

# U.S. Patent Law

## *A Changing Landscape*

*William D.A. Zerhouni  
Covington & Burling LLP  
202-662-5169  
WZerhouni@cov.com*

*Richard J. Johnson  
Covington & Burling LLP  
202-662-5323  
RJohnson@cov.com*

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# General Trends In Patent Law

- There is a general sense that the pendulum has swung too far in favor of patentees.
- Observers from Congress to the Supreme Court appear concerned that:
  - Patents are too easily acquired (declining quality) (see e.g. Patent Reform legislation, proposed PTO rules)
  - Patent litigation is too expensive and the results too asymmetrical (see e.g. *eBay v. MercExchange*)
  - Expansive notions of what is patentable discourages innovation (see e.g. *LabCorp*, *Nuijten*, *Comiskey*, *Bilski*)
- There is also a political dimension to the changing face of patent law

# All Three Branches of the Federal Government Now Involved In Changing the Patent Law Landscape

- **Legislative:** Patent Reform Act of 2007
- **Judicial:** Supreme Court and Federal Circuit
- **Executive:** PTO Proposed Rules

-- Congress: The Patent Reform Act --

# Patent Reform Act

- Damages
- First to File
- Interlocutory Appeal of Claim Construction
- Post Grant Re-examination
- Third Party Submission of Prior Art
- Inequitable Conduct

# Patent Reform Act - Damages

- Common points in House and Senate Bills (H.R. 1908 and S. 1145):
  - Gatekeeper function for courts: pretrial determination of factors to be considered in determining a reasonable royalty
  - Prior art subtraction: damages based over incremental improvement that invention adds over the prior art
  - Limits “entire market value rule”
  - Consideration of other factors is largely discretionary

# Patent Reform Act – First to File

- The act would switch the U.S. from a “first to invent” to a “first to file” system
  - Increases efficiency in priority disputes
  - Disfavors small and individual inventors
  - Harmonizes U.S. patent law with rest of the world

# Patent Reform Act – Interlocutory Appeal of Claim Construction

- Bill called for interlocutory appeals of claim construction orders upon district court approval
- Designed to promote litigation efficiency by short-circuiting trials and adjudication based on faulty claim construction
- Based on experience, claim construction has been a serious source of frustration between district courts and the Federal Circuit



# Patent Reform Act – Post-Grant Re-examination

- House bill:
  - Expands inter partes post-grant challenge
    - Administrative patent judge
  - Limits post-grant challenge to 12 months from issuance absent consent from patentee
    - Challenge may be based on any invalidity grounds
    - No presumption of validity
    - Preponderance of the evidence standard
    - One motion to amend patent absent good cause

# Patent Reform Act – Post-Grant Re-examination

- Senate bill:
  - Eliminates inter partes system
  - Post-grant system where petitioner has 2 windows to challenge
    - First window: within 12 months of issuance
    - Second window: throughout the life of the patent, within 12 months of receiving notice and proof of significant economic harm
    - Challenge may be based on any invalidity grounds
    - Presumption of validity applies to second window challenges
    - Preponderance burden of proof on all challenges

# Patent Reform Act – Third Party Submission of Prior Art

- Within 6 months of publication (usually 18 months after filing), a third party may file prior art with the PTO.
- Intended to improve quality of examination.
- No vocal opposition to this provision.

# Patent Reform Act – Inequitable Conduct

- House and Senate versions require clear and convincing evidence that material information was omitted or misrepresented with an intent to mislead or deceive
- House: material = supports prima facie finding of unpatentability or refutes applicant's position
- Senate: material = would have been considered important by examiner and is not cumulative
- House: intent requires specific facts
- Senate: intent can be inferred but not on the basis of gross negligence or materiality
- Both: court must balance the equities to determine the appropriate remedy

