

## Patent Year 2012 in Review

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## Topics

1. patent eligibility: *Prometheus* (S.Ct.)
2. patent prosecution: *Kappos v. Hyatt* (S.Ct.)
3. Infringement: *Akamai/McKesson* (Fed. Cir.) *en banc*
4. Defenses: *Marine Polymer v. HemCon* (Fed. Cir.) *en banc*
5. AIA status

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## Developments re Patent Eligibility

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## Historical Exclusions

- 3 specific subject matter exclusions from S.Ct. precedent:
  - Laws of nature
  - Natural phenomena
  - Abstract ideas
- In 2010, S.Ct. addressed abstract ideas in the *Bilski* case
  - invention for a method of managing costs associated with a commodity.

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## *Bilski v. Kappos*

- 3 main points in majority opinion:
  - (1) Business methods are not *per se* unpatentable.
  - (2) Bilski's claims are for an abstract idea and hence ineligible.
  - (3) "machine or transformation" is a **helpful clue** but **not an exclusive test**.

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## Subsequent Fed. Cir. Rule

- *Research Corp. v. Microsoft*, 627 F.3d 859 (12-8-10) (Rader, Newman, Plager)
- No rigid formula for abstractness
- To be "abstract," a claim must "**exhibit itself so manifestly**" as to override the broad statutory categories of eligible subject matter and the statutory context that directs primary attention on the patentability criteria of the rest of the Patent Act."

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## *Prometheus* (S.Ct. 3-20-12)

- Concerns determining a drug dosage for a patient
- Each patient metabolizes the drug uniquely.
- Inventors discovered that after administration:
  - if a level in blood of a certain metabolite is below [A], the dose is inefficacious; but
  - if the level is above [B], it is toxic.
- want to get between A and B.

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## *Prometheus* -- claim

- Representative claim 1 of '623 patent:
  1. A method of optimizing therapeutic efficacy for treatment of ... [a] disorder, comprising:
    - (a) **administering** a drug [containing a substance]...; and
    - (b) **determining** the level of [the substance] in said subject having said immune-mediated gastrointestinal disorder
      - [wherein a level below A indicates need to increase the drug and a level above B indicates need to decrease the drug]

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### *Prometheus*-case history

- D.Ct. granted SJ to defendant Mayo:
  - The patents effectively claim natural laws or natural phenomena—namely the correlations between thiopurine metabolite levels and the toxicity and efficacy of thiopurine drug dosages—and so are not patentable.
- Fed. Cir. reversed, 581 F.3d 1336 (2009), finding there was a transformation, so patent-eligible.

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### *Prometheus*-case history

- S.Ct. granted cert. petition of Mayo; vacated and remanded to Fed. Cir. for consideration in light of *Bilski*.
- On remand, Fed. Cir. reaffirmed its prior decision, 628 F.3d 1347 (12-17-10)
  - (Reported on this Fed. Cir. Opinion in November 2011 Symposium)

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### *Prometheus*-case history

- Fed. Cir. ruling (2010):
  - claims are not for a law of nature but instead to **a particular application** of naturally occurring correlations
  - claims do not preempt all uses
  - claims do not encompass laws of nature
  - **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.

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### *Prometheus*, S.Ct.

- S.Ct. ruling is difficult to grasp
  - brings prior art into §101 determination
- S.Ct. rejects Solicitor General suggestion that §§102, 103, etc. would be useful to address prior art and reject claims.
- **Is prior art relevant to §101?**

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## Prometheus - S.Ct.

- S.Ct.: line drawing issue:
  - "... all inventions at some level embody, use, reflect, rest upon, or apply laws of nature, natural phenomena, or abstract ideas." slip opin. at 2.
  - "We must determine whether the claimed processes have transformed these unpatentable natural laws into patent-eligible applications of those laws."

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## Prometheus - S.Ct.

