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The authors assess the potential impact of the recent *Mayo* decision on computer-implemented claims.

Diagnosing Patent Ineligibility: The Supreme Court's *Mayo v. Prometheus* Decision and Computer-Implemented Claims

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On March 20, the Supreme Court issued its unanimous decision in *Mayo Collaborative Services v. Prometheus Laboratories Inc.*,[1] holding that all of the claims of the challenged Prometheus patents covering a diagnostic test were invalid as being drawn to subject matter that failed to meet the patent-eligibility requirement of 35 U.S.C. § 101. In particular, the court held that the patents were primarily directed to ''laws of nature,'' and that these claims did not ''add enough'' regarding the application of these laws to qualify for patent protection.[2]

For anyone holding or prosecuting or hoping to prosecute a process patent, the holding in *Mayo* adds to the serious challenges already present in the wake of *Bilski v. Kappos*.[3] The only guidance offered by the court to inventors is that ''the use of a natural law [must] also contain other elements or a combination of elements, sometimes referred to as an 'inventive concept,' sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the natural law itself.''[4]

As noted, the court determined that the elements of the claims in *Mayo* which were not themselves natural laws were not sufficient to constitute an ''inventive concept'' eligible for protection. Innovators will now have to consider whether to more clearly identify and circumscribe whatever ''natural laws'' may be incorporated into the claimed invention and then distinguish

[1] 132 S. Ct. 1289, 101 USPQ2d 1961 (83 PTCJ 729, 3/23/12).

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[2] *Id.*, slip op. at 8.
[3] *Bilski v. Kappos*, 130 S. Ct. 3218, 95 USPQ2d 1001 (2010) (80 PTCJ 285, 7/2/10).
[4] *Mayo*, slip op. at 3.

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those additional elements intended to meet the court's threshold for an ''inventive concept.''

One district court has already used the reasoning of *Mayo* to bolster its rejection of a patent for a method to assist doctors in choosing optimal medical treatment regimens.[5]

For previously issued patents, the *Mayo* case may well embolden potential infringers who believe they can create reasonable challenges to those patents by alleging they are primarily patents of natural laws and seeking to convince a court that the ''other elements'' of the patent are insufficiently inventive. Thus, the cost of defending issued process patents is likely to increase.

A close examination of the case is essential to understanding the availability of protection for process patents, not only in medical diagnostics but also in software and other fields.

The Prometheus Patent Claims: Administering, Determining, and Wherein Clauses

The court first addressed the subject matter claimed in the Prometheus patents, focusing on a single representative claim directed to a ''method of optimizing therapeutic efficacy for treatment of an immune-mediated gastrointestinal disorder.''[6]

The first step of this claim required ''administering a drug providing'' a certain chemical substance to a patient suffering from the disorder.[7] The second step recited ''determining'' the level of that chemical substance in the patient.[8]

The final portion of the claim consisted of two ''wherein'' clauses requiring that a set low level of the chemical in the patient's red blood cells ''indicates a need to increase'' the drug dosage, and that a set high level ''indicates a need to decrease'' the drug's dosage.[9]

The court noted that it has ''long held'' that Section 101 of the Patent Act, which defines patent-eligible subject matter as including ''processes,'' ''contains an important implicit exception'' for ''[l]aws of nature, natural phenomena, and abstract ideas.''[10] On the other hand, applications of natural laws may be patent-eligible if they include an ''inventive concept'' that adds ''significantly more'' than the underlying natural law.[11]

Accordingly, the court analyzed the steps of the Prometheus claim to determine whether this threshold was met.

The court characterized the ''administering'' step as ''refer[ring] to the relevant audience'' of doctors who are already administering the drug.[12] Likewise, the ''determining'' step merely ''tells the doctor to determine the level'' of the chemical in the patient, a step found to be ''well known'' as well as ''well-understood, routine, conventional activity.''[13]

Finally, the ''wherein'' clauses were held to ''simply tell a doctor about the relevant natural laws, at most adding a suggestion that he should take those laws into account when treating his patient.''[14] The court concluded its claim analysis as follows:[15]

> [T]he claims inform a relevant audience about certain laws of nature; any additional steps consist of well understood, routine, conventional activity already engaged in by the scientific community; and those steps, when viewed as a whole, add nothing significant beyond the sum of their parts taken separately.

