2021

The Fate of Future Personalized Medicine Treatment Patents

Gyuhyun Bae

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I. Introduction

Since the founding of this country, patents have been at the heart of U.S. policy to incentivize and further innovation.[1] The great importance of patents in American society is evident through the Intellectual Property Clause of the Constitution, which recognizes the various rights of patent holders.[2] Under the Constitution, the main purpose of the patent system is "to promote the progress of science and useful arts" by rewarding innovation with a temporary monopoly.[3] Further, after the adoption of the Constitution, Congress passed the first patent statute the following year in 1790.[4] By granting an inventor a limited right of exclusion, patent law provides incentives for inventors to promote the improvement of new technologies, which in turn has a positive impact on our society by providing improved goods, services, and processes, which ultimately drives economic growth.[5]

Today, patents remain objects of prestige within our society and are regarded with esteemed status for the continuous growth in the field of technology and life sciences. In 2018, the United States Patent and Trademark Office (USPTO) received almost 650,000 patent applications and issued over 300,000 patents, which puts the U.S tied for second place as the strongest intellectual property regime in the world.[6] However, although the U.S remains a top contributor in the

*J.D. Candidate, 2021, Seton Hall University School of Law; Pharm.D., 2018, Rutgers University.
[1] Maureen K. Ohlhausen, *The Case for a Strong Patent System*, Federal Trade Commission (2016).
[2] U.S. CONST. art. 1. §8, cl.8.
[3] *Id.*
[4] Ohlhausen, *supra* note 1.
[5] Rebecca Lindhorst, Note, *Two-Stepping Through Alice's Wasteland of Patent-Eligible Subject Matter: Why The Supreme Court Should Replace The Mayo/Alice Test*, 69 CASE W. RES. 731, 732 (2019).
[6] Eileen McDermott, *IBM Tops Patent Charts (Again) with 9,100 U.S. Patents in 2018*, IPWATCHDOG (Jan. 19, 2019), https://www.ipwatchdog.com/2019/01/09/ibm-tops-patent-charts-9100-us-patents-2018/id=104889/.

patent world, there is a slowing trend in patent applications in recent years as these numbers represent a 3.5% decline from 2017.[7] Part of the reason may have to do with the patent applicant's struggle to balance the unpredictability of the patent grant with the enormous cost risks involved in developing these new technologies.[8] Thus, a predictable patent system is crucial in allowing inventors to protect their rewards for successful inventions and to make educated decisions on where to allocate resources when developing such new technologies.[9]

The patent applicant's confusion lies in the application of the current subject matter eligibility requirements under Section 101 of the Patent Act, which includes a judicially created exception for laws of nature, natural phenomena, and abstract ideas.[10] These exceptions are ineligible for patent rights, and the courts have unsurprisingly struggled to define what exactly fits within the definition of "laws of nature, natural phenomena, and abstract ideas." The Supreme Court's current patent-eligibility test, the Mayo/Alice Two-Step, has been criticized for rejecting and invalidating many patents since its adoption.[11] Recently, however, the Federal Circuit held that patent claims featuring a novel diagnostic discovery were not directed to a natural law "even though the natural law at issue was plainly the only inventive aspect of the claims."[12] In *Vanda Pharms. Inc. v. West-Ward Pharms. Int'l Ltd.*, part of the dispute was over a claim on methods of treating schizophrenic patients with a medication called iloperidone.[13] The Court held that the patent claims were not directed to a law of nature, even where claims relied on a natural law for their

[7] *Id.*
[8] Lindhorst, *supra* note 5.
[9] *Id.*
[10] *Id.*
[11] *Id.* The Mayo/Alice test involves a two-step analysis for patent eligible subject matter. Step one inquires whether the claims are directed to laws of nature, natural phenomena, and abstract ideas. If so, step two determines whether the claim contains an "inventive concept" sufficient to transform the claimed idea into a patent-eligible application. Vanda Pharms. Inc. v. West-Ward Pharms. Int'l Ltd., 887 F.3d 1117, 1133 (2018).
[12] Peter A. Hecker, *How To Claim Something When the Inventive Aspect Is A Natural Law*, 19 WAKE FOREST J. BUS. & INTELL. PROP. L. 1, 1 (2018).
[13] Vanda Pharms. Inc. v. West-Ward Pharms. Int'l Ltd., 887 F.3d 1117, 1133 (2018).

inventive concept.[14] Thus, such claims are still patent-eligible subject matter if detailed with specificity. In particular, if claims are "directed to a specific method of treatment for specific patients using a specific compound at specific doses to achieve a specific outcome."[15] But just how much specificity is required to meet this threshold? The *Vanda* outcome has inevitably added to the confusion in the debate of subject matter eligibility for patent rights and further highlights the need for clarification on this issue.

This Comment will examine the difficulties courts deal with regarding patent eligibility challenges, especially in method of treatment claims, and the need for reform of Section 101 of the Patent Act in determining what exactly constitutes patent eligible subject matter. Part II will analyze cases dealing with matters of subject matter eligibility and the difficulties in applying the current legal framework, the Mayo/Alice Two-Step. Part III will discuss the recent *Vanda* decision and compare it with *Mayo Collaborative Services v. Promethus Laboratories, Inc*. Part IV will examine the implications of the *Vanda* decision on future method of treatment claims. Part V will review the need for clarification of Section 101 of the Patent Act. Part VI will discuss the current draft reform bill and detail the shortfalls of the proposed solutions. Part Vll will conclude. To successfully achieve the purpose of the patent system, this Comment recommends adopting parts of the draft reform bill as its current form does not adequately address the current issues on subject matter eligibility of patents.

