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SPECIAL
REPORT

U.S. SUPREME COURT AGAIN ADDRESSES SCOPE OF PATENTABLE SUBJECT MATTER UNDER 35 U.S.C. §101

April 6, 2012

On March 20, the U.S. Supreme Court issued a unanimous decision in *Mayo Collaborative Services v. Prometheus Laboratories*. In that decision, the Court expanded on its decision in *Bilski v. Kappos*[1] regarding the nature of what is and is not patentable under 35 U.S.C. §101, this time in the context of claims directed to medical diagnostic technology. However, the implications of the decision appear to be applicable to other technologies, as well as being directly applicable to diagnostic and other medical technology.

The decision includes extensive discussion of §101, addressing various policy considerations, prior art issues, claim scope issues, the relationship of §101 to prior art sections 102 and 103 and specification and claim support section 112, and various arguments that had been made by the parties, the government and other third parties. This discussion meanders somewhat, and is difficult to parse between controlling law and non-controlling *dicta*. Furthermore, because the decision was unanimous, even the non-controlling *dicta* may be given substantial deference by other courts and the U.S. Patent and Trademark Office (USPTO).

The decision is subject to widely varying interpretations, which will have to be clarified and confirmed or repudiated in future court decisions, possibly including future decisions in the *Myriad* case discussed below. The early reaction to the decision in the patent community ranges from opinions that the effect of the case will be limited to its facts to the opinion that the decision will "Wreak Vast Patent Turmoil."[2]

We believe that the best way to assess *Mayo* and deal with its effects going forward is to thoroughly understand what the decision actually says. Thus, before providing our brief recommendations, which appear at the end of this Special Report, we provide a more-than-usually detailed discussion of the decision, the claims at issue in the case, and court decisions relied on in it.

I. The Claims In Issue

The Supreme Court expressly noted that "our conclusion rests upon an examination of the particular claims before us." The following claim was treated as representative of Prometheus's patent claims in issue:

[1] *Bilski v. Kappos*, 561 U.S. ___, 130 S.Ct. 3218 (2010). See our July 6, 2010 Special Report, "Supreme Court Holds That The Machine-Or-Transformation Test Is Not the Sole Test For Patentability Of Process Claims And That Business Methods May Be Patentable," available in the News & Events section of our website at www.oliff.com.

[2] Ryan Davis, "Prometheus to Wreak Vast Patent Turmoil, Experts Say," Law 360, April 2, 2012.

> 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.

Boiled down to simple terms, the claim recited:

> A method of optimizing treatment of a specified disorder, comprising:
>
> (a) administering to a patient having that disorder a synthetic drug that metabolizes in the patient to form a specified chemical (metabolite), and
>
> (b) determining the resulting amount of that chemical (metabolite) in the patient;
>
> wherein there is a specified correlation between the determined amount of the chemical in the patient and the safety and efficacy of the drug.

II. The District Court Decision

The District Court held Prometheus's claims invalid under §101.[3]

The District Court issued its decision based on a motion for summary judgment of invalidity under §101. Because the District Court granted that motion, no other validity issues came before that court, the Federal Circuit, or the Supreme Court in the decisions discussed herein. Those courts all made various comments about prior art, the scope of the claims, and the scope of the underlying disclosure. However, because the issues to be decided were limited by the §101 summary judgment motion, issues of prior art, written description and enablement invalidity were not before, or therefore decided by, the courts.

The District Court correctly acknowledged the Supreme Court's prior holdings that natural phenomena and abstract ideas are not patentable under §101. The District Court further noted that, in the context of method claims, "where the claim 'wholly pre-empts' all uses of the natural phenomenon or abstract idea such that the 'practical effect is a patent on the [phenomenon] itself' the claim is invalid under section 101," citing the Supreme Court's decisions in the *Benson* and *Diehr* cases.[4]

The District Court construed the claims as having three steps: the administering step (a), the determining step (b), and a notification or warning step (the "wherein" clauses) in which the doctor is informed (by the determined levels) of the facts stated in the "wherein" clauses, but need not take any action based on those facts. Thus,

[3] *Prometheus Laboratories, Inc. v. Mayo Collaborative Services*, 86 USPQ2d 1705 (S. D. California 2008).

[4] *Gottschalk v. Benson*, 409 U.S. 63, 71-72 (1972); *Diamond v Diehr*, 450 U.S. 175, 187 (1981).

the District Court treated the claims as having only two active steps.

