Hold the *Mayo*—Federal Circuit Fails to Apply Well Settled Subject Matter Eligibility Standard for Patent Law

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ABSTRACT

The patentable subject matter requirement for patent law has remained one of the most puzzling requirements in patent law. The Alice/Mayo framework was thought to have defined the bounds of patentable subject matter and clarified the issue. The recent *Vanda* case, however, has thrown this into disarray, as the appellate court declined to apply the straightforward Alice/Mayo framework, and the Supreme Court denied certiorari.

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I. INTRODUCTION

Patent law is a discipline full of statutory requirements.[1] Upon deciding to pursue patent protections for their inventions, innovators are thrust into a complicated legal framework.[2] For an invention to be patentable it must be novel, useful, and non-obvious.[3] The conditions for patentability do not come into play, however, unless the invention is *patentable subject matter*.[4] While this may not seem like a colossal hurdle when the provision classifies patentable subject matter in broad terms such as machines, processes, manufactures, and compositions of matter, several exclusions make traversing the patent system difficult.[5] These prohibitions against patentability include restrictions on patenting abstract ideas, laws of nature, and abstract ideas, among other things.[6]

The abstract idea exclusion, in particular, has spawned a significant number of cases.[7] Among these, *Mayo Collaborative Services v. Prometheus Laboratories, Inc.* and *Alice Corp. Pty. Ltd. v. CLS Bank Intern.* are recognized as the leading authorities regarding when an invention is an abstract idea versus a patentable application of that abstract idea.[8] The *Mayo* court applied a two-part test which was fully enumerated and adopted by the *Alice* court.[9] Now commonly referred to as the "Alice/Mayo framework," the standard is applied as follows: first, the court determines whether the claims at issue are directed to a patent-ineligible concept, and, if so, examines what

[1] *See* 35 U.S.C. § 101-103, 112.
[2] 35 U.S.C. § 101-103, 112.
[3] 35 U.S.C. § 101-103, 112.
[4] *See* 35 U.S.C. § 101 (1952).
[5] *Id.*
[6] *See* Mayo Collaborative Services v. Prometheus Laboratories, Inc., 566 U.S. 66, 71-72 (2012); Alice Corp. Pty. Ltd. v. CLS Bank Intern., 573 U.S. 208, 220-21 (2014).
[7] *See, e.g.* Diamond v. Diehr 450 U.S. 175 (1980); Vanda Pharms v. West-Ward Pharms. Int'l Ltd., 887 F.3d 1117 (Fed. Cir. 2018); *Mayo*, 566 U.S. 66.
[8] *See Mayo* 573 U.S. at 71-72; Vanda Pharm. Inc. v. Roxane Laboratories, Inc., 203 F. Supp. 3d 412, 427 (D. Del. 2016), aff'd sub nom. Vanda Pharm. Inc. v. W.-Ward Pharm. Intl. Ltd., 887 F.3d 1117 (Fed. Cir. 2018).
[9] *Mayo*, 566 U.S. at 71-72; Alice Corp. Pty, 573 U.S. 208 at 220-21.

else there is in the claims that might bring the invention out of the realm of abstraction.[10] Stage two of the *Alice/Mayo* framework was described by the *Alice* court as "a search for 'inventive concept'…an element or combination of elements that is 'sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the [ineligible concept] itself.'"[11]

Though the *Alice/Mayo* framework on the patentability of inventions involving abstract ideas has been settled for a significant amount of time, a recent application of the rule does not seem to square with the rule's application in *Mayo*.[12] The facts of the 2018 case *Vanda Pharm. Inc. v. W.-Ward Pharm. Intl. Ltd.* resemble those of *Mayo* as the two are nearly the same.[13] In *Vanda*, however, the Federal Circuit found that the invention in question was an application of an abstract idea, and thus patentable.[14] This is the opposite of the Supreme Court's holding in *Mayo*, where they found that the invention in question was not the application of an abstract idea, but the abstract idea itself, and denied patentability under 35 U.S.C. § 101.[15] The wildly different application of the *Alice/Mayo* framework is improper, as the facts of the cases are nearly identical.[16] Not only does the decision in *Vanda* seem to ignore *stare decisis*, but it will also likely lead to confusion among innovators about what inventions involving abstract ideas are patentable applications of those idea, and what inventions will be found unpatentable as abstract ideas themselves.[17]

[10] *Mayo*, 566 U.S. at 71-72.
[11] *Id.*
[12] *Compare* Mayo Collaborative Services v. Prometheus Laboratories, Inc., 566 U.S. 66, 71-72 (2012) *with* Vanda Pharms v. West-Ward Pharms. Int'l Ltd., 887 F.3d 1117 (Fed. Cir. 2018).
[13] *Vanda Pharms*, 887 F.3d at 1120-23.
[14] *Id.* at 1134-35.
[15] *Mayo*, 566 U.S. at 71-72.
[16] *Compare Mayo*, 566 U.S. at 74-75 (2012) *with Vanda Pharms*, 887 F.3d at 1120-23.
[17] *See generally Vanda Pharms*, 887 F.3d at 1134-35 (confusing the unpatentability of "abstract ideas".)