II. Development and Application of the Patent Act of 1952

A. Section 101 of the Patent Act

[14] *Id.*
[15] *Id.* at 1134.

To obtain a patent, an inventor must file an application with the United States Patent and Trademark Office (USPTO) that meets several requirements.[16] One of the requirements that needs to be met is Section 101, which states, "[w]hoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title."[17] Since the 1800s, however, courts have narrowed the types of subject matter that are considered patent eligible.[18] Notably, laws of nature, natural phenomena, and abstract ideas are ineligible for protection within the patent system.[19] This stems from the belief that these areas are inappropriate for patenting and granting a monopoly on the "basic tools of scientific and technological work" would essentially impede innovation by preventing others from using these basic building blocks of human creativity.[20] Without an objective standard set forth by these exceptions, however, courts have struggled to determine whether an invention is patent eligible or patent ineligible. This has, in turn, led to varying judicial applications of the subject matter eligibility requirement and confusion for both patent applicants and patent examiners.[21]

B. Supreme Court Cases Establishing Standards of Subject Matter Eligibility

In 2012, the Court in *Mayo Collaborative Services v. Promethus Laboratories, Inc.*, invalidated the claim as patent ineligible.[22] This case involved a claim to a method for determining the optimal dose range of an immunosuppressive drug, called thiopurine, by measuring the blood level

[16] 35 U.S.C. §101 (2012).
[17] *Id.*
[18] Lindhorst, *supra* note 5, at 738.
[19] *Id.*
[20] Interval Licensing, LLC v. AOL, Inc., 896 F.3d 1335, 1343 (Fed. Cir. 2018).
[21] Lindhorst, *supra* note 5, at 738.
[22] Mayo Collaborative Servs. v. Prometheus Labs., Inc., 566 U.S. 66, 71 (2012).

of its metabolite, which then informs the physician whether or not to adjust the dosage.[23] Relationships between concentrations of metabolites in the blood and the likelihood that a thiopurine drug dosage would prove ineffective or cause harm were determined to be known laws of nature.[24] The Court reasoned that there was a lack of a sufficiently inventive step.[25] Steps of administering drugs by physicians who already used the drugs, advising the physicians to apply the natural laws in making treatment decisions, and directing the measurement of metabolite levels "simply told physicians to engage in well-understood, routine, conventional activity previously engaged in by scientists in the field."[26] Further, the Court was concerned about preemption where "the grant of patents that tie up their use will inhibit future innovation premised upon them."[27] Thus, in order to overcome the hurdle of "laws of nature," a claim had to contain a sufficiently inventive step.[28] However, once again, the ambiguity of the term "inventive step" remains unsolved by this Court's decision.

The following year in 2013, the Court held that breast and ovarian cancer susceptibility genes were patent ineligible as well.[29] In *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, Myriad Genetics monopolized tests on the BRCA1 and BRCA2 genes, which can be used to test a person's predisposition to the development of breast or ovarian cancer.[30] The challenged patents covered sequences of parts of the genes' isolated DNA and "cDNA" (a synthetic type of DNA that is created in a lab).[31] Petitioners argued that because its scientists had identified and isolated the

[23] *Id.*
[24] *Id.*
[25] *Id.*
[26] *Id.* at 72.
[27] *Id.*
[28] *Mayo*, 566 U.S. at 72.
[29] Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 569 U.S. 576, 579 (2013).
[30] *Id.* Breast Cancer Genes (BRCA) are different genes that have been found to impact a person's chance of developing breast cancer. *BRCA: The Breast Cancer Gene,* National Breast Cancer Foundation, Inc. (Nov. 3, 2019).
[31] *Id.*

genes from the rest of the human genome, the genes contained a sufficiently inventive step that warranted a patent.[32] Here, the Court's analysis focused on whether the patent claims fell under the patent ineligible category of "natural phenomena."[33] The Court held that the company "did not create anything new" and that DNA is a product of nature that "is not patent eligible merely because it has been isolated."[34] Once again, there was a lack of inventive step required to survive the patent ineligible criteria of "natural phenomena."

Subsequently in 2014, the Court once again held claims on formulation and trading of risk management contracts patent ineligible for falling within the judicial exception of "abstract ideas."[35] In *Alice Corp. Pty. v. CLS Bank Int'l*, the claims were: (1) method for exchanging financial obligations, (2) computer system configured to carry out the method for exchanging obligations, and (3) computer-readable medium containing program code for performing the method of exchanging obligations.[36] The Court held that the claims were directed to the patent ineligible concept of the abstract idea of intermediated settlement.[37] Petitioners failed to transform this abstract idea into a patent eligible invention, and thus, the claims did not warrant a patent.[38]

C. Mayo/Alice Two-Step Test

Through the cases mentioned above, the Court established the legal framework, called the Mayo/Alice Two-Step Test, for distinguishing a patent that claims laws of nature, natural phenomena, and abstract ideas from those that claim patent eligible applications of those concepts.[39] The

[32] *Id.*
[33] *Id.* at 58.
[34] *Id.* at 582.
[35] Alice Corp. Pty. v. CLS Bank Int'l, 573 U.S. 208, 214 (2014).
[36] *Id.*
[37] *Id.*
[38] *Id.*
[39] Jack S. Barufka, Ngai Zhang, Matthew W. Hindman, & Tiffany C. Kuo, *Evaluating the Evaluation: Breaking Down New USPTO Guidance for Patent-Eligible Subject Matter*, PILLSBURY WINTHROP SHAW PITTMAN LLP (Jan. 1, 2019), https://www.pillsburylaw.com/en/news-and-insights/uspto-guidance-patent.html.