The District Court held that the active "administering" and "determining" steps were merely data-gathering steps required for any use of the correlation stated in the "wherein" clauses, and characterized those "data-gathering" steps as "conventional."[5] It distinguished those steps from treatment steps in a method comprising treating a patient with a synthetic drug, on the basis that the final step of the claim did not require adjusting a dosage "or any other action." It treated the "wherein" clauses as merely mental steps, requiring no action by the doctor or anyone else. Thus, it distinguished the claims from claims directed to treatment methods, in spite of the fact that the patentee had framed the claims as being directed to treatment methods in the preamble.

The District Court held that the correlation between the drug level in the patient and the safety and efficacy of the drug is a natural phenomenon. It rejected Prometheus's argument that such a correlation cannot be a "natural" phenomenon because it involves a synthetic drug that does not exist in nature. The District Court reasoned that the facts that (1) the metabolite was formed "naturally" by enzymes in the patient's body, and (2) the correlation was simply the observed result of that "natural" formation of the metabolite, indicated that the correlation was a "natural phenomenon" that was merely "observed" rather than "created" by the patentee. The District Court also distinguished hypothetical claims to a synthetic composition itself on this basis.

Finally, the District Court found that the claims "wholly preempt" the use of the recited correlation, because the only practical use of the correlation is by way of the claimed method, and anyone attempting to use that correlation would have to perform the "conventional" active steps of the claimed method.

III. The Federal Circuit Decisions

The Court of Appeals for the Federal Circuit (Judges Lourie, Michel and Clark[6]) reversed the District Court decision.[7] Following that reversal, the Supreme Court decided the *Bilski* case, and vacated and remanded the Federal Circuit's *Prometheus* decision for reconsideration in view of *Bilski*. On remand, the Federal Circuit (Judges Lourie, Rader and Bryson) maintained its decision to reverse the District Court decision.[8]

A. The First Federal Circuit Decision

In its initial decision, the Federal Circuit focused on "the key issue for patentability" of the subject claims under §101 being "whether a claim is drawn to a fundamental principle or an application of a fundamental principle." The court expressly noted that its decision did not address prior art or claim scope issues under §§102, 103 or 112.

The Federal Circuit applied the "machine-or-transformation" test of its own prior *Bilski* decision as being determinative of whether a process is patent eligible under §101. Under that test, a patentee "may show that a process claim satisfies §101 either by showing that his claim is tied to a particular machine, or by showing that his claim transforms an article." The court acknowledged that a "transformation" must be

[5] Mayo had argued to the court that such steps had been performed in the prior art "for decades."

[6] Judge Ron Clark of the U.S. District Court for the Eastern District of Texas was sitting on the Federal Circuit panel by designation.

[7] *Prometheus Laboratories v. Mayo Collaborative Services*, 581 F.3d 1336 (Fed. Cir. 2009), rehearing *en banc* denied (2010).

[8] *Prometheus Laboratories v. Mayo Collaborative Services*, 628 F.3d 1437 (Fed. Cir. 2010).

"central to the purpose of the claimed process" and not "insignificant extra-solution activity" or a "data-gathering step."[9]

Starting with claim construction, the Federal Circuit held that the claims are directed to methods of treatment, rather than merely data-gathering steps and natural correlations. The court pointed to the preamble of the claim, as well as to the patent specification, as making clear that the purpose of the claimed method is to treat the human body. The court stated that "methods of treatment … are always transformative when a defined group of drugs is administered to the body to ameliorate the effects of an undesired condition."

The Federal Circuit held that the claimed method involves two transformations in the "administering" step, which involves transformation of the human body through administration of the drug, and transformation of the drug into the subject metabolites in the body, and that these transformations are central to the treatment purpose of the claimed process. The court also held that the "determining" step involves a transformation, because the determination cannot be made by mere inspection but requires extraction of the metabolites from the body, and that this step too is central to the purpose of the claimed process.

The Federal Circuit distinguished the "administering" and "determining" steps from mere "data-gathering steps" or "insignificant extra-solution activity" on the basis that they are part of a treatment protocol in which the administering step is performed to treat a disease, as stated in the claim preamble, and are integrally involved in the therapeutic method. Thus, it distinguished a prior Federal Circuit decision in which similar steps were performed that only had diagnostic, rather than treatment, purposes.[10]

The court agreed that the final "wherein" clauses were directed to mental steps that would not by themselves be patentable. However, it pointed out that the presence of a mental step in an otherwise patentable process claim does not negate patentability of the claim.