II. FACTS AND PROCEDURAL HISTORY OF VANDA PHARM. INC. V. W.-WARD PHARM. INTL. LTD.

In 2016, Vanda Pharmaceuticals (Vanda) and Aventisub LLC alleged patent infringement by Roxane Laboratories ("Roxane") of "U.S. Reissue Patent No. 39,198 ('the '198 Patent') and U.S. Patent No. 8,586,610 ('the '610 Patent').[18] The court held a five-day bench trial on the validity of the '610 patent and, if the patent was valid, whether Roxane's products infringed the patent.[19] Roxane argued that the '610 patent was directed at two laws of nature, specifically, "(1) that mutations in the CYP2D6 genes can alter enzymatic activity, and (2) that a patient's CYP2D6 enzymatic activity affects their metabolism of iloperidone."[20] Roxane also stated that any additional steps taken by Vanda in the claims were routine and conventional, and thus, lack the "inventive concept" necessary to allow patentability of an invention involving an abstract idea.[21] Vanda argued that "§ 101 forbids patent claims 'directed to' patent-ineligible concepts, not claims that merely '*involve* a patent ineligible concept…." The court eventually sided with Vanda, holding

> "(1) all asserted claims of the patents-in-suit are valid; (2) Roxane's proposed products induce infringement of the asserted claims of the '610 Patent; (3) Roxane's proposed products do not contributorily infringe the asserted claims of the '610 Patent; and (4) each of the parties' Rule 52(c) motions are granted in part and denied in part."[22]

After Vanda won in district court, defendants (now West-Ward) appealed to the Federal Circuit.[23] West-Ward once again argued that the claims of the '610 patent were not patent-eligible subject matter, stating that they "[were] indistinguishable from those held invalid in *Association for Molecular Pathology v. Myriad Genetics, Inc.* and *Mayo Collaborative Services v. Prometheus*

[18] Vanda Pharm. Inc. v. Roxane Laboratories, Inc., 203 F. Supp. 3d 412, 417 (D. Del. 2016), aff'd sub nom. Vanda Pharm. Inc. v. W.-Ward Pharm. Intl. Ltd., 887 F.3d 1117 (Fed. Cir. 2018).
[19] *Id.*
[20] *Id.* at 428.
[21] *Id.*
[22] *Id.* at 436.
[23] Vanda Pharm. Inc. v. W.-Ward Pharm. Intl. Ltd., 887 F.3d 1117, 1133 (Fed. Cir. 2018), cert. denied sub nom. Hikma Pharm. USA Inc. v. Vanda Pharm. Inc., 18-817, 2020 WL 129534 (U.S. Jan. 13, 2020).

Laboratories, Inc."[24] In the appeal, Vanda proposed that the '610 patent satisfied both steps of the *Alice/Mayo* framework.[25] Additionally, Vanda claimed that the lower court erred in holding that the claims were directed to an abstract idea at all.[26] The Federal Circuit found Vanda's argument persuasive, as the court held that the claims were not directed to patent-ineligible subject matter, stating: "we agree with *Vanda* that the asserted claims are not directed to patent-ineligible subject matter."[27]

In the Federal Circuit decision, the court attempted to distinguish between *Vanda* and *Mayo*.[28] In justifying their refusal to apply *Mayo*'s holding to *Vanda*, the court differentiated the two cases by stating the claims in *Mayo* were directed to "a diagnostic method based on the 'relationships between concentrations of certain metabolites in the blood and the likelihood that a dosage of a thiopurine drug will prove ineffective or cause harm," instead of "a novel method of treating a disease."[29] The claims in *Vanda*, however, were directed to "a method of using iloperidone to treat schizophrenia."[30] Furthermore, the court worried less about the *Vanda* claims preempting further development than they did when examining the *Mayo* claims.[31] The Federal Circuit combined their interpretation of the claims with a supposed absence of preemption, ruling that the claims were not directed to patent-ineligible subject matter and were patentable under 35 U.S.C. §101.[32] Recently, the Solicitor General was asked to weigh in on the case, but certiorari was denied.[33]

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[24] *Id.*
[25] *Id.*
[26] *Id.*
[27] *Id.* at 1134.
[28] Vanda Pharm. Inc. v. W.-Ward Pharm. Intl. Ltd., 887 F.3d 1117, 1134 -35 (Fed. Cir. 2018).
[29] *Id.* at 1134.
[30] *Id.*
[31] *Id.* at 1135.
[32] *Id.* at
[33] Vanda Pharm. Inc. v. W.-Ward Pharm. Intl. Ltd., 887 F.3d 1117, 1133 (Fed. Cir. 2018), cert. denied sub nom. Hikma Pharm. USA Inc. v. Vanda Pharm. Inc., 18-817, 2020 WL 129534 (U.S. Jan. 13, 2020).

