MAYO v PROMETHEUS: ANOTHER GUIDEPOST ON THE ROAD TO DETERMINING PATENTABILITY IN THE POST-INDUSTRIAL AGE

JANE PLOMLEY
Partner, White & Case LLP, Washington
ROBERT COUNIHAN
Associate, White & Case LLP, New York

On 20 March 2012, in *Mayo Collaborative Servs v Prometheus Labs, Inc.*,[1] the Supreme Court of the United States invalidated diagnostic treatment process claims for effectively claiming the laws of nature underlying the claimed invention. To reach this decision, the court reviewed the 'guideposts'[2] set by its previous guidance regarding patent eligibility, and compared the claims-at-issue with those previously considered by the court. In *Mayo*, the court erected a new guidepost, one with particular relevance for the medical community, as the decision specifically addresses medical diagnostic treatments, but also one which may impact the general patentability of any invention that relies upon laws of nature or natural correlations to describe that invention.

Some patent attorneys in the United States fear that the court's invalidation of the medical diagnostic patents at-issue may unduly limit the patentability of future innovation in the medical community. This fear, in some respects, has already come to fruition in that a US District Court recently used *Mayo*'s guidance to invalidate claims drawn to methods and systems for selecting a therapeutic regimen, as discussed further below.[3]

Further, while the effect of *Mayo* is not yet clear, and may not be for years, another concern is that the court unduly expanded the patent eligibility doctrine beyond its ascribed 'screening function' and blurred the distinction between patent eligibility and the concepts of anticipation and obviousness.

The Role of Screening for Patent-eligible Subject-matter

35 U.S.C. §101, which outlines subject-matter eligible for patent protection in the United States, has been described by the Supreme Court as a 'threshold test' to be passed prior to consideration of novelty under 35 U.S.C. §102, obviousness under 35 U.S.C. §103, and the adequacy of the patent's written specification under 35 U.S.C. §103.[4] The screening function of this threshold test derives from the implicit, common law exception to §101 that 'laws of nature, natural phenomena, and abstract ideas are not patentable.'[5]

In the United States, it has long been understood that while laws of nature, natural phenomena, and abstract ideas are not patentable, 'an application of a law of nature or mathematical formula to a known structure or process may well be deserving of patent protection'.[6] However, the Supreme Court has provided caution about the scope of such an 'application' by warning against 'upholding patents that claim processes that too broadly preempt the use of a natural law'[7] and 'simply stat[ing] the law of nature while adding the words "apply it"'[8] are not patent-eligible 'applications'.

In *Mayo*, it was undisputed that the claims which are described further below relied, at least in part, on the natural correlations between certain metabolite levels and the effectiveness and/or toxicity of a treatment related to those metabolites. The ultimate question turned on whether the claims applied that correlation in a patent-eligible manner, which the Supreme Court determined that they did not. While the *Mayo* court stopped short of deciding that diagnostic treatment claims were as a class not patent-eligible, the application of this decision to other patents will impact the rapidly evolving area of medical diagnostics and similar areas of medicine.

1) *Mayo Collaborative Servs v Prometheus Labs, Inc.*, 132 S.Ct. 1289 (2012).

2) *Bilski v Kappos*, 130 S.Ct. 3218, 3231 (2010).

3) *SmartGene, Inc. v Adv. Bio. Labs, SA*, F.Supp.2d, 2012 WL 1059611, *7-10 (D.D.C. 2012).

4) See *Bilski*, 130 S.Ct. at 3225 (2010).

5) *Mayo*, 132 S.Ct. at 1293 (internal citations omitted).

6) *Ibid.*, at 1293 to 1294 citing *Diamond v Diehr*, 450 U.S. 175, 187, 101 S.Ct. 1048 (1981).

7) *Ibid.*, at 1294 citing *O' Reilly v Morse*, 15 How. 62, 112 to 120, 14 L.Ed. 601 (1854) and *Gottschalk v Benson*, 409 U.S. 63, 71 to 72, 93 S.Ct. 253 (1972).

8) *Ibid.*, citing *Benson*, 409 U.S. at 71 to 72.

