

The image shows the exterior of a modern building with large glass windows. A prominent sign in 3D block letters reads "FENWICK & WEST". The windows reflect the surrounding environment, including trees and a clear sky. The building's facade is light-colored, possibly white or light grey.

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Patent Law Update

The key patent law issues and topics you need to know for 2012

Seattle, Washington

May 23, 2012

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SEATTLE PATENT LAW UPDATE 2012

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Biographies of Faculty

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Darren Donnelly

Pauline Farmer-Koppenol

Melanie Mayer

Heather Mewes

Rajiv Patel

David Tellekson

PATENT LAW UPDATE
The key patent law issues and topics in 2012



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Topics

- Decisions on Patent Issues 2011 / 2012
- Patentable Subject Matter
- Claim Construction
- Section 112
- Overview of the America Invents Act ("AIA")
- Post-Grant Patent Oppositions Under the AIA
- Forum and Discovery Issues
- Patent Law and Ethics in 2011

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Faculty

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The key patent law issues and topics in 2012



**Supreme Court - Federal Circuit *en banc*
Decisions on Patent Issues - 2011/2012**

David K. Tellekson

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Microsoft v. i4i

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A Much-anticipated Event



PHOTO: SPENCER PLATT/GETTY IMAGES

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A Much-anticipated Event

i4i v. Microsoft: Patent Case of the Year? Supremes to Decide

Posted on April 16, 2011 by Henry Sneath | [1 Comment](#)

Microsoft vs. i4i at U.S. Supreme Court: Future of patent law at stake

April 18, 2011 at 7:58 am by [Todd Bishop](#) | [1 Comment](#)

Will the Supreme Court Relax the Burden of Proof for Patent Invalidation?

May 5, 2011

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Questioning the Law of Gravity

"Under §282 of the Patent Act of 1952, "[a] patent shall be presumed valid" and "[t]he burden of establishing invalidity of a patent claim shall rest on the party asserting such invalidity, 35 U.S.C. §282. **We consider whether §282 requires an invalidity defense to be proved by clear and convincing evidence.**"

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Microsoft's Proposed Hybrid Standard

"Microsoft's burden of proving invalidity and unenforceability is by clear and convincing evidence. **However, Microsoft's burden of proof with regard to its defense of invalidity based on prior art that the examiner did not review during prosecution of the patent-in-suit is by preponderance of the evidence.**"

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Why Do We Care?

"Preponderance" =
50.000000000000000001%

"Beyond a reasonable doubt" =
beyond a reasonable doubt

"Clear and convincing evidence" = ?

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Supreme Court Decision

- Unanimous Supreme court (8-0)
- Upheld “clear and convincing evidence” standard
- Patent owners rest easier
- Those attacked by trolls do not

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Global-Tech v. SEB S.A.

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Inducement of Infringement

“Whoever actively induces infringement of a patent shall be liable as an infringer.”

35 U.S.C. §271(b)

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Elements of Inducement

- Act(s) of inducement
- Underlying direct infringement
- Intent
 - To cause acts that constituted direct infringement?
 - Specific intent to cause infringement of patent?

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Specific Intent is Required

"Accordingly, inducement requires evidence of culpable conduct, directed to encouraging another's infringement, not merely that the inducer had knowledge of the direct infringer's activities"

DSU Medical v. JMS, 471 F.3d 1293, 1306 (Fed. Cir. 2006) (*en banc*)

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DSU Medical v. JMS

"The interesting portion of this opinion rests in Section III.B, where the CAFC convened an *en banc* panel to clarify that 'inducement' of infringement requires intent *to induce actual infringement, which necessarily requires knowledge of the patent.*"

Dennis Crouch

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Not So Fast . . .

- Inducement requires specific intent to cause infringement of a particular patent
- Have to be aware of the patent to do that
- Except when you do not . . .

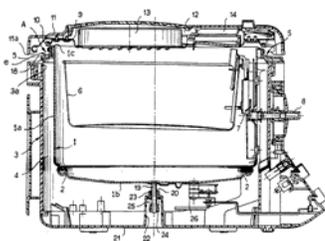
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PATENT LAW UPDATE

Global-Tech Appliances

- “Cool touch” deep fryer
 - Metal frying pot
 - Plastic housing
 - Air in between
- Defendant copied design
- Defendant conducted right-to-use study
- Did not tell lawyer it had copied plaintiff’s design



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Global-Tech Appliances

- “[W]e now hold that induced infringement under § 271(b) requires knowledge that the induced acts constitute patent infringement”
- Fed. Cir. standard: “Deliberate indifference to a known risk”
 - Recklessness
 - Too low
- Willful blindness is correct standard

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Willful Blindness?



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So What is Willful Blindness, Exactly?

- Subjective belief in high probability that a fact exists, plus
- Deliberate actions to avoid learning that fact
- “[A] willfully blind defendant is one who takes deliberate actions to avoid confirming a high probability of wrong doing and who can almost be said to have known the critical facts.”

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For Example . . . ?

- Plaintiff's cool-touch fryer was successful in U.S. market
- Defendant copied all but cosmetic features
- Defendant copied overseas model of fryer
 - No U.S. patent marking
- Defendant's CEO (Sham) was an inventor on his own patents
 - Knew about marking requirements
- Did not tell attorney product was copied

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Stanford v. Roche

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Stanford v. Roche

- Cetus developed PCR — a technique used here for measuring HIV in the bloodstream
- Cetus and Stanford worked on testing new AIDS drugs
- Stanford co-inventor conducted research at Cetus to learn about PCR
- Roche later acquired Cetus' assets

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Stanford v. Roche

- Stanford sued Roche for infringement by Roche's HIV test kits
- Roche claimed that it already had ownership rights in patent via assignment from the co-inventor
- Stanford asserted that Bayh-Dole Act negated Roche's defense

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Stanford v. Roche — Contract Rights and Federally-Funded Inventions

The diagram is a horizontal timeline with arrows at both ends. It marks the years 1988, 1989, 1992, 1995, and 2000. A double-parallel line symbol (ss) is placed between 1995 and 2000, indicating a break in the timeline. Five text boxes are connected to the timeline by lines:

- 1988:** Co-inventor signs Stanford patent agreement: "agree to assign . . . to Stanford" and agree "not enter into any agreement creating . . . patent obligations in conflict"
- 1989:** Co-inventor signs Cetus agreement: "will assign and do hereby assign to CETUS. . ."
- 1992:** Stanford files for patent protection
- 1995:** Cetus assigns rights to Roche
- 1995:** Co-inventor assigns invention to Stanford
- 2000:** Stanford asks Roche to take a license

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Bayh-Dole Act



Non-profit organization may “elect to retain title” to any “subject invention”

“Subject invention” = “any invention of the contractor conceived or first actually reduced to practice in performance of work under a funding agreement”

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Stanford v. Roche

- Question presented: Whether an inventor employed by a federal contractor may defeat the contractor’s right under the Bayh-Dole Act to retain title in inventions arising from federally-funded research by contractually assigning his rights to a third party

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Supreme Court Reasoning

- Inventor owns absent assignment
- Statutory exceptions are unambiguously stated
 - E.g., inventions under contracts with NASA “shall be the exclusive property of the United States”
 - No such language in Bayh-Dole Act
- “Invention of the contractor” → limits retention of rights to inventions owned by Stanford
- “Retain” means “hold or continue to hold”
 - Not “acquire” or “obtain”

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Stanford v. Roche — Contract Rights and Federally-Funded Inventions

- Holding: The Bayh-Dole Act does not automatically vest title to federally funded inventions in federal contractors or authorize contractors to unilaterally take title to such inventions

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Kappos v. Hyatt

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Kappos v. Hyatt

- Supreme Court argument held Jan. 9, 2012
- Issues:
 - When the PTO denies an application, and the applicant commences a civil action against the Director under 35 USC § 145, can the applicant introduce evidence of patentability that was not presented to the agency but could have been?
 - When new evidence is introduced, is there any deference to the PTO's prior decision?
- Federal Circuit allowed new evidence and found that no special deference owed beyond standard of review

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Kappos v. Hyatt

- April 18, 2012, Supreme Court affirmed CAFC decision (9-0)
- Patent applicant's ability to introduce new evidence is not limited in a Section 145 proceeding beyond Fed. R. Evid. and Fed. R. Civ. P.
- New evidence introduced must be reviewed *de novo*
- Improves usefulness of Section 145 actions, allowing patent applicant opportunity to introduce evidence not before examiner (e.g. oral testimony)

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Caraco Pharms. v. Novo Nordisk

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Caraco Pharms. v. Novo Nordisk

- Where formulation patents have expired, patent protection may be limited to particular uses
 - Repaglinide (PRANDIN – diabetes drug) uses:
 - Repaglinide by itself
 - **Repaglinide in combination with metformin**
 - Repaglinide in combination with thiazolidinediones
 - Formulation patent expired; only other patent covered repaglinide in combination with metformin
- Caraco sought ANDA approval for carve-out label (non-infringing) excluding use in combination with metformin

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Caraco Pharms. v. Novo Nordisk

- Carve-out labels only permitted if there is no overlap between proposed carve-out and the patent “use code”
 - Novo’s original use code: Use of repaglinide **in combination with metformin** to lower blood glucose
 - Novo’s amended use code: A method of improving glycemic control in adults with type 2 diabetes mellitus
- Caraco’s carve-out label denied because of overlap
- Caraco filed counterclaim, district court entered injunction requiring Novo to narrow “use code”
- Federal Circuit said no right to counterclaim applying strict statutory interpretation

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Caraco Pharms. v. Novo Nordisk

- Supreme Court argument held Dec. 5, 2011
- Issue:
 - Whether an ANDA applicant may assert a counterclaim when (1) there is an approved method of using the drug that the patent does not claim and (2) the brand manufacturer submits patent information to the FDA that misstates the patent's scope requiring correction

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Caraco Pharms. v. Novo Nordisk

- Supreme Court ruled 9-0 on April 17, 2012 that a generic drug manufacturer may file counterclaim to force correction of an overbroad use code that encompasses unclaimed methods of using the drug at issue.
- Supreme Court gave substantial weight to ensuring that FDA fulfills its statutory duty to approve non-infringing generics in accord with Congressional intent.
- Supreme Court interpreted "**an** approved method" to mean a "particular" method, and not "any approved method" as Federal Circuit had interpreted statute.
- Remains to be seen whether this will cause brand companies to more often forego Paragraph IV litigation and wait for launch and seek injunctive relief instead?

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Akamai v. Limelight

McKesson v. Epic

-Awaiting *en banc* CAFC decision

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Akamai v. Limelight/ McKesson v. Epic Systems

- “Divided infringement” issues considered *en banc* in two cases by CAFC
- Often relevant in software cases where end user performs some steps at client computer but other steps are performed by vendor’s server
- Also relevant in biotech/pharma, e.g. personalized medicine, another where testing step can be performed by or even outside U.S.

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Akamai v. Limelight/ McKesson v. Epic Systems

- Federal Circuit *en banc* arguments held November 2011
- Issue:
 - Whether all steps of a method claim must be performed by or under the direction of a single party for there to be infringement
- Federal Circuit panels followed prior CAFC precedent:
 - A single entity must practice every element of the claim
 - Except: Where defendant directs or controls infringing acts through:
 1. agency
 2. equivalent contract establishing control over infringing acts

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Divided Infringement Scenarios

Infringement?

271(b)	1. A actively induces B's practice of all method steps
No	2. A actively induces B's practice of all but one step, and C's practice of final step
No	3. A actively induces B's practice of all but one step, and practices the remaining step itself

Same culpable conduct in each scenario

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Divided Infringement Scenarios

Infringement?

271(a) 1. **A** practices all steps of patented method in U.S.

No 2. **A** practices all but one step of patented method in U.S., and practices final step in Ireland

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Divided Infringement Scenarios

1. **A** does five steps of method

2. **A** knows **B** (customer) will do final step

No liability

(Peerless case found liability)

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Divided Infringement Scenarios

A + B form collaboration to practice all steps of patented method in U.S. (but no agency/contractual requirement)

No liability

Golden Hour case

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Joint Infringement – Pre-1952 Patent Act

Peerless Equipment Co. v. W.H. Miner, Inc., 93 F.2d 98 (7th Cir. 1937)

- Patent on process for making train gears
- Last step – “successively compressing the mechanism to flatten down said protruding portion ...”
- Manufacturer left last step to customer to complete
- Defendant liable because it sold nearly finished gears “with the knowledge that the railroads will put them to use and thereby flatten the crown” to complete final step

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Patent Act of 1952 Codified Existing Precedent

- Supreme Court held that 1952 Act preserved then-existing infringement principles
- “In the context of infringement, we have already held that pre-1952 precedent survived the passage of the 1952 Act.” Warner-Jenkinson, Co. v. Hilton Davis Chemical Co., 520 U.S. 17, 26 (1997)
- “Section 271(a) was merely a codification of the common law of infringement that had developed up to the time of passage of the 1952 Patent Act. It was not meant to change the law of infringement.”

NTP, Inc. v. Research in Motion, Ltd., 418 F.3d 1282, 1319

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Federal Circuit Precedent Leading to McKesson/Akamai

- BMC Resources, Inc. v. Paymentech, L.P., 498 F.3d 1373 (Fed. Cir. 2007)
- Muniauction, Inc. v. Thomson Corp., 532 F.3d 1318 (Fed. Cir. 2008)
- Golden Hour Data v. emsCharts, Inc., 614 F.3d 1367 (Fed. Cir. 2010)

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McKesson

McKesson Technologies v. Epic Systems, 2011 U.S. App. LEXIS 7531 (Fed. Cir. 2011) (vacated)

- Process patent – claims electronic method of communications between healthcare providers and patients involving personalized web pages for doctors and patients
- Defendant (seller of software system “MyChart”) accused of inducing infringement
- Patient practiced first step, doctor practiced remaining steps (**A** induces **B + C** to practice patented steps)

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McKesson

McKesson Technologies v. Epic Systems, 2011 U.S. App. LEXIS 7531 (Fed. Cir. 2011) (vacated)

- Federal Circuit panel affirmed finding of no infringement because single entity did not practice all the steps
- “Without an agency relationship or contractual obligation, the MyChart users’ actions cannot be attributed to the MyChart providers, [defendants’] customers”
- “Absent direct infringement, [defendant] cannot be liable for indirect infringement”

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McKesson (Newman Dissent)

[T]he court concludes that the claims can never be infringed, although the patent meets every requirement of patentability and every step of the claimed method is practiced.

A patent that can never be infringed is not a patent in the definition of the law, for a patent that cannot be infringed does not have the "right to exclude."

McKesson (Newman dissent)

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McKesson (Newman Dissent)

A patent that cannot be enforced on any theory of infringement, is not a statutory patent right. It is a cynical, and expensive, delusion to encourage innovators to develop new interactive procedures, only to find that the courts will not recognize the patent because the participants are independent entities.

McKesson (Newman dissent)

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Akamai

Akamai v. Limelight, 629 F.3d 1311 (Fed. Cir. 2010)
(vacated)

- Patent directed to improved method of delivering web page content
- Defendant performs all steps but “tagging” and “serving”
- Defendant’s customers “tag” and “serve”
- Customers contractually obligated to perform tagging and/or serving if they want defendant’s service guarantee
- District court granted JMOL – reversing jury finding of infringement

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PATENT LAW UPDATE

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Akamai

Akamai v. Limelight, 629 F.3d 1311 (Fed. Cir. 2010)
(vacated)

Federal Circuit:

“It is well settled that direct infringement requires a party to perform every step of a claimed method” 629 F.3d at 1318

“This Court therefore holds as a matter of Federal Circuit law that there can **only be joint infringement** when there is an **agency relationship** between the parties who perform the method steps or when one party is **contractually obligated** to the other to perform the steps. Neither is present here” 629 F.3d at 1320

“The form contract does not obligate [defendant’s] customers to perform any of the method steps” **(i.e. they can choose not to use software for its intended purpose)**

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Akamai Proposed 3-Part Test for Joint Infringement

Akamai brief argues three types of vicarious liability:

1. Directs or controls
2. Acting in concert (“expressly or tacitly agreed-upon activity”)
 - Partners
 - Part of joint enterprise
 - Contractual relationship
3. A party knowingly combines its performance of claim steps with that of another so that together they perform all steps of the claim

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**Awaiting *en banc* rulings in
McKesson and Akamai**

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**Marine Polymer Technologies, Inc.
v. HemCon, Inc.**

(Federal Circuit *en banc* decision)

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Marine Polymer Technologies

- Marine Polymer sued HemCon for infringement
 - Claim construction – “biocompatible” means low variability, high purity, and [[little or]] no detectable reactivity
 - Elution test score of zero (no reactivity in test) in some dependent claims and test score of 1 or 2 (mild reactivity in test) in some dependent claims; claim 6 – no score noted
 - During litigation, patent sent to reexamination
 - Claim construction submitted to Examiner, but Examiner did not follow citing specificity of term and inconsistency between independent claims (no reactivity) and dependent claims (some reactivity)
 - Marine Polymer cancelled dependent claims and Examiner approved independent claim noting agreement with District Court definition

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Marine Polymer Technologies

- At District Court - final judgment ready
 - Prior to reexamination, finding that HemCon products were found to have no detectable reactivity
 - From reexamination, surviving claims corresponding to no detectable reactivity were not amended
- HemCon appealed to Federal Circuit arguing that finding of infringement should be reversed as scope of claims changed in reexamination and thus they are entitled to intervening rights
 - Marine Polymer argues that actual language of claim at issue was not amended; asserted claims require no detectable reactivity

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Marine Polymer Technologies

- Absolute intervening rights at issue:
 - Protects accused infringer's right to continue using, selling or offering to sell specific products covered by reissue or reexamined claims when particular accused product has been made before the date of the reissue or reexamination and the scope of the claims is substantively changed
 - In determining whether substantive changes have been made, must discern whether the scope of the claims has changed and not merely whether different words are used

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Marine Polymer Technologies

- September 2011 panel decision expanded intervening rights
- Federal Circuit in 2-1 (Garjarsa and Dyk) decision found District Court claim construction was incorrect as specification and claims both showed some biological reactivity (and not zero)
- “if the scope of the claims actually and substantively changed because of Marine Polymer’s arguments to the PTO, the claims have been amended by disavowal or estoppel, and intervening rights apply [even through the claims were not amended]”

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Marine Polymer Technologies

- March 15, 2012 *en banc* decision, Federal Circuit held that intervening rights only apply if claim language is substantively amended or new claims are added.
- In closely divided 6-4 ruling, Court specifically rejected panel’s determination that intervening rights can arise as a result of patentee’s statements during reexamination (that limit scope but do not use different words).
- Court relied on “plain and unambiguous” statutory language of 35 U.S.C. § 307(b), and held that regardless of any arguments made, intervening rights will not apply unless the reexamination resulted in a textual change to the language of the claims.
- Dissent argued that intervening rights should be available where arguments during reexamination rise to the level of a clear and unambiguous disclaimer or disavowal of scope.