Finally, the Federal Circuit held that the District Court "erred in finding that the claims wholly preempt use of correlations between metabolite levels and efficacy or toxicity." It held that "the claims do not preempt natural processes; they utilize them in a series of specific steps," and that "the inventive nature of the claimed methods stems not from preemption of all use of these natural processes, but from the application of a natural phenomenon in a series of transformative steps comprising particular methods of treatment." It emphasized that application of the machine-or-transformation test establishes that such claims do not preempt a fundamental principle.

B. The Second Federal Circuit Decision

In its *Bilski* decision, the Supreme Court held that the "machine-or-transformation" test is not determinative, although it is "a useful clue" to patentability under §101. The Supreme Court thus vacated the Federal Circuit's decision, and remanded *Mayo* to the Federal Circuit to reconsider the case in light of that holding. The Federal Circuit again reversed the District Court, emphasizing that the claims in issue are directed to a particular application of a natural phenomenon, as well as satisfying the "transformation" prong of the "machine-or-transformation" test.

[9] 581 F.3d at 1342-1343.

[10] *In re Grams*, 888 F.2d 835 (Fed. Cir. 1989).

IV. The Supreme Court Decision

In a unanimous decision, the U.S. Supreme Court reversed the Federal Circuit, and held the subject claims unpatentable under §101.

The Court stated a recurring theme of the decision: "to transform an unpatentable law of nature into a patent-eligible *application* of such a law, one must do more than simply state the law of nature while adding the words 'apply it.' "[11] A second theme stated by the Court was that "laws of nature" and "natural phenomena" are not themselves patentable, regardless of whether they were previously recognized, and that claims that wholly preempt natural laws are similarly not patentable. The Court commented that merely adding conventional, "insignificant" "extra-solution activities" (i.e., pre- or post-solution activities), such as "data-gathering" activities that are necessary to any solution of the algorithm or application of the natural law, is insufficient.

However, the Court acknowledged that "too broad an interpretation of this exclusionary principle could eviscerate patent law." The Court further acknowledged that "all inventions at some level embody, use, reflect, rest upon, or apply laws of nature, natural phenomena, or abstract ideas." Thus, it confirmed that applications of laws of nature are often patentable, and that it would be improper to treat previously unknown laws of nature as prior art.

Referring to its prior decisions relating to §101, the Court stated:

> Those cases warn us against interpreting patent statutes in ways that make patent eligibility "depend simply on the draftsman's art" without reference to the principles underlying the prohibition against patents for [natural laws]. … They warn us against upholding patents that claim processes that too broadly preempt the use of a natural law. … And they insist that a process that focuses upon the use of a natural law 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.[12]

Focusing on the "inventive concept" idea, the Court emphasized that "the steps in [Prometheus's] claimed processes (apart from the natural laws themselves [recited in the "wherein" clauses]) involve well-understood, routine, conventional activity previously engaged in by researchers in the field." The Court held that "upholding the patents would risk disproportionately tying up the use of the underlying natural laws, inhibiting their use in the making of further discoveries."[13]

The Court did not focus on the preamble of the claims, which had been important to the Federal Circuit's decision that the claims were directed to a method of medical treatment rather than merely to a "natural law" correlation. The Supreme Court's closest reference to that aspect of the claim appears to lay in its (like the District Court's) references to careful claim drafting as having the potential to obscure the real substance of a claim.

The Court held that the previously-unknown correlation in the "wherein" clauses, between (a) precise levels of metabolites of a synthetic drug in a patient and (b) safety and efficacy of the drug, is a "natural law." Regardless of the fact that the drugs in question are man-made, the

[11] Slip opinion at 3, 9, 10, 13, 16 and 17.

[12] Slip opinion at 2-3.

[13] Slip opinion at 4.

Court thus very specifically defined the "natural law" involved in the claims:

> 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.

The Court then posed the issue as whether "the patent claims add *enough* to their statements of the correlations to allow the processes they describe to qualify as patent-eligible processes that *apply* natural laws." The Court held that they do not do so.

In an odd characterization of the "administering" step of the claim, the Court stated that "the 'administering' step simply refers to the relevant audience, namely doctors who treat patients with certain diseases with thiopurine drugs." The Court also noted that this was a "pre-existing audience" and that doctors performed this step "long before anyone asserted these claims." The Court further suggested that this step might be an attempt to limit the use of the natural law to a particular technological environment, which had previously been held insufficient to establish patent eligibility.