Numerous third parties filed *amicus curiae* briefs in support of both arguments. Of particular interest was the Supreme Court's dismissal of the argument raised by the US Government that the claims-in-suit were best invalidated under the concepts of novelty (35 U.S.C. §102), obviousness (35 U.S.C. §103) and the sufficiency of the patent's written description (35 U.S.C. §112).[9] The court purported to reaffirm the separation between §101 and these other standards by characterising the government's argument as casting 'the "law of nature" exception to §101 a dead letter'.[10] As discussed further below, while paying lip service to separating these concepts, the court's analysis conflates certain concepts of novelty and obviousness, such as the use of 'conventional steps', into §101, thus potentially expanding the scope of §101 beyond the practical purposes envisioned by Congress. Consequently, the precise role of §101 remains in question.

Prometheus's Patents and the Claimed Technology

In *Mayo*, the patents in question relate to a diagnostic treatment, specifically they 'concern the use of thiopurine drugs in the treatment of autoimmune diseases, such as Crohn's disease and ulcerative colitis' and claim methods of optimising the therapeutic efficacy of such drugs.[11] Patients receiving thiopurine compounds metabolise them in different ways and the same dose may have different effects in different patients, including the possibility that safe doses for some patients may produce toxic effects in others.[12] Prior to the claimed invention, scientists generally understood that certain metabolites, such as 6-thioguanine ('6-TG') and 6-methyl-mercaptopurine ('6-MMP'), 'were correlated with the likelihood that a particular dosage of a thiopurine drug could cause harm or prove ineffective'.[13] The named inventors discovered a more precise correlation and the patents sought to claim treatment of patients by taking advantage of this discovery.

In particular, the patents described methods of monitoring 6-TG (U.S. Patent No. 6,355,623 ('the '623 patent')) and both 6-TG and 6-MMP (U.S. Patent No. 6,680,302 ('the '302 patent')).[14] As described in the representative claim analysed by the court (see Appendix 1), the claims of each patent may be broken into three limitations which require:

> (1) administration of a drug providing 6-TG or 6-TG and 6-MMP;
>
> (2) determination of the level of 6-TG or 6-TG and 6-MMP in the patient; and
>
> (3) based on that determination, adjustment of the amount of drug in subsequent administrations such that the levels of 6-TG or 6-TG and 6-MMP fall within a specified range.

Prometheus Laboratories, Inc. ('Prometheus'), the sole and exclusive licensee of the patents, sells diagnostic tests that embody the patented processes.[15] Accused infringer Mayo Clinic Rochester and Mayo Collaborative Services (collectively 'Mayo') had previously purchased diagnostic tests from Prometheus, but then, in 2004, Mayo announced that it would begin to sell its own test. Prometheus then initiated the underlying patent infringement action.[16]

Appendix 1

Representative Claim: Claim 1 of the '623 patent

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 8×10^8 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 8×10^8 red blood cells indicates a need to decrease the amount of said drug subsequently administered to said subject.

9) *Ibid.*, at 1303.

10) *Ibid.*

11) *Ibid.*, at 1294 to 1295.

12) *Ibid.*

13) *Ibid.*, at 1295.

14) *Prometheus Labs, Inc. v Mayo Collaborative Servs*, 628 F.3d 1347, 1350-51 (Fed. Cir. 2010).

15) *Mayo*, 132 S.Ct., at 1295.

16) *Ibid.*, at 1295 to 1296.

Application of the Machine-or-Transformation Test in the Underlying Decisions

At the trial level, the Southern District of California determined in 2008 that the patents failed to claim patentable subject-matter.[17] The district court held that 'the "administering" and "determining" steps are merely necessary data-gathering steps for any use of the correlations', which alone are insufficient for patentability.[18] Looking further to the third claimed step, the court stated that 'the final step – the "warning" step (i.e., the wherein clause) – is only a mental step' and it is the 'metabolite levels themselves that "warn" the doctor that an adjustment in dosage may be required', and not a warning from the doctor.[19] The court reasoned then that the claims recited only the 'correlations themselves', which does not constitute patentable subject-matter.[20]

On appeal by Prometheus, the Federal Circuit Court of Appeals reversed the district court.[21] In finding that the claims covered patentable subject-matter, the Federal Circuit relied on the 'machine-or-transformation test'. In *Mayo*, the Federal Circuit stated that under this test 'a claimed process is surely patent-eligible under §101 if: (1) it is tied to a particular machine or apparatus, or (2) it transforms a particular article into a different state or thing.'[22] Further, 'the use of a specific machine or transformation of an article must impose meaningful limits on the claim's scope to impart patent-eligibility and the involvement of the machine or transformation in the claimed process must not be merely insignificant extra-solution activity.'[23]