Mayo/Alice Two-Step Test consists of Step 2A and Step 2B. First, under Step 2A, the court determines whether a patent claim is "directed to a law of nature, a natural phenomenon or an abstract idea."[40] If not, then the invention is determined to be patent eligible and there is no need to proceed to step 2B.[41] Second, if the claim *is* directed to a law of nature, natural phenomenon or abstract idea, then under Step 2B, the court determines whether "the claim recites additional elements that amount to significantly more than the judicial exception."[42] In other words, this inquiry asks whether there is an inventive application of the judicial exception, otherwise known as an "inventive concept," to render the claim patent eligible. [43]

D. Difficulties of Mayo/Alice Two-Step Test

One of the main criticisms of this test was the difficulty for examiners to apply this in a predictable manner—particularly in the context of abstract ideas. This has, in turn, raised concerns that the patent office is reaching inconsistent results.[44] Under Step 2A, for example, the determination of what an abstract idea constitutes relied heavily on prior judicial examples.[45] Specifically, under Step 2A, examiners were required to compare a concept in a patent claim to concepts in prior court decisions to determine if the claimed concept was similar to a court-identified abstract concept.[46] Because the Federal Circuit has issued a large number of decisions identifying subject matter as abstract or not, it has become increasingly difficult for examiners to apply the Alice/Mayo Two-Step in a predictable manner. Additionally, due to the sheer volume of post-*Alice* case law that exists and the inconsistent application of the Alice/Mayo Two-Step framework

[40] *Alice*, 573 U.S. at 214.
[41] Barufka, Zhang, Hindman, & Kuo, *supra* note 39.
[42] *Alice*, 573 U.S. at 208.
[43] Barufka, Zhang, Hindman, & Kuo, *supra* note 39.
[44] *Id.*
[45] *Id.*
[46] *Id.*

by the courts, an examiner could now just easily pick and choose case examples to support a rejection under Section 101.[47] This raises the concern that different examiners within and between technology centers may ultimately reach inconsistent results.[48] Thus, even with the Alice/Mayo Two-Step legal framework for determining patent eligible subject matter, changes are necessary to increase clarity and consistency in this area of patent law.

In January of 2019, the USPTO revised its guideline to provide clarifications on this legal framework.[49] The guideline states that only when a claim recites a judicial exception *and* fails to integrate the exception into a practical application is the claim considered "directed to" a judicial exception under Step 2A, thereby triggering further analysis under Step 2B.[50] The revised guideline further provides specific groupings of subject matter that is considered to be an abstract idea.[51] In particular, examiners are directed to determine whether concepts recited in the patent claim fall within the following enumerated groupings of abstract ideas.[52] Except in rare cases, patent claims *not* falling within any of these categories do not recite an abstract idea and are thus patent eligible.[53] The specific groupings of abstract ideas are:

> a) Mathematical concepts (mathematical relationships, mathematical formulas or equations, mathematical calculations);
> b) Certain methods of organizing human activity (fundamental economic principles or practices, including hedging, insurance, mitigating risk); commercial or legal interactions (including agreements in the form of contracts; legal obligations; advertising, marketing or sales activities or behaviors; business relations); managing personal behavior or relationships or interactions between people (including social activities, teaching, and following rules or instructions); and
> c) Mental processes (concepts performed in the human mind, including an observation, evaluation, judgment, opinion).[54]

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[47] *Id.*
[48] *Id.*
[49] Barufka, Zhang, Hindman, & Kuo, *supra* note 39.
[50] *Id.* The practical application requirement is Prong 2 of Step 2A.
[51] *Id.*
[52] *Id.*
[53] *Id.*
[54] *Id.*

Overall, the revised guideline's list of what constitutes an abstract idea is likely to remedy examiners' picking and choosing case law to support their rejections.[55] The incorporation of Step 2A Prong 2's practical application requirement allows for more efficient resolution at an earlier stage.[56] Patentees should ensure that potentially abstract ideas are integrated into a practical application, whether through an improvement to computer technology or applying them to specific processes, machines or manufactures, etc.[57] The ability for Section 101 eligibility to be resolved through evaluation of all additional elements regardless of their conventionality in Step 2A Prong 2 should be favorable to patentees.[58] Therefore, the revised guideline is likely to diminish the number of patent applications that are rejected on eligibility grounds by reducing the number of things the USPTO can consider patent ineligible abstract ideas under Prong 1 of Step 2A and incorporating the practical application requirement under Prong 2 of Step 2A.[59]

E. Post *Mayo* and *Alice*

After the Mayo/Alice decision, the Federal Circuit upheld a patent claiming a method of producing liver cells that remain viable following multiple cryopreservation.[60] In *Rapid Litig. Mgmt. Ltd. v. CellzDirect*, the Court's decision was based on finding that the claim was directed not at the natural law defining liver cells' ability to survive multiple freeze-thaw cycles, but rather at a "new and useful laboratory technique for preserving" liver cells.[61] The Court reasoned that "the natural ability of the subject matter to undergo the process does not make the claim directed

[55] Barufka, Zhang, Hindman, & Kuo, *supra* note 39.
[56] *Id.*
[57] *Id.*
[58] *Id.*
[59] *Id.*
[60] Rapid Litig. Mgmt. Ltd. v. CellzDirect, Inc., 827 F.3d 1042, 1046 (Fed. Cir. 2016). Cryopreservation is the use of very low temperatures to preserve structurally intact living cells and tissues. Pegg, *Principles of Cryopreservation*, NCBI (Nov. 3, 2019), https://www.ncbi.nlm.nih.gov/pubmed/18080461.
[61] *Id.* at 1047.

to that natural ability."[62] Although the "individual steps of freezing and thawing were well known," the process of repeating those steps to preserve liver cells for multiple cycles was, as a whole, "far from routine and conventional."[63] Thus, this survived under Step 2B of the Mayo/Alice Two-Step and was patent eligible.