The Court further emphasized that the "determining" step did not specify any particular process by which the determination should be made, that "methods for determining metabolite levels were well known in the art," and that scientists "routinely" made such determinations with respect to the drugs in issue. Maintaining this focus on the apparently prior-art nature of the subject step, the Court stated that:

> this step tells doctors to engage in well-understood, routine, conventional activity previously engaged in by scientists who work in the field. Purely "conventional or obvious" "[pre]-solution activity" is normally not sufficient to transform an unpatentable law of nature into a patent-eligible application of such a law.

The Court also emphasized that the "wherein" clauses do not include any requirement that the doctor use the information provided in them, "at most adding a suggestion that he should take those laws into account when treating his patient." Thus, while the Court did not explicitly so state, the claims apparently did not include <u>any</u> application of the "law of nature," much less a non-conventional or non-obvious application of it.

The Court concluded that the combination of recited steps does not establish patent eligibility. It summarized that combination of steps as merely instructing doctors to gather data from which they may draw an inference in light of the stated correlation, and thus insufficient to transform unpatentable natural correlations into patentable applications of them.

The Court discussed various precedential Supreme Court decisions, but focused on *Diamond v. Diehr, supra,* and *Parker v. Flook*[14] as reinforcing its decision.

In *Diehr,* in which process claims were held patent-eligible, the claims were directed to "a method of operating a rubber-molding press for precision molded compounds with the aid of a digital computer." They included steps of (1) continuously monitoring temperature inside a

[14] *Parker v. Flook*, 437 U.S. 584 (1978).

rubber mold (arguably a data-gathering step), (2) feeding the resulting numbers into a computer which used them in a known mathematical equation (which, like a natural law, is itself unpatentable) to continuously recalculate the mold-opening time, and (3) configuring the computer to signal "a device" and thereby cause the press to open at the appropriate moment. As stated in *Mayo*, the Court had "found the overall process patent eligible because of the way the additional steps of the process integrated the equation into the process as a whole. … It nowhere suggested that all these steps, or at least the combination of those steps, were in context obvious, already in use, or purely conventional." Thus, the Court stated that the "other steps apparently added to the formula something that in terms of patent law's objectives had significance – they transformed the process into an inventive application of the formula."

Thus, in contrast to the *Mayo* claims, the *Diehr* claims involved an automatic opening step based on the unpatentable equation, and there was no evidence that all of the *Diehr* steps were conventional. In the automatic opening step, the results of the mathematical equation were actually applied in a non-comprehensive way (e.g., they did not encompass merely knowing when to open the mold, or even manually opening the mold), as opposed to the *Mayo* claims in which the results of the natural law did not lead to a requirement of any further activity applying those results, and merely implied that the results would even be communicated to the doctor.

In *Flook*, process claims were held patent-ineligible. The claims there were directed to "a method for updating the value of at least one alarm limit on at least one process variable involved in a process comprising the catalytic chemical conversion of hydrocarbons wherein said alarm limit has a current value" specified by a given equation. The claims included steps of (1) continuously monitoring the process variable (e.g., temperature) in a catalytic conversion process (arguably a data-gathering step), (2) using a novel mathematical equation (which, like a natural law, is itself unpatentable) to continuously recalculate current alarm limits, and (3) adjusting the system to reflect the new alarm-limit values. The Court characterized at least some of these steps as conventional. The updated "alarm limit" was merely an updated number resulting from the calculation, and the *Flook* claims did not recite "the means of setting off an alarm or adjusting the alarm limit," leaving open all means, including manual actions, of adjusting the system. The *Flook* scenario thus correlates more closely to the Prometheus patent claims, in that the manner in which the information derived from the "natural law" is to be used, if at all, is not limited.

The Supreme Court emphasized "a concern that patent law not inhibit further discovery by improperly tying up the future use of laws of nature." The Court cited cases in which the claims held unpatentable were very broadly stated, encompassing much more than had been disclosed by the patentee. The Court further emphasized that this concern "becomes acute when a patented process … forecloses more future invention than the underlying discovery could reasonably justify."[15] While noting that process claims "risk being applied to a wide range of situations that were not anticipated by the patentee," the Court applied this concern even as to very specific "laws of nature" that may be applicable only in very limited situations. The Court expressed particular concern that the claims used "highly general language covering all processes that make use of the correlations after measuring metabolites, including later discovered processes that measure metabolite levels in new ways." The Court distinguished what it

[15] Slip opinion at 17.

characterized as "a typical patent on a new drug or a new way of using an existing drug" in which the claims "confine their reach to particular applications of those laws."

