



Diagnostic Method Patents:

A Framework for Patent-Eligibility of Diagnostic Method Patents post-*Mayo*

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Diagnostic Method Patents:

Why this is Important?

PEOPLE!

- ❑ Patients Benefit from Diagnostics:
 - 70% of medical decisions by physicians rely on diagnostic assay results*
 - 1 in 8 women will develop breast cancer; 1 in 36 will die**

- ❑ Patients Benefit from Companion Diagnostics:
 - Quicker FDA Approval of New (more effective) Pharmaceuticals
 - Decreased Government spending on pharmaceuticals when ineffective

- ❑ Everyone Benefits from Jobs:
 - Diagnostics Companies & surrounding communities
 - hospitals and labs
 - USPTO, FDA
 - University funding

*Steve Burrill, Burrill & Co. Venture Capital, EMBO Rep. Oct., 2007; 8(10): 903-906

**American Cancer Society estimates for the U.S. as of 2014, www.cancer.org/cancer/breastcancer

Diagnostic Method Patents:

The Framework: Brief Overview

The Court's decision in *Mayo* must be analyzed in view of the *specific claims at issue* (and not in the abstract).

1. Consider the Court's analysis:
 - in the context / pre-text under which the claim was held invalid; and
 - in view of the specific claim language at issue in the case.
2. Apply the "*Useful Clues*" provided by the Court in *Mayo*
3. Follow the Fed. Cir.'s Lead in applying *Mayo* to diagnostic claims.

Diagnostic Method Patents:

The Framework: the “Context” or “Pre-text” of the *Mayo* decision

- ❑ “[T]oo broad an interpretation of this exclusionary principle could eviscerate patent law. For *all inventions at some level* embody, *use*, reflect, rest upon, *or apply laws of nature.*” (*Mayo*, p.2)
- ❑ “[A]n *application* of a law of nature...to a known structure or process may well be deserving of patent protection.” (*Mayo*, p.2)
- ❑ “Our conclusion rests upon *an examination of the particular claims before us* in light of the Court’s *precedents*.... [*which*] *warn* us *against* upholding *patents that* claim processes that *too broadly preempt the use of a natural law.*” (*Mayo*, p.3).
- ❑ “[W]e [do not] depart[] from *established general legal rules* lest a new protective rule [for] one field produce[s] unforeseen results in another.” (*Mayo*, p.24).

Diagnostic Method Patents:

The Framework: the Specific Claim Language

The patent claims seek to embody this research in a set of processes. Like the Federal Circuit we take as typical claim 1 of the '623 Patent, which describes one of the claimed processes as follows:

"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." '623 patent, col. 20, ll. 10-20, 2 App. 16.

Administering:

- "simply refers to the relevant audience."
- "attempt[s] to limit the use of the formula to a particular technological field."
- "inform[s] a relevant audience [about a law of nature]."
- "pick[s] out the relevant audience."
- "limit[s] an abstract idea to one field of use."
- "picks out the group ...interested in applying the law of nature."

= **Field of Use:** M.P.E.P. §2106 (*does not impose actual boundaries on the scope of the claim*)

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Determining:

- "[use] whatever process the doctor...wishes."
- "measure (somehow) the current level of the... metabolite."
- "conventional steps, specified at a high level of generality"
- "set forth in highly general language covering all processes that make use of the [law of nature], including later discovered processes that measure metabolite levels in new ways."
- "could be satisfied without transforming the blood, should science develop a...different system...that did not involve...a transformation."

=Pre-, Post- Solution: M.P.E.P. §2106 (*does not impose meaningful limits on the execution of the claimed method steps; not central to the method invented*)

Diagnostic Method Patents:

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Wherein:

- "not limited to instances in which the doctor actually [adjusts] the dosage level [based on] the test results."
- "inform the calibration of...dosages of...thiopurines."
- "at most adds a suggestion that [the doctor] should take those laws into account."
- "tell doctors...they may draw an inference in light of the correlations."

=Non-limiting: M.P.E.P. §2111.04 (*claim scope is not limited by wherein clause that does not require steps to be performed or limit a claim to a particular structure*)

Diagnostic Method Patents:

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Claim as a whole:

- "the claim before us [is] overly broad; it [does] not differ significantly from a claim that just said "apply the [law of nature]."
- "do not confine their reach to particular applications of th[e] law [of nature]."
- "cover[s] all processes that make use of the correlations."
- "effectively claim the underlying law of nature"
- "disproportionately t[ie] up the use of the underlying natural laws, inhibiting their use in the making of further discoveries."
- "the more abstractly [process] claims are stated, the more difficult it is to determine precisely what they cover."