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The key patent law issues and topics in 2012



Patentable Subject Matter

Pauline Farmer-Koppenol

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Fundamental Shift

- *Mayo Collaborative Services v. Prometheus Laboratories, Inc.* – Supreme Court decision March 20, 2012
 - Relevant outside of life science inventions as evidenced by the remand in *WildTangent v. Ultramercial* issued May 21, 2012
 - *Association for Molecular Pathology v. Myriad* also remanded – March 26, 2012

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Preempting Natural Phenomena
Prometheus Labs., Inc. v. Mayo Collaborative Services

- Optimizing efficacy of treatment by administering drug and determining level of drug metabolites that indicate a need to adjust dosage
- District court granted summary judgment of invalidity under § 101:
 - Patents claimed only correlations between drug metabolite and therapeutic efficacy
 - Correlations are natural phenomena and the patent claims “wholly pre-empt” the correlations
- Federal Circuit reversed under machine-or-transformation test

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Question on Appeal

- “This case concerns whether a patentee can monopolize basic, natural biological relationships
- The Question presented is: Whether 35 U.S.C. 101 is satisfied by a patent claim that covers observed correlations between blood test results and patient health, so that the claim effectively preempts all uses of the naturally occurring correlations, simply because well-known methods used to administer prescription drugs and test blood may involve “transformations” of body chemistry.”

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Representative Claim

“A method of optimizing therapeutic efficacy for treatment of an immune-mediated gastrointestinal disorder” comprising two steps: (a) **administering** one of a class of drugs (thiopurines) and (b) **determining** the level of a specified metabolite, “**wherein**” a level below a given threshold “indicates a need to increase the amount of said drug subsequently administered” [to improve efficacy], and a level above the threshold “indicates a need to decrease the amount of said drug subsequently administered” [to avoid toxicity].

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Unanimous Supreme Court

- Held claims to administering a drug, followed by measuring the levels of metabolites of the drug, in order to optimize the amount administered, are not patent eligible because they are attempts to **monopolize naturally occurring correlations**.
- The “administering step” of the drug and the “determining step” wherein the metabolite levels are measured were not transformative but “simply telling doctors to engage in **well understood, routine, conventional activity** previously engaged in by scientists in the field.

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Claim Analysis

- Administering step – simply refers to the relevant audience, doctors who treat patients with thiopurine drugs. Audience is preexisting.
- “Determining step” – no particular method for making the determination is specified, and thus the entirety of prior art methods for making the determination are encompassed by the claim.
- “Wherein” clause simply tells the doctor about the relevant natural laws.

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Policy Considerations

- Court concerned that patent would:
 - “Tie up doctor’s subsequent treatment decisions.”
 - “Inhibit the development of more refined treatment recommendations (like that embodied in Mayo’s test), that combine Prometheus’ correlations with later discovered features of metabolites, human physiology or individual patient characteristics.”

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Machine or Transformation Test

- Bilksi held useful but not necessary
- Prometheus held not sufficient
 - “. . .we have neither said nor implied that the test trumps the “law of nature” exclusion.”
 - Recognized that “administering” step gave rise to a transformation, but concluded that it was “irrelevant”
- Now just one factor for consideration, some say dead.

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Ramifications

- Diagnosing claims : risk that they will be seen as analogous to “method of optimizing” claim in Prometheus.
 - Ex. Correlating presence of gene mutation with risk of cancer

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Ultramercial v. Hulu

- "A method for distribution of products over the Internet via a facilitator, said method comprising the steps of:
 - a first step of receiving, from a content provider, media products that are covered by intellectual-property rights ... of at least one of text data, music data, and video data;
 - a second step of selecting a sponsor message to be associated with the media product, ...
 - a third step of providing the media product for sale at an Internet website;
 - a fourth step of restricting general public access to said media product;
 - a fifth step of offering to a consumer access to the media product without charge to the consumer on the precondition that the consumer views the sponsor message;
 - a sixth step of receiving from the consumer a request to view the sponsor message...;

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Ultramercial v. Hulu (continued)

- a seventh step of, in response to receiving the request from the consumer, facilitating the display of a sponsor message to the consumer;
- an eighth step of, if the sponsor message is not an interactive message, allowing said consumer access to said media product after said step of facilitating the display of said sponsor message;
- a ninth step of, if the sponsor message is an interactive message, presenting at least one query to the consumer and allowing said consumer access to said media product after receiving a response to said at least one query;
- a tenth step of recording the transaction event to the activity log, said tenth step including updating the total number of times the sponsor message has been presented; and
- an eleventh step of receiving payment from the sponsor of the sponsor message displayed."

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Ultramercial v. Hulu

- CAFC Decision - Rader
- Section 101 is coarse filter, not to be used in place of 112, 102, 103
- “By its terms, the claimed invention invokes computers and applications of computer technology.”
- Notes that claim requires “extensive and complex” programming

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Reconsideration Ordered in Myriad Case

- Three separate sets of patent claims at issue:
 1. the court upheld (with a partial dissent) Myriad’s *product* claims on cDNA and isolated DNA;
 2. the court also upheld Myriad’s claims to *methods* of screening potential cancer therapeutics by analyzing growth rates of cells with altered BRCA genes in the presence or absence of the treatments; **but**
 3. the court rejected Myriad’s claims to *methods* of analyzing BRCA gene sequences and comparing those with cancer-predisposing mutations to normal sequences.

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U.S. Pat. No. 5,709,999 Claim 1

1. A method for screening a tumor sample from a human subject for a somatic alteration in a BRCA1 gene in said tumor which comprises [] *comparing* a first sequence selected from the group consisting of a BRCA1 gene from said tumor sample, BRCA1 RNA from said tumor sample and BRCA1 cDNA made from mRNA from said tumor sample with a second sequence selected from the group consisting of BRCA1 gene from a nontumor sample of said subject, BRCA1 RNA from said nontumor sample and BRCA1 cDNA made from mRNA from said nontumor sample, wherein a difference in the sequence of the BRCA1 gene, BRCA1 RNA or BRCA1 cDNA from said tumor sample from the sequence of the BRCA1 gene, BRCA1 RNA or BRCA1 cDNA from said nontumor sample indicates a somatic alteration in the BRCA1 gene in said tumor sample.

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U.S. Pat. No. 5,709,999 Claim 1 (cont.)

- CAFC – “Myriad’s claims do not apply the step of comparing two nucleotide sequences in a process. Rather, the step of comparing two DNA sequences is the entire process claimed.”
- CAFC – Second time around?

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U.S. Pat. No. 5,747,282 Claim 20

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.

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U.S. Pat. No. 5,747,282 Claim 20

- CAFC – “The claim includes the steps of “growing” transformed cells in the presence or absence of a potential cancer therapeutic, an inherently transformative step involving the manipulation of the cells and their growth medium. The claim also includes the step of ‘determining’ the cells’ growth rates, a step that also necessarily involves physical manipulation of the cells. Furthermore, these steps are central to the purpose of the claimed process.”
- Potentially in danger now?

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U.S. Pat. No. 5,747,282

1. An isolated DNA coding for a BRCA1 polypeptide, said polypeptide having the amino acid sequence set forth in SEQ ID NO:2.
2. The isolated DNA of claim 1, wherein said DNA has the nucleotide sequence set forth in SEQ ID NO:1.
3. An isolated DNA having at least 15 nucleotides of the DNA of claim 1.

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What Now?

- What is a natural phenomenon?
- What is an abstract idea?
- Does this make invalidation under 35 USC § 101 a fact-based inquiry and thus require fact-finding?
- Options for prosecution – explicitly disclaim that the invention is not an abstract idea nor a natural phenomenon?

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PATENT LAW UPDATE
The key patent law issues and topics in 2012



Claim Construction and Section 112
Heather Mewes



**Who Really Won
in *Phillips*?**

PATENT LAW UPDATE

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Significant Claim Construction Decisions in 2011 and 2012

- *Arlington Industries, Inc. v. Bridgeport Fittings, Inc.*, 632 F.3d 1246, rehearing en banc denied, 2011 U.S. App. LEXIS 9463 (Fed. Cir. 2011)
- *Retractable Technologies, Inc. v. Becton, Dickinson and Co.*, 653 F.3d 1296, rehearing en banc denied, 659 F.3d 1369 (Fed. Cir. 2011)
- *Markem-Imaje Corp. v. Zipher Ltd.*, 657 F.3d 1293 (Fed. Cir. 2011), rehearing en banc denied, 2011 U.S. App. LEXIS 23484 (Fed. Cir. 2011)
- *MySpace, Inc. v. Graphon Corp.*, ___ F.3d ___, No. 2011-1149 (Fed. Cir. March 2, 2012)
- *Digital-Vending Services Int'l, LLC v. The University of Phoenix, Inc.*, ___ F.3d ___, No. 2011-1216 (Fed. Cir. March 7, 2012)

85

Arlington Industries v. Bridgeport

- Issue was the construction of the term “spring metal adaptor” for an electrical connector in junction box

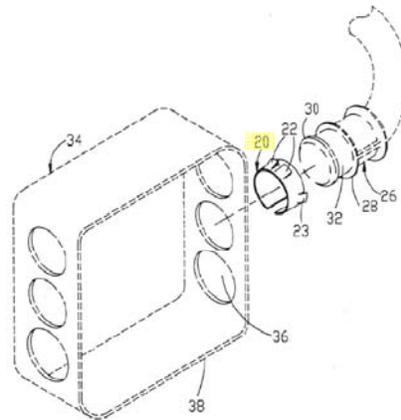


FIG. 5

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Arlington Industries v. Bridgeport

- Rader wrote Panel decision (with Moore):
 - Spring metal adapter is an adapter made of spring metal – no “split” limitation
 - Claim language: directional language used in claims (i.e., “spring inward”); some claims recite an adaptor with “less than a complete circle;” others do not
 - Specification: describes “spring metal” as type of metal; all drawings show a split in the ring, but only 1 of 4 embodiments explicitly describe “opening”
 - Prosecution: Amendment in earlier application to explicitly require “less than a complete circle” – broader claims prosecuted in continuation
 - Extrinsic: split is what makes adapter work

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Arlington Industries v. Bridgeport

- Majority: “Review of the intrinsic evidence reveals no intent to limit the term “spring metal adaptor” by using it in a manner that excludes unsplit adaptors.”
- Lourie dissent: “The bottom line of claim construction should be that the claims should not mean more than what the specification indicates, in one way or another, the inventors invented.”
 - One specification clearly shows inventors only invented an adaptor with a split; other specification not clear
 - “[C]laim differentiation should not enlarge claims beyond what the specification tells us the inventors contemplated as their invention.”

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RETRACTABLE TECHNOLOGIES

- Issue was the construction of the term “body” in claims to a tamperproof retractable syringe

Fig. 1

Fig. 2

Prior art

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RETRACTABLE TECHNOLOGIES

- Lourie wrote Panel decision (with Plager, concurring):
 - Claim language: independent claims use “body”; one dependent claim uses “one-piece body”
 - Specification: criticizes prior art syringe body as not one piece; summary of invention refers to “the invention” as featuring one-piece body; only embodiments are one piece, none are multi-piece
 - “A construction of ‘body’ that limits the terms to a one-piece body is required to tether the claims to what the specifications indicate the inventor actually invented.”

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Retractable Technologies

- Plager concurrence: actual invention should be focus of claim construction; patents should make “full disclosure of what is actually invented and . . . claim that and nothing more”
- Rader dissent: claims are not limited to one-piece body; no special definition of body in specification; no disavowal of claim scope; improper to import limitations from the specification into the claims; claim differentiation requires different conclusion

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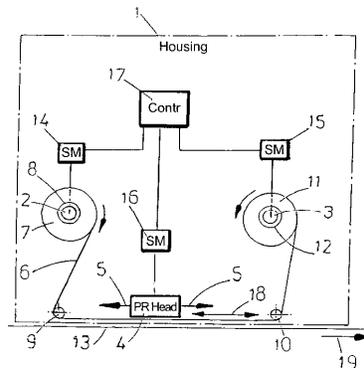
Retractable Technologies

- Court declined rehearing en banc on two issues:
 - Role of specification in construing claims
 - Whether appellate court should give deference to district court’s claim construction (*Cybor* issue)
- Moore/Rader in dissent cite split within the court on both issues, but also problem of uncertainty in “crucial” claim construction outcomes
- O’Malley, in dissent: “The fact . . . that the panel members could not agree on the proper claim construction in this case . . . underscores the complicated and fact-intensive nature of claim construction and the need to rethink our approach to it.”

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Markem-Imaje v. Zipher

- Issue was whether claims directed to regulating tension of tape used in thermal transfer printing required “some method of deriving a tension measurement”



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Markem-Imaje v. Zipher

- Linn/Clevenger wrote per curiam Panel decision:
 - Claim language: no explicit recitation of measuring tension in claims, but requirement to maintain tension “between predetermined values”
 - Specification: for invention to work, need to measure tension and process data to calculate a length of tape to be added/subtracted; only disclosure is measurement using contactless means during rotation of both motors
 - “[T]hough ‘some method of deriving a tension measurement’ may be required to make a claimed device operational, it is not proper to incorporate that method into the claim construction.”

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PATENT LAW UPDATE
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Markem-Imaje v. Zipher

- Newman dissent: “The panel majority . . . ignores the paramount importance of the specification in claim construction.” (citing *Retractable Technologies*)
 - Court may not enlarge the scope of the patent beyond what the patentee described as his invention
 - “Where a limitation is placed in a claim by the specification, the claim must be construed to include the limitation.”
 - Specification includes discussion of how tension may be measured, or calculated indirectly, and such measurement is necessary to the invention

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PATENT LAW UPDATE
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2011: Clearly Competing Views

<p>“If the metes and bounds of what the inventor claims extend beyond what he has invented or disclosed in the specification, that is a problem of validity, not claim construction.”</p> <p>(J. Moore, dissenting from en banc denial in <i>Retractable</i>)</p>	<p>“[T]he basic mandate is for claims to be interpreted in light of the specification of which they are a part because the specification describes what the inventors invented. The specification is the heart of the patent. In colloquial terms, ‘you should get what you disclose.’”</p> <p>(J. Lourie, concurring and dissenting in <i>Arlington</i>)</p>
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2012: MySpace – Complementary Views?

“One approach is to focus on the invention disclosed in the patent: ‘[t]ry to understand what the inventor has invented (what he says is his contribution in the art) and then choose the claim meaning that best fits the invention.’”

“The other is to focus on the words that the prosecuting lawyer used to craft the claims and ‘then apply legal rules of construction to divine the meaning of the claim.’”

“[I]t is an oversimplification to suggest that these are competing theories; rather, they are complementary.”

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2012: Digital-Vending Services – Further Divergence

Rader and Moore part ways:

- Rader finds that “registration server” need not be “free of content managed by the architecture”
- Moore follows “full breadth of its plain and ordinary meaning” approach like Rader, but finds disavowal:
 - Specification: “[e]ach registration server 108 is free of courseware or other deliverable content In particular, courseware is not stored on the registration server 108” and “[a] registration server 108 may not reside on the same computer because that would violate the requirement that registration servers 108 not contain courseware”
 - Clear disavowal overcomes claim differentiation
 - “Our precedent does not require that a patentee restate disavowal language repeatedly throughout the specification every time it references the same element.”

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Definiteness and Means-Plus-Function Claiming

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Significant 112 Indefiniteness Decisions in 2011 and 2012

Indefiniteness of computer processes:

- *In Re Katz Interactive Call Processing Patent Litigation*, 639 F.3d 1303 (Fed. Cir. 2011)
- *Inventio AG v. ThyssenKrupp Elevator Americas Corp*, 649 F.3d 1350 (Fed. Cir. 2011)
- *Typhoon Touch Technologies, Inc. v. Dell, Inc.*, 659 F.3d 1376 (Fed. Cir. 2011)
- *Noah Systems, Inc. v. Intuit Inc.*, ___ F.3d ___, No. 2011-1390 (Fed. Cir. April 2, 2012)

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Routes to Indefiniteness

- Section 112, paragraph 2, requires that the claims of a patent “particularly point out and distinctly claim the subject matter which the applicant regards as his invention. A claim is considered indefinite if it does not reasonably apprise those skilled in the art of its scope
- In *Aristocrat Technologies Australia Pty Ltd. v. International Game Technology*, 521 F.3d 1328 (Fed. Cir. 2008), the Federal Circuit held means plus function claims indefinite where the specification disclosed only general purpose processors and did not disclose an algorithm for performing the recited functions
- In *IPXL Holdings L.L.C. v. Amazon.com, Inc.*, 430 F.3d 1377, 1384 (Fed. Cir. 2005), the Federal Circuit held claims indefinite where they claim both an apparatus and a method of use

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In re Katz Interactive Call Processing

Interpreting *Aristocrat*:

- Claims directed to “processing means ... for receiving customer number data ... and for storing [same] based on a condition coupling an incoming call to the operator terminal” claims indefinite under *Aristocrat* – no disclosure of algorithm
- However, other claims simply reciting functions of “processing,” “receiving” and “storing” not indefinite – those functions can be performed by any general purpose computer without special programming, and therefore no algorithm need be disclosed

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In re Katz Interactive Call Processing

Interpreting *IPXL*:

- Claims directed to system with an “interface means for providing automated voice messages ... to certain of said individual callers, wherein said certain of said individual callers digitally enter data”
- Wherein clause is directed to user actions, not simply functional capability
- Because there is confusion as to when direct infringement occurs, claims invalid

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Inventio v. ThyssenKrupp

No 112 invalidity problem where “modernizing device” and “computing unit” held not to be means-plus-function terms:

- Use of the terms “modernizing device” and “computing unit” connote sufficiently definite structure
- Modernizing “device” functions as an electrical circuit that receives signals, processes signals, and outputs signals to other components
- Computing unit is connected to modernizing device and generates a destination signal for transmission
- Cannot overcome presumption that terms are not means-plus-function

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Typhoon Touch v. Dell

Stepping back from *Aristocrat*? – “means for cross-referencing” not indefinite despite concession that there was no explicit disclosure of a specific algorithm:

- “A description **of the function** in words may ‘disclose, at least to the satisfaction of one of ordinary skill in the art, enough of an algorithm to provide the necessary structure under § 112, ¶ 6.”
- “It is not disputed that the steps are carried out by known computer-implemented operations, and are readily implemented by persons of skill in computer programming.”