Finally, the Court addressed a number of other arguments that had been made by the Federal Circuit, the parties, and others who had filed briefs to the Court.

Regarding the "machine-or-transformation" test, the Court found the transformation involved in the "administering" step to be "irrelevant," again referring to its argument that this is simply an "audience-selection" step. The Court found that the "determining" step did not actually require a transformation, "should science develop" some hypothetical future non-transformative method to determine metabolite levels in a patient. Regardless of these statements, the Court pointed out that the "machine-or-transformation" test is not a definitive test for patent eligibility, and expressly stated that it has neither held nor implied "that the [machine-or-transformation] test trumps the 'law of nature' exclusion."

As to the highly specific nature of the "natural law" that it held was defined by the "wherein" clauses in the Prometheus claims, the Court stated that "the underlying fundamental concern here is a *relative* one: how much future innovation is foreclosed relative to the contribution of the inventor." The Court stated that the "creative value of the discovery is … considerably smaller" for "a patent upon a narrow law of nature."[16] The Court held that courts and judges are in any event not equipped to distinguish between broad and narrow laws of nature, and thus stated that "the cases have endorsed a bright-line prohibition against patenting laws of nature, mathematical formulas and the like," no matter how broad or narrow they may be.

The Court also addressed arguments that its decision would improperly conflate §101, §102, §103 and §112 issues, and that patentability of the Prometheus claims would better be judged under other statutes than §101. The Court acknowledged that under its decision, issues under those different statutes may overlap. The Court stated that it was required to apply §101 as an exclusionary statute regardless of such overlap to avoid a risk of "creating significantly greater legal uncertainty."[17]

Finally, the Court addressed arguments that its decision would significantly inhibit medical and diagnostic research by withholding patent protection from the fruits of that research. In *dicta*, the Court referred to arguments that exclusive rights should not be granted covering the body's natural responses to medical treatment and that methods of medical treatment are not patentable in most of Western Europe. The Court concluded that it is up to Congress, not the courts, to determine "whether, from a policy perspective, increased protection for discovery of diagnostic laws of nature is desirable."

V. Related Events

Following the Supreme Court's *Mayo* decision, the U.S. Patent and Trademark Office (USPTO) issued the attached memorandum providing initial guidance to its Examiners regarding the need to implement the *Mayo* decision in their examination practices, and the Supreme Court vacated the Federal Circuit's decision in the *Myriad* case[18] and remanded it to

[16] Slip opinion at 20.

[17] Slip opinion at 21-22.

[18] *Association for Molecular Pathology v. USPTO*, 653 F.3d 1329 (Fed. Cir. 2011), discussed in our August 3, 2011 Special Report entitled "Federal Circuit Addresses Patent Eligibility of Isolated DNA and Related Diagnostic Methods."

the Federal Circuit for reconsideration in light of *Mayo*.

The USPTO memorandum is broadly worded, and leaves most analysis up to the Examiners and a yet-to-be-written guidance paper. Summarizing the *Mayo* decision, the memorandum states, "Essentially, appending conventional steps, specified at a high level of generality, to laws of nature, natural phenomena, and abstract ideas cannot make those laws, phenomena, and ideas patent-eligible. … A claim that recites a law of nature or natural correlation, with additional steps that involve well-understood, routine, conventional activity previously engaged in by researchers in the field is not patent-eligible, regardless of whether the steps result in a transformation." The memo refers Examiners to the current *Interim Bilski Guidance* that it issued in 2010,[19] and indicates that the USPTO is developing further detailed guidance on patent subject matter eligibility under §101.

In the *Myriad* decision, a divided Federal Circuit held that certain composition claims directed to engineered or isolated DNA are patent-eligible under §101 in the face of arguments that mere isolated DNA is a natural phenomenon. It also held that some method claims, with only "comparing" and "analyzing" active steps, are not patent-eligible under §101, while other method claims, with "growing a … host cell" and "determining the rate of growth of the host cell" active, but arguably "data-gathering," steps, are patent-eligible under §101. Because both composition and method claims are involved, future decisions of the Federal Circuit and possibly the Supreme Court in that case may clarify the scope of the Supreme Court decision in *Mayo*.