III. LEGAL BACKGROUND

This section provides an overview of 35 U.S.C. § 101, as well as caselaw relevant to the subject matter eligibility requirement of 35 U.S.C. § 101, specifically cases dealing with the abstract idea exception. Several cases, including *Alice* and *Mayo* will be examined, their holdings discussed, and their effects on the patent eligibility inquiry explained.

35 U.S.C. § 101 states "Whoever 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."[34] Though there are no explicit exclusions from patentability present in the statutory provision, several have been imputed through Supreme Court precedent.[35] For example, in *Rubber-Tip Pencil Co. v. Howard*, the Supreme Court refused to allow uphold a patent on "a new and useful rubber head for lead-pencils," because "[a]n idea of itself is not patentable…."[36]

Diamond v. Diehr provides more insight into the difference between unpatentable abstract ideas and patentable applications of abstract ideas.[37] The patent at issue in *Diehr* disclosed "a process for curing synthetic rubber which includes in several of its steps the use of a mathematical formula and a programmed digital computer."[38] The process used a mold to shape uncured rubber into precise shapes before curing the rubber while it is still in the mold.[39] After this process, the rubber product would retain its shape after being removed from the mold.[40]

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[34] 35 U.S.C. § 101
[35] *See, e.g.* Mayo Collaborative Services v. Prometheus Laboratories, Inc., 566 U.S. 66 (2012); Parker v. Flook, 437 U.S. 584 (1978); Rubber-Tip Pencil Co. v. Howard, 87 U.S. 498 (1874).
[36] Rubber-Tip Pencil Co. v. Howard, 87 U.S. 498, 507 (1874).
[37] *See* Diamond v. Diehr, 450 U.S. 175, 185-187 (1981).
[38] *Id.* at 177.
[39] *Id.*
[40] *Id.*

The patentee in *Diehr* characterized the novelty of the invention as "the process of constantly measuring the actual temperature inside the mold."[41] By feeding the measurements of the actual mold temperature into a computer system, the patentee could solve a chronic issue in the industry—the over/under-curing of the rubber product due to uncertain temperature measurements inside the mold.[42] The patent examiner refused to grant the patent on the process because they reasoned that the claims were "drawn to nonstatutory subject matter under 35 U.S.C. § 101."[43] The Supreme Court held for *Diehr*, holding the process for molding synthetic rubber into precise shapes patentable under § 101.[44] In their discussion, the court reiterated recognized limits to the text of § 101, stating

> "[e]xcluded from such patent protection are laws of nature, natural phenomena, and abstract ideas," as well as "[a] new mineral discovered in the earth or a new plant found in the wild is not patentable subject matter. Likewise, Einstein could not patent his celebrated law that $E = mc^2$; nor could Newton have patented the law of gravity. Such discoveries are 'manifestations of ... nature, free to all men and reserved exclusively to none."[45]

In recognizing these limitations on patentable subject matter, the *Diehr* court upheld the prohibition against patenting laws of nature, abstract ideas, and natural phenomena while also distinguishing between abstract ideas and the application/use of an abstract idea that provides some "inventive concept" to enter the realm of patentability.[46]

The next important case for this analysis is the case most similar to *Vanda*. *Mayo Collaborative Services v. Prometheus Laboratories, Inc.* is one of the two cases that established the *Alice/Mayo* framework for determining the patentability of inventions that deal with abstract

[41] *Id.* at 178.
[42] Diamond v. Diehr, 450 U.S. 175, 177-178 (1981).
[43] *Id.* at 179.
[44] *Id.* at 184.
[45] *Id.* at 185 (citing Diamond v. Chakrabarty, 447 U.S. 303, 308 (1980)).
[46] *Id.* at 191-193.

ideas.[47] The patents at issue in *Mayo* concerned "the use of thiopurine drugs in the treatment of autoimmune diseases, such as Crohn's disease and ulcerative colitis."[48] The two patents at issue were specifically drawn to findings by doctors that showed a correlation between levels of certain metabolites in a patient's blood and the likelihood that a certain dose of thiopurine drugs would be dangerous to that patient.[49]