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Noah Systems v. Intuit

Or not? – “access means” indefinite where spec discloses only one of two distinct functions:

- “Given the purpose for requiring disclosure of an algorithm in special purpose computer implemented means-plus-function claims, we conclude that where, as here, a claim recites multiple identifiable functions and the specification discloses an algorithm for only one, or less than all, of those functions, we must analyze the disclosures as we do when no algorithm is disclosed.”

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PATENT LAW UPDATE
The key patent law issues and topics in 2012

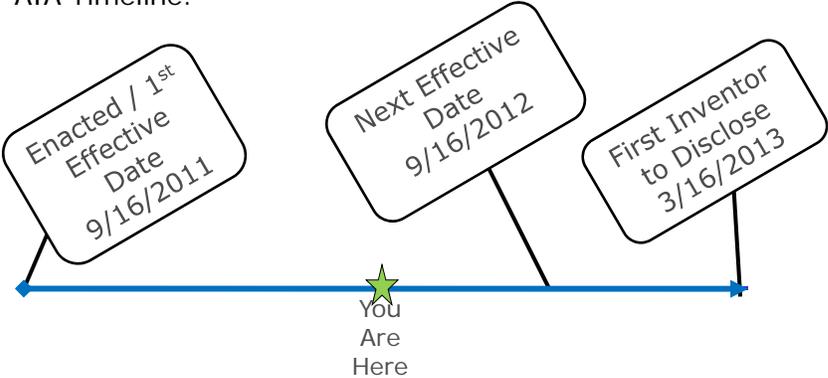


Overview of the America Invents Act (AIA)
Rajiv Patel

Fenwick
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Leahy-Smith America Invents Act

- Public Law No. 112-29 (H.R. 1249)
- Changes Title 35 of the U.S. Code and related statutes
- Effective date of changes varies by provision
- AIA Timeline:



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AIA Key Provisions
Effective September 16, 2011

- Elimination of best mode as a defense: applies to proceedings commenced on or after 9/16/2011
- Limitations on false marking lawsuits: applies to all cases pending on or commenced on or after 9/16/2011
- Virtual patent marking option: applies to any case pending on, or commenced on or after 9/16/2011
- New *Inter Partes* Reexamination

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AIA Key Provisions
Effective September 16, 2012

- Revisions to inventor's oath or declaration: applies to any patent application filed on or after 9/16/2012
- Expansion of right to submit prior art and statements regarding pending patent applications
- *Inter partes* review
- Supplemental examination

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**AIA Key Provisions
Effective March 16, 2013**

- First inventor to disclose
- Applies to any application where at least one claim has priority date on or after 3/16/2013
- Inventors will still have one year grace period for their own actions – unchanged
- Actions more than a year before the priority date are still prior art – also unchanged
- 3rd party actions less than a year before the priority date:
 - Old rules: can possibly avoid based on invention date (swear behind)
 - New rules: can possibly avoid based on public disclosure date (but remember that such a disclosure would bar foreign patents)
- Can initiate derivation proceedings

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**AIA Key Provisions
Effective March 16, 2013**

- Patent Challenges/Oppositions
 - Derivation Proceedings:
 - Applies to instances in which first inventor to file may have filed based on invention details derived from second inventor
 - In such instances, second inventor may initiate a “derivation proceeding”, i.e., ask the USPTO to change inventorship on application filed by first inventor so that second inventor is instead named as an inventor (and thus first inventor to file)
 - Post Grant Review:
 - Challenge validity on patent on any available grounds within 9 months of patent issuance
 - (See next section for more details)

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Post Grant Patent Oppositions Under the AIA

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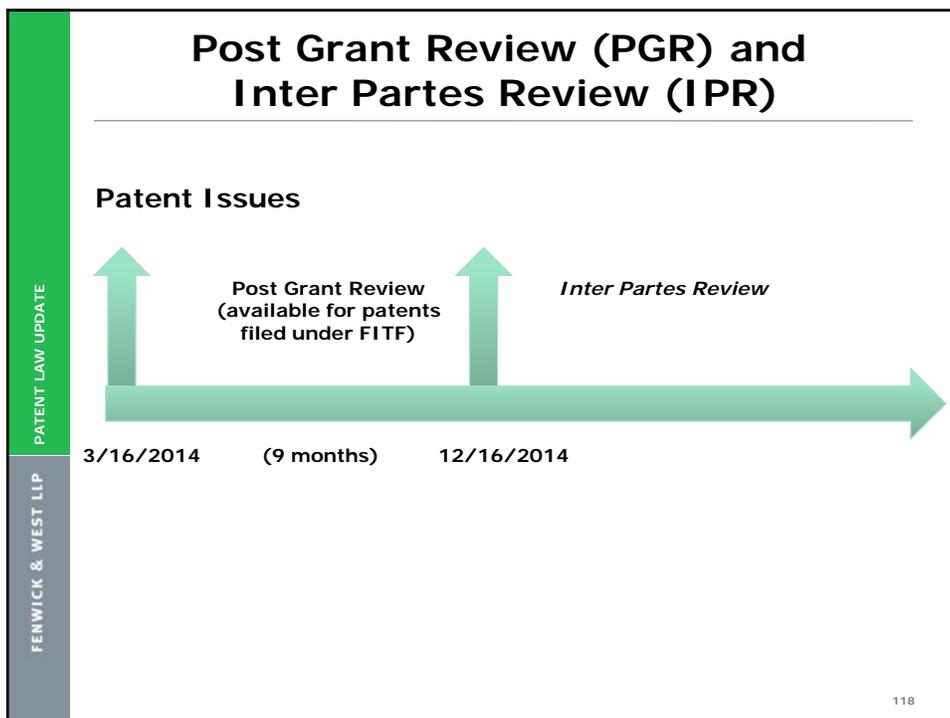
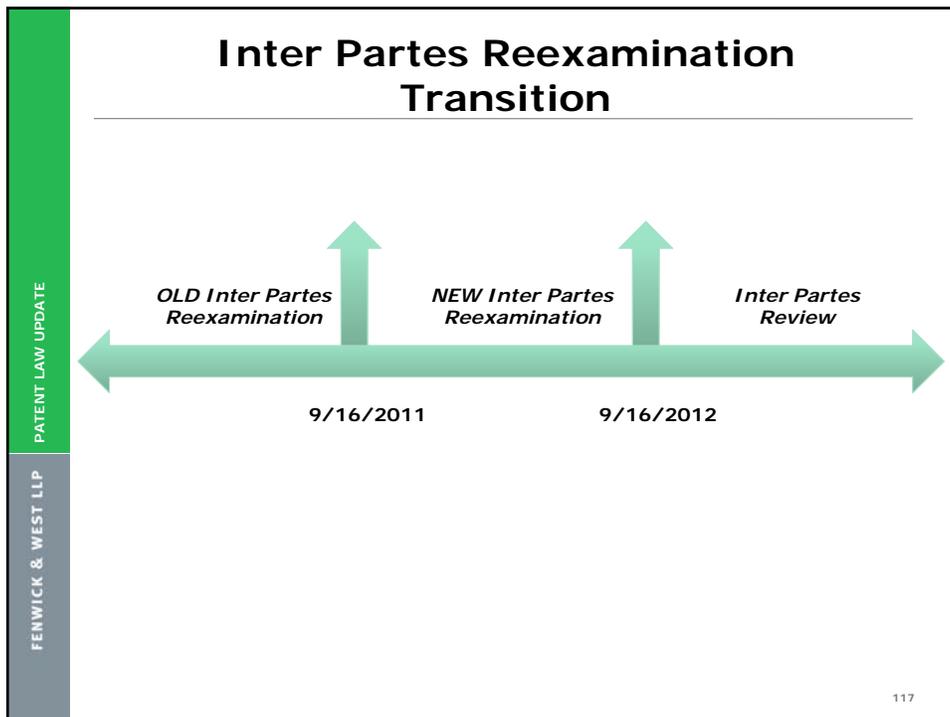
Post Grant Proceedings - Standards

Proceeding	Standard
Ex Parte Reexamination	SNQ (Substantial New Question of patentability)
Inter Partes Reexam – <i>until 9/16/2012, then replaced by Inter Partes Review</i>	Grant request if reasonable likelihood of prevailing on at least one challenged claim
Inter Partes Review – <i>effective 9/16/2012 (but 9 months after a issuance or date of when PGR period terminates)</i>	Grant petition if reasonable likelihood of prevailing on at least one challenged claim
Post Grant Review – <i>effective 9/16/2012, and only for patents with a filing date on or after 3/16/2013</i>	Grant petition if reasonable likelihood that at least one challenged claim is unpatentable or determination that petition raises a novel or unsettled important legal question important to other patents or patent applications

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		Post Grant Proceedings - Summary		
	Ex Parte Reexam	Post Grant Review (PGR)	Inter Partes Review	
Effective	Now	9/16/2012 for patents filed on/after 3/16/2013	9/16/2012 (9 months after a issuance or date of when PGR terminates)	
Threshold Standard	Substantial new question of patentability	Reasonable likelihood that Petitioner would prevail on a claim	Reasonable likelihood of prevailing on at least one challenged claim	
Challenge Basis	102/103 (printed prior art only)	101, 112, 102/103 (any)	102/103 based on printed prior art	
Discovery	None	Limited discovery	Limited discovery	
Duration	About 2-3 years	12-18 months (statute)	12-18 months (statute)	
Estoppel	n/a	Yes ("could have been raised")	Yes ("could have been raised")	
Settlement Effect	Does not stop proceeding	Stops proceeding	Stops proceeding	115

		Post Grant Proceedings v. Litigation			
	Ex Parte Reexam	PGR	IPR	Litigation	
Presumption of Validity	n/a	n/a	n/a	Yes	
Burden of Proof	Preponderance of Evidence	Preponderance of Evidence	Preponderance of Evidence	Clear and convincing evidence	
Claim Scope	Broadest reasonable meaning	Broadest reasonable meaning	Broadest reasonable meaning	Legal claim construction (e.g., <i>Phillips</i>)	
Basis for challenging patent	102/103 (printed refs)	101, 102/103 (not limited to printed prior art), 112	102/103 (printed refs)	Any basis	
Venue – Decision maker	Central Reexam Unit (CRU)	Patent Trial and Appeals Board (PTAB)	PTAB	District Court Judge/Jury	116



PATENT LAW UPDATE

Covered Business Method Patents



US000615270B1

(11) United States Patent
 Young et al.

(10) Patent No.: US 6,915,270 B1
 (45) Date of Patent: Jul. 5, 2005

(54) CUSTOMER RELATIONSHIP MANAGEMENT BUSINESS METHOD

(57) Abstract: *Business Method*, Richard H. (US); Cynthia Adams, Bryan, TX (US); Narda Enard, Corvallis, NC (US); Martha Ernst, Fairportville, OH (US); Harvey Thompson, Ridgefield, CT (US); May Sun Zhi, Becket, OH (US)

(71) Assignee: International Business Machines Corporation, Armonk, NY (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 479 days.

(21) Appl. No.: 08/723,519
 (22) Filed: Nov. 28, 2000
 (51) Int. Cl. G06F 17/00
 (52) U.S. Cl. 705/19
 (53) Field of Search 705/19

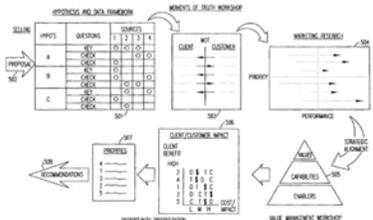
(56) References Cited
 U.S. PATENT DOCUMENTS
 4,843,361 A 8/1992 Cadote et al.
 5,241,072 A 8/1993 Ives
 5,124,051 A 6/1992 Park
 5,278,751 A 1/1994 Adams et al.
 5,174,800 A 8/1993 Lee et al.
 5,822,744 A 10/1998 Kuhl

5,963,001 A 10/1999 Ushack
 FOREIGN PATENT DOCUMENTS
 JP 2000-010000 A 3/2000
 OTHER PUBLICATIONS
 Goodwin et al. "Using the Loop on Loyalty." Marketing Management, vol. 8, No. 1, pp. 24-34, Spring 1999.*
 * cited by examiner

Primary Examiner—Antonio M. Diaz
 (70) Attorney, Agent, or Firm—Whitman, Curtis & Christensen, P.C.; Jay H. Anderson

(57) ABSTRACT
 A loyalty sales business method is described for building profitable customer relationships. The method is based on a combination of Customer Relationship Management (CRM), Business Intelligence (BI) and Customer Value Management (CVM). The structure of the method is based on an engagement model, followed by phases, activities, tasks, work products and technique papers. The Loyalty Sales approach takes a customer-oriented view and integrates CRM operational processes, customer collaboration toolkits and CRM analytical processes. This results in identification of factors which engender loyalty from a customer perspective. This then determines the enablers and capabilities needed by a client enterprise seeking to deliver customer value.

7 Claims, 15 Drawing Sheets



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PATENT LAW UPDATE

Section 18 – Transitional Program for Covered Business Method Patents

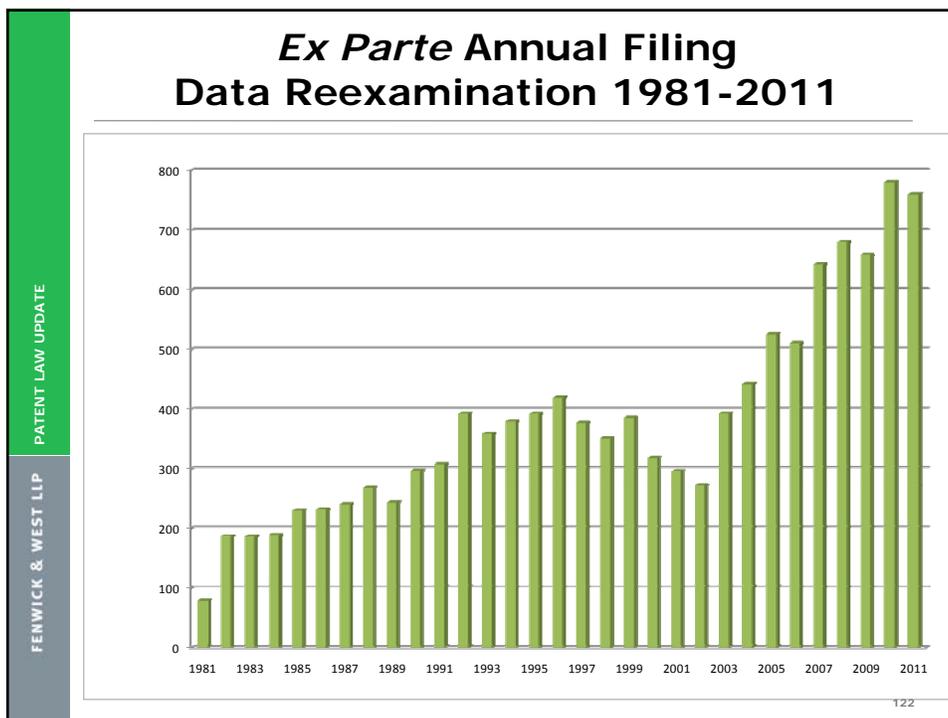
- PGR proceeding for review of validity of covered business method patents
- Applies to any business method patent regardless of issue date
- Can only be used if petitioner has been sued for infringement
- Limited window – 8 years (sunset in 2020)
- Fees/Rules – Same as PGR w/o time limit
- Petition – 70 pp limit
- Still “broadest reasonable interpretation”

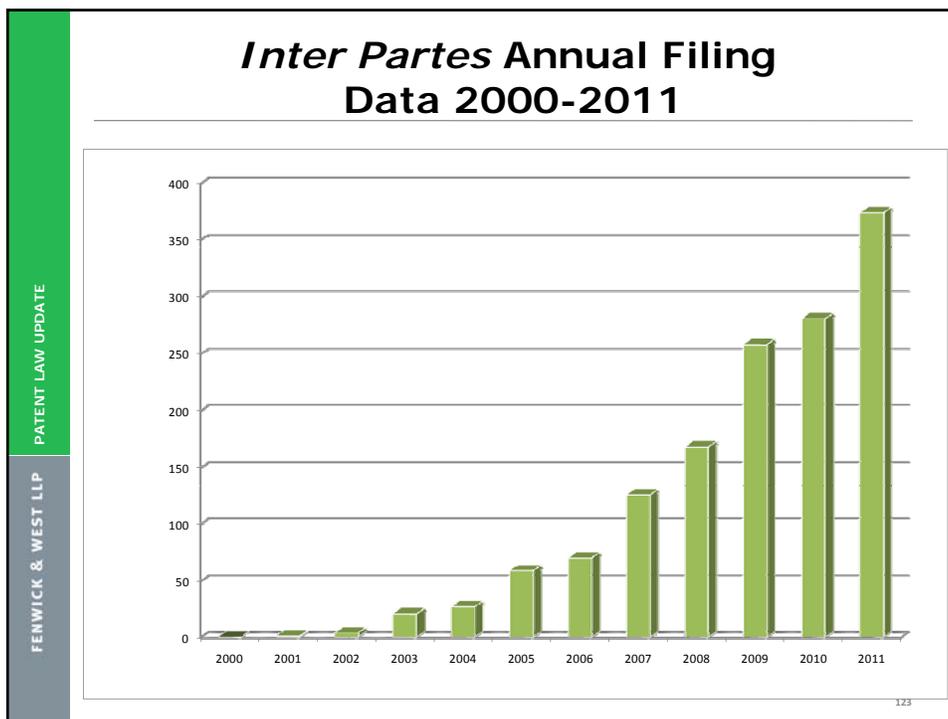
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**Covered Business Method Patents:
Proposed Rules**

- Definition of CBMP:
 - (a) Covered business method patent means a patent that claims a method or corresponding apparatus for performing data processing or other operations used in the practice, administration, or management of a financial product or service, except that the term does not include patents for technological inventions.