# Patent Reform Act Status

- The Patent Reform Act passed the House 220-175 in September 2007
- On January 24, 2008, the bill was reported out of the Senate Judiciary Committee
- At the time, the thinking was that the bill would be scheduled for debate on the floor in mid-February
- The bill has not yet come to the Senate floor
- With each passing day and election season near, the chances of passage in the 110<sup>th</sup> Congress fade
- The bill will likely have to be re-introduced from scratch in the 111<sup>th</sup> Congress

# Patent Reform and the 2008 Presidential Election

- Patent reform is not a key issue in the election
- The general sense is that pharma would be in better hands if McCain wins and that IT would be in better hands if Obama wins given the stakeholders for both campaigns
- There are, however, issues that are far more pressing on the next president's agenda – and patent reform may be pushed back to the second session of the 111<sup>th</sup> Congress (or even to the 112<sup>th</sup> Congress)

-- The Supreme Court --

# The Supreme Court and Patent Law

- The Supreme Court appears engaged in an effort to strike a balance in patent law that more closely reflects the balance that exists in tort law
- Over the past 2 years, the Supreme Court has weighed in on injunctions, obviousness, patent exhaustion, declaratory judgment jurisdiction in patent cases and patentability under 101
- The Court may also be ready to trim its holding in *Florida Prepaid*



## Supreme Court – *eBay v. MercExchange*

- No presumption that an injunction will issue in a patent case
- Injunctions in patent cases should be granted in accordance with the same equitable principals used to determine issuance of injunction in non-patent cases

## Supreme Court – *MedImmune v. Genentech*

- “Reasonable apprehension of suit” no longer the standard for declaratory judgment jurisdiction
- Standard should be the same as in other cases – whether facts alleged show:
  - a substantial controversy
  - between parties having adverse legal interests
  - of sufficient immediacy and reality to warrant the issuance of a declaratory judgment

# Supreme Court – *KSR v. Teleflex*

- Rigid application of teaching, motivation or suggestion test no longer the standard in determining obviousness
- Courts may consider if a skilled artisan would be inclined to vary parameters to arrive at invention
- No restriction of consideration to only the problem that the inventor was trying to solve
- Not quite an “obvious to try” standard – but closer to “obvious to try” than the old standard

# Supreme Court – *Quanta v. LG*

- Patent exhaustion lives
- Applies to a method of use patent
- Components of a product which have “no reasonable noninfringing use” trigger patent exhaustion of method of use patent claims
- The Court is looking to reduce second bites at the patent apple

## Supreme Court – *LabCorp v. Metabolite*

- Supreme Court first granted certiorari and then withdrew certiorari after briefing
- This was to be the Court's major foray into 101 issues and whether or not the patent at issue (related to "correlating" homocysteine levels with vitamin-B deficiencies) was patentable subject matter
- Instead, it served as a warning to the Federal Circuit to start taking 101 more seriously
- The Federal Circuit in *Comiskey*, *Nuijten* and *Bilski* may have gotten the message
- Depending on the Federal Circuit's decision in *Bilski*, the Court may leave 101 alone for now.

## Supreme Court – *BPMC v. California Dept. of Health* (cert petition)

- *Florida Prepaid* gave broad immunity to arms of states in infringing patent rights
- This case touches directly on the waiver required to subject an arm of a state to suit for infringement of a patent
- The Court has not yet decided whether to grant cert in this case, but it has asked for the SG's opinion on the cert petition
- The Court may be interested in trimming back on its broad holding in *Florida Prepaid*

-- The Court of Appeals for the Federal Circuit --



## The United States Court of Appeals for the Federal Circuit – An Introduction

- 1 of 13 Federal Courts of Appeal
- Jurisdiction defined largely by subject matter
- Central role in resolving U.S. patent disputes
- Near\* total control over substantive patent law