- Precedents warn against eligibility depending simply on patent drafting skill.
  - (Does this mean *State Street*, Fed. Cir. 1998?)
- Fed. Cir. rule (2010):
  - abstractness must be show itself "so manifestly" that it overrides ... (*Research Corp.*)

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## Prometheus - S.Ct.

- S.Ct. rule (2012) seems opposite:
  - Court must "insist that a process that focuses upon the use of a natural law [will] 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.
  - Cites *Flook*, 437 U.S. 584, 594 (1978); *Bilski* slip op. at 10

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## Prometheus - S.Ct.

- Prohibition against abstract ideas cannot be overcome by:
  - Limiting claims to particular technology, or
  - Adding insignificant post-solution activity
  - Cites *Bilski*, quoting *Diehr*, 450 U.S. 175, 191-192 (1981)
  - **Wasn't *Bilski* a case about abstract claims, not natural laws?**

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### *Prometheus - S.Ct.*

- S.Ct. uses the prior art to show that all that is being claimed here is a natural law plus (1) field of use, and (2) well-known technology.
- Combining a natural law with “well-understood, routine, conventional activity...in the field” is not enough.  
– Slip op. at 4

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### *Prometheus - S.Ct.*

- Also, Court wants to avoid tying the hands of others from using the natural law to make further discovery.
- Necessary building blocks for the future.

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### *Prometheus - S.Ct.*

- Court does not challenge the Fed. Cir. ruling that this invention is transformative.
- Instead, S.Ct. says that machine-or-transformation is merely an “important clue,” not a definitive test.  
– slip op. at 7

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### *Prometheus - S.Ct.*

- Court requires SIGNIFICANTLY MORE than describing the natural relations.  
[*Id.* at 8]
- Must have “additional features that provide practical assurance that the process is more than a drafting effort designed to monopolize the law of nature itself.” *Id.* at 8-9.

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### *Prometheus* - S.Ct.

- Here, the “administering” step simply identifies the relevant audience. *Id.* at 9.
- The “wherein” clause simply tells the doctor about the relevant natural laws and suggesting that he account for them in treatment. *Id.*
- The “determining” step is well known in the art.

### *Prometheus* - S.Ct.

- Purely conventional or obvious pre-resolution activity is normally not sufficient to make a law of nature a patent-eligible appln. of the law. *Id.* at 10.
- *Diehr* (patent eligible) was very specific (making molded rubber products). Not obvious, already in use, or purely conventional.

### *Prometheus* - S.Ct.

- *Flook* (patent ineligible) adjusted alarm limits in a catalytic conversion process.
  - Invention was an improved system for updating by measuring, using a novel math formula, and adjusting the system to reflect the new alarm values.
  - *Flook's* process was unlike *Diehr* because *Flook* had no “inventive concept” in the *application* of the formula.

### *Prometheus* - S.Ct.

- Claims here are weaker than *Diehr* and no better than *Flook*.
- Court reinforced its concern that patent law must not inhibit further discovery by improperly tying up the future use of laws of nature. *Id.* at 16.
- “Machine-or-transformation” test does not trump the law of nature exclusion. *Id.* at 19.

## *Prometheus - S.Ct.*

- Court recognizes the role of Congress in making finely tailored rules where necessary.
  - Cites special rules for plant patents
  - Slip op. at 24 (last page)

## Developments re Patent Prosecution

*Kappos v. Hyatt*,  
132 S.Ct. 1690 (2012)

## *Kappos v. Hyatt*

- Hyatt filed patent appln; 117 claims
- Examiner denied all claims – lack of written description
- On appeal, Board approved 38 claims; denied the rest
- Hyatt filed a §145 civil action in U.S. District Court against USPTO Director

- 35 USC §145: An applicant dissatisfied with the decision of the Board ... in an appeal under §134(a) may, unless appeal has been taken to the ... Federal Circuit, have remedy by **civil action** against the Director in the [U.S.] District Court ... The court may adjudge that such applicant is entitled to receive a patent for his invention, as specified in any of his claims involved in the decision of the Board ..., **as the facts in the case may appear** \*\*\*

- Hyatt filed a written declaration in court explaining the support in spec'n.
- D.Ct. ruling: Hyatt was precluded from raising new issues absent "some reason of justice ... for [the] failure to present the issue to the Patent Office."
- Only other evidence was the PTO record.
- D.Ct. reviewed the fact findings under the APA deferential "substantial evidence" standard.
- Summary judgment to USPTO Director.