Regarding the claims-at-issue, the Federal Circuit disagreed with the district court that 'the disputed claims are merely claiming natural correlations and data-gathering steps'.[24] Instead, the Federal Circuit held that 'the asserted claims are in effect claims to methods of treatment, which are always transformative when a defined group of drugs is administered to the body to ameliorate the effects of an undesired condition'.[25] The Federal Circuit further found these steps 'sufficiently definite to confine the patent monopoly within rather definite bounds'.[26]

Mayo then appealed to the Supreme Court. The Supreme Court granted Mayo's appeal, vacated the underlying judgment and remanded to the Federal Circuit for further consideration in light of the Supreme Court's determination in *Bilski v Kappos*.[27] In *Bilski v Kappos*, the Supreme Court considered the relevance, to computer claims, of the machine-or-transformation test used by the Federal Circuit in its decision in *Mayo*. Prior to the Supreme Court's ruling in *Bilski*, this test had served as the primary means to determine patent eligibility of process or method claims. The Supreme Court stated in *Bilski* that while that test 'may well [have] provide[d] a sufficient basis for evaluating [claimed] processes [of] ... the Industrial Age – for example, inventions grounded in a physical or other tangible form', it no longer sufficiently served its role such that it could be the sole test for patent eligibility.[28] Consequently, the Supreme Court held that while the machine-or-transformation test may be used to determine the patent eligibility of a process claim, it is not the sole test.

Because the Supreme Court had not outright rejected the use of the machine-or-transformation test, on remand the Federal Circuit in *Mayo* relied again on the machine-or-transformation test and again found that the Prometheus patents claimed patent-eligible subject-matter.[29] The Federal Circuit reiterated its previous reasoning, stating that 'the claims recite specific treatment steps, not just the correlations themselves. And the steps involve a particular application of the natural correlations: the treatment of a specific disease by administering specific drugs and measuring specific metabolites.'[30]

17) *Prometheus Labs, Inc. v Mayo Collaborative Servs*, 2008 WL 878910 (S.D.Cal. 2008).

18) *Ibid.*, at *6.

19) *Ibid.*

20) *Ibid.*

21) *Prometheus Labs, Inc. v Mayo Collaborative Servs*, 581 F.3d 1336 (Fed. Cir. 2009).

22) *Ibid.*, at 1342 (citing *In re Bilski*, 545 F.3d 943, 953 (Fed. Cir. 2008) (en banc).

23) *Ibid.*, at 1342 to 1343 (citing *In re Bilski*, 545 F.3d at 961 to 962).

24) *Ibid.*, at 1346.

25) *Ibid.*

26) *Ibid.*, at 1346 to 1347 (citing *In re Bilski*, 545 F.3d at 962).

27) *Mayo Collaborative Servs v Prometheus Labs, Inc.*, 130 S.Ct. 3543 (2010) remanding in light of *Bilski*, 130 S.Ct. 3218.

28) *Bilski*, 130 S.Ct. at 3227.

29) *Mayo*, 628 F.3d 1347.

30) *Ibid.*, at 1355.

The Supreme Court's Invalidation of the Prometheus Patents

Mayo again appealed the Federal Circuit's decision to the Supreme Court. The Supreme Court declined to use the machine-or-transformation test relied upon by the Federal Circuit and expressly rejected that analysis by stating that neither step relied upon by the Court of Appeals requires a transformation: the administering step 'simply helps to pick out the group of individuals who are likely interested in applying the law of nature' and the determining step could be met by techniques that do not require transforming the blood to determine metabolite levels.[31] Consequently, no transformation was claimed by the patent according to the Supreme Court. The court expressly declined to address whether finding a transformation under the machine-or-transformation test would 'trump the law of nature exclusion'.[32]

For its own analysis, the Supreme Court first determined that the claims themselves set forth a law of nature, stating that the claims describe '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'.[33] Specifically, the court simplified the representative claim, to show that it, in effect, stated that 'if the levels of 6-TG in the blood … exceed about 400 pmol per 8×10^8 red blood cells, *then* the administered dose is likely to produce toxic side effects.'[34] Thus, even though human action is required (that is, to administer the drug and determine the levels of 6-TG), the claims rely on a relationship that 'itself exists in principle apart from any human action'.[35]

Because the patents-in-suit set forth laws of nature, the court stated that the patent eligibility question turned on whether 'the patent claims add enough to their statements of correlations to allow the processes they describe to qualify as patent-eligible processes that apply natural laws'.[36] The Supreme Court addressed this question by analysing each of the three limitations of the representative claim.