Diehr, Flook, and Inhibiting Further Discovery

The court bolstered its views by comparing the claims of the Prometheus patents to those at issue in its *Diehr* and *Flook* cases of over 30 years ago.[16]

The claims in *Diehr* involved an application of an abstract mathematical equation to a rubber-molding process, where the steps included loading the rubber in a mold, closing it, measuring its temperature, continuously calculating cure time using the formula in a computer, and automatically opening the mold at the proper time.[17] According to the court, nothing in the *Diehr* decision indicated that the non-equation steps, alone or in combination, were ''obvious, already in use, or purely conventional.''[18]

In addition, because the *Diehr* claims were drawn to the use of the patent-ineligible formula ''in conjunction with all of the other steps,'' there was no danger that the patent would ''pre-empt the use'' of the equation.[19]

The claims in *Flook* were similarly directed to the use of an ''apparently novel algorithm'' in hydrocarbon catalytic conversion, which involved measuring temperature and other process variables and using these measurements via a computer to calculate and update ''alarm limits'' that signaled inefficiency or danger.[20] The *Flook* court held that the claims were not limited ''to a particular application,'' and that the use of computers for ''automatic process monitoring-alarming'' was ''well known'' and ''purely conventional or obvious,'' and thus ''there was no inventive concept in the claimed application of the formula.''[21]

In finding that the case for patent-eligibility of the claims at issue in *Mayo* was ''weaker'' than in *Diehr* and ''no stronger'' than in *Flook*, the court reiterated that those claims ''add nothing specific to the laws of nature other than what is well-understood, routine, conventional activity.''[22]

The court also reviewed *Bilski*, its most recent case on patent-eligibility, its *Benson* decision, as well as the *Morse* and *Nielsen* cases from over 150 years ago.[23] These cases were held to support ''the view that simply appending conventional steps, specified at a high level

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[5] Discussed below at note 46 et. seq.
[6] *Id.* at 5.
[7] *Id.*
[8] *Id.*
[9] *Id.* at 5-6.
[10] *Id.* at 1 (citations omitted).
[11] *Id.* at 2-3 (citations omitted).
[12] *Id.* at 9.
[13] *Id.* at 10.
[14] *Id.* at 9.
[15] *Id.* at 11.
[16] *Diamond v. Diehr*, 450 U. S. 175, 185, 209 USPQ 1 (1981) (1981); *Parker v. Flook*, 437 U. S. 584, 590, 198 USPQ 193 (1978).
[17] *See Mayo*, slip op. at 11-12.
[18] *Id.* at 12.
[19] *Id.* (citations omitted).
[20] *Id.* (citations omitted).
[21] *Id.* at 12-13 (citations and quotations omitted).
[22] *Id.* at 13.
[23] *Bilski*, supra note 4; *Gottschalk* v. *Benson*, 409 U. S. 63, 175 USPQ 673 (1972); *O'Reilly v. Morse*, 15 How. 62 (1854); *Neilson v. Harford*, Webster's Patent Cases 295, 371 (1841) (English case discussing whether a claim is directed to a principle or a machine embodying that principle).

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of generality, to laws of nature, natural phenomena, and abstract ideas cannot make those laws, phenomena, and ideas patentable.''[24]

After summarizing these earlier cases, the court noted that it had ''repeatedly emphasized'' its ''concern that patent law not inhibit further discovery by improperly tying up the future use of laws of nature.''[25] The claims in *Morse* were characterized as ''general,'' those in *Benson* as ''abstract and sweeping,'' and the *Flook* claims covered ''a broad range of potential uses.''[26] Thus, the court issued the following warning regarding natural laws:[27]

> [T]here is a danger that the grant of patents that tie up their use will inhibit future innovation premised upon them, a danger that becomes acute when a patented process amounts to no more than an instruction to ''apply the natural law,'' or otherwise forecloses more future invention than the underlying discovery could reasonably justify.

Rejection of Other Arguments for Finding Patent-Eligibility

The arguments of Prometheus and the U.S. government (as amicus curiae) were also rejected by the court. Prometheus had argued that its claimed processes were patent-eligible because ''they involved transforming the human body'' by administering the drug and ''transforming the blood'' itself by analyzing it to determine the level of metabolites.