Though the Federal Circuit upheld the patents at issue in *Mayo*, the Supreme Court saw the matter differently, holding Prometheus's patents invalid as laws of nature.[50] In making their determination, the Supreme Court addressed the relationship between administered drugs and a toxic reaction to those drugs and summarized their findings by stating:

> "Claim 1, for example, states that if the levels of 6–TG in the blood (of a patient who has taken a dose of a thiopurine drug) exceed about 400 pmol per 8x10 8 red blood cells, then the administered dose is likely to produce toxic side effects. While it takes a human action (the administration of a thiopurine drug) to trigger a manifestation of this relation in a particular person, the relation itself exists in principle apart from any human action. The relation is a consequence of the ways in which thiopurine compounds are metabolized by the body—entirely natural processes. And so a patent that simply describes that relation sets forth a natural law."[51]

After determining that the claims at issue set forth a natural law, the Court considered other arguments that were set forth to justify a finding of patentability for the claims at issue.[52] The Court first reaffirmed that the machine-or-transformation test is not the sole test for the determining patentability of a process, but instead is "an '*important and useful clue*' to patentability."[53] Next, the Court disregarded Prometheus's invitation for the court to distinguish between laws of nature-based upon how significantly a patent on that law of nature would interfere

[47] *See* Mayo Collaborative Services v. Prometheus Laboratories, Inc., 566 U.S. 66, 73-77 (2012).
[48] *Id.* at 73.
[49] *Id.* at 74.
[50] *Id.* at 77.
[51] *Id.*
[52] Mayo Collaborative Services v. Prometheus Laboratories, Inc., 566 U.S. 66, 77-78 (2012).
[53] *Id.* at 89.

with further innovation, as "courts and judges are not institutionally well suited to making the kinds of judgments needed to distinguish among different laws of nature."[54] Finally, the Court declined to hold that any step beyond a statement of the law of nature would transform that law of nature into patentable subject matter.[55] The reason for requiring a more substantial step to satisfy the "inventive concept" allowance for laws of nature was that anything less would "make the 'law of nature' exception to § 101 patentability a dead letter."[56]

The second half of the *Alice/Mayo* framework is, of course, *Alice Corp. Pty. Ltd. v. CLS Bank Intl.*[57] The patents at issue in *Alice* disclosed a method of mitigating the risk that one party to an agreement would refuse to uphold its obligations under the agreement.[58] CLS Bank argued that the patents were invalid as directed to an abstract idea—a proposition with which the district court and Federal Circuit agreed.[59] The Supreme Court also refused to allow patentability of the claims at issue based upon the same reasoning as the district and appellate courts—that the claims were directed to a nonpatentable abstract idea.[60] Despite the holding, the Court emphasized that care must be taken in applying the exclusionary principle "lest it swallow all of patent law."[61]

The Court's analysis of *Alice* began with the first step of the *Alice/Mayo* framework, which requires a decision as to whether an abstract idea is present in the claim.[62] Likening the claims at issue to those in *Bilski v. Kappos*, the Court held that the claims were directed to "the abstract idea of intermediated settlement."[63] Because the claims at issue were directed to an abstract idea, the

[54] *Id.* at 88-89.
[55] *Id.* at 89.
[56] *Id.*
[57] *See* Alice Corp. Pty. Ltd. v. CLS Bank Intern., 573 U.S. 208 (2014).
[58] *Id.*at 213.
[59] *Id.* at 214-215.
[60] *Id.* at 216.
[61] *Id.*at 217 (quoting Mayo Collaborative Services v. Prometheus Laboratories, Inc., 566 U.S. 66 (2012)).
[62] Alice Corp. Pty. Ltd. v. CLS Bank Intern., 573 U.S. 208, 218 (2014).
[63] *Id.*

second step of the *Alice/Mayo* framework was required.[64] The second step looks to whether "the elements of the claim to determine whether it contains an 'inventive concept' sufficient to 'transform' the claimed abstract idea into a patent-eligible application."[65] Specifically, the court summarized the requirements of the step two analysis as "[a] claim that recites an abstract idea must include 'additional features' to ensure "that the [claim] is more than a drafting effort designed to monopolize the [abstract idea]," and "Mayo made clear that transformation into a patent-eligible application requires more than simply stat[ing] the [abstract idea] while adding the words 'apply it.'"[66]

In holding the claims unpatentable as directed toward an abstract idea, the court enumerated the standard used in the *Mayo* decision.[67] The *Alice/Mayo* framework, which consists of (1) determining whether the claims at issue are directed to an abstract idea and (2) if the claims are directed to an abstract idea examining the claims for any "inventive concept" has become the applicable standard for most abstract idea analyses.[68]

IV. COMPARISON OF REASONING BETWEEN *MAYO* AND *VANDA*

This section examines court justifications for the decision is *Mayo* and *Vanda* and provides examples of relevant claim language from the cases. When examining the inconsistent application of the *Alice/Mayo* framework regarding the *Vanda* case, it is useful to compare the language in the claims at issue for each case, as the examination provides useful insight into the similarity of the two cases. Despite this, the court came out differently in *Vanda*, holding the claims patentable and not directed to an abstract idea under the first phase of the *Alice/Mayo* framework.

