstract ideas that do not involve economics, or financial transactions, but do require generic computer hardware, software, or communication networks (e.g., the Internet). The guidance inexplicably excludes ideas such as these, which the Federal Circuit has repeatedly classified as abstract at step one of *Alice*.[59]

Additionally, the guidance should be revised to permit examiners to classify ideas as abstract when they match those courts have identified without getting a supervisory patent examiner's permission. This requirement imposes a burden that deters examiners from identifying ineligible subject matter at step one of *Alice* and determining whether an inventive concept exists at step two. Given that the identification of an abstract idea at step one does not conclusively render a claim ineligible, and merely prompts the inventive concept analysis at step two, there is no reason to constrain examiners' ability to identify them as rigidly as the current guidance does.

This approach prevents examiners from creating a more comprehensive and helpful prosecution history record, increases the likelihood they will issue ineligible patents, and thus threatens the public's ability to collect, organize, and store information using generic and conventional computer equipment.

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[54] *Elec. Power Grp.,* 830 F.3d at 1353–54 (collecting cases identifying abstract ideas).
[55] *Content Extraction & Transmission LLC v. Wells Fargo Bank, Nat'l Ass'n*, 776 F.3d 1343, 1349 (Fed. Cir. 2014).
[56] *Internet Pats. Corp. v. Active Network, Inc.*, 790 F.3d 1343, 1348 (Fed. Cir. 2015).
[57] *In re TLI Commc'ns LLC Pat. Litig.*, 823 F.3d 607, 611 (Fed. Cir. 2016).
[58] *Intell. Ventures I LLC v. Cap. One Bank (USA*), 792 F.3d 1363, 1369–70 (Fed. Cir. 2015).
[59] *See supra* notes 54–58.

IV. CONCLUSION

It is crucial that the USPTO's guidance help patent examiners apply patent eligibility law in a manner that is consistent with controlling Supreme Court and Federal Circuit jurisprudence. The current guidance falls far short of that goal and must be revised extensively to achieve it. Doing so will clarify and simplify patent eligibility guidance used by examiners, enhance the quality of granted patents, and protect the public's access to subject matter which humans did not create, but rely on to develop patent-eligible inventions into the future. We are grateful to the USPTO for working to improve its guidance on an issue that matters so much to the public, and hope that it considers the public's interest throughout this process.

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