III. Vanda Pharmaceuticals v. West-Ward Pharmaceuticals (2018)

A. Overview

A split Federal Circuit held that method of treatment claims are not directed to laws of nature and are therefore patentable subject matter.[64] In *Vanda*, the petitioner claimed a method for treating schizophrenic patients with a medication called iloperidone.[65] This method required obtaining a biological sample from the patient and performing a genotype assay to determine if the patient was a CYP2D6 poor metabolizer.[66] The rationale behind this method claim was the ability to control the patient's risk of adverse effects from the medication.[67] Iloperidone is metabolized by CYP2D6 and thus, poor metabolizers have a higher chance of experiencing adverse effects, such as QT prolongation, which can lead to serious cardiac complications.[68] Following this method claim, if the patient was identified as a CYP2D6 poor metabolizer, then physicians were

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[62] *Id.*
[63] *Id.*
[64] Vanda Pharms. Inc. v. West-Ward Pharms. Int'l Ltd., 887 F.3d 1117, 1132 (2018).
[65] *Id.*.
[66] *Id.* at 1133. Cytochrome P2D6 (CYP2D6) is an enzyme involved in the metabolism of various drugs. CYP2D6 poor metabolizers are unable to break down drugs, which then accumulates within the body and increases the person's chances of experiencing adverse effects from the medication. John R. Horn & Philip D. Hansten, *Get to Know an Enzyme: CYP2D6*, PHARMACY TIMES (Nov. 3, 2019), https://www.pharmacytimes.com/publications/issue/2008/2008-07/2008-07-8624.
[67] *Id.*
[68] *Id.* The QT interval is the length of time required for the heart to repolarize following the onset of depolarization. Drugs that induce QT interval prolongation can lead to fatal ventricular arrhythmias and sudden cardiac death. Jamie L. Thompson, *Drug-Induced QT Prolongation*, U.S. PHARMACIST (Nov. 3, 2019), https://www.uspharmacist.com/article/drug-induced-qt-prolongation.

to administer 12mg/day or less.[69] However, if the patient was *not* a CYP2D6 poor metabolizer, then physicians were to administer 12–24mg/day.[70]

1. Main Dispute Regarding Subject Matter Eligibility

West-Ward's argument asserted that the claim was ineligible subject matter under Section 101 because the claim is directed to a natural relationship between iloperidone, CYP2D6 metabolism, and QT prolongation.[71] Thus, the asserted claim added nothing inventive to those natural laws and phenomena, as required under Step 2B of the Mayo/Alice Two-Step Test.[72]

On the contrary, Vanda's argument focused on Step 2A of the Mayo/Alice Two-Step Test. Here, the relevant inquiry was whether the claims at issue were "directed to" one of those patent-ineligible exceptions.[73] The opinion notes that the Supreme Court has cautioned against an overly broad interpretation of ineligible subject matter as it could "eviscerate patent law" since "all inventions at some level embody, use, reflect, rest upon, or apply laws of nature, natural phenomena, or abstract ideas."[74] Following this guidance, Vanda's asserted claim of "a method for treating a patient with iloperidone, wherein the patient is suffering from schizophrenia" can be understood as requiring specific steps.[75] The claim requires a physician to administer specific doses: either 12 mg/day or less or between 12–24 mg/day depending on the result of the genotype assay.[76] It is a new way of using an existing drug, iloperidone, to reduce the adverse risk of QT prolongation that is associated with its use.[77] In other words, West-Ward's argument for a Step 2B analysis was

[69] *Id.*
[70] *Vanda*, 887 F.3d at 1133.
[71] *Id.*
[72] *Id.*
[73] *Id.*
[74] *Id.*
[75] *Id.*
[76] *Vanda*, 887 F.3d at 1136.
[77] *Id.* at 1137.

unnecessary because Step 2A was already satisfied. Ultimately, the Court upheld this claim as valid under subject matter eligibility.[78]

2. Chief Judge Prost's Dissent

Naturally, this decision invokes the continuing debate regarding the exact scope of patent eligible subject matter and the perplexity of classifying "laws of nature, natural phenomena, or abstract idea." This ongoing struggle is illustrated by Chief Judge Prost's dissent, which states that Vanda "claims no more than instructions directing an audience to apply the natural law in a routine and conventional manner."[79] Physicians have used iloperidone to treat schizophrenia long before the patent claim at issue in this case.[80] Chief Judge Prost contends that this claim simply discloses a natural law: that a known side effect of an existing medication could be reduced by administering a lower dose to patients who are CYP2D6 poor metabolizers.[81] Because the claim relies on a natural law, a Step 2B analysis of the Alice/Mayo Two-Step governs. Simply administering a medication is routine and conventional for physicians, without the addition of an inventive concept. Therefore, the claim should fail because it is not patent eligible subject matter under Step 2B.[82]

B. Differentiating *Vanda* and *Mayo*

In *Mayo,* the claims were directed to a diagnostic method based on the "relationships between concentrations of certain metabolites in the blood and likelihood that a dosage of a thiopurine drug will prove ineffective or cause harm."[83] This relationship is a consequence of the ways in which thiopurine compounds are metabolized by the body, which is an entirely natural process.[84]

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[78] *Id.*
[79] *Id.*
[80] *Id.*
[81] *Id.*at 1138.
[82] *Vanda,* 887 F.3d at 1138.
[83] *Mayo,* 566 U.S. at 66.
[84] *Id.* at 71.