[64] *Id.* at 221.
[65] *Id.*
[66] *Id.*
[67] Alice Corp. Pty. Ltd. v. CLS Bank Intern., 573 U.S. 208, 221 (2014).
[68] *Id.*

The *Mayo* court took claim 1 of the patent as representative when examining whether the whole patent was directed to patentable subject matter.[69] Claim 1 of the patent in *Mayo* reads:

> A method of optimizing therapeutic efficacy for treatment of an immune-mediated gastrointestinal disorder, comprising: (a) administering a drug providing 6–thioguanine to a subject having said immune-mediated gastrointestinal disorder; and (b) determining the level of 6–thioguanine in said subject having said immune-mediated gastrointestinal disorder, wherein the level of 6–thioguanine less than about 230 pmol per $8x10^8$ red blood cells indicates a need to increase the amount of said drug subsequently administered to said subject and wherein the level of 6–thioguanine greater than about 400 pmol per 8x10 8 red blood cells indicates a need to decrease the amount of said drug subsequently administered to said subject.[70]

The court found that this claim was directed to a process reciting a law of nature, and thus, not patentable.[71] In so holding, the court noted that, while the claim requires human action, the method itself describes using a natural law—specifically the relationship between "concentrations of certain metabolites in the blood and the likelihood that a dosage of thiopurine drug will prove ineffective or cause harm."[72]

Claim 1 of the patent in *Vanda* was also representative and used to evaluate the patent as a whole, reading:

> A method for treating a patient with iloperidone, wherein the patient is suffering from schizophrenia, the method comprising the steps of: determining whether the patient is a CYP2D6 poor metabolizer by: obtaining or having obtained a biological sample from the patient; and performing or having performed a genotyping assay on the biological sample to determine if the patient has a CYP2D6 poor metabolizer genotype; and if the patient has a CYP2D6 poor metabolizer genotype, then internally administering iloperidone to the patient in an amount of 12 mg/day or less, and if the patient does not have a CYP2D6 poor metabolizer genotype, then internally administering iloperidone to the patient in an amount that is greater than 12 mg/day, up to 24 mg/day, wherein a risk of QTc prolongation for a patient having a CYP2D6 poor metabolizer genotype is lower following the internal

[69] Mayo Collaborative Services v. Prometheus Laboratories, Inc., 566 U.S. 66, 74 (2012).
[70] *Id.* at 74-75.
[71] *Id.* at 77.
[72] *Id.*

> administration of 12 mg/day or less than it would be if the iloperidone were administered in an amount of greater than 12 mg/day, up to 24 mg/day.[73]

The court differentiates between *Vanda* and *Mayo*, stating that the claim in *Mayo* "[was] not directed to a novel method of treating a disease."[74] Whereas the method in *Mayo* did not purport to treat a particular disease, the claims in *Vanda* were specifically directed to a method of treating schizophrenia.[75] This specificity regarding the claims is one of the factors enumerated by Federal Circuit in their justification of treating *Vanda* differently from *Mayo.*[76]

In addition to the specific treatment of schizophrenia, the Federal Circuit discusses several other determinations that they used to support the disparate treatment of *Vanda* and *Mayo*. First among the considerations is whether the *Vanda* claims were directed to an abstract idea at all.[77] The court held that the claim in *Vanda* was not directed to an abstract idea under the *Alice/Mayo* framework, but an application of that abstract idea, stating "unlike the claim at issue in Mayo, the claims here require a treating doctor to administer iloperidone in the amount of either (1) 12 mg/day or less or (2) between 12 mg/day to 24 mg/day, depending on the result of a genotyping assay."[78] In explaining the *Vanda* claims this way, the court seemingly likens the *Vanda* case to *Diamond v. Diehr* and, in doing so, widens the gap between *Vanda* and *Mayo*.[79]

Preemption, or lack thereof, was another factor influencing the court's determination in *Vanda*.[80] Allowing the claims in *Mayo* to be patented risked infringement in cases where