In addition, the Federal Circuit has taken up for *en banc* review its *McKesson* and *Akamai* decisions, and is expected to issue decisions in them in the next few months.[20] Those cases relate to the current state of the law that there is generally no infringement liability when different actors perform different steps of a claimed method. This law is important in a field such as that at issue in *Mayo*, where a doctor may apply the results of diagnostic steps performed by others such as an independent laboratory. In fact, the claims at issue in *Mayo* may have been drafted with that law in mind, focusing purely on the diagnostic steps and not on the therapeutic steps.

VI. Analysis

The claims at issue were extremely broad, and, as characterized by the Supreme Court, all of their active steps were anticipated by prior use: "the steps in [Prometheus's] claimed processes (apart from the natural laws themselves) involve well-understood, routine, conventional activity previously engaged in by researchers in the field." The claims included "wherein" clauses that did not add any further limitation on the claimed method, but rather just stated facts about the information gathered by way of the active steps.

Particularly in view of its statement that its "conclusion rests upon an examination of the particular claims" in suit, the Supreme Court's *Mayo* decision could be construed narrowly as holding that a claim is not patent eligible if it merely recites a correlation of facts that occur in a natural environment, and conventionally practiced data-gathering steps for obtaining the information involved in that correlation, without any novelty in those data-gathering steps and

[19] See our July 29, 2010 Special Report entitled "Patent Office Issues Interim Guidance On Patent-Eligibility For Process Claims."

[20] *McKesson Technologies Inc. v. Epic Systems Corp.*, Appeal No. 2010-1291, and *Akamai Technologies Inc. v. Limelight Networks Inc.*, Appeal No. 2009-1372, both argued November 18, 2011.

without any requirement for actually using the correlation. A difficulty with the *Mayo* decision is that much of the discussion in it is more broadly stated, and does not appear to be directed to the actual Prometheus patent claims.

For example, a dominant refrain in the decision is that a claim will not be patentable if it merely identifies a natural law and adds the words "apply it." However, construing the "administering" and "determining" steps of the claim as mere data-gathering steps, as the Court did, the claim did not "add the words apply it." To the contrary, as noted by the Court, the claim required the data-gathering steps and identified the subject natural law (a correlation of the data gathered to the effect of the drug), but did not require that the natural law be applied at all. The claim did not even require that the determined levels of metabolite be compared to the identified range or be communicated to a doctor, much less used to adjust levels of administration of the drug.

Thus, the court's catch-phrase concerning identifying a natural law and adding the words "apply it" appears to be mere non-controlling *dicta*. It also is in tension with the Court's own acknowledgements in *Mayo* and *Bilski* that the practical application of a law of nature remains a factor that weighs in favor of subject-matter eligibility.[21] However, because it is a statement of a unanimous Supreme Court, which is the ultimate appellate court for all U.S. courts, future courts are likely to try to implement this catch-phrase in various unpredictable ways.

The Court's second catch-phrase, stating a prohibition against claims that preempt all practical applications of a natural law, could also be applied rather narrowly. The claims at issue were process claims, and the Court expressly stated that the concern against preempting all practical applications of a natural law applies to process claims. Thus, future courts could reasonably limit application of this test to process claims. As noted above, the claims at issue did not include any limitations on the application of the natural law. To the contrary, they only broadly required gathering the data that would be necessary to apply an identified "natural law." Furthermore, the Court expressly declined a suggestion to treat the "natural law" as prior art in analyzing patentability of claims under §§102 or 103. Thus, it could be argued that the case could be distinguished by claims including any non-comprehensive application step, or at least any non-conventional such step.

However, in view of the Court's emphasis of the "preempting all practical applications of a natural law" catch-phrase, there is a danger that future courts may apply that catch-phrase more broadly. This creates a danger to many patent claims, because many claims necessarily preempt all application of "natural laws" if those "natural laws" are sufficiently narrowly defined.

The most troubling aspect of the Mayo decision in both of these regards is its broad definition of a "law of nature." In *Mayo*, the Court found that a correlation between a specific range of amounts of a synthetic drug metabolite in a patient and the likely danger or ineffectiveness of that metabolite in the patient is a law of nature, even though that correlation was previously unknown and even though the presence of that metabolite in a patient does not occur without human intervention. The Court thus made clear that neither prior art knowledge nor the absence of such prior art knowledge of a correlation affects whether a correlation is a "law of nature." The Court further made clear that a law of nature may be very specific, and need not ever be manifested without human intervention.