On the contrary, in *Vanda*, the claims were directed to a specific method of treatment for specific patients using a specific compound at specific doses to achieve a specific outcome.[85] The asserted claims encompass more than the natural relationship between compounds.[86] Instead, they recite a method of treating patients based on this relationship.[87]

Also in *Mayo,* the claims "tie up [a] doctor's subsequent treatment decision whether that treatment does, or does not, change in light of the inference the doctor has drawn using the correlations."[88] This threatens to inhibit the development of more refined treatment recommendations.[89] Thus, it could be infringed by treatment with thiopurine "whether that treatment does, or does not, change in light of the inference" indicated by the natural law.[90]

Finally, in *Vanda*, the claims require physicians to "internally administer iloperidone to patient an amount" such as 12 mg/day whereas in *Mayo*, the claim stated that the metabolite level in blood simply suggests "a need to increase or decrease dosage, without prescribing a specific dose regimen or other gadded steps to take as a result of that indication."[91] This highlights the specific dosage indicated by the method claim in *Vanda* and offers the possibility to reconcile the different outcomes held by the courts.

IV. The Implications of *Vanda*

A. Impact On Method of Treatment Patents in the Pharmaceutical And Biologics Industry

Vanda sets a precedent that diagnostics may be patent eligible if they include a method of treatment step.[92] This is well illustrated by Peter Hecker's hypothetical example: "Suppose you

[85] *Vanda,* 887 F.3d.at 1135.
[86] *Id.*
[87] *Id.*
[88] *Mayo*, 566 U.S. at 71.
[89] *Id.*
[90] *Id.*
[91] *Id.; Vanda,* 887 F.3d at 1135.
[92] Hecker, *supra* note 12, at 6.

discovered Vandase, an enzyme encoded by a well-known gene, enhances patent bar passage rates when expressed at high levels."[93] Here, patent applicants will likely get a 101 subject matter rejection if the claim is "a method for predicting whether a subject will pass a patent bar, comprising: obtaining an expression level of a nucleic acid encoding Vandase; and prognosing whether the subject will pass the patent bar based on said expression."[94] Thus, a better claim would be a method for treating a subject suffering from the patent bar, comprising of:

> Obtaining an expression level of a nucleic acid encoding Vandase; Prognosis whether the subject will have difficulty passing the patent bar based on said expression; and administering a patent bar preparation course comprising videos of John White or Gene Quinn for 8–12 hours per day for 4–8 weeks if the subject is prognoses as having difficulty passing the patent bar based on said expression, and administering a patent bar preparation course comprising 1–2 hours per day of past patent bar questions for 1–2 weeks if the subject is prognoses as not having difficulty passing the patent bar based on said expression.[95]

Utilizing *Vanda*, one can claim that this only touches upon a law of nature and is directed to a method of treatment because it "recites a specific treatment for specific patients using a specific study strategy at specific doses."[96] In essence, the claim recites significantly more to fall under the "inventive aspect" determination of Step 2B of Alice/Mayo Two-Step.[97] Because *Vanda* did not consider whether the treatment steps were routine or conventional, one could also argue that method of treatment claims are outside the scope of Section 101 scrutiny and are in fact, patent eligible.[98]

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[93] *Id.*
[94] *Id.*
[95] *Id.*
[96] *Id.*
[97] *Id.*
[98] Hecker, *supra* note 12, at 7.

Overall, incorporating what is considered "natural law" does not necessarily destroy an applicant's claim.[99] Rather, the applicant simply needs to define an application of law that is specific enough.[100] However, this problem continues to be an issue because of the difficulty of diagnostic claims being in fact redrafted as method-of-treatment claims.[101]

V. The Need for Clarification of Section 101 of the Patent Act

A. Potential Problems Arising From *Vanda*

The uncertainty and confusion resulting from the Court's recent decisions create significant problems for many companies and investors as well. These problems arise when contemplating research and development projects, as well as for patent prosecutors, patent examiners, and patent jurists.[102] As mentioned previously, a test requiring a search for an "inventive" application of a natural law or physical phenomenon does not provide adequate objective guidance.[103] If the Federal Circuit decision stands, *Vanda* sets a precedent that diagnostics may be patent eligible if they include a method of treatment step.[104] Following the *Vanda* decision, the Federal Circuit issued two more decisions concerning the patent eligibility of method of treatment claims by reversing the District Court decisions. In *Endo Pharmaceuticals Inc. v. Teva Pharmaceuticals USA, Inc.*, methods of using oxymorphone to treat pain in patients with impaired kidney function were determined to be legally indistinguishable from the claims at issue in *Vanda*.[105] Additionally, in *Natural Alternatives International, Inc. v. Creative Compounds, LLC*, claims relating to the use of beta-