[73] Vanda Pharm. Inc. v. W.-Ward Pharm. Intl. Ltd., 887 F.3d 1117, 1121 (Fed. Cir. 2018), cert. denied sub nom. Hikma Pharm. USA Inc. v. Vanda Pharm. Inc., 140 S. Ct. 911 (2020).
[74] *Id.* at 1134.
[75] *Id.* at 1135.
[76] *See Id.*
[77] *Id.*
[78] *Id.*
[79] *Compare* Diamond v. Diehr, 450 U.S. 175 (1981) *with* Mayo Collaborative Services v. Prometheus Laboratories, Inc., 566 U.S. 66, 74 (2012).
[80] Vanda Pharm. Inc. v. W.-Ward Pharm. Intl. Ltd., 887 F.3d 1117, 1135 (Fed. Cir. 2018), cert. denied sub nom. Hikma Pharm. USA Inc. v. Vanda Pharm. Inc., 140 S. Ct. 911 (2020).

physicians used the diagnostic method to see if a patient needed an increased or decreased dose, but did not change the treatment plan based upon those results.[81] If the claims were allowed patentability, infringement would not occur when doctors used the natural relationship at all, not only when the use reduced the likelihood of harm from a dose of thiopurine.[82] This broad area of infringement can "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 correlations."[83] Not only that, the claims in *Mayo* "threaten[ed] to inhibit the development of more refined treatment recommendations."[84]

In contrast to the claims in *Mayo*, the Federal Circuit held in *Vanda* that preemption was not a concern.[85] Because the claims in *Vanda* recited "carrying out a dosage regimen based on the results of genetic testing," the court was convinced that preemption would not be as grave a concern in this case as in *Mayo*.[86] The court summarized their reasoning, stating

> The claims require doctors to "internally administer[ ] iloperidone to the patient in an amount of 12 mg/day or less" if the patient has a CYP2D6 poor metabolizer genotype; and "internally administer[ ] iloperidone to the patient in an amount that is greater than 12 mg/day, up to 24 mg/day" if the patient does not have a CYP2D6 poor metabolizer genotype. These are treatment steps. In contrast, as shown above, the claim in Mayo stated that the metabolite level in blood simply "indicates" a need to increase or decrease dosage, without prescribing a specific dosage regimen or other added steps to take as a result of that indication. Here, the claims do not broadly "tie up the doctor's subsequent treatment decision."[87]

V. Analysis of The Court's Decision and Comparison of Claim Language

[81] *Id.*
[82] *See Id.*
[83] *Id.*
[84] *Id.*
[85] Vanda Pharm. Inc. v. W.-Ward Pharm. Intl. Ltd., 887 F.3d 1117, 1135 (Fed. Cir. 2018), cert. denied sub nom. Hikma Pharm. USA Inc. v. Vanda Pharm. Inc., 140 S. Ct. 911 (2020).
[86] *Id.*
[87] *Id.*

This section examines the Federal Circuit's decision in *Vanda* and posits that, despite their insistence in *Vanda*, *Mayo* requires a different outcome. First, this section will take the position that the decision in *Vanda* is, in fact, a departure from the well settled *Alice/Mayo* framework. This section will then walk through each of the justifications provided by the Federal Circuit in their *Vanda* opinion and discuss why none of them are sufficiently persuasive to justify straying from the *Alice/Mayo* Framework. The first justification set forth by the court is the claims in *Vanda* do not purport to claim an abstract idea under the *Alice/Mayo* framework.[88] The second is that the claims in *Vanda* held less concern about preemption than those in *Mayo*, and thus, could be safely patented.[89] Finally, this section addresses the Federal Circuit's reliance on the preamble of the patent claims despite recent precedent by the same court holding that, as a general rule, preambles of patent claims are not limiting.[90] By comparing the claims in *Vanda* and *Mayo*, the flaws in the court's reasoning can be revealed.

Despite the Federal Circuit's insistence that *Vanda* "is not *Mayo*," the claims at issue in the cases are very similar and do not justify a departure from the *Alice/Mayo* framework.[91] Additionally, the court's decision to depart from the *Mayo* precedent further blurs the "thin—and often unpredictable—line that divides eligible and ineligible subject matter."[92] The claims in both cases "correlate an individual's ability to metabolize the drug with the proper dosage for that individual."[93] The claims in *Mayo* claimed "[a] method of optimizing therapeutic efficacy for

[88] *See generally Id.* at 1134.
[89] *See Id.* at 1135.
[90] *See* Arctic Cat Inc. v. GEP Power Products, Inc., 919 F.3d 1320, 1325 (Fed. Cir. 2019); Stephanie Sivinski, *Vanda v. West-Ward: This Time, Dosage Adjustment Claims are Patent Eligible Subject Matter*, IPWATCHDOG (May 16, 2018), https://www.ipwatchdog.com/2018/05/16/vanda-v-west-ward-dosage-adjustment-claims-patent-eligible/id=97117/.
[91] *Compare* Mayo Collaborative Services v. Prometheus Laboratories, Inc., 566 U.S. 66, 74-75 (2012) *with* Vanda Pharms v. West-Ward Pharms. Int'l Ltd., 887 F.3d 1117, 1121 (Fed. Cir. 2018).
[92] Sivinski, *supra* note 90.
[93] *Id.*

treatment of an immune-mediated gastrointestinal disorder…."[94] Similarly, the claims in *Vanda* were directed to "[a] method for treating a patient with iloperidone, wherein the patient is suffering from schizophrenia…."[95]