The court found that the so-called ''machine or transformation test'' was not helpful because the claim relating to administration of the drug merely identified those who would need to consider the affects of the drug and the claim relating to determining metabolic levels involved a measurement which might not necessarily require transformation of the blood. Thus, ''transformation'' was not integral to the claims, and even if it had been, the court determined that such a transformation would not ''trump[] the law of nature exclusion.''[28]

Prometheus further argued that its claims were drawn to ''narrow and specific'' natural laws and therefore would not interfere significantly with future innovation. The court asserted that judges were ill equipped to distinguish broad from narrow laws of nature, explaining that this was why its precedents had asserted a ''bright line prohibition against patenting laws of nature, mathematical formulas, and the like.''[29]

The U.S. government took the position that the requirements of novelty (Section 102), nonobviousness (Section 103), and complete and accurate description (Section 112) could screen out claims improperly covering laws of nature. The court declined this ''invitation to substitute §§ 102, 103, and 112 inquiries for the better established inquiry under § 101.''[30]

Although recognizing that the requirements of these other sections of the patent code ''might sometimes overlap'' with the patent-eligibility inquiry, the court held that relying solely on those provisions ''risks creating significantly greater legal uncertainty.''[31] Furthermore, these sections are ''not equipped'' to address ''the risk that a patent on the [natural] law would significantly impede future innovation.''[32]

Policy arguments made by Prometheus and some of the amici raised the concern that invalidation of these claims ''will interfere significantly with the ability of medical researchers to make valuable discoveries, particularly in the area of diagnostic research,'' as the lack of exclusive protection would make investment in this research less attractive.[33] The court dispatched these assertions by noting that other amici, notably those associated with healthcare providers, maintained an opposite view of the policy considerations.[34]

Rather than adopting a ''new protective rule'' in this case, the court recognized ''the role of Congress in crafting more finely tailored rules where necessary.''[35]

Lessons From *Mayo*

It is interesting to note that the *Mayo* decision did not engage in (or require) a construction of claims before embarking on the patent-eligibility analysis, as would be necessary in any analysis under 35 U.S.C. § § 102 (novelty), 103 (nonobviousness), and 112 (written description, best mode, enablement, and definiteness). Since a rigorous claim construction does not appear to be necessary to challenge the patent-eligibility of a claim, the case may subject patent-holders to new challenges alleging that the novel or nonobvious aspects of its invention are simply natural laws or mathematical algorithms, and that the claims are so broadly or abstractly worded that it would foreclose innovation.

More particularly, *Mayo* states that no amount of ''conventional'' or ''obvious'' matter can be added to overcome the recitation of an ineligible natural law or algorithm. Thus, challengers may also now allege with greater impunity that those elements of a claim which are *not* natural laws are entirely obvious based on prior art references under Sections 102 or 103 of the patent code.

Alternatively, a challenger can take the position that the additional elements of the claim include language that is so broad as to be indefinite, or that lacks a written description or enablement in the specification, under Section 112 of the code. The potential for such challenges should motivate those prosecuting new or existing applications to consider drafting or revising their claims with language designed to convince a court that the additional elements are neither ''conventional'' or ''obvious'' but are ''definite'' and ''enabling.''

In the case of pharmaceutical companies, *Mayo* seems to offer some comfort in the form of an apparent exception to the *Mayo* holding. The court recognized that ''a typical patent on a new drug or a new way of using an existing drug'' which includes claims that ''confine their reach to particular applications'' of natural laws may survive scrutiny.[36]

But other companies, such as those with software-implemented inventions (since algorithms are treated by the courts in the same manner as natural laws) or companies that are active in the medical diagnostic field should be especially concerned after *Mayo*, and should

[24] *Mayo*, slip op. at 14.
[25] *Id.* at 16.
[26] *Id.* at 16-17 (citations omitted).
[27] *Id.* at 17.
[28] *Id.* at 19 (citations and quotations omitted).
[29] *Id.* at 19-20.
[30] *Id.* at 22.
[31] *Id.* at 21.
[32] *Id.* at 21-22.
[33] *Id.* at 22-23.
[34] *Id.* at 23.
[35] *Id.* at 24.
[36] *Mayo*, slip op. at 18.

review their method patents to determine whether they include significant novel and nonobvious steps beyond the algorithm or any natural laws that may be recited.

More immediately, the *Mayo* case is likely to have a significant impact on the patent-eligibility cases currently pending before the Federal Circuit as well as any such cases for which a petition for certiorari is pending before the Supreme Court. As just one example, within a week after the case was decided, the court vacated and remanded to the Federal Circuit for reconsideration in light of *Mayo* the closely-watched *Myriad* case involving the patentability of a particular sequence of DNA isolated from a human gene.[37]

In light of *Mayo*, the Federal Circuit (or ultimately the Supreme Court) could decide that genes are not patentable subject matter because the information encoded in the DNA sequence is a ''law of nature'' or that the gene itself is a ''natural phenomenon.''