## Initial Observations

Paul R. Michel

Pauline Newman

Haldane Robert Mayer

Alan D. Lourie

Randall R. Rader

Alvin A. Schall

William Curtis Bryson

Arthur J. Gajarsa

Richard Linn

Timothy B. Dyk

Sharon Prost

Kimberly Moore

*Daniel M. Friedman*

*Glenn Leroy Archer, Jr.*

*S. Jay Plager*

*Raymond C. Clevenger, III*



## Initial Observations

	Reversed/ Remanded	Affirmed
Ill. Tool Works, Inc. v. Indep. Ink, Inc.	✓	
eBay, Inc. v. MercExchange, LLC	✓	
MedImmune, Inc. v. Genentech, Inc.	✓	
Teleflex, Inc. v. KSR Int'l Co.	✓	
AT&T Corp. v. Microsoft Corp.	✓	
Quanta Computer, Inc. v. LG Electronics, Inc.	✓	



## Initial Observations

Phillips v. AWH Corp.  
(Fed. Cir. 2005)

Has anything changed?



# Initial Observations

- “[T]he court should keep in mind the flaws inherent in each type of evidence and assess that evidence accordingly.”  
(*Phillips v. AWH Corp.*, Fed. Cir. 2005)
- “The sequence of steps used by the judge in consulting various sources is not important; what matters is for the court to attach the appropriate weight to be assigned to those sources in light of the statutes and policies that inform patent law.”  
(*Has anything changed?*)



# Initial Observations

- Less dissent?

Phillips v. AWH Corp.

(Fed. Cir. 2005)

- Dictionary citations?

Has anything changed?

- Reversal rate?



# **I. Claim Construction**

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## **II. Patent Validity**

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## **III. Patent Enforceability -- Inequitable Conduct**

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## **IV. Patent Infringement**

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## **V. Remedies**

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## **VI. Jurisdictional/Procedural/Evidentiary Issues**

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## **VII. Patent Acquisition/PTO Issues**

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## **VII. Patent Licenses and Agreements**

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## ***Claim Construction—A Question Of Law?***

-- *TiVo, Inc. v. EchoStar Commc'ns Corp.* (Fed. Cir. 2008) --

“Although we have characterized claim construction as a question of law even when it involves competing presentations of extrinsic evidence, . . . we recognize that there is substantial force to the proposition that such a conclusion is indistinguishable in any significant respect from a conventional finding of fact, to which we typically accord deference. . . . Applying our governing non-deferential standard of review, we uphold the district court’s conclusion in this case. If we were to treat that ruling as a finding of fact, we would uphold the district court’s ruling *a fortiori* in light of the more deferential ‘clear error’ standard applicable to factual findings.”

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## ***The Federal Circuit Addresses Patent Eligibility***

- The invention of a new or improved process, machine, manufacture or composition of matter is eligible for patent protection.
- Though eligibility does not extend to mathematical algorithms or mental processes in the abstract, courts have determined that business methods and software are eligible for patent protection if they operate on or involve a machine, composition of matter or manufacture.
- Arrhenius Equation -- *Diamond v. Diehr*, 450 U.S. 175 (1981).

# *The Federal Circuit Addresses Patent Eligibility*

*-- In re Nuijten (Fed. Cir. 2007) --*

- A signal containing embedded information, or a “watermark,” is not a process, machine, manufacture or composition of matter and thus is not eligible for patent protection.
- While “a signal is physical and real, it does not possess concrete structure,” and no part of it “is a mechanical ‘device’ or ‘part’.”
- It is “fleeting” and “devoid of any semblance of permanence during transmission.”

# *The Federal Circuit Addresses Patent Eligibility*

*-- In re Comiskey (Fed. Cir. 2007) --*

- Certain methods for mandatory arbitration involving legal documents are not patent eligible. Operation depends entirely on mental processes and human intelligence.
- The Court noted, however, that methods that incorporate the use of general purpose computers and modern communications devices in the arbitration system are eligible.
- Follows often criticized litmus test.