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Reexamination: What Art Units

Percentage of requests	Ex Parte	Inter Partes
Chemical	27%	18%
Electrical	37%	52%
Mechanical	34%	29%
Design	2%	1%

Source: U.S. PTO Filing Data as of September 30, 2011.
 Data on ex parte reexaminations is for 1981-2011. data on inter partes reexaminations is for 2000-2008.

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Reexamination: In Litigation		
Percentage of Requests	<i>Ex Parte</i>	<i>Inter Partes</i>
granted	92%	95%
known to be in litigation	33%	70%

Proceedings in which...	<i>Ex Parte</i>	<i>Inter Partes</i>
all claims confirmed	23%	11%
all claims cancelled	11%	44%
claim changes	66%	45%

Source: U.S. PTO Filing Data as of September 30, 2011.
 Data on *ex parte* reexaminations is for 1981-2011. data on *inter partes* reexaminations is for 2000-2008.

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Motions to Stay Pending Reexamination						
	2008		2009		2010	
Venue	Percentage Granted	Percentage Denied	Percentage Granted	Percentage Denied	Percentage Granted	Percentage Denied
N.D. Cal	70.59%	29.41%	86.67%	13.33%	71.43%	28.57%
C.D. Cal	28.57%	71.43%	53.85%	46.15%	77.78%	22.22%
Del	16.67%	83.33%	50.00%	50.00%	33.33%	66.67%
E.D. Tx	55.81%	44.19%	21.05%	78.95%	47.62%	52.28%
N.D. Tx	83.33%	16.67%	63.64%	36.36%	33.33%	66.67%
E.D. Wi	50.00%	50.00%	100.00%	0.00%	0.00%	100.00%
E.D. Va	0.00%	0.00%	0.00%	100.00%	66.67%	33.33%

Source: As compiled by Bijal Vakil, White & Case LLP

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Motions to Stay Pending Reexamination

Venue	2008			2009			2010		
	Granted	Denied	Total cases	Granted	Denied	Total cases	Granted	Denied	Total cases
N.D. Cal	12	5	170	13	2	168	15	6	206
C.D. Cal	4	10	201	7	6	276	14	4	236
Del	1	5	166	4	4	233	3	6	259
E.D. Tx	24	19	302	4	15	250	10	11	647
N.D. Tx	5	1	42	7	4	42	2	4	62
W.D. Tx	0	1	15	0	0	25	0	0	38
S.D. Tx	1	0	34	1	1	38	3	2	47
E.D. WI	1	1	24	2	0	26	0	2	20
W.D. WI	0	0	41	0	0	25	0	0	39
E.D. Va	0	0	63	0	3	58	6	3	65

Source: As compiled by Bijal Vakil, White & Case LLP

■ Data Sources

- Docket Navigator; Lexis Courtlink; James Pistorino, *Concentration of Patent Cases in Eastern District of Texas Increases in 2010*, 81 BNA Patent, Copyright & Trademark Journal 803 (2011)

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PATENT LAW UPDATE

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PATENT LAW UPDATE

The key patent law issues and topics in 2012



Forum and Discovery
 Darren Donnelly

Fenwick
 FENWICK & WEST LLP

Patent Litigation: Forum and Discovery Issues

- Forum — International Trade Commission
 - Domestic Industry Requirement
 - Importation
- Forum — Venue In District Court Litigation
 - Recent Venue Developments
 - (Non)Joinder under AIA and Fed.R.Civ.P. and its effects
- Discovery Developments

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Evolving Contours of ITC Forum

- Context: ITC sought as post-*eBay* forum for NPEs and other entities primarily litigating for licensing revenue to obtain threat of injunction-like remedy
- 2010 *Spansion* decision rejected that ITC should consider *eBay* factors when deciding to issue exclusion order or other remedy
- Recent decisions refine when it will be available as a forum
- Issues
 - Domestic Industry
 - Importation

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PATENT LAW UPDATE

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Enforcement Litigation Expense May Not Establish Domestic Industry — *PPC, Inc.*

- Section 337 requires that a domestic industry “relating to the articles protected by the patent . . . exists or is in the process of being established.” 19 U.S.C. § 1337(a)(2).
 - Significant investment in plant and equipment;
 - Significant employment of labor or capital; or
 - Substantial investment in its exploitation (engineering, R&D, licensing)
- What must a licensing entity do to establish a domestic industry?

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PATENT LAW UPDATE

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Enforcement Litigation Expense May Not Establish Domestic Industry — *PPC, Inc.*

- Expenses incurred on infringement litigation do not automatically establish domestic industry
 - Must be related to licensing and be substantial
 - Factors
 - Existence of licensing efforts before litigation
 - Remedy sought in litigation
 - Number of licenses
 - Existence of formal licensing program
- Reyna, dissenting-in-part, more open to litigation costs, in combination with other activities, sufficing
- Driving non-token licensing by NPEs before filing
- Domestic industry requirement for NPEs is an issue to watch

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FENWICK & WEST LLP	PATENT LAW UPDATE	<h2>Requirement Article Be “Infringing” at the Time of Importation — S3G</h2>
		<ul style="list-style-type: none">▪ Graphics encoding technology<ul style="list-style-type: none">▪ Only “data format” claims found infringed for certain devices▪ At the time of importation, no data encoded in the way found to infringe▪ HELD: Infringement (direct or indirect) must be based on the articles as imported to satisfy §337<ul style="list-style-type: none">▪ Not jurisdictional issue; question is importation▪ Statute proscribes “The importation into the United States . . . of articles that . . . <i>infringe</i> . . .”▪ On Appeal to CAFC▪ Important issue for mobile device and other C.E. companies▪ Watch for future litigation regarding indirectly “infringing” articles

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FENWICK & WEST LLP	PATENT LAW UPDATE	<h2>Venue Developments — Delaware Limited ?</h2>
		<ul style="list-style-type: none">▪ <i>In re Link_A Media Devices Corp. (LAMD)</i> (Fed. Cir., Dec. 2, 2011)<ul style="list-style-type: none">▪ LAMD (Del. corp. with HQ in N.D. Cal) sued by Marvell (Bermuda holding co. with inventors in N.D. Cal)▪ HELD: D. Del. erroneously denied transfer motion where the only reasons for not transferring the case were the defendant’s incorporation in the forum and the plaintiff decision to file suit there▪ Subsequent cases distinguishing <i>LAMD</i><ul style="list-style-type: none">▪ Stark (<i>Intellectual Ventures</i>), Andrews (<i>Investpic</i>), Bumb (<i>Tessera</i>): Plaintiff’s incorporation in Delaware▪ Robinson: Infringement in Del. (<i>Collectis</i>), (<i>Helicos Biosciences</i>) extended analysis<ul style="list-style-type: none">▪ “The court declines at this juncture to assign greater weight to the fugacious criterion of convenience than to, e.g., the historic privilege accorded plaintiffs in choosing their forum.”▪ Watch for further CAFC mandamus petitions

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(Non)Joinder of Accused Infringers and Its Effects

- For cases filed after September 15, 2011, accused infringers may be joined in one action as defendants under AIA only if:
 - (1) right to relief sought jointly, severally, or in the alternative respecting same transaction/occurrence and accused product
 - (2) questions of fact common to all defendants
 - Allegation of infringing same patent insufficient
- *In re EMC Corp.* (Fed. Cir. May 4, 2012) interprets Fed.R.Civ.P. 20 to nearly same effect

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(Non)Joinder — Effects

- Massively multi-defendant cases are gone at complaint stage; being revived at consolidation phase
- Increased effort for coordination among accused infringers
- Plaintiff may face limits on venue
 - Separately-sued defendants each better able to argue for transfer
 - Countervailing efforts for R. 42 consolidation
 - Some migration from Texas to D. Del. and C.D. Cal.
 - Case management burden on courts
- Multidistrict Litigation Panel (MDL) likely to see increased use
- Watch for discovery, claim construction, S.J., and trial management issues consolidated cases

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Chief Judge Rader — Model E- Discovery Order and Principles

- Patent cases “suffer from disproportionately high discovery expenses”
- “Blanket stipulated orders requiring the production of all relevant documents lead[] to waste”
 - No email collection unless specific email production requests are propounded for specific issues
 - Email production to be limited to five custodians
 - No metadata
- Eastern District of Texas adopts (significantly) modified version

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Discoverability of Settlement Communications — *In re* MSTG

- Discovery of settlement negotiations opposed via mandamus
 - Ordered after plaintiff’s expert’s opinions go beyond agreements to reasons for rates in them
- HELD: (1) Applying CAFC law, no settlement negotiation privilege;
- (2) negotiations may be discoverable
 - Abuse of discretion standard
 - Admissibility is a separate issue
- Effects are likely to be contentious in the near term

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Cases

- John Mezzalingua Associates, Inc. (d/b/a PPC, Inc.) v. International Trade Commission, 660 F. 3d 1322 (Fed. Cir. 2011)
- In Re Certain Electronic Devices with Image Processing Systems (S3 v. Apple), USITC Inv. No. 337-TA-724 (July 1, 2011)
- In re Link A Media Devices Corp., 662 F.3d 1221(Fed.Cir. 2011)
- Intellectual Ventures I LLC, et al. v. Altera Corporation, et al., Civ. No.10-1065-LPS (D.Del. January 23, 2012)
- Investpic, LLC v. SAS Institute, Inc., Civ.No. 10-1028-RGA (D.Del. May 15, 2012)
- Tessera, Inc. v. Sony Electronics Inc., et al, Civ. No. 10-838-RMB (D.Del. Mar. 30, 2012)
- Collectis S.A. v. Precision Biosciences Inc., Civ. No. 11-173-SLR (D.Del. May 3, 2012)
- Helicos Biosciences Corporation v. Illumina, Inc., et al., Civ. No. 10-735-SLR (D.Del. May 3, 2012)
- In re EMC Corp., Misc. no. 100 (Fed. Cir. May 4, 2012)
- Discovery order and speech (available at <http://www.fedcirbar.org/olc/pub/LVFC/cpages/homepage/homepage.jsp>)
- E.D. Texas order and commentary (http://www.txed.uscourts.gov/cgi-bin/view_document.cgi?document=22223&download=true)
- In re MTSG Inc., Misc no. 996 (Fed. Cir. April 9, 2012)

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PATENT LAW UPDATE

The key patent law issues and topics in 2012



Patent Law and Ethics in 2011
Ewa Davison and Melanie Mayer

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Inequitable Conduct

Therasense, Inc. v. Becton, Dickinson & Co.

Ewa Davison

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Inequitable Conduct Prior to *Therasense*

- Inequitable conduct:
 - An equitable defense to patent infringement arising from Supreme Court unclean hands cases
 - Renders the entire patent (and possibly related patents) unenforceable
- Standard:
 - Must prove by clear and convincing evidence:
 - that patent applicant misrepresented or omitted material information
 - with the specific intent to deceive the PTO
 - Court decides if equities warrant rendering patent unenforceable

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Standards for Materiality

- “Reasonable Examiner”
 - Reference is material if there is a substantial likelihood that a reasonable examiner would consider it important in deciding whether to issue a patent
- PTO Rule 56
 - Reference is material if it establishes a prima facie case of unpatentability, by itself or in combination with other information, OR
 - It refutes or is inconsistent with applicant’s arguments to PTO regarding patentability

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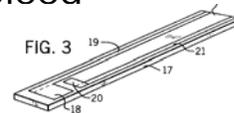
Standards for Intent

- Specific intent to deceive PTO
- *Kingsdown* (1988): CAFC’s first attempt to crack down on inequitable conduct cases
 - raised intent standard — gross negligence insufficient
- Whittling away at *Kingsdown*:
 - sliding scale: if clear and convincing evidence exists of both materiality and intent, then these two factors can be balanced
 - “should have known”

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Therasense: Background

- Abbott alleged that BD infringed the '551 patent
- Claims directed to disposable blood glucose test strips for diabetes management
 - Electrical current generated when blood glucose reacts with enzyme on strip
- 13+ year prosecution
- Repeated rejections based on '382 Patent



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Therasense: Background

- Strategy — add key limitation
 - "active electrode...exposed [to whole blood] *without an intervening membrane*"
- Prior art used membranes with whole blood:
 - to prevent blood cells from fouling electrode
 - to slow glucose flow to electrode
- '382 Patent:
 - "*optionally, but preferably, when being used on live blood, a protective membrane surrounds*"

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Therasense: Background

- To overcome rejection based on '382 patent, Examiner requests declaration that prior art required membrane for whole blood
 - Declaration (Abbott's R&D Director):
 - (1) One skilled in the art at the time would think a protective membrane was required;
 - (2) Would not understand '382 patent to teach that use of protective membrane is optional with whole blood
 - Argument (Abbott's patent attorney):
"Mere patent phraseology"

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Therasense: Background

- Earlier position in European Patent Office (EPO) proceedings re: '382 specification

"It is submitted that this disclosure is *unequivocally clear*. The protective membrane is *optional*, however, it is preferred when used on live blood"

- Not submitted to PTO

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**Therasense:
Changing the Standard for Materiality**

- District court finds patent unenforceable
 - Arguments to EPO were material and inconsistent with arguments for patentability
 - '382 patent also invalidated claims
- Federal Circuit panel affirms with J. Linn dissenting
- *En banc* Federal Circuit creates new standard of materiality and clarifies intent
 - Concurring and dissenting opinions
 - Vacates and remands

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**CAFC Characterizes
Inequitable Conduct as a "Plague"**

- Litigation tactic:
 - 80% of patent infringement cases allege inequitable conduct
 - "Atomic bomb of patent law": unenforceability of patent, cannot be cured by reissue, can taint entire family, "exceptional case"
 - Expands discovery, paints patentee as "bad actor"
 - Discourages settlement, increases litigation cost and complexity
- Patent prosecution:
 - Encourages prosecutors to "bury" PTO in prior art references
 - Strains PTO resources, increases PTO backlog

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Held: Higher Standard of Materiality

- “This court holds that, as a general matter, the materiality required to establish inequitable conduct is **but-for materiality**.”
- Exception for “**affirmative acts of egregious misconduct**.”

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Held: “But-for” Standard of Materiality

- Non-disclosure of prior art to the PTO
 - Material if the PTO would not have allowed a claim but for the non-disclosure
 - Patentee obtains no advantage from misconduct if patent would have issued anyway.
 - Court applies preponderance of evidence standard
 - Claims must be given broadest reasonable construction
 - Finding of invalidity is a sufficient but not necessary condition

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Held: Exception for “affirmative Acts of Egregious Misconduct”

- Incorporates holdings from Supreme Court unclean hands cases
 - “deliberately planned and carefully executed scheme[s] to defraud PTO and the courts”
- Example:
 - Filing of an unmistakably false affidavit
- Failure to disclose information still requires “but-for” materiality
 - Non-disclosure of prior art references
 - Failure to mention prior art references in affidavit

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Held: Specific Intent to Deceive PTO Standard

- Clear and convincing evidence that applicant:
 - (1) Knew of the withheld reference,
 - (2) Knew that it was material, and
 - (3) Made a deliberate decision to withhold it
- Separate requirement from materiality
 - District court should not use a “sliding scale”
- May infer from indirect and circumstantial evidence
 - Must be the single most reasonable inference
 - May not be found if multiple reasonable inferences
- Patentee need not offer any good faith explanation unless challenger first makes clear and convincing threshold showing

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O'Malley — Equitable Doctrine Requires Permitting More Flexible Standard

- Dissents from materiality standard
 - Equitable nature of doctrine demands flexibility
 - Concerned some unforeseen type of intentional misconduct may warrant equitable relief but be outside of rigid rules
 - Would allow district court discretion on remedy — patent unenforceability not required
- Material where:
 - but for the conduct the patent would not have issued; or
 - the conduct constitutes a false or misleading representation of fact; or
 - the district court finds that the behavior is so offensive that the court is left with a firm conviction that the integrity of the PTO process as to the application at issue was wholly undermined
- Generally concurs with majority intent holdings

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Dissenters Argue for PTO Rule 56

- Bryson (joined by Gajarsa, Dyk, & Prost) would adopt Rule 56 materiality standard:
 - Court split because of (1) deference to PTO position and (2) belief majority's standard will undermine disclosure incentives
 - View "but for" materiality as too restrictive
 - Example: no incentive to disclose information that would result in rejection of application – no patent if disclose versus unenforceable patent if discovered
 - Doctrine can be fixed through consistent implementation:
 - Clear-and-convincing standard, no sliding scale
 - Rule 9 pleading standard, Rule 11 sanctions

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PTO Proposed Rulemaking

- PTO announced proposed new Rule 56(b) materiality standard to match *Therasense*:
 - (1) The Office would not allow a claim if it were aware of the information applying appropriate standards; or
 - (2) The applicant engages in affirmative egregious misconduct before the Office as to the information
- Contradictory?