Given such a definition of "law of nature," application of the Court's injunctions against (1) claims that "simply state the law of nature

[21] *In re Bilski*, 130 S.Ct. at 3231.

while adding the words 'apply it' " and (2) claims that "too broadly preempt the use of a natural law" can be troubling. If the USPTO and future courts do not carefully heed the warning that "too broad an interpretation of this exclusionary principle could eviscerate patent law," broad application of the Court's catch-phrases could have a very wide-ranging effect on validity of many patent claims.

The following is a practical example that highlights the breadth with which the decision might conceivably be applied: A company may want to obtain patents based on its discovery that novel and non-obvious synthetic compound X, when it is injected into a patient's bloodstream in an amount of 10-100 mg per day for five days, is effective to cure lung cancer in the patient. The company has confirmed this discovery by injecting a population of patients who have lung cancer with amounts of compound X inside and outside of the above parameters, and observing that the patients in whom the amounts were inside those parameters were cured, while the others were not cured.

Applying the Court's definition of "natural law," the above statement would appear to be a statement of a natural law: there is a previously unknown correlation between injection of 10-100 mg per day for five days of compound X into a patient's bloodstream and the cure of lung cancer in the patient.

One might consider trying to obtain the following claims:

1. A compound having the structural formula X.

2. A composition comprising compound X in a form suitable for injection into a patient's bloodstream.

3. A method of treating lung cancer, comprising injecting an effective amount of compound X into the bloodstream of a patient suffering from lung cancer.

4. A method of treating lung cancer, comprising injecting 10-100 mg per day for five days of compound X into the bloodstream of a patient suffering from lung cancer.

5. A method of treating lung cancer, comprising injecting 10-100 mg per day for five days of compound X into the bloodstream of a patient suffering from lung cancer, wherein injecting 10-100 mg per day for five days of compound X into the bloodstream of a patient suffering from lung cancer is effective to cure the lung cancer in the patient.

Under a broad interpretation of both of the Court's above-discussed catch-phrases, none of the above claims should be patentable. Each of those claims completely preempts any unlicensed entity from applying the law of nature stated above. The chemical compound claim 1 preempts any unlicensed entity from applying any law of nature involving the compound, thus preempting application of the identified law of nature and any other law of nature involving the compound. It preempts use of the compound in any method, whether already invented or not. It inhibits future research involving the compound, since the compound will be unavailable in the absence of licenses or production by the patentee. The composition claim 2 is more tailored to the disclosed use of the compound, but has the same effect of preemption as to that use. Method claim 5 is most similar to the Prometheus claims, in that it identifies the natural law to which it is directed. However, it would have the same preemptive effect as the Prometheus claims, in that the identified "natural law" is completely preempted by the active injecting step. Method claims 3 and 4 are less specific in identifying the "natural law," but are accordingly even broader in their preemptive effect.

Indeed, all chemical composition claims, not merely medical treatment or diagnosis claims, preempt all applications of any natural laws involving those compositions – the compositions cannot be made or used in any way without infringing the claims. Take, for example, a claim to novel synthetic compound Y that has been discovered to bond to untreated wood by modifying proteins in the wood in such a way that they bond to one another. In view of the Court's narrow definition of a natural law as a previously unknown effect that a synthetic composition has in a natural context, a claim to the composition would preempt all uses of the natural law that compound Y bonds to natural wood. Application of the Court's catch-phrases to that composition claim would thus render it patent-ineligible.

Even limiting application of the Court's catch-phrases to process claims, broad method claims applying the full scope of a narrowly defined natural law would be patent-ineligible. For the same novel compound Y, for example, a claim to a method of bonding wood, comprising applying to wood a bonding effective amount of compound Y, would preempt application of the natural law, and thus render the claim patent-ineligible.

Particularly in view of the disruption to the U.S. patent system that could be caused by such broad application of catch-phrases in the *Mayo* decision, we consider it unlikely that the courts or the USPTO will so apply it. In fact, the Court itself expressly distinguished "a typical patent on a new drug or a new way of using an existing drug" from the situation in *Mayo*, thus suggesting that the Court itself does not foresee such broad application of its words.

The Court's emphasis on process claims and the lack of novelty of the active steps of the Prometheus claims may provide guidance on how to avoid such broad application of the decision. The Court appears to have relied heavily on the fact that the active steps of the claimed method were conventional and well-known in the art, and on the fact that the claims did not require any novel application of the natural law, to reach its conclusions. This appears to have been necessary to avoid logical implications of its definition of a "natural law" and its injunctions against any claims that merely identify a natural law and add the words "apply it" or that fully preempt all applications of the natural law, as discussed above.