[99] *Id.* at 9.
[100] *Id.*
[101] *Id.*
[102] *See* David O. Taylor, *Confusing Patent Eligibility*, 84 TENN. L. REV. 157 (2016).
[103] Jeffrey A. Lefstin, et al., *Addressing Patent Eligibility Challenges*, 33 BERKELEY TECH. L. J. 551,552 (2018).
[104] *Id.*
[105] Donald Zuhn, *Patent Legislation*, PATENT DOCS (Jan. 2, 2020) https://www.patentdocs.org/patent_legislation/.

alanine in dietary supplements to increase the anaerobic working capacity of muscle and other tissue, were patent eligible.[106]

However, another possible hurdle is that the addition of a method of treatment step to make a claim patent eligible may be viewed as mere "draftsman's art."[107] This was a concern raised in *Mayo* that patent statutes should not be interpreted in ways that make patent eligibility "depend simply on draftsman's art" without reference to the "principles underlying the prohibition against patents for [natural laws]."[108] There seems to be no clear way to draw the line for such matters.

B. Role in Future Personalized Medicine Treatment Patents

In addition to the potential problems articulated above, there is also uncertainty in the fate of future personalized medicine treatment patents. Molecular diagnostics play a central role in driving precision medicine research and development.[109] It provides the clues for determining disease predisposition, diagnosing disease, assessing disease prognosis, predicting drug response, and targeting prescriptions and diagnostics.[110] Thus, precision medicine depends critically upon balanced regulation and intellectual property rights.[111] However, the Mayo/Alice Two-Step has resulted in significant uncertainty in biotechnology.[112] Commentators have criticized the test as being "indeterminate" and "overly restrictive" as the test has been applied to invalidate a wide range of patents.[113] It certainly seems that the vagueness surrounding biotechnology patent protection has contributed to the weakening of the U.S patent system as well.[114]

VI. Draft Reform Bill

[106] *Id.*
[107] Mayo Collaborative Servs. v. Prometheus Labs., Inc., 566 U.S. 66, 71 (2012).
[108] *Id.*
[109] Lefstin & Menell, *supra* note 103, at 551.
[110] *Id.*
[111] *Id.*
[112] Lindhorst, *supra* note 5, at 734.
[113] *Id.*
[114] *Id.*

A. Background

On May 22, 2019, a bipartisan group of lawmakers released a draft bill that would reform Section 101.[115] In addition to Section 101, the bill included proposals to amend Section 100 (k) and 112 (f) of the Patent Act as well.[116] During the four hearings held regarding the state of patent eligibility in the United States, a total of forty-five witnesses testified, which once again highlights the great importance of the draft bill and the many debates surrounding this area of patent law.[117] The witnesses included stakeholders, industry leaders, and small business owners across a wide range of the technology spectrum.[118]

B. Changes to Section 101

The draft bill includes three legislative provisions that require further deliberations as they appear to have the most significant impact, if enacted in their current form.[119]

1. First legislative provision

The "provisions of section 101 shall be construed in favor of patentability."[120] This language signals a potential return to what many referred to as the original interpretation of Section 101—a gate keeper threshold of what types of inventions are patent eligible and what types are not.[121] Accordingly, this first legislative provision appears to reflect the committee's intent to refocus Section 101 as an eligibility threshold and not a standard for determining patentability.[122]

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[115] The group of lawmakers include U.S. Senators Tillis and Coons, Chair and Ranking Member of the Senate Judiciary Subcommittee on Intellectual Property, and Representative Doug Collins, Ranking Member of the House Judiciary Committee, Hank Johnson, Chairman of the House Judiciary Subcommittee on Intellectual Property and the Courts, and Representative Steve Stivers. Michelle K. Holoubek & Ali Allawi, *The Draft Subject Matter Eligibility Bill: A Work in Progress,* STERNE, KESSLER, GOLDSTEIN & FOX PLLC (June 17, 2019) https://www.sternekessler.com/news-insights/client-alerts/ip-hot-topic-draft-subject-matter-eligibility-bill-work-progress.
[116] *Id.*
[117] *Id.*
[118] *Id.*
[119] *Id.*
[120] *Id.*
[121] Holoubek & Allawi, *supra* note 115.
[122] *Id.*

2. Second legislative provision

The second provision states that all cases establishing or interpreting the judicially created exceptions to subject matter eligibility are "hereby abrogated."[123] In addition, this provision states that "no implicit or other judicially created exceptions to subject matter including 'abstract ideas, laws of nature, or natural phenomena' shall be used to determine patent eligibility."[124] This is by far the most drastic reform proposed in this bill. Essentially, adoption of this provision would eliminate a decade's worth of Supreme Court precedent.[125]

3. Third legislative provision

The third provision states that eligibility of a claimed invention under Section 101 shall be determined "without regard to: the manner in which the claimed invention was made; whether individual limitations of a claim are well known, conventional or routine; the state of the art at the time of the invention; or any other considerations relating to sections 102, 103, or 112 of this article."[126] This is further evidence, along with the first legislative provision, that Section 101 is intended to be a mere eligibility threshold and not a final determinate on patentability.[127] By explicitly removing the controversial "well known, conventional, or routine" standard for Section 101 analysis, the Subcommittee leaves such determination for analysis under Sections 102, 103, and 112 instead.[128] This should reduce the conflation between eligibility and patentability standards currently applied by the USPTO and the Federal Courts.[129]

C. Proponents of the Draft Bill

[123] *Id*.
[124] *Id*.
[125] *See supra* Part ll.
[126] *Id*.
[127] *Id*.
[128] Holoubek & Allawi, *supra* note 115.
[129] *Id*.