“The Office . . . expects that patent applicants are inclined to be forthcoming and submit information beyond that required by proposed Rule 56, in an effort to assist examiners in performing their duties.”
- “[T]he Office is considering further actions that may provide an incentive for applicants to assist the Office by explaining/clarifying the relationship of prior art to the claimed invention.”

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Conclusions and Implications: Patent Litigation

- Materiality:
 - Key role of invalidity analysis in determining materiality of undisclosed art
 - Two claim constructions?
 - *Markman* for infringement, validity
 - *Therasense* (broadest reasonable construction) for inequitable conduct
 - Scope of “affirmative acts of egregious misconduct” exception

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Conclusions and Implications : Patent Litigation

- Intent
 - Pleading stage — tension between particularity requirement of *Exergen* and burden under *Therasense* standard
 - Facts and credibility crucial:
 - Is intent to deceive the “single most reasonable inference” from all the evidence?
 - Is good faith explanation sufficient?

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CAFC Post-*Therasense*

	District Court	Federal Circuit	Materiality	Intent
<i>Am. Calcar, Inc. v. Am. Honda Motor Co.</i>	IC	Vacated	• Ref1 material because verdict of anticipation not appealed • Ref2 remanded b/c district court used reasonable examiner	Remanded b/c district court used sliding scale analysis
<i>Aventis Pharma S.A. v. Hospira, Inc.</i>	IC	Affirmed	Yes: affirmed finding that withheld prior art invalidated asserted patents	Yes: based on district court's assessment of facts / credibility in rejecting good faith explanation

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		CAFC Post-<i>Therasense</i>			
		District Court	Federal Circuit	Materiality	Intent
FENWICK & WEST LLP PATENT LAW UPDATE	<i>Cordis Corp. v. Boston Sci. Corp.</i>	No IC	Affirmed	n/a	No: based on district court's assessment of facts / credibility in accepting good faith explanation
	<i>Powell v. Home Depot U.S.A.</i>	No IC	Affirmed	No: failure to inform PTO that circumstances supporting a Petition to Make Special no longer existed	n/a
	<i>August Tech. Corp. v. Camtek, Ltd.</i>	No IC	Affirmed	No: undisclosed reference lacked claim element that was also not provided by other prior art	n/a

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- ### Conclusions and Implications: Patent Prosecution
- Effects on PTO practice to be determined:
 - Disclosure or Analysis?
 - Continued flood of prior art — cheaper, avoids “but for” materiality finding in case of litigation
 - Careful analysis of prior art and limited submission to PTO could allow for more meaningful examination
 - Dissent: no incentive to disclose information that would result in rejection of application
 - Practitioners should revisit “but-for” materiality of a withheld reference at or near close of prosecution
 - Declarations under §131 and §132 warrant heightened attention
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Therasense on Remand: District Court Again Finds Inequitable Conduct

- But-for materiality:
 - Patentability based on assertion that '551 patent for first time revealed that protective membrane was unnecessary
 - '382 patent said such membrane was "optional[], but preferabl[e]"
 - PTO-required declaration: skilled artisan would have understood that membrane was "required"
 - Declaration expressly contradicted by previous EPO brief that membrane was optional
 - Examiner would not have allowed '551 patent

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Therasense on Remand: District Court Again Finds Inequitable Conduct

- Specific intent to deceive PTO:
 - Threshold:
 - Declarant, prosecuting attorney knew of EPO brief
 - Made conscious decision not to disclose to PTO
 - Knew that disclosure of the EPO argument would lead to patent rejection — analysis based on materiality of non-disclosed information
 - Intent to deceive = single most reasonable inference
 - Patentee explanation not convincing:
 - "lacked sufficient coherence and consistency compared to the rest of the record"
 - "not one shred of documentary evidence to corroborate their testimony"

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Document Retention

Melanie Mayer

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2011 Federal Circuit *Rambus* Cases

- Two related cases:
 - *Micron Tech., Inc. v. Rambus Inc.*, 645 F.3d 1311 (Fed. Cir. 2011) ("*Micron*")
 - *Hynix Semiconductor Inc. v. Rambus Inc.*, 645 F.3d 1336 (Fed. Cir. 2011) ("*Hynix*")
- Federal Circuit clarifies when litigation is "reasonably foreseeable" for purposes of spoliation
- Federal Circuit also weighs in on piercing of attorney-client privilege

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Spoliation

- “[S]poliation refers to the destruction or material alteration of evidence or to the failure to preserve property for another’s use as evidence in pending or **reasonably foreseeable litigation.**”

- *Micron* at 1320 (quoting *Silvestri v. General Motors Corp.*, 271 F.3d 583, 590 (4th Cir. 2001).

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Technology

- Two related types of dynamic random access memory (“DRAM”)
 - Rambus DRAM (“RDRAM”)
 - Synchronous DRAM (“SDRAM”)
- Rambus believed its U.S. patent applications were broad enough to cover not only RDRAM, but also SDRAM

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Rambus' Business Strategy

- Rambus employed a two-prong business strategy:
 - License chip makers to make chips that complied with RDRAM stds;
 - Prepare to demand license fees and to potentially bring infringement suits against those manufacturers who adopted the competing SDRAM std.

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Timeline

- ~ 1992: developed strategy of demanding license fees & litigation damages for SDRAM
- Feb. 1998: need to get "battle-ready"
- March 1998: presentation to Board proposing litigation strategy
- July 1998: new document retention policy presented to employees; employees told to keep documents establishing a conception date; erased 1,268 email backup tapes and kept 1 relating to priority date
- August/Sept. 1998: hired outside counsel to prepare for litigation

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Timeline

- Sept. 1998: held first shred day – 400 boxes
- April 1999: instructs outside patent counsel to discard non-official documents from files
- June 1999: first patent-in-suit issued
 - Two days later CEO requests that first licensing or litigation target be identified
- July 1999: timeline shows litigation in Oct. 1999
- Aug. 1999: held second shred day – 300 boxes
 - No record of specific documents, but related to contract and licensing negotiations, patent prosecution, JEDEC participation, Board meetings and finances
- Dec. 1999: litigation hold implemented
- Jan. 2000: Rambus filed suit against Hitachi

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CAFC Presented with Two Conflicting Rulings

- *Hynix* case – Northern District of California found no spoliation:

“[T]he path to litigation was neither clear nor immediate. Although Rambus began to plan a litigation strategy as part of its licensing strategy as early as February 1998, the institution of litigation could not be said to be reasonably probable because several contingencies had to occur before Rambus would engage in litigation...”

- *Hynix Semiconductor Inc. v. Rambus Inc.*, 591 F. Supp. 2d 1038, 1062 (N.D. Cal. 2006)

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CAFC Presented with Two Conflicting Rulings

- *Micron* case – District of Delaware held Rambus' patents unenforceable due to spoliation

“The court concludes that litigation was reasonably foreseeable no later than December 1998, when Karp had articulated a time frame and a motive for implementation of the Rambus litigation strategy.... Therefore, a duty to preserve potentially relevant evidence arose in December 1998 and any documents purged from that time forward are deemed to have been intentionally destroyed, i.e., destroyed in bad faith.”

- *Micron Tech., Inc. v. Rambus Inc.*, 255 F.R.D. 135, 150 (D. Del. 2009)

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Federal Circuit Holdings in *Rambus* Cases

- *Micron*
 - District Court: litigation reasonably foreseeable as of December 1998; case dismissed due to spoliation
 - Federal Circuit: affirms district court's finding of spoliation; litigation was reasonably foreseeable at least as of second shred day in August 1999
- *Hynix*
 - District Court: litigation not reasonably foreseeable on shred days due to contingencies; no spoliation
 - Federal Circuit: district court applied wrong standard (requiring litigation be imminent or probable without significant contingencies); “litigation was reasonably foreseeable prior to Rambus's Second Shred Day”

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Litigation Can Be Reasonably Foreseeable Even if Contingencies Exist

- The reasonable foreseeability standard “is not so inflexible as to require that litigation be ‘imminent, or probable without significant contingencies.’” *Micron* at 1320.
- “Contingencies whose resolutions are reasonably foreseeable do not foreclose a conclusion that litigation is reasonably foreseeable.” *Hynix* at 1346.

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Contingencies Cited by the Northern District of California and Rambus

- (1) the direct RDRAM ramp had to be sufficiently developed so as not to jeopardize RDRAM production
- (2) Rambus’ patents covering non-RDRAM technology had to issue
- (3) product samples from potentially infringing DRAM manufacturers had to be available in the market
- (4) the noncompatible products had to be reverse engineered and claim charts made showing coverage of the actual products
- (5) Rambus’ Board had to approve commencement of negotiations with a DRAM manufacturer
- (6) the targeted DRAM manufacturer had to reject Rambus’ licensing terms

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Guidance Offered by the Federal Circuit

- Knowledge of actual infringement increases foreseeability
 - “While it may not be enough to have a target in sight that the patentee believes may infringe, the **knowledge of likely infringing activity** by particular parties **makes litigation more objectively likely to occur** because the patentee is then more likely to bring suit.” *Micron* at 1323.

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Guidance Offered by the Federal Circuit

- Federal Circuit noted that steps taken by Rambus in furtherance of litigation suggested reasonable foreseeability
 - “Rambus concluded that it would ‘need to litigate against someone to establish [a] royalty rate and have [the] court declare [the Rambus] patent[s] valid’”
 - Evaluated forums and prioritized targets
 - Prepared claim charts and determined an expected timeline for litigation

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Guidance Offered by the Federal Circuit

- “In general, when parties have a business relationship that is mutually beneficial and that ultimately turns sour, sparking litigation, the litigation will generally be less foreseeable than would litigation resulting from a relationship that is not mutually beneficial or is naturally adversarial.” *Micron* at 1325.
- Rambus had no mutually beneficial relationship with manufacturers re SDRAM; relationship re RDRAM did not make litigation significantly less likely

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Document Destruction Policies Are Legitimate

- “[W]here a party has a long-standing policy of destruction of documents on a regular schedule, with that policy motivated by general business needs, which may include a general concern for the possibility of litigation, destruction that occurs in line with the policy is relatively unlikely to be seen as spoliation.” *Micron* at 1322.

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Piercing of Attorney-Client Privilege

- Federal Circuit pierced Rambus' attorney-client privilege based on crime-fraud exception
 - California Penal Code § 135 bars destruction of documents "about to be produced in evidence"
 - Documents were "about to be produced" in *Hitachi* litigation
 - Time frame between destruction of documents and Rambus filing suit against Hitachi was within Rambus' control
 - Rambus began destroying documents based on communications with counsel

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Thank you for attending!

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Highlights of the America Invents Act (AIA): An Executive Summary of the New Patent Law

Rajiv P. Patel, Partner, IP/Patent Group, Fenwick & West LLP

The American Invents Act (AIA) was signed into law on September 16, 2011. It is the first significant amendment to U.S. Patent Law since 1999, and possibly since 1952. The Act changes the structure in which a patent protection may be procured and how issued patents may be challenged.

The chart below highlights some of the key provisions of this act from a Patent Procurement and Portfolio Development (activities before the U.S. Patent and Trademark Office) perspective and a Patent Challenges (including patent litigation and reexamination) perspective of this Act. The chart highlights key provisions of the AIA, notes the effective date of the particular provision, and provides insights on potential impact of the provision.

Patent Procurement and Portfolio Development: Before the U.S. Patent and Trademark Office

Provision of AIA	Statute 35 U.S.C.	Effective Date	Impact and Other Notes
<u>First Inventor To File</u>			
<p>The U.S. patent system is moving from a first inventor to invent system to a first inventor to file system. In this system, it no longer matters as to who first invented the invention, but rather who first filed for patent protection.</p> <p>Unlike true first to file systems found in jurisdictions outside the U.S., the U.S. first inventor to file system is more of a first to disclose system. Specifically, the new law provides that the first inventor to publicly disclose their invention is permitted a one year period in which to file for patent protection and not have that public disclosure asserted as prior art against their filed application.</p>	§102; §103	March 16, 2013	<p>A primary impact of this provision will be removing flexibility on timing of patent preparation and filing as well as when costs can be incurred.</p> <p>Under the old law, an inventor had a one year grace period after any public disclosure in which to prepare and file a patent application. Hence, if a current quarterly budget did not allow for preparation and filing of patent application to be publicly disclosed within the quarter, it could be pushed into another quarter. Under the new law, this would result in a potential loss of patent rights.</p>
<u>Prioritizing Patent Application Examination</u>			

Provision of AIA	Statute 35 U.S.C.	Effective Date	Impact and Other Notes
<p>The AIA allows an applicant to request prioritization of an application for products, processes, or technologies important to the U.S. economy or U.S. competitiveness.</p> <p>The AIA also allows for prioritized examination of a patent application. Under this provision, for a fee of \$4,800, examination of a patent application can be accelerated by being placed higher within a prioritization queue at the U.S. Patent and Trademark Office.</p>	§2(b)(2)	September 26, 2011	<p>Once rules are promulgated for requesting prioritization, the impact for using this provision is expected to increase filing costs as certain aspects of the rules would have to be satisfied in order for the request to be considered by the U.S. Patent and Trademark Office.</p> <p>For the fee based prioritization, the cost impact of this provision is an additional fee of \$4,800 per application in addition to any patent application preparation and filing fees.</p>
<u>Supplemental Examination</u>			
<p>Supplemental examination allows a patent holder to request examination of a patent to consider, reconsider, or correct information believed to be relevant to the patent. The idea behind this provision is to give a patent holder an opportunity to correct issues involving initial examination of the patent. An example of when this provision may be used is a patent holder having the U.S. Patent and Trademark Office review a reference that perhaps should have been submitted in an initial examination; once considered by the U.S. Patent and Trademark Office, it may eliminate an issue of inequitable conduct counterclaim in a subsequent litigation.</p>	§257	September 16, 2012	<p>The impact of this provision is one or more potential initial rounds of examination. The process used for evaluating the information will be similar to ex parte reexamination – i.e., is there a substantial new question of patentability raised by the one or more items of the information in the request.</p>
<u>Patent Fees Increase</u>			
<p>The AIA increases patent fees by 15% (or more) for everything from application filing fees, petition fees, and maintenance fees.</p>		September 26, 2011	<p>Two immediately felt cost impacts of this provision is a 15% increase in filing costs and maintenance fee costs. The total impact can be fairly significant for a</p>

Provision of AIA	Statute 35 U.S.C.	Effective Date	Impact and Other Notes
			company having a patent portfolio that number hundreds of patent assets.
Virtual Marking			
Once a patent is issued a patent holder has the option of either physically marking the product (same as old law) or affixing an internet address that associates the patented article with a patent number.	§287(a)	Sept. 16, 2011	This provision is likely to provide a cost savings because products with expiring patent numbers do not have to be retooled or redesigned to include patent numbers.

Patent Challenges: Patent Litigation and Reexamination

Provision of AIA	Statute 35 U.S.C.	Effective Date	Impact and Other Notes
<u>Derivation Proceedings</u>			
There may be instances in which a first inventor to file may have filed based on invention details derived from a second inventor. In such instances, the second inventor may initiate a “derivation proceeding” in which they can ask the U.S. Patent and Trademark Office to change inventorship on the application filed by the first inventor so that the second inventor is instead named as an inventor (and thus first inventor to file).	§135; §291	March 16, 2013	This provision of the law had no prior corollary under the old law. Hence, the impact of this provision is not yet known, but is anticipated to potentially increase costs from a few thousand to many thousands of dollars based on the contentiousness of the proceedings.
<u>Post-Grant Review</u>			
Post-Grant Review allows a third-party may seek to	§§321-	March 16,	One potential cost impact may include monitoring

Provision of AIA	Statute 35 U.S.C.	Effective Date	Impact and Other Notes
cancel one or more claims of a patent. The challenge must be brought within 9 months after a patent issued (or reissued). The challenge can be lack of novelty, obviousness, indefiniteness, or lacking support in specification. The basis for challenge can be other patents, printed publications, affidavits, or declarations, e.g., of expert witness.	329	2013* (September 16, 2012)	patent activity of particular companies or inventors to identify when particular patents are issued or reissued. There will be cost impact for companies that focus on prior art searching and analysis and/or expert witness analysis to determine whether to bring a challenge and on what grounds. Thereafter, the costs impact will turn to preparing and filing the challenge. *Note that this provision is noted to take effect on September 16, 2012; however, it only applies to patents based on first to file applications, which are not filed until March 16, 2013. Hence, practically this provision may not be effective until sometime after March 16, 2013, when such first to file applications begin to issue.
<u>Inter Partes Review</u>			
Inter Partes Review is similar to inter partes reexamination, which is being phased out. Inter Partes Review allows a third-party may seek to cancel one or more claims of a patent. Inter partes review can be asserted 9 months after a patent issues (or reissues) or the date of when Post-Grant Review terminates. The challenge can be lack of novelty or obviousness only and the basis for challenge only can be other patents or printed publications.	§§311-318	September 16, 2012	A cost impact here will focus on prior art searching and analysis to determine whether to bring a challenge and on what basis. Thereafter, the costs impact will turn to preparing and filing the challenge.
<u>Prior User Rights Defense</u>			
A defense to infringement now includes an accused infringer's own prior commercial use in the U.S. of	§273	September	A cost impact here will correspond to investigating and maintaining accurate recordkeeping of the prior

Provision of AIA	Statute 35 U.S.C.	Effective Date	Impact and Other Notes
the subject matter claimed in a patent. This provision applies to any patent issued on or after September 16, 2011.		16, 2011	commercial use in the U.S.
<u>Review of Business-Method Patents</u>			
There will be a separate set of rules promulgated for review of business method patents. Only a party sued or charged with infringement by a patent holder may request this review.		September 16, 2011	This provision may reduce the costs associated with challenging the validity of business method patents by using an administrative process rather than a judicial process.
<u>Best Mode Requirement</u>			
The AIA continues to require an applicant for a patent to disclose the best mode known at filing of the application to carry out the invention. However, if an applicant fails to do so, under the AIA this cannot be the basis for invalidity or unenforceability.	§282	Sept. 16, 2011	A cost impact here will be negligible here for preparation of applications. However, for litigation, the potential for cost savings could be high due to possible reduced discovery burdens.
<u>Advice of Counsel in Willfulness Allegations</u>			
The AIA now includes a specific provision that states that a failure to obtain advice of counsel may not be used to prove willful infringement.	§298	September 16, 2012	This provision may help to reduce costs with respect to necessarily having to obtain an opinion of counsel for each instance in which willfulness allegations could arise.
<u>False Marking</u>			
Allows only for the U.S. government to sue for penalties associated with false marking of a patented article. A third party may sue for damages due to false marking if that party has suffered a competitive injury. Also, it is no longer a false marking penalty when products are marked with a patent number that	§287	September 16, 2011	There appears to be no cost impact here, and likely a cost savings here because products with expiring patent numbers do not have to be retooled or redesigned to remove expired patent numbers.