The Court's comments regarding the *Diehr* decision may be particularly helpful in this regard. In that decision, the application of the mathematical equation involved automatically opening a mold door in view of the solution of the unpatentable mathematical equation. Opening a mold door was undoubtedly also conventional. Thus, a key to patentability was apparently the automated opening of the door in response to the information derived from the mathematical equation. Thus, the unpatentable equation was used as the basis for a novel step applying the solution to the algorithm. Similarly, a novel adjustment of dosages of thiopurine drug in accordance with the natural law identified in the Prometheus patent claims may have been patentable.

Thus, future courts may require novel active steps in process claims to render them patentable under §101. However, the Court's remand of the *Myriad* decision, which addressed both method claims and composition claims in a natural context, hints that the Court may have intended the present decision to have broader effect than might be anticipated, particularly in light of the Court's ambiguous comments about other patent systems precluding patentability of diagnostic and treatment method claims.

VII. Recommendations

For patent applicants and patentees:

1. Avoid reciting a "natural phenomenon" in the claims; save it for the specification.

2. A major point of disagreement among the courts was whether or not the language of the claim preamble was merely an attempt to frame a claim to a natural phenomenon as a treatment method. Thus, we strongly recommend that one not rely on the preamble of a claim to establish the nature of a method being claimed – instead, include active steps in the claim that define the nature of the method, e.g., by the result achieved.

3. Use active language in connection with the recited steps of a claimed method.

4. Include in process claims at least one step applying any correlation or mathematical formula or other concept that could be argued to be a natural law, natural phenomenon, mathematical algorithm, or otherwise an abstract idea, in an active step that acts on a physical object rather than just updating information.

5. Consider including claims focusing only on steps that apply a potential "natural law" correlation, rather than the steps involved in gathering the information needed to apply the natural law. For example, "product-by-process" concepts may be included in a claim such as "a method of treating disease X, comprising administering drug Y in a dosage amount that has been determined by …".

6. Include claims specifically identifying any automated or computer-based physical responses to correlations or calculations identified in a claim, such as was done in the *Diehr* claims.

7. Include a wide range of claims of varying type (e.g., apparatus, method-of-use, method-of-making, product, product-by-process, etc. claims) and varying scope (broad to narrow) to avoid all claims in a patent being invalidated by a single shift in the law or adverse interpretation of a single aspect of the claims.

8. Particularly for chemical and diagnostic industry patentees, but additionally for other patentees, review your important patents for claims that may be adversely affected by this decision, to determine whether those patents should be reissued to add claims that would not be adversely affected.[22] This review should be done soon, to maximize the potential of adding claims that might be considered broadening within the two-year-from-issuance window for filing broadening reissue applications.

9. Similarly, review pending patent applications to determine whether claims should be added, either in existing applications or continuing applications, to avoid implicating §101 unpatentability under *Mayo*.

10. Watch for the decisions in the *McKesson* and *Akamai* cases relating to different method steps being performed by different actors. Consider including claims that would not likely be infringed under current law, but that might be infringed if the law is changed by those decisions. Also continue to include claims drafted such that all active method steps are performed by the same actor.

For our clients who are concerned with potential or actual assertion of a patent against them:

1. Review the claims and specification for potential identification of natural laws, natural phenomena, mathematical algorithms, or the like, no matter how narrowly defined, whose

[22] Particularly in light of the Federal Circuit decision in *In re Tanaka*, 640 F.3d 1246 (Fed. Cir. 2011), even merely narrowing claims could be added without changing existing claims. See our April 29, 2011 Special Report entitled "Federal Circuit Approves Reissue Applications That Only Add Dependent Claims To An Issued Patent."

application would be wholly preempted by the subject patent claims.

2. Review the claims for non-limiting language, such as in "wherein" or "whereby" clauses, that may be construed not to require application of a natural law, natural phenomenon, mathematical algorithm, or the like, when the application of the natural law or the like is critical to patentability.

3. Review the claims for very broad, all-encompassing method steps that may be characterized as overly preemptive, particularly if they are significantly broader than the supporting disclosure of embodiments of the invention.

4. Watch for the decisions in the *McKesson* and *Akamai* cases relating to non-infringement by reason of different method steps being performed by different actors. Meanwhile, consider a non-infringement defense that different actors carry out any recited or implied steps of applying correlations or the like than the actors that carry out recited or implied steps of gathering the underlying information.

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