=Pre-emption: M.P.E.P. §2106 (*claim not limited to a particular, practical application; recites only a field of use step and a pre-, post- solution activity step, neither impose meaningful limits on the execution of the claimed method*)

Diagnostic Method Patents:

The Framework: the “Useful Clues” in *Mayo*

- ❑ The Court’s decision relies on “*established general legal rules*”
 - Specifically, the judicial rule that prevents too broadly preempting the use of a law of nature
 - Court does not recite a new rule for biotech or diagnostic patents

- ❑ Machine of Transformation Test *Unchanged:*
 - applied (according to precedent, as reflected in M.P.E.P. §2106), not changed!
 - Court points out the Fed. Cir. analysis/application of existing M-or-T test was wrong
 - ❖ neither step requires transformation (e.g., field-of-use + pre-/post-solution activity)

- ❑ Just Breyer’s big, blinking roadmap for understanding *Mayo*:
 - contrasts Prometheus’ claims with claims to a new way of using an existing drug
 - “Unlike, say, a typical patent on...a new way of using an existing drug, the patent claims [at issue in *Mayo*] do not confine their reach to particular applications of those laws [of nature]. ... [T]hese patents tie up too much future use of laws of nature.” (*Mayo*, p.18)

Diagnostic Method Patents:

Fixing Prometheus' claims:

The patent claims seek to embody this research in a set of processes. Like the Federal Circuit we take as typical claim 1 of the '623 Patent, which describes one of the claimed processes as follows:

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Administering:

- Specific drug administered (e.g., specific compound, not just any 6-thioguanine producing drug)
- Specific dosage of drug (e.g., dosage range)
- Specific time points for administration (e.g., once daily for a full week)
- Specific form of administration (e.g., I.V., oral, etc.)

= No longer a Field of Use step:

- ❖ *Imposes meaningful limits/actual boundaries on "administering" step*
- ❖ *Complies with precedent which Mayo was based on that "warns against too broadly preempting a use of a law of nature!"*

Diagnostic Method Patents:

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Determining:

- Recite specific steps for "determining" (e.g., steps of ELISA; PCR; HPLC; flow cytometry; mass spec)
- Recite specific compositions used in specific steps (e.g., antibodies; primers; controls)

=No longer a **Pre-, Post- Solution** step:

- ❖ *Imposes meaningful limits on the execution of the claimed steps;*
- ❖ *Performance of specific action is central to the method invented;*
- ❖ *Requires use of certain compositions*
- ❖ *Complies with precedent which Mayo was based on that "warns against too broadly preempting a use of a law of nature!"*

Diagnostic Method Patents:

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Wherein:

- Make active steps of overall claim:
 - ❖ Method of treating claims (dosage is actively altered based on metabolite level)
 - ❖ Method of diagnosing (diagnosis is provided based on metabolite level)

=No longer **non-limiting** clauses:

- ❖ *Claim scope is limited by altering dosage or by reciting positively providing a diagnosis;*
- ❖ *Recited as steps that require steps to be performed;*
- ❖ *Complies with precedent which Mayo was based on that "warns against too broadly preempting a use of a law of nature!"*

Diagnostic Method Patents:

Fixing Prometheus' claims: From invalid to valid

A method of treating an immune-mediated gastrointestinal disorder in a patient, comprising:

- (a) administering [**compound X** or derivative thereof] to a patient, said step of administering comprising one of *intravenous* or *oral administration* of [compound X or derivative thereof] in a *range of [Xmg – Ymg]*, ;
- (b) measuring the level of 6-thioguanine in one of a *blood or urine sample* obtained from the patient between *6 to 18 hours after* said step of administering, said step of determining comprising one of *cation-ion exchange, NMR analysis and mass spectrometry*, whereby a level of 6-thioguanine is obtained; and
- (c) *treating* the immune-mediated gastrointestinal disorder in the patient with a *dosage of [compound X* or derivate thereof] *greater than Ymg* if the level of 6-thioguanine is less than 230 pmol per 8×10^8 red blood cells.