Application of *Mayo* to Software and Business-Method Patents

In view of the court's remand of the *Myriad* case, it seems likely that the court may take similar action with the pending certiorari petition in the *Ultramercial* case.[38]

The claim in *Ultramercial* was for a method whereby a consumer would receive a copyrighted product for free in exchange for viewing an advertisement, while the advertiser would be charged and pay the copyright holder for the copyrighted content delivered to the consumer. Citing one of its own earlier precedents,[39] the Federal Circuit found that the ''abstract idea'' underlying the claimed invention did not ''exhibit itself so manifestly as to override the broad statutory categories of eligible subject matter.'' Rather, the opinion determines that the steps set forth in the claims constitute a particular, useful application of the abstract idea of using advertising as a form of currency.

If the Federal Circuit is required to reexamine *Ultramercial* (or if it must revisit the patent eligibility of a software or business method patent for any other reason), the holdings of the *Mayo* decision will force it to confront a number of questions. Perhaps the primary issue relates to the fact that most challenges to the eligibility of software or business methods for patent protection are based on the argument that the invention represents an ''abstract idea'' rather than a ''law of nature,'' as in *Mayo*.

Will the Federal Circuit apply the same reasoning set forth in *Mayo* to distinguish between an unpatentable ''law of nature'' and a patentable application of such a law when confronted with a challenge to a software patent that the claimed invention is an unpatentable ''abstract idea'' rather than a patentable application of that idea?

The *Mayo* court seems to have intended its decision to apply to all categories of exceptions to Section 101 patentable subject matter, as attested by its remand of the *Myriad* case (which involved both the ''law of nature'' and the ''abstract idea'' exceptions). The court hinted at a roadmap for arguing the patent-eligibility of software or a business method in the face of challenges based on these exceptions by virtue of its extensive reliance on *Diehr*.

Accordingly, a patent applicant (or patentee facing a patent-eligibility challenge) should make every effort to call attention to the ways in which its claims are like those in *Diehr*.

According to the *Mayo* court, the *Diehr* claims were held to be patent-eligible ''because of the way the additional steps of the process *integrated* the equation into the process as a whole.''[40] So the smart applicant or patentee should craft software or business method claims so as to identify as clearly as possible steps that are patent-eligible (i.e., neither abstract, part of a mental process, or a mathematical algorithm), and explain how those steps integrate (or apply) the patent-ineligible aspect of the invention in a way that demonstrates a measurable improvement over existing technology.

In other words, for many software or business method patents, the non-patent eligible steps should be recited using language that makes clear that they are part of an ''improved process'' that ''solv[es] a practical problem which has arisen'' in the field of the invention.[41]

Furthermore, the *Mayo* court took the position that, as to those steps of the *Diehr* claims which were not patent-ineligible, it was ''nowhere suggested that all these steps, or at least the combination of these steps, were in context obvious, already in use or purely conventional.''[42] As a result, a patent applicant or patentee should include steps, or a combination of steps, that themselves describe subject matter that can be characterized as novel or nonobvious—despite the admonition in *Diehr* that ''the 'novelty' of any element or steps in a process, or even of the process itself, is of *no relevance* in determining whether the subject matter of a claim falls within the § 101 categories of possibly patentable subject matter.''[43]

The court noted that the *Diehr* patentees ''did not seek to pre-empt the use of the equation, but sought only to foreclose from others the use of that equation in conjunction with all the other steps in their claimed pro-

[37] *Association for Molecular Pathology v. U.S. Patent and Trademark Office*, 653 F.3d 1329, 99 USPQ2d 1398 (Fed. Cir. 2011) (82 PTCJ 449, 8/5/11); cert. granted, vacated, and remanded, *Association for Molecular Pathology v. Myriad Genetics Inc.*, No. 11-725 (U.S. March 26, 2012) (83 PTCJ 761, 3/30/12).

[38] *Ultramercial LLC v. Hulu LLC*, 657 F.3d 1323, 100 USPQ2d 1140 (Fed. Cir. 2011) (82 PTCJ 689 9/23/11). It appears that the court will likely address the petition in May.

[39] *Research Corporation Technologies Inc. v. Microsoft Corp.*, 627 F.3d 859, 97 USPQ2d 1274 (Fed. Cir. 2010) (81 PTCJ 171, 12/10/10).