# *The Federal Circuit Addresses Patent Eligibility*

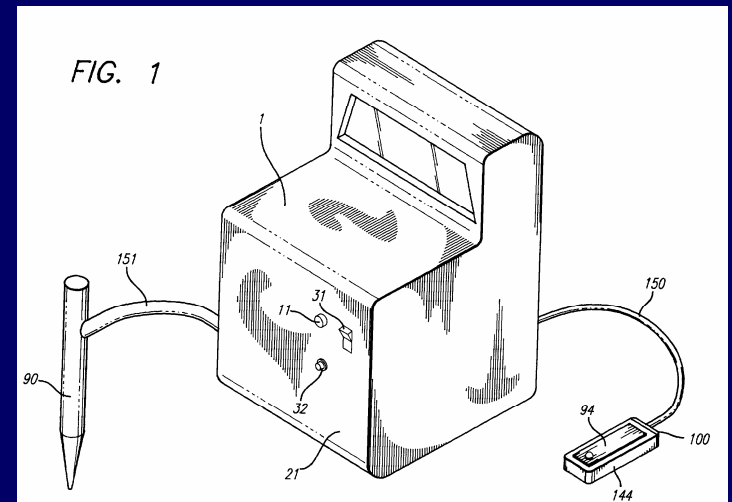
## *-- In re Bilski --*

- Whether claim 1 of the 08/833,892 patent application claims patent-eligible subject matter under 35 U.S.C. § 101?
- What standard should govern in determining whether a process is patent-eligible subject matter under section 101?
- Whether the claimed subject matter is not patent-eligible because it constitutes an abstract idea or mental process; when does a claim that contains both mental and physical steps create patent-eligible subject matter?
- Whether a method or process must result in a physical transformation of an article or be tied to a machine to be patent-eligible subject matter under section 101?
- Whether it is appropriate to reconsider State Street Bank & Trust Co. v. Signature Financial Group, Inc., 149 F.3d 1368 (Fed. Cir. 1998), and AT&T Corp. v. Excel Communications, Inc., 172 F.3d 1352 (Fed. Cir. 1999), in this case and, if so, whether those cases should be overruled in any respect?

## *The Federal Circuit Deals With KSR*

-- *Agrizap, Inc. v. Woodstream Corp.* (Fed. Cir. 2008) --

- Agrizap sued Woodstream in E.D. Pa. for fraudulent misrepresentation and infringement of U.S. Patent No. 5,949,636
- The 636 patent pertains to an electronic rodent-killing device—the “Rat Zapper”



## ***The Federal Circuit Deals With KSR***

**-- *Agrizap, Inc. v. Woodstream Corp.* (Fed. Cir. 2008) --**

### **Obviousness – “A Textbook Case”**

- “This is a textbook case of when the asserted claims involve a combination of familiar elements according to known methods that does no more than yield predictable results. . . . The asserted claims simply substitute a resistive electrical switch for the mechanical pressure switch employed by the Gopher Zapper. As illustrated by the Dye and Madsen patents, the use of an animal body as a resistive switch to complete a circuit for the generation of an electric charge was already well known in the prior art.”
- Objective evidence of nonobviousness “cannot overcome such a strong prima facie case”

## *The Federal Circuit Deals With KSR*

### *-- Cordis Corp. v. Medtronic Ave, Inc. (Fed. Cir. 2008) --*

- Instruction: “A suggestion to combine references may also flow from the nature of the problem or from the ordinary knowledge of those skilled in the art that certain references are of special importance. If the prior art references as a whole do not teach, suggest or motivate that combination, then they may not be combined. The mere fact that the prior art can be modified does not make the modification obvious unless the prior art suggests the desirability of the modification.”
- *KSR*: “Helpful insights, however, need not become rigid and mandatory formulas; and when it is so applied, the TSM test is incompatible with our precedents. The obviousness analysis cannot be confined by a formalistic conception of the words teaching, suggestion, and motivation . . . . There is no necessary inconsistency between the idea underlying the TSM test and the *Graham* analysis. But when a court transforms the general principle into a rigid rule that limits the obviousness inquiry, as the Court of Appeals did here, it errs.”