Not a Field of Use step:

- ❖ *Recites actual boundaries on compound administered; method of administration; and dosage*

Not a Pre-, Post- Solution step:

- ❖ *imposes meaningful limits on type of sample; when sample is obtained; type of analysis performed;*
- ❖ *performance of specific action is central to the method invented;*
- ❖ *requires use of certain compositions;*
- ❖ *requires_a transformation of sample*

Limiting step of the claim:

- ❖ *claim scope is limited by requiring treating disorder with altered dosage;*
- ❖ *Requires performance of “treating” step (with specific compound)*

Diagnostic Method Patents:

Guidance from the Fed. Cir.: **Claim 20 from Pat. No. 5,747,282**

20. A method for screening potential cancer therapeutics which comprises: growing a transformed eukaryotic host cell containing an altered BRCA1 gene causing cancer in the presence of a compound suspected of being a cancer therapeutic, growing said transformed eukaryotic host cell in the absence of said compound, determining the rate of growth of said host cell in the presence of said compound and the rate of growth of said host cell in the absence of said compound and comparing the growth rate of said host cells, wherein a slower rate of growth of said host cell in the presence of said compound is indicative of a cancer therapeutic.

Fed. Cir. Holding (applying *Mayo* to a § 101 Analysis):

- Does more than state “apply it” (*AMP*, p.60).
- Transformation = man-made host cells (*AMP*, p.60-61).
- Not merely conventional: applies certain steps to man-made (“transformed”) subject matter (*AMP*, p.61).
- Does not preempt all uses. (*AMP*, p.61).
- Notes the “administering” and “determining” steps of the claim in *Mayo* did not differentiate that claim from the law of nature alone. (*AMP*, p.60).

* *AMP v. Myriad*, 689 F.3d 1303 (Fed. Cir. 2012)

Diagnostic Method Patents:

Guidance from the Fed. Cir.: **Claim 20 of '282 Patent is Instructional**

Fed. Cir. Holding

(Claim 20 of the '282 Patent is Instructional in a *Mayo*-based § 101 Analysis):

- “The key distinction...between claims that [are] ineligible...and claims to specific inventive applications...[is] the latter do not risk the broad preemption of the ‘basic tools of scientific ...work,’...and therefore clear the threshold of section 101.” (*PerkinElmer*, p.7).
- “As the Court in *Mayo* reasoned, anyone who wants to use this...natural law must follow the claimed process.” (*PerkinElmer*, p.12).
- “The claims held patent-eligible in *Myriad* [claim 20 of the '282 patent] bolster our decision here.” (*PerkinElmer*, p.13).
- “[T]he host cells [of claim 20] did not occur naturally; they were man-made and, thus, were themselves patent-eligible subject matter...their inclusion in the process made the claims patent-eligible.” (*PerkinElmer*, p.13).

**PerkinElmer, Inc. v. Intema Ltd.*, 496 Fed. Appx. 65 (Fed. Cir. 2012)



Diagnostic Method Patents:

The 2014 Subject Matter Eligibility Guidance: *Breakdown at a Glance*

<u>Areas that got it right!</u>	<u>Areas that need improvement!</u>
Preemption of <u>entire use of a law of nature</u> is central to analysis	Weighted analysis for §101 is not proper
No single super-factor	Better instruction for applying the “well-understood, purely conventional or routine” analysis (e.g., done on context of determining if a step is “field of use” or “pre-/post-solution activity”)
Claim to be reviewed as a whole	A new Machine-or-Transformation test created for diagnostics (e.g., new definition for “transformation” in diagnostic claims)
The US PTO has been very forthcoming that “self-correction” will occur!	Contradicts <i>Mayo</i> by stating: “a new way of using an existing drug” does not recite or involve a law of nature”
	Fails to consider <i>AMP</i> and <i>PerkinElmer</i> (e.g., claim 20 of the ‘282 Patent)

Diagnostic Method Patents:

Conclusion: *A Framework for Diagnostic Method Claims post-Mayo*

Why: Because Diagnostics are Important!

- The Guidance Needs to Analyze *Mayo* in view of the Specific Claim Considered; Not in the Abstract.
- No New “Diagnostic Patent” Rules; Expressly Stated in *Mayo*!
- Machine-or-Transformation Test not changed!
- Apply the Useful Clues from *Mayo*!
- Follow the Fed. Cir.’s Lead in applying *Mayo* to diagnostic method claims!



*Thank
You!*

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Doing now what patients need next