Highlights of the America Invents Act: An Executive Summary of the New Patent Law (Rajiv Patel)

Provision of AIA	Statute 35 U.S.C.	Effective Date	Impact and Other Notes
previously covered the product, but which patent has since expired.			

Patent Litigation Alert

Federal Circuit Issues *En Banc* Decision in *Marine Polymer*:
No Reexamination Intervening Rights Absent Textual Amendment to
Claim Language

HEATHER N. MEWES, RAJIV P. PATEL AND BETSY WHITE

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Should intervening rights apply to claims that were not textually amended during a reexamination proceeding but were effectively narrowed by the patentee's arguments? Following a controversial panel decision last September in *Marine Polymer Technologies, Inc. v. Hemcon, Inc.* that expanded intervening rights for reexamination, an *en banc* Federal Circuit on March 15 ruled that intervening rights only apply if claim language is substantively amended or new claims are added. In a closely divided 6-4 ruling, the court specifically rejected the original panel's determination that intervening rights can arise as a result of the patentee's statements to the U.S. Patent and Trademark Office ("PTO") during reexamination that effectively limit the claim but do not result in an amendment to the claim language.

Marine Polymer sued HemCon, alleging that HemCon infringed certain claims of U.S. Patent No. 6,864,245 (the '245 patent), which claims a biocompatible polymer p-GlcNAc that accelerates hemostasis and is useful in trauma units for treating serious wounds. A central issue during the district court's claim construction proceedings, which would ultimately be the focus of the appeal, was the interpretation of the term "biocompatible" in an asserted independent claim of the '245 patent. The district court construed the term to mean "polymers . . . with low variability, high purity, and *no detectable biological reactivity* as determined by biocompatibility tests" (emphasis added). Applying this construction, the district court granted summary judgment of literal infringement of all seven asserted claims, relying on expert evidence that biocompatibility tests of HemCon's accused products had shown "no detectable biological reactivity." At trial, the jury upheld the validity of the '245 patent and found that Marine Polymer was entitled to a reasonable royalty of approximately 88% of HemCon's profits. The district court entered final judgment in September 2010, granting reasonable royalty damages for the past infringement in the amount of \$29,410,246 and issuing a permanent injunction barring future infringement of the asserted claims of the '245 patent.

During the district court proceedings, HemCon requested reexamination of the '245 patent. In reexamination, the examiner initially adopted a different claim construction than the district court, finding that "biocompatible" meant "low variability, high purity, and *little or no detectable reactivity*" (emphasis added). The examiner argued that the court's construction was inconsistent with several dependent claims of the '245 patent that required biocompatibility test result scores of zero, one, or two on a five-point scale. Applying this broader construction, the examiner issued a preliminary rejection of all the claims of the '245 patent as invalid in light of the prior art. In response, Marine Polymer argued for an adoption of the district court's interpretation of the term "biocompatible," and it cancelled the six original dependent claims that had specifically required a test score of one or two (i.e., that required at least some reactivity). The examiner approved the claims as amended, and in March 2011, the PTO issued a reexamination certificate cancelling dependent claims 4, 5, 13, 14, 21, and 22.

Following the issuance of the reexamination certificate, HemCon appealed the district court's final judgment to the Federal Circuit, arguing that the scope of the claims of the '245 patent had been substantively narrowed during reexamination and that it was therefore entitled to absolute and equitable intervening rights under 35 U.S.C. §§ 252 and 307, which provide an accused infringer the right to use or sell specific products made, used, or purchased before the grant of the reexamined patent. In a 2-1 decision by the three-judge panel in September 2011, the majority agreed with HemCon, finding that intervening rights should apply in light of Marine Polymer's arguments to the PTO during reexamination, which it argued had substantively narrowed the construction of "biocompatibility" even though the language of the asserted independent claim had not ultimately changed.

The panel majority reasoned that if a patentee is able through argument to preserve the validity of its patent over prior art during reexamination by narrowing the scope of the claims, those same arguments should give rise to intervening rights even if the actual language of the claims is not amended. In a dissenting opinion, Judge Lourie argued that under the plain language of the relevant statute, 35 U.S.C. § 307(b), an amendment or claim addition was a threshold requirement for considering whether claim scope has changed for purposes of an intervening rights analysis.

On January 20, 2012, the full Federal Circuit decided to hear this case *en banc* and ordered that the original panel decision be vacated and the appeal reinstated. In a March 15, 2012 *en banc* decision, a 6-4 majority of the full Court held that the rule of reexamination intervening rights articulated in the earlier panel decision was wrong. Citing the “plain and unambiguous” statutory language of 35 U.S.C. § 307(b), the Court held that regardless of any arguments made by the patentee during reexamination, intervening rights will not apply unless the reexamination resulted in a textual change to the language of the claims. The dissent, conceding that “not every argument during reexamination should give rise to intervening rights,” argued that intervening rights should be available at least where “an argument during reexamination rises to the level of a clear and unambiguous disclaimer or disavowal of the original, correct claim construction.”

The Federal Circuit’s decision to reject the panel’s ruling in favor of the status quo will come as a relief to patent owners, who will be free to argue against asserted rejections of their claims during reexamination without risking their right to collect past damages for infringement. The fact that a patentee’s statements to the PTO can result in a change of the claim meaning for purposes of prosecution history estoppel, but cannot on their own give rise to intervening rights, is an inconsistency that remains unresolved.

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Supreme Court Issues Groundbreaking Decision Limiting the Types of Methods that are Eligible for Patenting

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Today, the U.S. Supreme Court handed down a unanimous decision holding that method claims for applying a law of nature using merely conventional steps are not eligible for patent protection. While the Court's reasoning in this decision has a dramatic impact on the patentability of various innovations in the life sciences, its scope extends far beyond that field. The ramifications of the decision will be significant for fields such as software engineering, information science, chemistry and electrical engineering.

In *Mayo Collaborative Servs. v. Prometheus Laboratories, Inc.*, 10-1150, 566 U.S. ____ (March 20, 2012) the Court once again reversed the Federal Circuit on a fundamental issue of patent law. The Court stated that the "Machine or Transformation" test for patentability, which the Court endorsed as a useful, though not exclusive, test for the patentability of method claims less than two years ago in the *Bilski* case, does not trump the prerequisite requirement that "laws of nature, natural phenomena and abstract ideas" cannot be patented.

The Court's ruling puts to rest a developing rift within the Federal Circuit regarding how and when patent-eligibility should be considered by courts. One line of recent Federal Circuit decisions, led by the opinions of Chief Judge Rader, cautioned that courts ought not venture into the "swamp" of patentability analysis if other provisions of the patent law can determine the outcome of a case. Another line of opinions held that patentability analysis is the gateway that courts must use to determine validity of a contested patent. In its holding today, the Court rejected the notion that a patentability determination under other provisions of the patent laws could displace a threshold analysis of patentable subject matter under 35 U.S.C. § 101.

Further, the Court's ruling appears to revive the previously discredited practice of dissecting a claim into its parts, in this instance to determine whether the claim does more than simply recite a law of nature and then set forth conventional steps for applying that law. In recent years, claim analysis had shifted away from such dissection to analysis of the claim as a whole, since many inventions result from innovative combinations of known elements.

At issue in *Mayo* was a method of determining whether a given dose of a particular drug is too high, resulting in toxicity, or too low, rendering it ineffective. The method at issue involves measuring the level of certain metabolites in a patient's blood.

The Court determined that the claimed method simply recited a law of nature and a series of steps that "involve well-understood, routine, conventional activity previously engaged in by researchers in the field." The Court held that upholding such claims "would risk disproportionately tying up the use of the underlying natural laws, inhibiting their use in the making of further discoveries."

The Court stated, without analysis, that the relationships between the metabolite concentrations and the likelihood that a drug dosage would be ineffective or cause harm were "laws of nature." The Court found that the claims did not do significantly more than simply describe these natural (*i.e.*, biological) relationships. "To put the matter more precisely, do 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?" (italics in original).

The Court answered that question with a resounding "no" by looking at each of the additional claimed steps, which were an "administering" step, a "determining" step and a "wherein" step. The Court found those steps insufficient "to transform the nature of the claim." The Court also stated, "[T]o consider the three steps as an ordered combination adds nothing to the laws of nature that is not already present when the steps are considered separately."

Explaining the situation in another manner, the Court stated that, "the claims inform a relevant audience about certain laws of nature; any additional steps consist of well-understood, routine, conventional activity already engaged in by the scientific community; and those steps, when viewed as a whole, add nothing significant...."

The Court supported its reasoning with its own precedents as well as others, for instance a 19th century English case for improving the manner in which air was introduced to a

furnace. The Court in *Mayo* found it important that such a patent was upheld where it included not only a law of nature, but also “several unconventional steps.”

The reference to constituent process steps as conventional or non-conventional means that in determining whether an invention is drawn to subject matter that is statutory (*i.e.*, patent-eligible), the U.S. Patent and Trademark Office or a court must consider not only the subject matter itself, but the state of the art in that field. While some lower courts after *Bilski* had been determining subject matter eligibility with scant, if any, reference to the specific language of the claims, this decision calls on them to analyze not only the claim language itself but the prior art as well, even before determining whether that prior art makes the claim unpatentable due to lack of novelty or to obviousness. This approach risks blurring the analysis of patent eligibility with the analysis of novelty and non-obviousness.

In finding the claims unpatentable, the Court repeatedly used comparative and conclusory phrases such as “*overly broad*,” “*improperly tying up the future use of laws of nature*” and “*forecloses more future invention than the underlying discovery could reasonably justify*” (italics added). The Court aptly observes that, “Courts and judges are not institutionally well suited to making the kinds of judgments needed to distinguish among different laws of nature.” Undoubtedly, future commentators will wonder how such institutions can be expected to make the italicized comparisons, given such limitations.

Regardless, the Court explicitly instructs in *Mayo* that such institutions make these determinations as part of a subject-matter eligibility analysis, rather than by relying on the other sections of the patent law that may be easier to apply, lest the “law of nature” exception to patent-eligibility become a “dead letter.”

For companies and researchers in the life sciences, the impact of this decision cannot be underestimated. Claims directed to simple correlations between a conventional assay result and a biological outcome (such as those at issue in *Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc.*, 548 U.S. 124 (2006)) are now almost certainly invalid for being drawn to unpatentable subject matter because they preempt a law of nature, under the *Mayo* Court’s analysis. Less clear is the fate of claims that rely on a larger number of biological inputs and the use of complex algorithms to generate useful information about biological outcomes such as those covering multi-analyte index assays.

For other industries as well, this decision has a clear impact. For instance, the question about whether patent-eligibility is merely a “coarse filter” that should be avoided when possible is now settled—the patent eligibility analysis must be undertaken. The Court’s approach of dissecting method claims to determine which portions state laws of nature and which portions recite conventional steps is in sharp contrast with how the USPTO and courts have been analyzing claims in recent years. If such holding is extended to include the other branches of the “implicit exception” to patentability that the Court references (*i.e.*, natural phenomena and abstract ideas), then a very wide swath of science and technology areas are implicated. Given that lower courts are currently struggling with how best to circumscribe all three of these judicially created exception areas, it will be a number of years before there is settled law that will provide guidance for the types of methods that remain patentable.

The continued viability of the Machine-or-Transformation test, itself only a few years old, is now in doubt, given that the Court has now held it neither necessary (*Bilski*) nor sufficient (*Mayo*) to determine that an invention is patent-eligible.

The *Mayo* decision further highlights a neglected area in the law regarding patentability. The Constitution secures “for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.” The section on patentability in the patent statute at issue in *Mayo* (§ 101) begins, “Whoever invents or discovers any new and useful process....” The Court’s opinion repeatedly references discoveries as examples of subject matter that is not eligible for patenting. If the toxicity level of a particular drug is not a “discovery” in the classic sense of the term, then it will be very difficult to know what kinds of “discoveries” may be patentable.

Given that Congress has just concluded significant patent reform with passage of the America Invents Act in September 2011, it is unlikely that Congress will be able to address any concerns that may arise from this decision in the near future. Likewise, as the *Mayo* decision is a unanimous decision of the Court, it is highly unlikely that the Court itself will move significantly from what it has pronounced today. As such, this decision is likely to do precisely what the Court thought it was avoiding — “creating significantly greater legal uncertainty” — by making patent-eligibility a primary consideration.

We will continue to address issues that are sure to arise from this decision in the coming months and years.

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Patent Litigation Alert

Supreme Court Allows Generic Manufacturers To Challenge Overbroad Use Codes

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The United States Supreme Court has again reversed the Federal Circuit, ruling unanimously that a generic drug manufacturer may file a counterclaim to force correction of an overbroad use code that encompasses unclaimed methods of using the drug at issue. In interpreting the text of 21 U.S.C. § 355(j)(5)(C)(ii)(I), the Court in *Caraco Pharmaceutical Laboratories, Ltd. v. Novo Nordisk A/S*, No. 10-844, 566 U.S. ___ (2012), gave substantial weight to ensuring that the FDA fulfill its statutory duty to approve non-infringing generics in accord with Congressional intent. Brand manufacturers are advised to review active use codes to ensure that they reasonably reflect the scope of any claimed methods of use.

STATUTORY AND REGULATORY FRAMEWORK

When a brand manufacturer seeks to market a new drug, it must file a New Drug Application (“NDA”) with the FDA detailing clinical studies of the drug’s safety and efficacy. As part of this process, the brand manufacturer must identify by number and expiration date all patents that claim the drug or any methods of using that drug. 21 U.S.C. § 355(b)(1), (c)(2). For any patent claiming a method of use, the FDA also requires that the brand manufacturer describe the claimed methods, a description commonly referred to as the “use code.” 21 C.F.R. § 314.53(c)(2)(ii)(P)(3), (e). The FDA does not verify the accuracy of use codes, instead viewing its role as purely ministerial.

In order to facilitate the approval of generic pharmaceuticals, and thus speed the availability of less expensive prescription drugs to the public, the Hatch-Waxman Amendments allow generic manufacturers to bypass clinical testing by relying, in an Abbreviated New Drug Application (“ANDA”), on the safety and efficacy studies originally submitted by the brand manufacturer. An ANDA filer seeking to market a generic equivalent prior to the expiration of a patent covering either the brand-name drug or a method of use for that drug then has two choices.

First, the generic manufacturer can make a “Paragraph IV certification,” thereby asserting that any such patents are invalid or will not be infringed. A Paragraph IV certification is considered an act of infringement, and the brand manufacturer has 45 days from its filing to initiate litigation against the generic manufacturer. If the brand manufacturer fails to file suit, the FDA may approve the ANDA (although this would still allow the brand manufacturer to later file a typical patent infringement lawsuit based on sales of the generic manufacturer’s drug). If the brand manufacturer sues based on the ANDA filing, then the FDA may not approve the ANDA until whichever of the following occurs first — expiration of the patent, resolution of the litigation, or thirty months.

Alternatively, the generic manufacturer can seek FDA approval for a use not covered by the patents by making a “section viii statement” and submitting a proposed label to the FDA omitting the patented method of use. This alternative route is typically used when the brand manufacturer’s patent on the drug itself has expired, but patents claiming methods of using the drug remain. The FDA can only approve a section viii statement, however, if there is no overlap between the proposed carve-out label and the use code for the brand-name drug.

Following reports that brand manufacturers were exploiting the framework established by the Hatch-Waxman Amendments in order to prevent or delay competition from generic drugs, Congress created a mechanism for generic manufacturers engaged in Paragraph IV litigation to challenge the accuracy of the patent information submitted by brand manufacturers to the FDA:

[The ANDA] applicant may assert a counterclaim seeking an order requiring the [NDA] holder to correct or delete the patent information submitted by the holder under

subsection (b) or (c) of this section on the ground that the patent does not claim either —

- (aa) the drug for which the application was approved; or
- (bb) an approved method of using the drug.

21 U.S.C. § 355(j)(5)(C)(ii)(I). At issue in this case was whether a generic manufacturer has the right to bring such a counterclaim to correct an overbroad use code.

BACKGROUND OF THE CASE

Novo Nordisk filed suit against Caraco in 2005 alleging infringement of U.S. Patent No. 6,677,358 (“the ’358 patent”) after Caraco filed an ANDA for generic repaglinide with a Paragraph IV certification. Repaglinide, which is marketed by Novo Nordisk under the brand name PRANDIN®, has been approved by the FDA for three uses with respect to improvement of glycemic control in adults with type 2 diabetes: (1) repaglinide by itself; (2) repaglinide in combination with metformin; and (3) repaglinide in combination with thiazolidinediones. The ’358 patent is the sole unexpired Novo Nordisk patent relating to repaglinide, and claims only the second use, i.e., repaglinide-metformin combination therapy.