Judge Michel delivered the most resounding endorsement of the bill stating that, after spending twenty-two years on the Federal Circuit and nine years deciding on patent cases, he "cannot predict in a given case whether eligibility will be found or not found."[130] He followed by stating "if I can't do it, how can bankers, venture capitalists, business executives, and all the other players in the system make reliable predictions and sensible decisions?"[131] This perspective clearly articulates the need for clarifications of the current patent eligible subject matter requirements, which warrants review.

D. Shortfalls of the Draft Bill

Although a reform of the Patent Act is crucial, the proposed draft bill in its current form will be unhelpful in promoting future innovation for several reasons. First, a broad eligibility requirement will "increase the issuance of bad patents, and therefore, will increase frivolous litigation."[132] Second, the current draft law would abolish the holding in *Alice* to the detriment of individuals and small businesses.[133] Small entities have benefited from *Alice* because "courts have been able to invalidate patent claims and dismiss cases before the expensive discovery and expert witness phases."[134] Third, the draft bill would allow for patenting of genes due to the abrogation of *Myriad*.[135] Sean George, CEO of Invitae, noted that the "golden age of precision medicine ushered in by the unanimous [Myriad], [Alice], and [Mayo] decisions has just begun. Patient care has improved and innovation in genetics has thrived because of the lack of patents on DNA, not

[130] *Id.*
[131] *Id.*
[132] *Id.*
[133] *Id.*
[134] Holoubek & Allawi, *supra* note 115.
[135] Krista A Cox, *Changes coming to Section 101 of the Patent Eligibility?*, ABOVE THE LAW (Nov. 3, 2019), https://abovethelaw.com/2019/04/changes-coming-to-section-101-patent-eligibility/?rf=1.

in spite of it."[136] The dangers of opening the door for patenting of personalized medication treatment may do more harm than good by hindering the continuous developments of such treatments and negatively impacting the nation's status as a top contributor to the patent regime.

1. Exclusive Categories of Statutory Subject Matter

It is unclear whether the bill will be revised to include the closed list of exclusive categories of statutory subject matter that would not be eligible for patent protection, as previously proposed in the Subcommittee's draft outline back in April of 2019.[137] The proposed exclusive categories are fundamental scientific principles, products that exist solely and exclusively in nature, pure mathematical formulas, economic or commercial principles, and mental activities.[138] If it is included, the language is once again vague and subjective, likely to result in various interpretations and adding to the confusion it purports to clarify.[139] The claims that are currently rejected as being directed to natural phenomena or laws of nature will likely continue to be rejected as being directed to a fundamental scientific principle under this new provision.[140] Thus, the need for further judicial interpretation leads us back to the current dilemmas of Section 101.[141]

Moreover, having a set exclusionary list would require regular updating and may not adequately protect new and emerging technology.[142] Congress must recognize the confusion that this language presents, and ensure that any statutory exclusion more clearly defines the bounds of the exclusion.[143] Similarly, Congress would need to clearly define the bounds of any statutory inclusion.

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[136] *Id.*
[137] *Id.*
[138] *Id.*
[139] *Id.*
[140] *Id.*
[141] Cox, *supra* note 135.
[142] *Id.*
[143] *Id.*

2. Constitutional Concerns

The draft reform bill's expansion of patent eligibility also triggers constitutional concerns as well.[144] For example, it would "permit government-sanctioned monopolies to private parties over fields of knowledge, limiting information sharing and free experimentation, raising serious concerns about whether the patent system would be blocking, rather than promoting, progress."[145] The concern is that government-granted exclusive monopolies over bodies of knowledge, such as patents on human genes, human thought processes, or abstract ideas, would violate our constitutional rights to speak and express ourselves, and receive information free from government restraint.[146] Accordingly, an overly broad application would hinder the growth of our patent system.

3. Policy Concerns

Finally, there are other policy concerns at issue as well. For example, there could be negative impacts on the cost, quality, and availability of American healthcare with the enactment of this current draft reform bill.[147] This viewpoint was articulated by Charles Duan, director of technology and innovation policy at the R Street Institute.[148] He warned that the draft legislation would lead to "the practice of 'evergreening,' in which a drug company obtains a patent on a minor modification to a known drug compound, often years after the initial patent application on the drug was filed."[149] The potential adverse impact on healthcare by a broad eligibility standard can be articulated through *Myriad* as well.[150] Once Myriad could not enforce its patents, competitors offering

[144] Courtenay C. Brinckerhoff, *The Senate Holds Hearings on The State of Patent Eligibility in America*, FOLEY & LARDNER LLP (June 11, 2019) https://www.foley.com/en/insights/publications/2019/06/senate-hearings-on-patent-eligibility-in-america.
[145] *Id*.
[146] *Id*.
[147] *Id*.
[148] *Id* (R Street Institute is an organization that "engages in policy research and educational outreach to promote free markets as well as limited yet effective government").
[149] *Id*.
[150] Brinckerhoff, *supra* note 144.

diagnostic screening for breast and ovarian cancer could, and did, enter the market immediately, charging just a fraction of what Myriad's test cost.[151] Thus, patents on natural laws and products would reduce development of lifesaving tests and treatments.[152] In particular, patents on genes and diagnostics would prevent patients from obtaining second opinions as well.[153]

