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Subject-Matter Eligibility In The Wake of *Mayo v. Prometheus*

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Mayo v. Prometheus

In *Mayo Clinic v. Prometheus Labs.*, a unanimous Supreme Court struck down medical treatment claims as directed to a law of nature and thus patent ineligible.

Claim 1 is representative:

> A "method of optimizing therapeutic efficacy for treatment" of an immune-mediated GI disorder, comprising:
>
> (a) "administering" to a subject having a GI disorder a drug that provides 6-TG; and
>
> (b) "determining" the level of 6-TG in the subject;
>
> wherein the measured level of 6-TG "indicates a need" to increase or decrease the amount of drug subsequently administered to the subject.

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Mayo v. Prometheus

The Supreme Court was the final stop in a long and tumultuous journey for these method claims:

- In 2004, Prometheus sued Mayo over its diagnostic tests embodying the claimed methods;
- District court granted summary judgment of invalidity under § 101, holding the patents claimed correlations that were natural phenomena;
- Federal Circuit reversed, holding the claims met the MOT test since "administering" and "determining" were transformative and not merely data-gathering.
- Supreme Court vacated and remanded for reconsideration in light of *Bilski*.
- On remand, Federal Circuit affirmed its earlier decision, again relying on the MOT test and holding that "methods of treatment … are always transformative when one of a defined group of drugs is administered to the body to ameliorate the effects of an undesired condition."

Question Presented:

The question before us is whether the claims do significantly more than simply describe … natural relations. To put the matter more precisely, do the patent claims ad *enough* to their statements of the correlations to allow the processes they describe to qualify as patent-eligible processes that *apply* natural laws. We believe that the answer to this question is no.

Mayo v. Prometheus

The Court rejected the Federal Circuit's reliance on the MOT test and struck down the claims as directed to patent-ineligible laws of nature:

- The MOT test is "an important useful clue" to patentability, but cannot trump the "law of nature" exclusion.
- Because the recited laws of nature—correlations between metabolite concentration and drug effectiveness—are not themselves patent-eligible, the claimed process likewise fails unless it has "additional features that provide practical assurances that the process is more than a drafting effort designed to monopolize the law of nature itself."
- While it takes a human action (administering the drug) to trigger the correlation, that correlation exists apart from any human action; it is a consequence of how the body naturally metabolizes the drug.

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Mayo v. Prometheus

The Court articulated an "inventive concept" test of patent-eligibility, in which the claim recite "significantly more" than the natural law:

- Methods that depend on natural laws must "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."
- Here, the claimed "additional" steps consisted of "well-understood, routine, conventional activity already engaged in by the scientific community," and thus failed the "inventive concept" test.
- The Court distinguished Prometheus' claims, which do not confine their reach to particular applications of natural laws, from "a typical patent on a new drug or a new way of using an existing drug."

Mayo v. Prometheus

The Court feebly distinguished its 1981 *Diehr* decision:

- The claimed method in *Diehr* (held to be patent eligible) recited a method for molding rubber using the Arrhenius equation to determine when, based on temperature, to open the molding press.

> [*Diehr*] nowhere suggested that all these steps, or at least the combination of those steps, were in context obvious, already in use, or purely conventional. … These 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.

- According to the Court, Prometheus' claims, by contrast, merely pick out the relevant audience (doctors) and tell them to apply the unpatentable law of nature when treating their patients: "The process in *Diehr* was not so characterized."

Mayo v. Prometheus

The Court declined to address the broader implications of its decision raised by the *amicus* briefs:

- Rejecting the government's argument that sections 112, 102, and 103 were adequate to address the Court's concerns of impeding future innovation, the Court reasoned that this "risks creating greater legal uncertainty, while assuming those sections can do the work that they are not equipped to do."
- The Court concluded its opinion by noting that it "need not determine here whether, from a policy perspective, increased protection for discoveries of diagnostic laws of nature is desirable." That's the job of Congress.

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PTO Response

The PTO recently issued a memo "to provide preliminary guidance" on section 101 in the wake of *Mayo*:

- Reminds examiners that the MOT test "is an investigative tool, it is not the sole or a determinative test for deciding whether an invention is patent-eligible."
- "[T]o be patent-eligible, a claim . . . should include other elements or combinations of elements such that, in practice, the claimed product or process amounts to significantly **more than** a law of nature, a natural phenomenon, or an abstract idea with conventional steps specified at a high level of generality appended thereto."

AMP v. Myriad

In the wake of *Mayo*, the Supreme Court set aside the Federal Circuit's decision in *AMP v. Myriad*, remanding the case for further consideration:

- In *Myriad*, the Federal Circuit struck down a method of determining cancer predisposition by "analyzing" or "comparing" different gene sequences. But the court affirmed the patent-eligibility of:

  (1) "isolated DNA" claims; and

  (2) a method of screening potential cancer therapeutics comprising "comparing" and "determining" the growth rates of cells transformed with different gene sequences.

- On remand, the Federal Circuit will likely uphold at least some of the DNA claims of (1) but may strike down the method claim of (2).

AMP v. Myriad

Myriad's imperiled method claim recites:

> A method for screening potential cancer therapeutics comprising:
>
> (a) "growing" host cells transformed with an altered *BRCA1* gene in the presence or absence of a potential cancer therapeutic,
>
> (b) "determining" the growth rate of the host cells with or without the potential therapeutic, and
>
> (c) "comparing" the growth rate of the host cells.