In 2008, Caraco stipulated that its ANDA would infringe the ’358 patent if it included a label for repaglinide administered in combination with metformin, and sought FDA approval for a label omitting such combination therapy. As explained above, however, the FDA can only approve such a “carve-out” label if it does not overlap with the use code submitted by the brand manufacturer. Although the original use code for the ’358 patent was limited to the claimed repaglinide-metformin combination therapy, Novo Nordisk subsequently amended the use code to broadly encompass “[a] method for improving glycemic control in adults with type 2 diabetes mellitus.” This new use code thus encompassed all three FDA-approved uses. As a result, although the FDA initially indicated that it would approve Caraco’s proposed carve-out label, it declined to do so following Novo Nordisk’s amendment of the use code.

Caraco sought to force Novo Nordisk to reinstate the original use code by filing a counterclaim pursuant to 21 U.S.C. § 355(j)(5)(C)(ii)(I) in the ongoing Paragraph IV litigation. The district court entered an injunction ordering Novo Nordisk to request that the FDA reinstate the original use code. On appeal, however, the Federal Circuit vacated the injunction, finding that Caraco did not have a statutory basis to request such relief. The U.S. Supreme Court granted *certiorari*, and oral argument was held on December 5, 2011.

THE SUPREME COURT’S DECISION

In adopting a sweeping construction of the counterclaim provision to encompass challenges to overbroad use codes, the Court considered three key phrases in the governing statute.

First, the Court interpreted “on the ground that the patent does not claim . . . *an* approved method of making the drug” to mean “on the ground that the patent does not claim . . . *a particular* method of making the drug.” In so doing, the Court rejected the primary basis on which the Federal Circuit rested its opinion — that this phrase should be interpreted to mean “on the ground that the patent does not claim . . . *any* approved method of making the drug.” The Court noted that the meaning of “not an” depends on its context and provided several examples, including the following:

[I]f a sports-fan friend bemoans that “the New York Mets do not have a chance of winning the World Series,” you will gather that the team has no chance whatsoever (because they have no hitting).¹ But now stop a moment. Suppose your spouse tells you that he got lost because he “did not make a turn.” You would understand that he failed to make a particular turn, not that he drove from the outset in a straight line.

¹ Mets fans would note that the Mets are off to a 7-3 start this year.

The Court further observed that its broad reading ensured that the scope of the counterclaim right would match the availability of FDA approval under the statute, which “contemplates that one patented use will not foreclose marketing a generic drug for other unpatented ones.”

Second, the Court interpreted “patent information submitted by the holder under [21 U.S.C. § 355(b) or (c)]” to include not only the information specified in those statutory subsections — namely, the patent number and expiration date of any patent claiming the drug or its method of use — but also any patent information required by regulations implemented pursuant to § 355. As these implementing regulations require submission of use codes, the counterclaim provision encompasses this descriptive information also:

Use codes are pivotal to the FDA’s implementation of the Hatch-Waxman Amendments — and no less so because a regulation, rather than the statute itself, requires their submission. Recall that those Amendments instruct the FDA (assuming other requirements are met) to approve an ANDA filed with a section viii statement when it proposes to market a drug for only unpatented methods of use. To fulfill that charge, the FDA must determine whether any patent covers a particular method of use; and to do that, the agency (which views itself as lacking expertise in patent matters) relies on the use codes submitted in the regulatory process. An overbroad use code therefore throws a wrench into the FDA’s ability to approve generic drugs as the statute contemplates.

The Court thus again turned to Congressional intent to defend its broad interpretation of the “patent information” subject to deletion or correction via the counterclaim provision.

Third, the Court observed that the counterclaim provision provides two independent remedies — deletion and correction — and that its reading gives effect to both. By contrast, if the counterclaim only applied to patent numbers and expiration dates, the

term “correct” would be effectively read out of the statute. For example, where the brand manufacturer owns a patent claiming a relevant method of use, the brand manufacturer will have every incentive to correct the patent number if it is provided incorrectly to the FDA. On the other hand, a manufacturer seeking to market a generic version of the same drug would have no incentive to bring the mistake to a court’s attention via the counterclaim provision.

Having dispensed with textual interpretation, the Court also rejected the contention that a narrow construction of the counterclaim provision was mandated by its drafting history. Admittedly, Congress had previously considered but failed to enact a bill that would have required brand manufacturers to submit a description of claimed methods of use, and would have furthermore created an independent cause of action allowing a generic manufacturer to challenge overbroad descriptions of a patent. But even setting aside the fact that the proposed legislation could have been rejected for any number of untold reasons, the drafters of the counterclaim provision later enacted were aware that the FDA had in the meantime issued a rule requiring brand manufacturers to supply such descriptions in the form of use codes. Accordingly, there was no need to statutorily duplicate what was already required by regulation. Moreover, Congress was aware when enacting the counterclaim provision “that generic companies generally had no avenue to challenge the accuracy of brands’ patent listings, and that the FDA therefore could not approve proper applications to bring inexpensive drugs to market.” The evolution of the statutory framework ultimately adopted by Congress thus supports an intent to enforce the use-code requirement through the counterclaim provision.

Not until the end of its opinion does the Court touch on what likely motivated its sweeping interpretation of the counterclaim — the lack of an effective forum for addressing overbroad use codes were it to reach a contrary holding. Because a Paragraph IV certification requires that the generic drug be labeled in the same way as the brand drug, no carve-out label can be devised in light of an overbroad use code, and infringement would be unavoidable. The Court thus concludes that “the counterclaim offers the *only* route to bring the generic drug to market for non-infringing uses.”

JUSTICE SOTOMAYOR'S CONCURRENCE

Perhaps most interesting is the concurrence filed by Justice Sotomayor emphasizing the deficiencies of the current statutory and regulatory framework. In effect, Justice Sotomayor asks Congress and the FDA to strengthen and clarify the mechanism by which generic manufacturers challenge overbroad use codes.

With respect to the counterclaim provision, Justice Sotomayor notes that a generic manufacturer can only file a counterclaim challenging an overbroad use code if the brand manufacturer first initiates Paragraph IV litigation. Even setting aside the expense and length of such litigation, a loophole exists — the brand manufacturer may decline to file suit in response to a Paragraph IV certification. If so, the FDA may approve the ANDA with a label materially identical to that of the brand-name drug, and without prejudice to any infringement claims that the brand manufacturer might bring upon production or marketing of the generic drug. This situation thus sets the stage for the generic manufacturer to induce infringement of the method-of-use patent, which, as Justice Sotomayor dryly notes, “is not a position I imagine a generic manufacturer wants to be in.”

Justice Sotomayor also criticizes the FDA's regulatory guidance as “remarkably opaque.” In particular, Justice Sotomayor faults the FDA for limiting use codes to no more than 240 words, and for promulgating regulations that suggest that use codes may describe either a claimed method of use or an approved indication.

IMPLICATIONS

It remains to be seen whether Congress and the FDA will accept Justice Sotomayor's challenge. In the meantime, it seems likely that counterclaims alleging overbroad use codes will be raised in Paragraph IV litigations where the use code does not precisely reflect the claimed method of use. Such situations may be more common than expected given the FDA's 240-word limit. In addition, buried within a footnote

in today's opinion is an explicit rejection of Novo Nordisk's contention that a use code may describe either an approved method of use *or indication*. Brand manufacturers are thus advised to review active use codes to ensure that they reasonably reflect the scope of any claimed methods of use.

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Patent Litigation Alert

Supreme Court Rejects Deference to PTO in *Hyatt*

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On April 18, 2012, the Supreme Court of the United States affirmed the Court of Appeals for the Federal Circuit and clarified the evidentiary rules and procedures for a 35 U.S.C. § 145 proceeding before a district court. *Kappos v. Hyatt*, 560 U.S. ____ (2012). Specifically, the Court held that a patent applicant's ability to introduce new evidence is not limited in a section 145 proceeding beyond those limitations already imposed by the Federal Rules of Evidence and Civil Procedure. Moreover, when new evidence is introduced, a district court must review that new evidence *de novo* and in doing so can take into account both the new evidence and the administrative record before the Patent and Trademark Office (PTO). Justice Thomas delivered the unanimous opinion of the Court, with Justice Sotomayor filing a concurring opinion, in which Justice Breyer joined.

If a patent applicant is dissatisfied with the decision of the Board of Patent Appeals and Interferences (BPAI), then the applicant may either appeal to the Federal Circuit, or, pursuant to section 145, file a civil action against the Director of the PTO to obtain a patent. In this case, Gilbert Hyatt filed a patent application in 1995 including 117 claims, all of which were rejected by the examiner for lack of an adequate written description. Hyatt initially appealed the examiner's decision to the BPAI, and the BPAI approved 38 claims, but denied the rest. Needless to say, Mr. Hyatt was dissatisfied.

Hyatt then filed a civil action under 35 U.S.C. § 145 against the Director of the PTO at the district court rather than an appeal under 35 U.S.C. § 141 directly to the United States Court of Appeals for the Federal Circuit. In the district court action, Hyatt filed a written declaration identifying portions of the application that he asserted were supported by the claims—evidence that was not before the PTO. The district court determined that it could not consider Hyatt's declaration because applicants are “precluded from presenting new issues, at least in the absence of some reason of justice put forward for failure to present

the issue to the Patent Office.” *Hyatt v. Dudas*, Civ. Action No. 03-0901 (D. D.C. Sept. 30, 2005), p. 9. Applying the deferential substantial evidence standard of the Administrative Procedures Act (APA) to the BPAI's findings, the district court then granted summary judgment in favor of the Director. Hyatt appealed to the Federal Circuit.

Initially, a divided panel affirmed the district court decision, holding that the APA imposes restrictions on the admission of new evidence in a section 145 proceeding and that the district court could not review the record “wholly *de novo*.” However, after granting rehearing *en banc*, the Federal Circuit vacated the district court's grant of summary judgment. The *en banc* Federal Circuit held that applicants are “free to introduce new evidence in § 145 proceedings subject only to the rules applicable to all civil actions, the Federal Rules of Evidence and the Federal Rules of Civil Procedure” even if the applicant had no justification for failing to present the evidence to the PTO. *Hyatt v. Doll*, 625 F. 3d 1320, 1331-36 (Fed. Cir. 2010) (*en banc*). Further, the Federal Circuit held that the district court must make *de novo* findings to take such evidence into account. *Id.*

The Director challenged both aspects of the Federal Circuit decision at the Supreme Court, arguing that PTO decisions were due broad deference under the APA. The Supreme Court rejected this argument, and affirmed the Federal Circuit on both grounds. The Court found that section 145 expressly contemplates the introduction of new evidence and by its terms imposes no special limits or heightened standard of review. Further, the district court in cases where new evidence is introduced serves as the factfinder, and while that court may consider whether the applicant had an opportunity to present the newly proffered evidence before the PTO, it reviews any factual issues on which the new evidence bears *de novo*.

In arriving at its decision, the Court considered two cases: *Butterworth v. United States ex rel. Hoe*, 112 U.S. 50 (1884), and *Morgan v. Daniels*, 153 U.S. 120 (1894), which both considered a previous version of section 145, Revised Statute § 4915 (R.S. 4915). In *Butterworth*, the Court held that a proceeding pursuant to R.S. 4915 was to be conducted “according to the ordinary course of equity practice and procedure” and that the court was not confined to the record before the PTO, but could hear “all competent evidence adduced and upon the whole merits.” *Butterworth*, 112 U.S., at 61. On the other hand, in *Morgan*, the Court described the R.S. 4915 proceeding as one over a question of fact that had already been “settled by a special tribunal [e]ntrusted with full power in the premises” and characterized it not as an independent civil action, but as “something in the nature of a suit to set aside a judgment.” *Morgan*, 153 U.S., at 124.

After considering both cases, the Court distinguished *Morgan* on the grounds that no new evidence had been presented in that case, unlike here. Therefore, the Court chose to follow *Butterworth* and decided that “a district court conducting a § 145 proceeding may consider all competent evidence adduced, and is not limited to considering only new evidence that could not have been presented to the PTO.” *Kappos*, slip. op. at 12.

Justice Sotomayor joined in the Court’s opinion in full, but offered a clarification of the Court’s holding, which Justice Breyer joined. Justice Sotomayor wrote that she agreed with the Court’s decision that the applicant in this case was entitled to present evidence to the district court which he failed to present to the PTO due to “ordinary negligence, a lack of foresight, or simple attorney error”. *Kappos*, concurrence, slip. op. at 2. However, she felt that there are instances when the district court has authority to exclude evidence “deliberately suppressed from the PTO or otherwise withheld in bad faith.” *Id.* at 3. Justice Sotomayor wrote that this conclusion was consistent with the majority decision because the authority to exclude such evidence was consistent with regular equity practice and procedure affirmed by the Court. *Id.*

Although section 145 actions before the district court are relatively rare, this decision makes such actions a potentially very useful tool for patent applicants. Specifically, the decision gives patent applicants an opportunity to introduce new evidence previously not before an examiner and BPAI. Unlike directly appealing to the Federal Circuit in a section 141 action, the section 145 action allows not only the introduction of new evidence, but also requires the district court to make its own findings *de novo*. The PTO, despite being an expert agency, is given no deference—a departure from typical administrative law policy. Further, evidence that can be introduced includes oral testimony, which is not provided for at the PTO. However, the expanded opportunity for patent applicants to present new evidence in section 145 proceedings will have to be carefully evaluated against the higher costs of bringing such actions.

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Patent Litigation Alert

Federal Circuit Clarifies Standard for Joinder of Multiple Defendants in Patent Infringement Cases

MAY 8, 2012

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***In re EMC Corporation*, Misc. Dkt. No. 100 (Fed. Cir. May 4, 2012)**

On May 4, 2012, a Federal Circuit panel decided the circumstances when a plaintiff may join multiple defendants with unrelated products in a patent infringement suit. The court concluded that independent defendants satisfy the same transaction-or-occurrence test required for joinder when there is a logical relationship between the separate causes of action. This occurs “if there is substantial evidentiary overlap in the facts giving rise to the cause of action.” That is, “the defendants’ allegedly infringing acts, which give rise to the individual claims of infringement, must *share* an aggregate of operative facts.” However, “[t]he sameness of the accused products is not enough to establish that claims of infringement arise from the ‘same transaction.’ Unless there is an actual link between the facts underlying each claim of infringement, independently developed products using differently sourced parts are not part of the same transaction, even if they are otherwise coincidentally identical.”

The case was decided under the rules in place before Congress enacted the new joinder provision in the Leahy-Smith America Invents Act (“AIA”) and applies to cases filed before its effective date.

Background of the Case

Oasis Research brought a single suit against eighteen companies in the Eastern District of Texas. The complaint alleged infringement of the method claims of four patents relating to off-site computer data storage and stated that all of the defendants provided online backup and storage for home and business users. Eight of the eighteen defendants moved to sever and transfer the claims against them to more appropriate venues. They argued that because there was no concert of action, the claims against them did not arise out of the same transaction or occurrence, as required by Federal Rule of Civil Procedure 20, which governs permissive joinder of parties.

Oasis Research opposed, arguing that because the accused infringement was limited only to online backup/storage, each defendant offered a similar online backup/storage service, and the steps taken to provide those services were all alleged to infringe, the claims arose out of the same transaction or occurrence. Applying the standard used by the Eastern District of Texas, the district court concluded the claims arose out of the same transaction, occurrence, or series of transactions or occurrences because the defendants’ accused services were “not dramatically different.” The defendants sought review of the district court’s decision via a petition for writ of mandamus.

The Federal Circuit’s Decision

Applying its own law to the issue of whether the motion to sever should be granted, the Federal Circuit held that the district court applied the wrong standard in determining whether joinder of the multiple defendants was appropriate. The decision explained that Rule 20 allows joinder of multiple defendants if two independent requirements are satisfied: 1) the claims against them must be asserted “with respect to or arising out of the same transaction, occurrence, or series of transactions or occurrences,” and (2) there must be a “question of law or fact common to all defendants.”

After analyzing the text and history of Rule 20, the Federal Circuit explained that the rule is not limited only to joint liability situations, but also can apply in cases involving defendants who are independent actors. In such situations, Rule 20’s same transaction-or-occurrence requirement is satisfied when there is a “logical relationship” between the separate causes of action, which the Federal Circuit described as a “substantial evidentiary overlap in the facts giving rise to the cause of action against each defendant.” That is, the defendants’ allegedly infringing acts “must *share* an aggregate of operative facts.” The Federal Circuit rejected the district court’s “not dramatically different” standard

as inconsistent, explaining that it would “require little more than the existence of some similarity in the allegedly infringing products or processes, similarity which would exist simply because the same patent claims are alleged to be infringed.”

Applying the proper logical relationship test, the Federal Circuit held that joinder in patent cases “is not appropriate where different products or processes are involved.” However, simply showing that the accused products are the same is not enough. As the Federal Circuit explained:

To be part of the “same transaction” requires shared, overlapping facts that give rise to each cause of action, and not just distinct, albeit coincidentally identical, facts. The sameness of the accused products is not enough to establish that claims of infringement arise from the “same transaction.” Unless there is an actual link between the facts underlying each claim of infringement, independently developed products using differently sourced parts are not part of the same transaction, even if they are otherwise coincidentally identical.

To assist district courts in determining whether the joinder test is satisfied, the Federal Circuit identified multiple factors to be considered:

- Whether the alleged acts of infringement occurred during the same time period;
- The existence of some relationship among the defendants;
- The use of identically sourced components;
- Licensing or technology agreements between the defendants;
- Overlap of the products’ or processes’ development and manufacture; and
- Whether the case involves a claim for lost profits.

Since the district court applied the incorrect test, the Federal Circuit vacated the district court’s decision and directed the district court to reconsider the issues of severance and joinder under the proper standard.