[40] *Mayo,* slip. op. at 11-12 (emphasis added).

[41] *Diehr* at 450 U.S. 181. The *Research Corporation Technologies* case echoes the *Diehr* court's approbation of the patent-eligibility of computerized improvements to existing technical problems (''Indeed, this court notes that inventions with specific applications or improvements to technologies in the marketplace are not likely to be so abstract that they override the statutory language and framework of the Patent Act.''); *Ultramercial*, 657 F.3d at 1328 (citing *Research Corporation Technologies*, and noting that ''[b]y its terms, the claimed invention purports to improve existing technology in the marketplace.'').

[42] *Mayo*, slip. op. at 12. This view is somewhat curious, as the *Diehr* opinion, quoting the examiner's rejection, noted that ''[t]he remaining steps . . . were conventional and necessary to the process and cannot be the basis for patentability.'' *Diehr* at 450 U.S. 180-181 (quotation omitted).

[43] *Diehr* at 45 U.S. 188-189.

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cess.''[44] Thus, one key to overcoming a Section 101 challenge may be inclusion of a significant number of steps, or one substantial step, that acts to limit the claimed use of the patent-ineligible subject matter in a meaningful way.

One strategy for accomplishing this would be to forgo broad claiming and add more independent claims that include steps drafted to cover specific applications of the technology. As the *Mayo* court made clear in its review of *Bilski*, however, mere ''field of use'' restrictions are insufficient.[45] Since *Bilski* did not recite such limiting steps, it is likely that a court faced today with claims similar to those at issue in *Bilksi* would reach the identical result through application of the *Mayo* ''inventive concept'' test.

A District Court Application of *Mayo*

In *SmartGene*, which appears to be the first case applying *Mayo*, the U.S. District Court for the District of Columbia invalidated a patent drawn to a computer-implemented method of determining optimal medical treatment regimens.[46] These claims were held to recite ''nothing more than a mental process,'' and were thus ineligible under the abstract idea exception to § 101.[47]

The court took the position that the steps in the claimed invention ''described abstract ideas that are commonly performed by medical professionals in evaluating, considering and constructing treatment options for a patient presenting a specific medical condition.''[48] The court held that the recited ''computing device'' elements ''cannot serve as a significant limitation or constraint on the claimed invention,[49] stating elsewhere that ''[a]s in *Flook*, the computing device referenced in the claims is incidental to the claimed invention. . .''[50] Like the claims in *Bilski* and *Mayo*, the claims in *SmartGene* were also held to fail the machine-or-transformation test.[51]

Notably, the district court determined (like the court in *Mayo*) that it was ''not necessary to formally construct the [patentee's] claims'' in order to address the ''threshold'' issue of patentability. Nevertheless, the court pointed out that the patentee's refusal to accept a narrower construction of the claims proposed by SmartGene reinforced concern that the claims ''could encompass far more than the common understanding of therapeutic treatment regimens and could for example, include financial information about the patient and the most economic treatment options available.''[52]

Thus, while the briefs and arguments of the parties in the *SmartGene* case pre-dated the Supreme Court's *Mayo* decision,[53] the decision seems to reinforce the idea that *Mayo* may bolster *Bilski*-based arguments by patent challengers that broad claims based on automating human analysis are in reality efforts to control abstract ideas and hence fall outside patentable subject matter under Section 101. This leads to one possible conclusion that process patents might best be drafted or defended by convincing the PTO or the court that the patent leaves open the possibility for someone to ''invent around'' the claims.

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[44] *Mayo,* slip. op. at 12 (quotation omitted).
[45] *Mayo,* slip. op. at 15 (quotation omitted).
[46] *SmartGene Inc. v. Advanced Biological Laboratories SA*, No. 08-642 (D.D.C. March 30, 2012) (83 PTCJ 811, 4/6/12).
[47] *Id.*, slip op. at 21 (quotation omitted). The claim at issue recited ''providing patient information'' pre-loaded with to ''*a computing device*,'' three ''knowledge bases'' ''generating *in said computing device* a ranked listing of available therapeutic treatment regimens'' and ''generating *in said computing device* advisory information for one or more therapeutic regimens.''
[48] *Id.*, slip op. at 23.
[49] *Id.*, slip op. at 35.
[50] *Id.*, slip op. at 29
[51] *Id.*, slip op. at 23-32.
[52] *Id.*, slip op. at 36.
[53] *Id.*, slip op. at 6 (motion filed Dec. 12, 2011; hearing held March 9, 2012).