- A divided Fed. Cir. panel affirmed
  - Said APA restricts the admission of new evidence in a §145 action
  - D.Ct. review is "wholly *de novo*"
- En banc Fed. Cir. reversed
  - Vacated D.Ct. grant of SJ
  - Applicants are free to add new evidence in §145 proceedings, subject to F.R.Evid., "even if the applicant had no justification for failing to present the evidence to the PTO."
  - De novo review by D.Ct.

### *Kappos v. Hyatt*

- **S.Ct. affirmed the Federal Circuit.**
- 2 questions:
- Q1: Are there any limitations on the applicant's ability to introduce new evidence before the district court?
- **A1: There are no evidentiary restrictions beyond those already imposed by the Federal Rules of Evidence and the Federal Rules of Civil Procedure.**

### *Kappos v. Hyatt: S. Ct. ruling*

- Q2: What standard of review should the D.Ct. apply when considering new evidence?
- **A2: The D.Ct. must make *de novo* findings when new evidence is presented on a disputed fact question.**
  - In deciding the weight to give that evidence, the D.Ct. may consider whether the applicant had an opportunity to present the evidence to the PTO.

## Developments re Infringement

*Akamai v. Limelight /  
McKesson v. Epic Sys.*  
692 F.3d 1301 (Fed. Cir.  
2012) en banc

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## *Akamai-2012*

- 35 U.S.C. 271 (b): “Whoever **actively induces** infringement of a patent shall be liable as an infringer.”
- Issue: for a method claim, to induce under §271(b), must there be direct infringement **by a single entity**?

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## *Akamai*

- Inducement does not require direct infringement by a single entity.
- Sufficient that:
  - Defendant had knowledge of the patent;
  - Defendant induced others to perform the method steps; and
  - All the method steps **were performed** as a result of the inducement.
- Defendant may have performed one or more of the steps.

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- Akamai patent: method to deliver web content
  - Method places some of the content provider’s content on a set of replicated servers;
  - modify the content provider’s web page to instruct web browsers to retrieve that content from those servers.
- Δ Limelight maintains a network of servers.
- Δ allows for efficient content delivery by placing some content elements on its servers.
- Δ does not modify the content providers’ web pages itself.
- Instead, Δ instructs its customers on the steps needed to do that modification.

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- McKesson patent: method of electronic communication between healthcare providers and patients.
- Δ Epic licenses software app “MyChart” to healthcare organizations:
  - MyChart permits healthcare providers to communicate electronically with patients.
  - Epic performs NO steps of the patent.
  - Instead, method steps are divided:
    - patients initiate communications;
    - healthcare providers do the remaining steps.

## Akamai

- A defendant may be liable for induced infringement of a method patent:
  - if the defendant performed some of the steps of a claimed method and induced other parties to commit the remaining steps, or
  - if the defendant induced other parties collectively to perform all the steps of the claimed method, but no single party performed all of the steps itself.
- *BMC Res. v. Paymentech*, 498 F.3d 1373 (2007) is overruled.

## On remand re Epic:

“Epic can be held liable for inducing infringement if it can be shown that

1. it knew of McKesson's patent,
2. it induced the performance of the steps of the method claimed in the patent, and
3. those steps were performed.”

– 692 F.3d 1301, 1318

## On remand re Limelight:

“Limelight would be liable for inducing infringement if the patentee could show...