Implications

Prior to *In re EMC*, district courts had split on the issue of when multiple unrelated defendants could be joined in single patent infringement case. The Eastern District of Texas, from which *In re EMC* arose, used a standard that, as applied, ordinarily would permit joining any number of defendants accused of infringing the same patent. The practical effects of this touched on many aspects of patent litigation, particularly under the general practice of that district where multiple unrelated defendants often had to undertake a single coordinated defense for purposes of discovery, claim construction, motions for summary judgment, and even trial. *In re EMC* has implications for those aspects and others. Those defending a multi-defendant case in the Eastern District filed before the effective date of the AIA may want to evaluate options for severing the claims against them.

Additionally, as discussed below, the cases to which this holding specifically applies likely are limited to those cases filed before the AIA; however, the Federal Circuit’s holding that it will apply its own law to the issue of severance (and its reasoning here) likely has implications for how the joinder provisions of the AIA will be interpreted. Furthermore, many of the implications of *In re EMC* are similar to those that the joinder provision of the AIA have created.

As the Federal Circuit notes, being forced to defend claims alongside unrelated parties with different products or services and possibly different strategies may create prejudice and confusion, which severing claims can mitigate. For example, separate actions tend to allow defendants to present individualized arguments on non-infringement, invalidity, and claim construction. On the other hand, for plaintiffs, maintaining multiple separate actions adds a layer of complication when plaintiffs accuse multiple defendants of infringement. Thus, one implication is for case management by the courts of separated cases.

For cases that previously could have been brought as a multi-defendant case, having them filed and litigated as separate actions will give the courts an opportunity to explore options for case management that are efficient and just. The Federal Circuit identified existing mechanisms for case management, such as consolidation under Rule 42 or multidistrict litigation (“MDL”) procedures under 28 U.S.C. § 1407, which do not necessarily have the same effect of maintaining a single case in a single forum. For example, the MDL procedures allow pretrial issues to be adjudicated together in one district court, but cases must be transferred back to their home districts for purposes of trial.

Another implication is the impact on venue and transfer determinations in cases filed both before and after the enactment of the AIA. Under the existing law governing venue and transfer, a defendant in a separate case may be better positioned to change venue than in a multi-defendant case. If separate cases are brought in the same jurisdiction, the impact of the Rule 42 consolidation mechanism noted above, and the change of venue jurisprudence will be a topic to watch. Similarly, when plaintiffs sue defendants in multiple venues or as the result of transfer at the request of defendants, the MDL procedure noted above likely will take on increased importance. For both procedures, it remains to be seen how courts will balance the interplay of separately-filed cases, transfer and venue jurisprudence applicable to each of them, and the case management options consolidation provides.

Impact of the AIA Joinder Provision

The recently enacted AIA provision on joinder provides that accused infringers may be joined in one action as defendants or have their actions consolidated for trial only if the allegations of infringement “aris[e] out of the same transaction, occurrence, or series of transactions or occurrences relating to the making, using, importing into the United States, offering for sale, or selling of the same accused product or process.” Since the AIA joinder provision is not retroactive and applies only to cases filed on or after the effective date of the AIA (September 16, 2011), the Federal Circuit declined to rule on whether the

new provision changes the test for joinder. However, since the new AIA joinder provision focuses the same transaction-or-occurrence requirement on acts of infringement similar to those considered in *In re EMC*, the decision may be instructive for cases subject to the AIA.

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Legal Publications

- Steve P. Calandrillo and Ewa M. Davison, *The Dangers of the Digital Millennium Copyright Act: Much Ado About Nothing?*, 50 Wm. & Mary L. Rev. 349 (2008).
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Darren E. Donnelly is a partner in the Litigation and Intellectual Property Groups and focuses on patent and other technology litigation and counseling. Mr. Donnelly practices out of the firm's Mountain View, California office. His practice emphasizes data management, technical computing, telecommunications, and Internet technologies. The clients Mr. Donnelly has represented include:

- Amazon.com, Inc.
- Cognos, Inc.
- Cryptography Research, Inc.
- Electronic Arts
- Good Technology
- Hewlett Packard
- Informatica Corporation
- Intuit
- Netflix
- Symantec Corporation
- VIA Technologies, Inc.
- Zappos

Mr. Donnelly received undergraduate degrees from Stanford University in mathematical and computational science and economics. He received an M.S. from Stanford where his graduate work focused on the design of intelligent decision systems. He attended law school at Santa Clara University, graduating with a J.D. in 1997.

Mr. Donnelly served as trial counsel for Amazon.com in *Cordance Corp. v. Amazon.com*, winning a defense verdict before a Delaware jury that found two of three patents not infringed and the one remaining patent invalid.

Mr. Donnelly served as trial counsel for Informatica in *Informatica Corp. v. Business Objects*, winning a \$25 million jury award in its patent suit against Business Objects.

Mr. Donnelly represented Cryptography Research, Inc. ("CRI") in *Cryptography Research v. VISA*, a watershed case for the secure smart card industry, where CRI asserted eight fundamental patents covering differential power analysis countermeasure against Visa International. VISA settled on terms very favorable to CRI.

Mr. Donnelly represented Netflix in *Lycos v. Netflix et al.* where, after transferring the case from a "rocket docket" to a more favorable venue, he convinced the court to stage the case to allow accelerated — and ultimately successful — summary judgment of non-infringement with minimal discovery. Mr. Donnelly has subsequently represented Netflix in other several other matters all to favorable resolution.

For over a decade, Mr. Donnelly has represented Amazon.com and its affiliates in several patent infringement cases, including against Barnesandnoble.com, where he helped enforce via preliminary injunction, Amazon.com's 1-click® patent.

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Selected Publications:

- Michael Shuster and Pauline Farmer-Koppenol, *A Comparison of US and EU Biosimilars Regimes*, January 6, 2012.
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- Michael Shuster and Pauline Farmer-Koppenol, *Biotech in the Wake of 'Bilski'*, The Recorder, July 2010.
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- Jarstfer A.G., P. Farmer-Koppenol, and D.M. Sylvia, *Tissue magnesium and calcium affect development and reproduction of an arbuscular mycorrhiza*, Mycorrhiza.7:237-242, 1998.

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- American Chemical Society
- American Intellectual Property Law Association
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Ms. Mewes is active in the San Francisco Bay Area Intellectual Property American Inn of Court and the Federal Circuit Bar Association. She also serves on the Board for the Boalt Hall Alumni Association.

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In patent procurement matters, Mr. Patel creates patent strategies and counsels, prepares and prosecutes patents in areas such as integrated circuit design, mobile, media and gaming, and medical device and analytics technologies. He advises companies on strategic uses of patent reissue proceedings and actively prosecutes such proceedings. He also appears in appeals before the Board of Patent Appeals and Interferences. In addition, Mr. Patel develops and executes global patent strategies involving patent procurement in Europe, Canada, Australia, Japan, Korea, China, Taiwan, Brazil and India.

In patent dispute matters, Mr. Patel is active in reexamination and litigation proceedings in technology areas that include solid-state memories, electronic gaming, Internet infrastructure, electronic commerce, and media and entertainment.

In patent transaction matters he is involved with negotiations of patent and intellectual property ("IP") licenses, and leads IP due diligence and audit matters in corporate transactions in industries such as clean technology and social media.

Among the clients Mr. Patel has represented are:

- Amazon.com, Inc.
- Canon Research Americas, Inc.
- Hewlett-Packard Company/Palm, Inc.
- Logitech, Inc.
- Sipro Lab Telecom, Inc.
- Synopsys, Inc.
- Twitter, Inc.
- Ustream, Inc.
- VoiceAge Corporation
- Woodman Labs, Inc. (dba GoPro)

In addition to his law practice, Mr. Patel was an Adjunct Professor of Law at the University of California, Hastings College of the Law where he taught a patents course. Presently, he is on the faculty of Practising Law Institute and chairs the Advanced Patent Prosecution program.

Mr. Patel has been recognized as a Northern California "Super Lawyer" in the area of Intellectual Property each year since 2006.

Mr. Patel received his Bachelor of Science (with high honors) in Electrical Engineering from Rutgers University (NJ). He received his Juris Doctor and Master of Intellectual Property from the University of New Hampshire (formerly Franklin Pierce Law Center). He is a member of the California Bar and is registered to practice before the U.S. Patent and Trademark Office.

Highlighted Legal Experience:

Patent Strategy and Portfolio Development

- Served as in-house patent counsel role for large electronics industry company, managing patent portfolio and instructing outside counsel.
- Created patent strategy and developing patent portfolio for \$500 million plus product line for a peripherals company.
- Restructured existing portfolio of 100-plus patents for a devices company to align patent portfolio with re-directed business strategy.
- Created patent strategy and advised on patent portfolio for on-line auction company. Patent portfolio sold for over \$750,000.
- Sample Patents (Electrical / Electronics):
 - U.S. Patent No. 7,058,907 Reduction of Cross-Talk Noise in VLSI Circuits
 - U.S. Patent No. 6,246,294 Supply Noise Immunity Low-Jitter Voltage-Controlled Oscillator Design
 - U.S. Patent No. 6,052,033 Radio Frequency Amplifier System and Method
 - U.S. Patent No. 5,991,296 Crossbar Switch with Reduced Voltage Swing and No Internal Blocking Path
 - U.S. Patent No. 5,948,083 System and Method for Self-Adjusting Data Strobe
- Sample Patents (Consumer / Mechanical Products):
 - U.S. Patent No. 6,813,372 Motion and Audio Detection Based Webcamming and Bandwidth Control
 - U.S. Patent No. 6,246,016 Optical Detection System, Device, and Method Utilizing Optical Matching
 - U.S. Patent No. 5,835,852 Integrated Electronic Communication Device and Clip
- Sample Patents (Computer Architecture/Software):
 - U.S. Patent No. 6,389,405 Processing System for Identifying Relationships Between Concepts
 - U.S. Patent No. 6,275,622 Image Rotation System
 - U.S. Patent No. 6,055,629 Predicting Branch Instructions in a Bunch Based on History Register Updated Once
 - U.S. Patent No. 5,995,955 System and Method for Expert System Analysis Using Quiescent and Parallel Reasoning and Set Structured Knowledge Representation

Highlighted Legal Experience:

Patent IP Transactions (Representative Matters)

- Led intellectual property audit for Fortune 500 communication company's intellectual property in wireless technology and advised on intellectual property issues in context of tax framework.
- Led intellectual property audit for electronic gaming company and developed intellectual property management structure for company.
- Conducted numerous intellectual property due diligence projects for high-technology investments by venture capital companies and for targets and acquirers in merger and acquisition matters.

Patent Litigation (Representative Cases)

- *Nomadix v. Hewlett-Packard Company et al.* – patent litigation involving Internet protocol network redirection.
- *Reunion.com and GoodContacts Ltd. v. Plaxo, Inc.* – patent litigation involving social media and contact management technology.
- *Akamai Technologies, Inc. v. Speedera Networks, Inc.* – patent litigation involving Internet content delivery services.
- *Planet Bingo, LLC v. GameTech International, Inc.* – patent litigation involving casino style games on electronic devices.
- *GameTech International, Inc. v. Bettina Corporation* – patent litigation involving electronic gaming.
- *SanDisk Corporation v. Lexar Media, Inc.* – patent litigation involving flash memory consumer products.
- *ICTV, Inc. v. Worldgate Communications, Inc.* – advised on patent litigation strategy in interactive television market.
- Litigation and reexamination crossover matters – advised on and led *ex parte* and *inter partes* reexaminations in litigation context.
- Reexamination patent defense – advised on and led defense of patents in reexamination, including highly visible electronic commerce patent at U.S. Patent and Trademark Office.

Teaching Experience

- Program Co-Chair; ITechLaw India Conference.
- Program Chair; Practising Law Institute course on “Advanced Patent Prosecution”.
- Program Chair; Practising Law Institute course on “Reexamination and Patent Litigation Crossover Proceedings”.
- Faculty Member; Practising Law Institute courses on “Fundamentals of Patent Prosecution,” and “Patent Law for the Non-Specialist”.
- Adjunct Professor of Law at University of California, Hastings College of the Law.

Publications

- *"Eighteen Months Later: How Bilski has Impacted Process Patents"*, 2011.
- *"Seven Sins – IP Mistakes Technology Start Ups Should Avoid"*, 2010.
- *"Developing a Patent Strategy - A Checklist for Getting Started"*, 2003-2008.
- *"International Patent Strategy"*, www.fenwick.com, 2006-2007.
- *"An Introduction to U.S. Patent Prosecution,"* Fundamentals of Patent Prosecution, Practising Law Institute, 2005-2008.
- *"Challenging (or Strengthening) Patents in the U.S. Using Patent Reexamination"*, ITechLaw Association Asian Conference, Mumbai, India, 2008.
- *"Patent Reexamination and the Crossover with Litigation"*, Practising Law Institute, 2007-2008.
- *"Software Escrows as Part of an Intellectual Property Strategy,"* ITechLaw Association First Asian Conference, Bangalore, India, 2005.
- *"Underutilized Patent Reexaminations Can Improve Business Strategy,"* Daily Journal, Vol. 110, No. 75, April 19, 2004.
- *"Software Outsourcing Offshore – Business and Legal Issues Checklist,"* SHG Software 2004 Conference, 2004.
- *"A Strategic Look at the Final Rejection,"* Advanced Patent Prosecution Workshop, Practising Law Institute, 2003 - 2006.
- *"Think Value, Not Cheap, For Long-Term Success,"* Succeeding with New Realities, TiEcon 2003, Published by TiE Silicon Valley 2003.
- *"The Intellectual Property Audit,"* Building and Enforcing Intellectual Property Value, An International Guide for the Boardroom 2003, Published by Globe White Page 2002.
- *"Patent Portfolio Strategy for Start-Up Companies: A Primer,"* Patent Strategy and Management, Vol. 3, No. 7, Nov. 2002.
- *"Potent Portfolio,"* Daily Journal, Vol. 106, No. 244, Dec. 15, 2000.
- *"Own Idea,"* Daily Journal, Vol. 105, No. 10, Jan. 15, 1999.
- *"Disclose Lite,"* Daily Journal, Vol. 103, No. 55, Mar. 21, 1997.

Organization and Community Participation

- Board Member, University of New Hampshire School of Law
- Board Member (past), ITechLaw Association
- American Intellectual Property Law Association
- TiE ("The Indus Entrepreneurs"/"Talent, Ideas, Enterprise")
- Coach (Soccer and Baseball)



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Emphasis:

Patent Litigation

Intellectual Property Litigation

Intellectual Property Strategy
and Counseling

David Tellekson is a partner in the Litigation Group of Fenwick & West LLP, a law firm specializing in technology and life sciences matters. Mr. Tellekson is resident in the Seattle office and his practice focuses on litigating patent cases for clients in the areas of biotechnology, pharmaceuticals, polymer chemistry, medical devices, industrial chemistry and a wide variety of other technologies including: contact lenses, retroreflective sheeting, orthodontic brackets, silicon chemistry and electronic printing. In addition to his trial work, he also consults on patent strategy and opinions.

Mr. Tellekson received his J.D. from DePaul University in 1983. Prior to law school, he earned his B.S. degree in biochemistry from the University of Wisconsin in 1979.

Mr. Tellekson is a frequent writer and lecturer in areas of patent law and patent litigation. He has been selected as a Washington "Super Lawyer" in the area of Intellectual Property Litigation each year since 2008. Prior to joining Fenwick & West, he was the managing principal at Darby & Darby P.C. in Seattle.

Mr. Tellekson is admitted to practice in Washington, New York, Illinois and Minnesota, before the United States District Court of Appeals for the Federal Circuit and multiple district courts. He is also registered to practice before the United States Patent and Trademark Office. Mr. Tellekson is a Master Member of the Seattle Intellectual Property American Inn of Court.

Representative Engagements

- **Novozymes v. Danisco:** Lead counsel representing Novozymes in a successful action against rival Danisco for infringement of Novozymes' patent for an improved alpha-amylase useful for fuel ethanol production, among other industrial applications. A jury found that Danisco willfully infringed Novozymes' patent and awarded over \$18.2 million in damages.
- **Novozymes v. Genencor:** Represented Novozymes as lead trial counsel asserting patent on genetically modified alpha-amylases. Genencor was found to willfully infringe and ordered to pay double damages and attorneys' fees.
- **Sigma-Aldrich and Oxford Biomedica (UK) Ltd. v. Open Biosystems:** Represented patent owner Oxford Biomedica as lead trial counsel in patent infringement action involving HIV vectors useful for drug delivery. Markman victory led to favorable settlement.
- **Cardiac Science v. Philips Electronics:** Represented plaintiff as lead counsel in case involving 21 patents. Damages asserted by each side combined in excess of \$200 million. Key victories by Cardiac Science at Markman and summary judgment led to favorable settlement hours before seven-week trial set to begin.
- **Schering v. Glenmark:** Lead counsel representing defendant Glenmark, the only challenger to Schering's ezetimibe patent covering \$5 billion per year drug. Favorable settlement on the eve of trial followed a Glenmark summary judgment victory.
- **3M v. Seibu Polymer Chemical Co., Ltd. (ITC):** Co-trial counsel at patent infringement trial protecting retroreflective sheeting market valued at more than \$1 billion per year.

Publications

- David K. Tellekson and John LaBarre, *The Intersection of Antitrust and Intellectual Property: A Review of Recent Case Law and Trends*, BNA's Patent, Trademark & Copyright Journal, August 11, 2006.
- David K. Tellekson, Sandra S. Lee and Elizabeth A. Richardson, *Strategies for Attacking and Defending Pharmaceuticals Patents; A Modern Take on 'The Art of War,'* Intellectual Property & Technology Law, December 2005.
- David K. Tellekson and Elizabeth Bernard, *Have Patent, Will Travel: Can One Infringe a U.S. Patent by Making, Using, and Selling a Product Solely Outside the United States?*, Intellectual Property Today, July 2004.

Presentation

- *Litigation Issues/Trends in Licensing/Case Law Update*, WSBA-CLE Seminar Look Before You License: Valuation, Negotiation, and More, September 2005.

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