According to the court, the 'administering' step, which requires administration of a drug providing 6-TG, 'simply refers to the relevant audience, namely doctors who treat patients with certain diseases with thiopurine drugs'.[37] 'Limit[ing] the use of the formula to a particular technological environment', such as doctors, has previously been found insufficient to circumvent the prohibition against patenting abstract ideas.[38]

The determining step, which requires determination of the level of 6-TG in the patient, 'tells the doctor to determine the level of the relevant metabolites in the blood, through whatever process the doctor or laboratory wishes to use'.[39] Given that the patent states that such methods were well known, this step simply 'tells doctors to engage in well-understood, routine, conventional activity previously engaged in by scientists who work in the field'.[40] Such 'conventional or obvious pre- [or post-]solution activity is normally not sufficient to transform an unpatentable law of nature into a patent-eligible application of such a law.'[41]

The wherein clauses, which instruct the doctor to increase or decrease subsequent dosages based on the determined level of 6-TG, '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'.[42] In other words, these clauses merely inform the relevant audience about the law of nature and expect the audience to apply the law appropriately.

Finally, the court addressed the claim limitations together and held that the combination 'adds nothing to the laws of nature that is not already present when the steps are considered separately'.[43] Specifically, combining the steps 'amounts to nothing significantly more than an instruction to doctors to apply the applicable laws when treating their patients'.[44]

31) *Mayo*, 132 S.Ct. at 1303.

32) *Ibid.*

33) *Ibid.*, at 1296.

34) *Ibid.*, at 1296 to 1297 (*emphasis in original*).

35) *Ibid.*, at 1297.

36) *Ibid.*

37) *Ibid.*

38) *Ibid.*, citing *Bilski*, 130 S.Ct. at 3230.

39) *Ibid.*

40) *Ibid.*, at 1298.

41) *Ibid.*, citing *Parker v Flook*, 437 U.S. 584, 590, 98 S.Ct. 2522 (1978) (internal quotations omitted).

42) *Ibid.*, at 1297.

43) *Ibid.*, at 1298.

44) *Ibid.*

Comparison to the Supreme Court's Own Precedent

After presenting its analysis, the court reinforced its conclusions by reviewing its own precedent and an 1841 decision from the British Court of the Exchequer.[45] The court determined that these decisions consistently stood for the principles that 'patent law not inhibit further discovery by improperly tying up the future use of laws of nature'[46] and that claims must be confined 'to a particular, useful application of the principle'.[47]

In reviewing the 'guideposts' set out by its previous analyses, the court began by comparing Prometheus's claims to those in *Diehr*[48] and *Flook*.[49] The claims of *Diehr*, which covered a process for curing rubber, were held patentable because, although they relied on a basic mathematical equation, 'the additional steps of the process integrated the equation into the process as a whole' and were nowhere suggested to be 'in context obvious, already in use or purely conventional'.[50] Consequently, the *Diehr* patentees sought 'only to foreclose from others the use of that equation in conjunction with all of the other steps in their claimed process'.[51] Conversely, the claims of *Flook*, which also relied on a basic mathematical equation to claim a method for adjusting alarm limits in the catalytic conversion of hydrocarbons, were held not patentable. The *Flook* claim was not patent-eligible because it 'did not explain how the variables used in the formula were to be selected, nor did the claim contain any disclosures relating to chemical processes at work or the means of setting an alarm or adjusting the alarm limit' and so the other steps did not limit the claim to a particular application.[52] The Supreme Court found the *Mayo* claims were more similar to the unpatentable *Flook* claims because they 'add nothing specific to the laws of nature other than what is well-understood, routine, conventional activity, previously engaged in by those in the field'.[53]

The Supreme Court then compared the *Mayo* claims to those analysed in its decisions in *Bilski*,[54] *Benson*[55] and *Morse*.[56] The court found a consistent concern in those decisions about the breadth of patents and their ability to inhibit future innovation. Specifically, it stated that the *Bilski* claims, which covered a process for hedging the risk of price changes, were not patentable because they merely 'limit[ed] an abstract idea to one field of use or add[ed] token postsolution components'.[57] In *Benson*, where the claims covered a process for converting binary-coded decimal numbers into pure binary numbers on a general purpose computer, the court derived the principle that 'simply implementing a mathematical principle on a physical machine … was not a patentable application of that principle' because such a claim was overly broad.[58] Similarly, in *Morse*, where the claims generally covered the concept of the telegraph, the court expressed a general concern about tying up the use of laws of nature from future innovation. With respect to the *Mayo* claims, the court held that because the 'steps add nothing of significance to the natural laws themselves', they also improperly prevent future innovation.[59]