## *The Federal Circuit Deals With KSR*

-- *Cordis Corp. v. Medtronic Ave, Inc.* (Fed. Cir. 2008) --

- Medtronic has not demonstrated that the instruction was not proper.
  - Medtronic did not object to the instruction, and instead actually proposed it. That either constitutes invited error that is not reviewable, or at most is subject to review under the “plain error” standard.
  - Medtronic says that it should not be penalized for requesting an instruction based on the state of the law prior to *KSR*. But *KSR* states that “there is no necessary inconsistency between the idea underlying the TSM test and the *Graham* . . . analysis.”



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## ***The Federal Circuit Is Strict On Inequitable Conduct***

**-- *Monsanto Co. v. Bayer Bioscience N.V.* (Fed. Cir. 2008) --**

- Employee notes - Widely circulated at Bayer (including to its IP attorney) but not disclosed to the PTO

**-- *McKesson Information Solutions, Inc. v. Bridge Medical, Inc.* (Fed. Cir. 2007) --**

- Simultaneous prosecution of similar patent applications

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## ***The Bayh-Dole Act Is Not A Patent law***

**-- *WARF v. Xenon Pharmaceuticals, Inc.* (Fed. Cir. 2007) --**

- WARF sued Xenon, claiming that Xenon committed various violations of the parties' agreement.
- On appeal, Xenon argued that the reference in WARF's initial complaint to the Bayh-Dole Act gave the Federal Circuit jurisdiction.
- "At its heart, the Bayh-Dole Act concerns government funding agreements . . . an area that is outside our . . . jurisdiction." The Court transferred the case to the Court of Appeals for the Seventh Circuit, the regional circuit court that has jurisdiction over appeals from the district court in Wisconsin in which WARF filed suit.

## ***The Bayh-Dole Act Is Not A Patent law***

-- *WARF v. Xenon Pharmaceuticals, Inc.* (Fed. Cir. 2007) --

- Non-precedential.
- Four judges dissented from the Court's denial of a motion by Xenon to rehear the appeal.
- "The Bayh-Dole Act is, 'at its heart,' a patent law, albeit a patent law that employs some government contract rules to facilitate its patent-related policy objectives."

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## ***Patents At Increased Risk Of Attack***

- A licensee may file a suit for a declaration that a licensed patent is not infringed, is invalid or is unenforceable without first breaching a licensing agreement with the licensor. *MedImmune, Inc. v. Genentech, Inc.*, 127 S. Ct. 764 (2007).
- Prior to this ruling, the Federal Circuit had long required, for jurisdictional reasons, that a party be under a reasonable apprehension of suit before filing a declaratory judgment action.
- After *MedImmune*, however, a “reasonable apprehension of suit” is no longer required.

## ***Patents At Increased Risk Of Attack***

### ***-- SanDisk Corp. v. STMicroelectronics, Inc. (Fed. Cir. 2007) --***

- “[W]here a patentee asserts rights under a patent based on certain identified ongoing or planned activity of another party, and where that party contends that it has the right to engage in the accused activity without license,” then the party may file a declaratory judgment action against the patentee.

### ***-- Micron Technology, Inc. v. MOSAID Technologies, Inc. (Fed. Cir. 2008) --***

- Federal Circuit allowed a declaratory judgment action to go forward even though the party that filed the action had not heard from the patentee in four years.
- The patentee in the meantime had asserted its patents against other parties and publicly announced its intent to aggressively enforce its patent portfolio.