1. Limelight knew of Akamai's patent,
2. it performed all but one of the steps of the method claimed in the patent,
3. it induced the content providers to perform the final step of the claimed method, and
4. the content providers in fact performed that final step.” *Id.*

## Akamai

- Lengthy dissents by (1) Judge Newman, and (2) Judge Linn, who was joined by Judges Dyk, Prost, and O'Malley.
- Many practitioners expect the Supreme Court to grant *certiorari*.

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## Developments re Defenses

*Marine Polymer Tech., Inc. v. HemCon, Inc.*, 672 F.3d 1350  
(Fed Cir. 2012) (en banc)

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## *Marine v. HemCon*

- Q: can intervening rights apply without a change to a claim or by adding a new claim?
- A: No
- BUT, this was a sharply divided court

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## *Marine v. HemCon*

- Patent -- medical treatment field
- Claims for *biocompatible* compositions.
- Unclear what *biocompatible* means.
- D.Ct. ruled that it means "low variability, high purity, and ***no detectable biological reactivity*** as determined by biocompatibility tests.
- Verdict for plaintiff-patentee.

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## *Marine v. HemCon*

### Reexamination:

- Exmr. Rejected D.Ct. interpretation because dependent claims allowed for a small amount of biological reactivity.
- Exmr. construction: "... **little or no** detectable reactivity"
- Exmr. rejected all claims under this broader construction over prior art cited by HemCon.

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## *Marine v. HemCon*

### Reexamination, ctd.:

- Marine then canceled all of the dependent claims that allowed non-zero reactivity.
- Exmr. then agreed with D.Ct. construction and confirmed all remaining claims.
- This was not cited to the D.Ct. but was relied upon by Fed. Cir. panel.

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## *Marine v. HemCon*

- Fed. Cir. panel reversed the D.Ct. judgment
- Basis: HemCon acquired intervening rights during the reexamination.
- En banc rehearing granted.

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## *Marine v. HemCon*

- Fed. Cir. en banc affirmed the D.Ct. claim construction by an equally divided court.
- Then turned to intervening rights
- Argument by HemCon was that the **scope of the claims** changed during reexam when Marine canceled dependent claims, thus allowing the surviving claims to be given a narrower scope.

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## *Marine v. HemCon*

- Majority disagreed due to wording of reexam statute:
- “Any proposed ***amended or new*** claim determined to be patentable and incorporated into a patent following a reexamination proceeding will have the same effect as that specified in section 252 \*\*\*”  
– Emphasis by the Court

## *Marine v. HemCon*

- Whether the argument and cancellation of other claims led to a change in effective scope of remaining claims is not the point.
- Under the statute, the surviving claims were not “amended” or “new”
- Therefore no intervening rights.

## *Marine v. HemCon*

### **Dissent:**

- intervening rights discussion is dictum: D.Ct. ruling was affirmed
- For intervening rights, starting point is the meaning of the claims.
- Claim differentiation raises a presumption.
- “amended” should not require a change in language.

## **Developments re the Patent Statute**

America Invents Act  
2011-2013

## America Invents Act-1

**Sept. 16, 2011:**

- *qui tam* suits ended
- Virtual patent marking
- Prioritized exam
- Enlarged prior user defense: new patents
- best mode *defense* in new cases
- *inter partes* reexams: threshold changed from SNQ to reasonable probability that petitioner will succeed as to 1 claim.

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## America Invents Act-2

**Sept. 16, 2012:**

- *Inter partes* review (IPR)
- No new *inter partes* reexaminations.
- Post-grant review (PGR) of covered business method (CBM) patents
- Supplemental examinations
  - inequitable conduct “washing machine”

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## America Invents Act-3

**March 16, 2013:**

- First-inventor-to-file
  - Plan now for pending applns and disclosures ready to support new applns.
- New definitions of prior art
- Modified grace period
- Post-grant review of FITF patents
  - Plan now re attacking adverse published applications when they issue
  - After issuance, only 9 months to file PGR.
- AIA fully in effect.

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## Thank you!

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