E. Adoption of the Draft Reform Bill

There is no doubt that Section 101 warrants clarification in order to create a more predictable judicial application of subject matter eligibility. Thus, patent eligibility should be judged by what is defined by the claims as a whole, instead of engaging in claim dissection. This is part of the proposed bill: "Eligibility under this section shall be determined only while considering the claimed invention as a whole, without discounting or disregarding any claim limitation."[154]

This proposal is also supported in the cases of *Diamond v. Chakrabarty* and *Diamond v. Diehr*. In *Chakrabarty*, the patent claims were for human-made, genetically engineered bacterium that was capable of breaking down multiple components of crude oil.[155] Claims "plainly qualif[y] as patentable subject matter" because they were directed to a non-naturally occurring manufacture or composition of matter.[156] Here, the Court focused on the significant amount of human intervention in the claims, as well as the markedly different characteristics of the bacteria from any found in nature and the significant utility of the claimed bacteria.[157] Ultimately, the Supreme Court

[151] *Myriad*, 569 U.S. at 582.
[152] Stuart P. Meyer, *Still No Shortage of Viewpoints As Eligibility Debate Moves to the Hill*, FENWICK & WEST (June 27, 2019), https://www.bilskiblog.com/2019/06/still-no-shortage-of-viewpoints-as-eligibility-debate-moves-to-the-hill/.
[153] *Id.*
[154] Eileen McDermott, *Draft Text of Proposed New Section 101 Reflects Patent Owner Input*, IPWATCHDOG (May 22, 2019) https://www.ipwatchdog.com/2019/05/22/draft-text-proposed-new-section-101-reflects-patent-owner-input/id=109498/.
[155] Diamond v. Chakrabarty, 447 U.S. 303, 310 (1980).
[156] *Id.*
[157] *Id.*

held that a claim to a genetically engineered bacterium was patent eligible because the claimed bacterium did not fall within the "product of nature" exception.[158]

In *Diehr*, the claims were directed to a process for curing synthetic rubber.[159] While the claims employed a mathematical equation, they were not directed solely to the equation.[160] In determining the eligibility of the claimed process for patent protection under Section 101, the Court held that their claims must be considered as a whole.[161] The reasoning behind this was that it was inappropriate to dissect the claims into old and new elements and then to ignore the presence of the old elements in the analysis.[162] This is especially true in a process claim because a new combination of steps in a process may be patentable even though all the parts of the combination were well known and in common use before the combination was made.[163]

Furthermore, the new bill should contain language expressly eliminating judicial exceptions and requiring the Court to adhere to strict statutory construction instead. The proposed bill does include a provision stating, "No implicit or other judicially created exceptions to subject matter eligibility, including 'abstract ideas,' 'laws of nature,' or 'natural phenomena,' shall be used to determine patent eligibility under section 101, and all cases establishing or interpreting those exceptions to eligibility are hereby abrogated."[164] However, as noted in Section D above, there is a list of exclusive categories of statutory subject matter including fundamental scientific principles, products that exist solely and exclusively in nature, pure mathematical formulas, economic or commercial principles, and mental activities.[165] This subjective language leads to the

[158] *Id.*
[159] Diamond v. Diehr, 450 U.S. 175, 180 (1981).
[160] *Id.*
[161] *Id.*
[162] *Id.* at 181.
[163] *Id.*
[164] Holoubek & Allawi, *supra* note 115.
[165] Cox, *supra* note 135.

danger of varying interpretations and continued confusion for patent applicants and exmainers alike. Therefore, adding the requirement for the Courts to carry out strict statutory construction would help to moderate some of the potential issues that may arise with the list of exclusive categories requiring judicial interpretation.

VII. Conclusion

The current patent eligible subject matter requirement under Section 101 of the Patent Act has led to different interpretations by the Courts and confusion for patent applicants and examiners alike. It is promising that Congress has taken steps to attempt to correct the uncertainty created by the Supreme Court in deciding what falls within the categories of "laws of natural, natural phenomena, and abstract ideas." However, the current draft reform bill should not be enacted in its current form as it broadens the eligibility of patents that could potentially lead to adverse effects and thwart, rather than promote, innovation. The broadening of the eligibility threshold potentially increases assertions and litigation, leaving innovators to be preoccupied with litigation, rather than innovation.

In addition, the proposed outline merely changes the exceptions from judicially created to legislatively created exceptions. The danger lies in the Court's subsequent determinations of what exactly constitutes a "fundamental scientific principle, product that exist solely and exclusively in nature, pure mathematical formulas, economic or commercial principles, or mental activities." Thus, a defined, closed set of categories of excluded subject matter would in essence be codifying the judicially created exceptions of the current statute. For example, "fundamental scientific principles" can be construed by the Court to indicate an approval of their "abstract ideas" or "law of nature" test and to decide cases in the same manner as before. Likewise, the "products that exist solely and exclusively in nature" category could be construed by the Court to affirm the *Myriad*

decision. Therefore, the proposed excluded categories are too vague, inviting the Court to create more difficult law.

Responsibilty lies with Congress to bring greater clarity, consistency, and logic to the patent eligible subject matter requirements under Section 101 of the Patent Act. Thoughtful legislation can further improve the patent system and provide increased protection for therapeutic methods, which are crucial for new innovations and continuous development, especially in the area of life sciences. The monopoly granted to a patent owner is a property right and its boundaries should be clear. Therefore, it would be helpful to include language in the new bill expressly prohibiting judicial exceptions and requiring the Court to carry out strict statutory construction instead. This clarity is essential to promote progress, because it enables efficient investment in innovation and the ability to maintain the nation's esteemed status in the world of patents.