The Supreme Court also briefly discussed an English decision relating to a similar patent claim – *Neilson v Harford*.[60] The English court, in finding the claims in that case, which related to the principle of heating air to promote ignition, patentable, stated that 'we think that the plaintiff does not merely claim a principle, but a *machine* embodying a principle, and a very valuable one.'[61] From *Neilson*, the Supreme Court identified the principle that a process may be patentable even if it includes a law of nature, if it includes 'several unconventional steps … that confined the claims to a particular, useful application of that principle'.[62] As expressed above, according to the Supreme Court, the steps in Prometheus's claims relied on only conventional steps; they did not meet the criteria for patent eligibility set forth by the English court either.

45) *Neilson v Harford*, 151 E.R. 1266 (1841).
46) *Mayo*, 132 S.Ct. at 1301.
47) *Ibid.*, at 1300.
48) *Diamond v Diehr*, 101 S.Ct. 1048.
49) *Parker v Flook*, 98 S.Ct. 2522.
50) *Mayo*, 132 S.Ct. at 1298 to 1299.
51) *Ibid.*, at 1299 citing *Diehr*, 45 U.S. at 187.
52) *Ibid.*, citing *Flook*, 437 U.S. at 586.
53) *Ibid.*, at 1299 to 1300.
54) *Bilski*, 130 S.Ct. 3218).
55) *Benson*, 93 S.Ct. 253.
56) *Morse*, 15 How. 62.
57) *Mayo*, 132 S.Ct. at 1301 citing *Bilski*, 130 S.Ct. at 3231.
58) *Ibid.*, citing *Benson*, 93 S.Ct. 253.
59) *Ibid.*, at 1301.
60) *Ibid.*, at 1300 discussing *Neilson*, 151 ER 1266.
61) *Ibid.*, citing *Neilson*, 151 ER 1266.
62) *Ibid.*, at 1300.

Ultimately, the *Mayo* analysis exemplifies the Supreme Court's view, as instructed in *Bilski*, that precedent should serve as guideposts and comparison points for the patent-eligibility analysis. While such instruction is clear, the Supreme Court's repeated reference to concepts typically considered part of the novelty and nonobviousness analysis, such as whether steps in a process claim are "conventional," muddies the Court's instruction that novelty and nonobviousness should not influence patent-eligibility consideration. It remains to be seen whether the Federal Circuit Court of Appeals will successfully clarify the respective roles of these patent doctrines.

Appellate Application of the *Mayo* Decision to the Biomedical Field

After its decision in *Mayo*, the Supreme Court remanded two decisions to the appellate court for further consideration in view of *Mayo: Association for Molecular Pathology v Myriad Genetics, Inc.*[63] and *WildTangent, Inc. v Ultramercial LLC, et al*,[64] providing the Federal Circuit with such an opportunity to clarify the role of novelty and nonobviousness concepts in assessing patent-eligibility. The patents at issue in *Myriad* and *Ultramercial* cover significantly different subject matter and their remand in light of *Mayo* indicates the Supreme Court's view of the breadth of *Mayo*'s potential implications: the *Myriad* patents, like the *Mayo* patents, cover medical diagnostic methods and also isolated DNA sequences, whereas the *Ultramercial* patents relate to methods of advertising on the internet. The potential implications of *Ultramercial* are discussed further below, but the Federal Circuit recently decided *Myriad*[65] on 16 August 2012 and reached conclusions consistent with its prior ruling despite the Supreme Court decision in *Mayo*.[66]

Myriad involved technology related to the diagnosis of breast cancer based on the detection of mutations in particular DNA sequences. There were three sets of claims at issue in *Myriad*: (1) composition of matter claims covering "isolated human genes, [known collectively as ("BRCA")] and certain alterations, or mutations, in these genes;" (2) method claims covering "methods of 'analyzing' or 'comparing' a patient's BRCA sequence with the normal, or wild type, sequence to identify the presence of cancer-predisposing mutations;" and (3) a method claim covering "a method of screening potential cancer therapeutics."[67] Consistent with its previous decision, on remand the Federal Circuit held that the claims covering methods of analyzing or comparing were not patent-eligible, whereas the composition of matter and method of screening claims were patent-eligible.