-- The Patent and Trademark Office --



# Ex Parte Reexamination

**TABLE 13A: EX PARTE REEXAMINATION  
(FY 2003 - FY 2007)**

Activity	2003	2004	2005	2006	2007
<b>Requests filed, total</b>	<b>392</b>	<b>441</b>	<b>524</b>	<b>511</b>	<b>643</b>
By patent owner	136	166	166	129	124
By third party	239	268	358	382	519
Commissioner ordered	17	7	-	-	-
<b>Determinations on requests, total <sup>1</sup></b>	<b>381</b>	<b>419</b>	<b>537</b>	<b>458</b>	<b>594</b>
Requests granted:					
By examiner	360	408	509	422	575
By petition	1	-	2	5	2
Requests denied	20	11	26	31	17
<b>Requests known to have related litigation</b>	<b>109</b>	<b>138</b>	<b>176</b>	<b>229</b>	<b>369</b>
<b>Filings by discipline, total</b>	<b>392</b>	<b>441</b>	<b>524</b>	<b>511</b>	<b>643</b>
Chemical	124	130	138	118	133
Electrical	118	156	188	228	275
Mechanical	150	155	198	165	235

**Notes:**

1: Past years' data have been revised from prior year reports. ([back to text](#))



# Inter Partes Reexamination

**TABLE 13B: INTER PARTES REEXAMINATION  
(FY 2003 - FY 2007)**

Activity	2003	2004	2005	2006	2007
Requests filed, total	21	27	59	70	126
Determinations on requests, total	20	25	57	47	119
Requests granted:	18	25	54	43	118
By examiner	18	25	54	43	118
By petition	-	-	-	-	-
Requests denied	2	-	3	4	1
Requests known to have related litigation	7	5	29	32	81
Filings by discipline, total	21	27	59	70	126
Chemical	3	6	17	17	30
Electrical	7	7	20	27	53
Mechanical	11	14	22	26	43



## PTO's Promulgation of New Rules

- Rule changes that shift the burden from the Examiner to the Applicant
  - 35 U.S.C. § 102: “A person shall be entitled to a patent unless”
  - The language of section 102 “clearly places a burden of proof on the Patent Office.” *In re Warner*, 379 F.2d 1011, 1016 (CCPA 1967).



## *Tafas/GSK v. Dudas*

- PTO instituted new rules that create changes to the examination process that would limit the number of continuing applications, RCEs, and claims that an applicant could make as a matter of right. See 72 Fed. Reg. 46, 716-843 (Aug. 21, 2007).
- E.g.: An applicant may have more than 5 independent claims or 25 total claims but must provide an Examination Support Document that contains information about the claims that may assist the examiner in determining the patentability of the claimed invention.



# 1. The PTO's Rule-Making Authority?

- Procedural Rules – **Yes**
  - *Lacavera v. Dudas*, 441 F.3d 1380, 1383 (Fed. Cir. 2006):  
“Under 35 U.S.C. 2(b)(2), the PTO has broad authority to govern the conduct of proceedings before it and to govern the recognition and conduct of attorneys.”
  - *In re Borgese II*, 303 F.3d 1362, 1367-68 (Fed. Cir. 2002):  
“The PTO has inherent authority to govern procedure before the PTO, and that authority allows it to set reasonable deadlines and requirements for the prosecution of applications.” (citations omitted)



# 1. The PTO's Rule-Making Authority?

- Substantive Rules – No
  - *Brand v. Miller*, 487 F.3d 862, 869, n.3 (Fed. Cir. 2007):  
“But this is not a *Chevron* situation both because the issue is factual, not legal, and because we have held in any event that the Board does not earn *Chevron* deference on questions of substantive patent law.”
  - *Merck & Co., Inc. v. Kessler*, 80 F.3d 1543, 1550 (Fed. Cir. 1996): “[The statute] does NOT grant the Commissioner the authority to issue substantive rules . . . . Congress has not vested the Commissioner with any general substantive rulemaking power . . . .”



## 2. Are the Rules Substantive?

- District Court's Findings
  - Any rule that affects individual rights and obligations is substantive.
  - These rules are a “drastic departure” from the applicant’s rights and obligations under the Patent Act, and are neither procedural nor lead only to collateral substantive consequences.





## Final BPAI Rules – June 10, 2008

- Applicant must file a “claims analysis” – Points to “the page and line or paragraph after each limitation where the limitation is described in the specification.”
- 30-page limit for Grounds of Rejection, Statement of Facts, Arguments.