Though the claim in *Vanda* seems more specific than those in *Mayo* and seems to be directed to treatment of a specific disease, the difference between the claims is less stark than the Federal Circuit posits in their majority opinion. The similarity of the claims enjoys an inverse relationship with the emphasis placed on the preambles.[96] Looking past the preambles, the *Mayo* claim continues "comprising: (a) administering a drug providing 6-thioguaniine to a subject having said immune-mediated gastrointestinal disorder; and (b) determining the level of 6-thioguanine or 6-methyl mercaptopurine in said subject having said immune-mediated gastrointestinal disorder…."[97] These steps of the claim make up most of the natural law that rendered the patent claims ineligible under what would be become known as the *Alice/Mayo* framework.[98]

Once again moving past the preamble the *Vanda* claim sets forth "comprising the steps of: determining whether the patient is a CYP2D6 poor metabolizer by: obtaining or having obtained a biological sample from the patient; and performing or having performed a genotyping assay on the biological sample to determine if the patient has a CYP2D6 poor metabolizer genotype…."[99] The matter claimed here is strikingly similar to the highlighted subject matter of the *Mayo* patent. The relevant portion of each patent claims a process by which a natural law pertaining to certain

[94] Mayo Collaborative Services v. Prometheus Laboratories, Inc., 566 U.S. 66, 74 (2012).
[95] Vanda Pharm. Inc. v. W.-Ward Pharm. Intl. Ltd., 887 F.3d 1117, 1135 (Fed. Cir. 2018), cert. denied sub nom. Hikma Pharm. USA Inc. v. Vanda Pharm. Inc., 140 S. Ct. 911 (2020).
[96] *See* Mayo, 566 U.S. at 74; Vanda Pharm. Inc., 887 F.3d at 1135.
[97] Mayo, 566 U.S. at 74.
[98] *See Id.*
[99] Vanda Pharm. Inc., 887 F.3d at 1135.

relationships within the human body is used to ascertain the presence of a relevant trait in a patient.[100]

Immediately after setting forth the natural law, the claims in both *Mayo* and *Vanda* continue, enumerating similar "applications" of the law.[101] The claim in *Mayo* states:

> wherein the level of 6-thioguanine less than about 230 pmol per $8x10^8$ red blood cells indicates a need to increase the amount of said drug subsequently administered to said subject and wherein the level of 6-thioguanine greater than about 400 pmol per $8x10^8$ red blood cells or a level of 6-methyl mercaptopurine greater than about 7000 pmol per $8x10^8$ red blood cells indicates a need to decrease the amount of said drug subsequently administered to said subject,[102]

whereas the claim in *Vanda* continues, stating:

> and if the patient has a CYP2D6 poor metabolizer genotype, then internally administering iloperidone to the patient in an amount of 12 mg/day or less, and if the patient does not have a CYP2D6 poor metabolizer genotype, then internally administering iloperidone to the patient in an amount that is greater 12 mg/day, up to 24 mg/day, wherein a risk of QTc prolongation for a patient having a CYP2D6 poor metabolizer genotype is lower following the internal administration of 12 mg/day or less than it would be if the iloperidone were administered in an amount of greater than 12 mg/day, up to 24 mg/day.[103]

Both claims purport to set forth an "application" of a natural law. In both cases, however, the "application" is a change in dosage based on the results of using a natural law—essentially "use the natural law and adjust dosage based on the result. This kind of dosage change was held by the *Mayo* court to be insufficient to justify recognition of patentability for natural laws.[104] Because of the similarity of the claims, the result in *Vanda* is not justifiable based upon the Supreme Court precedent set out in *Mayo*.

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[100] *Compare* Mayo Collaborative Services v. Prometheus Laboratories, Inc., 566 U.S. 66, 74 (2012) *with* Vanda Pharm. Inc. v. W.-Ward Pharm. Intl. Ltd., 887 F.3d 1117, 1135 (Fed. Cir. 2018), cert. denied sub nom. Hikma Pharm. USA Inc. v. Vanda Pharm. Inc., 140 S. Ct. 911 (2020).
[101] *Compare* Mayo, 566 U.S. at 74 *with* Vanda Pharm. Inc., 887 F.3d at 1135.
[102] Mayo, 566 U.S. at 74.
[103] Vanda Pharm. Inc., 887 F.3d at 1135.
[104] Mayo, 566 U.S. at 74.