With respect to *Mayo*'s impact on the composition of matter claims, the Federal Circuit, after stating that *Mayo* "provide[s] valuable insights and illuminate[s] broad, foundational principles," expressly limited the scope of *Mayo* to method claims.[68] Instead, the Federal Circuit focused on other Supreme Court precedent such as *Chakrabarty*[69] and *Funk Bros.*,[70] which it stated "set out the primary framework for deciding the patent eligibility of compositions of matter, including isolated DNA molecules."[71]

For the method claims, the Federal Circuit compared the *Myriad* claims to the diagnostic methods found not patentable in *Mayo* and held that the *Myriad* claims covering the analysis or comparison of DNA sequences did not cover patentable subject matter because "[a]lthough the *application* of a formula or abstract idea in a process may describe patentable subject matter, Myriad's claims do not apply the step of comparing two nucleotide sequences in a process. Rather, the step of comparing two DNA sequences is the entire process that is claimed."[72]

Meanwhile, for the claim covering screening for potential cancer therapeutics, the Federal Circuit focused on the fact that "the claim does not cover all cells, all compounds, or all methods of determining the therapeutic effect of a compound. Rather, it is tied to specific host cells *transformed* with specific genes and grown in the presence or absence of a specific type of therapeutic."[73] The Federal Circuit's reasoning appears to hinge almost entirely on the claim's use of a "*transformed* eukaryotic host cell."[74] Although the claim "appl[ies] various known types of procedures," the use of transformed cells demonstrated to the court that the claim

63) *Association for Molecular Pathology, et al. v Myriad Genetics, Inc., et al.*, 132 S.Ct. 1794 (2012).

64) *WildTangent, Inc. v Ultramercial LLC, et al.*, 132 S.Ct. 2431 (2012).

65) *The Association for Molecular Pathology v Myriad Genetics, Inc.*, -- F.3d --, 2012 WL 3518509 (Fed. Cir. 2012).

66) *The Association for Molecular Pathology v Myriad Genetics, Inc.*, 653 F.3d 1329 (Fed. Cir. 2011).

67) *Myriad*, 2012 WL 3518509 at *2.

68) *Ibid*., at *17.

69) *Diamond v Chakrabarty*, 447 U.S. 303, 100 S.Ct. 2204 (1980).

70) *Funk Bros. Seed Co. v Kalo Inoculant Co.*, 333 U.S. 127, 68 S.Ct. 440 (1948).

71) *Myriad*, 2012 WL 3518509 at *172.

72) *Ibid*., at *24 (*emphasis in original*).

73) *Ibid*., at *27 (*emphasis in original*).

74) *Ibid*., at *2 (*emphasis in original*).

does more than simply apply a law of nature.[75] Interestingly, the Federal Circuit also read in concepts of novelty and nonobviousness when it stated that "where the objects or results of such steps [i.e., performing operations, even known types of steps] are novel and nonobvious, they should be patent-eligible."[76]

Unfortunately, the *Myriad* panel missed this opportunity to clarify the role of novelty and nonobviousness when determining patent-eligibility since it chose, without discussion, to invoke these patent law principles to explain its patent-eligibility determination. A recent Federal Circuit decision, decided by three other Federal Circuit judges, directly addressed this issue in the context of computer claims and abstract ideas and applied a patent-eligibility standard that did not depend on any novelty or obviousness concepts.[77] The issuance of separate and somewhat conflicting decisions by each of the three judges on the *Myriad* panel regarding the patentability of the isolated gene claims will likely draw the focus of future commentary; however, the role of novelty and nonobvious when determining the patent-eligibility of method claims in the biomedical field also remains an open question for future litigants and academic discourse and may ultimately result in a greater impact on the medical community.

Appellate Application of the *Mayo* Decision beyond Patents Drawn to Biology

The Federal Circuit recently addressed the patent-eligibility of computer claims in light of *Mayo* when, on 9 July 2012, it ruled in *CLS Bank Int'l v Alice Corp. Pty. Ltd.*[78] The claims there covered a "computerized trading platform for exchanging obligations in which a trusted third party settles obligations between a first and second so as to eliminate settlement risk."[79] The majority opinion distinguished *Mayo* on the grounds that "it did not explicitly address how to determine whether a claim is drawn to an abstract idea."[80] Because the majority distinguished *Mayo* and the claims did not cover biological subject matter, the most interesting aspect of *CLS Bank* for purposes of this discussion is that it arguably created a new standard for patent-eligibility, one that makes no mention of novelty or obviousness concepts: "when – after taking all of the claim recitations into consideration – it is not manifestly evident that a claim is directed to a patent ineligible abstract idea, that claim must not be deemed for that reason to be inadequate under §101."[81]