- It's questionable whether this claim survives in view of *Mayo*'s proscription against claims that rely on natural laws and recite mere conventional steps. Myriad might argue that step (a) of the claim recites a novel and active step.

Classen v. Biogen

Mayo now also calls into question the viability of the Federal Circuit's holding in *Classen v. Biogen*:

- In *Classen*, the Federal Circuit court struck down a method whereby mammals having a disorder are "immunized" according to a schedule, and the severity of the disorder is "compared" to a control group. But the court upheld a method whereby information on immunization schedules is "screened" and "compared," the lower risk schedule is "identified," and subjects are "immunized" according to that schedule.
- The distinction the court drew was that the second method recited the physical step of immunizing subjects and thus were directed to a specific, tangible application, whereas the first method only recited the step of immunization for gathering information and comparing results.
- It's unclear whether, *post-Mayo*, the second method in *Classen* would still survive section 101 scrutiny. One possible distinction is that it is a therapeutic claim, rather than a diagnostic claim.

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Claims Drafting Tips

1. Satisfying the MOT test is not enough!

2. Style the claims as ***therapeutic*** methods, not diagnostic methods:

   - ***Not this:*** "A method of diagnosing a patient having disease X comprising measuring the level of expression of gene Y, comparing that expression to a control, wherein overexpression of gene Y is indicative of a need to administer drug Z."
   - ***But this:*** "A method for treating a patient having disease X comprising administering drug Y in a concentration optimized for that patient based on a prior diagnostic test."
   - ***Or this:*** "A method for treating a patient having disease X comprising administering drug Y in a concentration that yields no more than 100 pmol per $8x10^8$ of metabolite Z."
   - ***Or this:*** "A method for treating a patient having disease X comprising determining the expression profile of gene Y, comparing that expression with a reference expression profile, and administering a therapeutically effective amount of drug Z based on said gene Y expression profile.

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Claims Drafting Tips

- Diagnostic claims are harder to disentangle from the natural law underlying the diagnosis because the diagnosis is typically based on a result (*e.g.*, gene expression, metabolite levels, etc.) that is driven entirely by how the patient's body functions (*e.g.*, expression a gene or metabolizes a protein).

- Therapeutic claims, on the contrary, have the advantage of ***applying*** diagnostic information (*e.g.*, treat disease X based on gene expression profile) instead of simply gathering it.

Claims Drafting Tips

3. Include "unconventional" steps that confine the invention to a particular, useful application of the principle, *i.e.*, where:

   - What's being administered is novel (*e.g.*, a novel drug or combination of drugs, a novel dosage concentration)
   - What's being detected is novel (*e.g.*, a newly discovered biomarker, isolated metabolite);
   - The relationship between what's being detected and the disease is novel (*e.g.*, previously unknown correlation between gene X and disease Y); or
   - The method by which the drug is being administered or detected is novel (*e.g.*, a novel drug dosage form, a novel detection assay)

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Claims Drafting Tips

4. Consider claiming some features more narrowly in order to clarify the “inventive concept”, e.g., where the invention rests in part on:

   - The nature of the sample (*e.g.*, the test works better with urine samples than blood samples);
   - The nature of the detection technique (e.g., gene expression is superior to protein expression).

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Joint Infringement Issues

- As biotech patentees figure out how redraft their claims to satisfy *Mayo*, they are increasingly likely to encounter thorny issues of joint and indirect infringement.
- Presently, these very issues are being reviewed by the Federal Circuit sitting *en banc*:
  - *Akamai Technologies v. Limelight Networks* (2010)
  - *McKesson Technologies v. Epic Systems* (2011)
- The panels in *Akamai* and *McKesson* held that joint infringement of a method claim requires an agency relationship between the accused joint infringers.

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Joint Infringement Issues

- The issues on appeal are:

1. If separate entities each perform separate steps of a method claim, under what circumstances would that claim be directly infringed and to what extent would each of the parties be liable? (*Akamai*)

2. If separate entities each perform separate steps of a method claim, under what circumstances, if any, would either entity or any third party be liable for inducing infringement or for contributory infringement? (*McKesson*)

3. Does the nature of the relationship between the relevant actors—e.g., service provider/user; doctor/patient—affect the question of direct or indirect infringement liability? (*McKesson*)

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Joint Infringement Issues

- Oral argument was held on November 18, 2011:
  - Pointing to common law principles of joint liability, Akamai argued that when multiple parties perform the steps of a method claim, there is direct infringement if: (1) one party directs or controls the other; (2) the parties act in concert; or (3) one of the parties has knowledge that all the steps are being performed.
  - Pointing to the Patent Act, Limelight and Epic argued that joint infringement liability was strictly limited to indirect forms of infringement (*i.e.*, inducement and contributory infringement).

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Joint Infringement Issues

- If the Court loosens the standard for establishing infringement liability when multiple parties act in concert—as Akamai and McKesson are urging—therapeutic claims reciting multiple steps be performed by multiple actors (e.g., doctor, outside laboratory, etc.) should be easier to enforce.

- But if the Court holds that joint infringement requires an agency relationship between the actors, therapeutic claims will be susceptible to circumvention by multiple actors performing different steps independently of one another.

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Thank You!

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