The majority's justifications for ignoring the *Alice/Mayo* framework are unpersuasive and inappropriately emphasize the preamble of the claims as distinguishing *Vanda* from *Mayo*.[105] As stated in Chief Judge Prost's dissent,

> The majority relies on the claims' recitation of specific applications of the discovery underpinning the patent to find no natural law is claimed. But it conflates the inquiry at step one with the search for an inventive concept at step two. Once the natural law claimed in the '610 patent is understood in a manner consistent with Mayo, what remains fails to supply the requisite inventive concept to transform the natural law into patent-eligible subject matter.[106]

Chief Judge Prost appropriately recognizes that the claims in *Vanda*, much like the claims in *Mayo* do no more than "simply state the law of nature while adding the words 'apply it.'"[107] Due to the uncanny similarity between the claims, the patent in *Vanda* should have been invalidated as directed to unpatentable subject matter as in *Mayo*.

Preemption is another factor to consider when applying the *Alice/Mayo* framework.[108] In *Vanda*, the Federal Circuit cited their lack of concern about preemption as a factor that distinguished the case from *Mayo*.[109] An examination of the practical scope of the claims, however, results in finding the same risk of preemption in *Vanda* as there was in *Mayo.*[110] The court emphasized that the claims in *Mayo* could preempt further innovation in that field because the patent could be infringed even if treatment did not change as a result of using the method and because the claim was addressed to the method of determining the dosage generally.[111] The supposed specificity of the *Vanda* claim should not save it. The specific treatment claimed in

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[105] *See* Vanda Pharm. Inc. v. W.-Ward Pharm. Intl. Ltd., 887 F.3d 1117, 1134-35 (Fed. Cir. 2018), cert. denied sub nom. Hikma Pharm. USA Inc. v. Vanda Pharm. Inc., 140 S. Ct. 911 (2020).
[106] *Id.* at 1140 (Prost, C.J., dissenting).
[107] *Id.*
[108] *See* Mayo Collaborative Services v. Prometheus Laboratories, Inc., 566 U.S. 66, 72-73 (2012); Alice Corp. Pty. Ltd. v. CLS Bank Intern., 573 U.S. 208, 223-224 (2014).
[109] Vanda Pharm. Inc., 887 F.3d at 1134-35.
[110] *Compare* Mayo 566 at 74 *with* Vanda Pharm. Inc., 887 F.3d at 1135.
[111] Vanda Pharm. Inc. v. W.-Ward Pharm. Intl. Ltd., 887 F.3d 1117, 1135 (Fed. Cir. 2018), cert. denied sub nom. Hikma Pharm. USA Inc. v. Vanda Pharm. Inc., 140 S. Ct. 911 (2020).

Vanda is likely the only particularly applicable use for the method. As a result, the claims in *Vanda* preempt as much of the possible market as the claims in *Mayo*—in *Vanda's* case the treatment of schizophrenia using the claimed method.

Finally, the Federal Circuit improperly relied on the preamble to the *Vanda* claim in their decision.[112] In *Arctic Cat, Inc. v. GEP Power Products, Inc.*, the Federal Circuit reiterated,

> preamble language is limiting when the claim recites a combination in the way specified in the one PTO regulation on preambles, i.e., by describing the "conventional or known" elements in a "preamble," followed by a transition phrase "such as 'wherein the improvement comprises,"' and then an identification of elements that 'the applicant considers as the new or improved portion."[113]

In *Vanda*, the preamble claiming a method of treating schizophrenia is not one of the instances in which preamble language is considered limiting. [114] The Federal Circuit allowed the specificity of the preamble to substitute for necessary specificity in the claims and, in doing so, they improperly distinguished between *Vanda* and *Mayo*.

VI. CONCLUSION

The Federal Circuit's decision in *Vanda* is at odds with Supreme Court precedent and further blurs the already unclear line between patentable and unpatentable subject matter in the area of abstract ideas. Though the claim at issue in the two cases are nearly identical, the majority in *Vanda* disregarded the *Mayo* precedent and found for the patentability of the claims. The dissent by Chief Judge Prost addresses many of the issues present in the case and represents a more accurate understanding of the *Alice/Mayo* framework. Because the Supreme Court denied certiorari, the landscape of patentable subject matter is more confusing than ever.

[112] *See Id.*
[113] Arctic Cat Inc. v. GEP Power Products, Inc., 919 F.3d 1320, 1330 (Fed. Cir. 2019).
[114] Vanda Pharm. Inc., 887 F.3d at 1134-35.