Judge Prost, writing in dissent, criticized the majority's holding, characterizing the decision as "an entirely new framework that in effect allows courts to avoid evaluating patent eligibility under §101 whenever they so desire."[82] In her dissent, Judge Prost referred to the Supreme Court's *Mayo* decision for the concept that "[n]ow there is no doubt that to be patent eligible under §101, the claims must include an 'inventive concept.'"[83] While different standards could potentially apply under §101 depending on whether the claim-in-question involves an abstract idea, like *CLS Bank*, or a law of nature, like *Mayo* and *Myriad*, such a split seems difficult and burdensome to apply in practice because claims do not necessarily fit within one category or the other.

The Federal Circuit will have the ability to further clarify the extent to which novelty and obviousness concepts are included or excluded from the patent-eligibility question when it decides *WildTangent, Inc. v Ultramercial LLC*, which, like *Myriad*, was also remanded by the Supreme Court for consideration in light of *Mayo*.[84] The *Ultramercial* patents cover "a method for monetizing and distributing copyrighted products over the Internet."[85] Previously, the Federal Circuit held that these claims covered patentable subject matter because they claim a "practical application" of a basic idea and the steps for implementing this idea "are likely to require intricate and complex computer programming" and, viewed as a whole, "the invention involves an extensive computer interface."[86] The Federal Circuit was careful to limit its opinion and explain that its decision "does not define the level of programming complexity required before a computer-implemented method can be patent-eligible."[87] While it is possible that the Federal Circuit will limit the scope of its decision in *Ultramercial* to the patent-eligibility of computer claims, it may take the opportunity to clarify the potential conflict with *Mayo* that Judge Prost identified in her dissent in *CLS Bank*.

75) *Ibid*., at 26.

76) *Ibid*.

77) See discussion below of *CLS Bank Int'l v Alice Corp. Pty. Ltd.*, 685 F.3d 1341 (Fed. Cir. 2011).

78) *CLS Bank*, 685 F.3d 1341.

79) *Ibid*., at 1343.

80) *Ibid*., at 1348.

81) *Ibid*., at 1352.

82) *Ibid*., at 1356.

83) *Ibid*., at *1357, citing Mayo, 132 S.Ct. at 1294.

84) *Ultramercial*, 132 S.Ct. 2431.

85) *Ultramercial, LLC v Hulu, LLC*, 657 F.3d 1323, 1327 (Fed. Cir. 2011).

86) *Ibid*., at 1328.

87) *Ibid*.

Other Application of the Supreme Court's *Mayo* Decision

U.S. trial courts and the U.S. Patent & Trademark Office have also begun to consider the implications of the *Mayo* decision. Although many litigants have sought to dismiss patent claims asserted against them in light of *Mayo*'s apparent narrowing of the scope of patent-eligibility, to the knowledge of these authors, only one trial court has applied the *Mayo* ruling in detail as of this writing. In *SmartGene, Inc. v Advanced Biological Laboratories, SA*, the District Court for the District of Columbia, on 30 March 2012, invalidated SmartGene's patents related to "system[s], method[s], and computer program[s] for guiding the selection of therapeutic treatment regimens for complex disorders … by ranking available treatment regimens and providing advisory information."[88] The district court relied on the Supreme Court's direction to use its precedent as "guideposts when considering exceptions to patent subject matter eligibility" and analyzed how the claims-in-suit compared to claims previously subjected to the Supreme Court's analysis.[89] The district court ultimately determined that the claims improperly claimed abstract ideas most similar to those claims found invalid in *Flook* and *Mayo*, "because it is merely a recitation of abstract steps, rather than an innovation that adds something specific to the laws of nature or abstract ideas other than what is well-understood, routine, conventional activity, previously engaged in by those in the field."[90] As *SmartGene* was decided prior to *CLS Bank*, that court did not face the difficulty of deciding which of the arguably different standards of patent eligibility posed by *Mayo* and *CLS Bank* to apply. Future trial courts will be forced to make this decision.

The United States Patent and Trademark Office ("USPTO"), in early July 2012, took action in light of *Mayo* when it issued interim guidance[91] for patent examination in light of the decision.[92] This guidance sets forth subject matter eligibility determinations of process claims that involve laws of nature and natural correlations.[93] The USPTO set out a three-step analysis as follows:

1. Is the claimed invention directed to a process, defined as an act, or a series of acts or steps?

2. Does the claim focus on use of a law of nature, a natural phenomenon, or naturally occurring relation or correlation (collectively referred to as a natural principle herein)? (Is the natural principle a limiting feature of the claim)?

3. Does the claim include additional elements/steps or a combination of elements/steps that integrate the natural principle into the claimed invention such that the natural principle is practically applied, and are sufficient to ensure that the claim amounts to significantly more than the natural principle itself? (It is more than a law of nature + general instruction to simply "apply it"?)

The USPTO guides examiners that negative answers to the first two questions render the analysis inapplicable. A patent claim that passes the first two questions and answers the third negatively should be rejected as invalid. As examiners begin to gain comfort with the *Mayo* guidance, it will be interesting to see how the standards for patentability evolve at the USPTO.

Future Guidance from *Mayo*

The decisions in *SmartGene* and *Myriad* and Judge Prost's dissent in *CLS Bank* demonstrate that, despite the Supreme Court's statements to the contrary in *Mayo*, factors such as whether an application of an abstract idea or law of nature is "well-understood" or "routine," concepts which are associated with the determination of novelty and obviousness, are also relevant in the patent-eligibility analysis. In effect, the Supreme Court's guidance, as reiterated in *Mayo*, has been understood to require not only that the inventor add something to the unpatentable abstract idea or law of nature, but that their addition must not be well-understood or routine. In other words, their additional activity must itself be novel and nonobvious.

88) *SmartGene* 2012 WL 1059611 at *1.

89) *Ibid*., at *7 discussing *Bilski*, 130 S.Ct. at 3229-3231 and *Mayo*, 132 S.Ct. at 1298-1301.

90) *Ibid*., at *10 citing *Mayo*, 132 S.Ct. at 1299.

91) The USPTO's guidance is "interim" in light of the Supreme Court's decisions to vacate and remand two Federal Circuit decisions in light of *Mayo – Myriad*, 132 S.Ct. 1794 and *Ultramercial*, 132 S.Ct. 2431. As of this writing, no further guidance has been issued in light of the Federal Circuit's recent decision in *Myriad*.

92) Memorandum from Andrew H. Hirshfeld, Deputy Commissioner for Patent Examination Policy, dated 3 July 2012 and entitled "2012 Interim Procedure for Subject Matter Eligibility Analysis of Process Claims Involving Laws of Nature," available at: http://www.uspto.gov/patents/law/exam/2012_interim_guidance.pdf ("USPTO 2012 Interim Guidance.")

93) It is worth noting that the guidance makes reference to previous guidance issued in light of *Bilski* that discusses process claims directed to abstract ideas. *See Interim Guidance for Determining Subject Matter Eligibility for Process Claims in View of Bilski v Kappos*, 75 Fed. Reg. 43922, 37 July 2010.

At first blush, the need for clarity about whether novelty and obviousness concepts are excluded from the patent-eligibility question may appear to place form over substance. Practically speaking, however, this is not the case, because in U.S. patent litigation, the patent-eligibility determination may occur very early in the action prior to construction of the claims.[94] This rarely occurs for determinations of novelty and obviousness. Challenging patent eligibility can therefore be an effective sword for patent challengers to seek an early advantage or decisive victory before major discovery costs have been incurred.

The opinions expressed by the majority and dissent in *CLS Bank* explicitly highlight that the role of novelty and obviousness in the patent-eligibility determination remains an open question, especially in view of the Federal Circuit's decision not to discuss *Mayo* in detail in the *Myriad* decision. While it is always difficult to predict how the Federal Circuit may rule on remand, this is especially true with respect to *Ultramercial* due to this open question. The Federal Circuit may, in keeping with *CLS Bank*, find that it is not "manifestly evident" that the *Ultramercial* claims are drawn to a law of nature or an abstract idea, a position not previously mentioned in either original decision. While we won't speculate on the potential outcome of *Ultramercial* or any other litigation, it can certainly be said that *Mayo* will serve as another guidepost of Supreme Court precedent regarding patent-eligibility and, for the medical community, a significant guidepost regarding discoveries and inventions directly tied to laws of nature.

94) *Ultramercial*, 657 F.3d at 1325 (stating that there is no bright line rule requiring claim construction prior to the §101 analysis because "eligibility is a coarse gauge of the suitability of broad subject matter categories of patent protection.")