



**Patent Reform Legislation
Intellectual Property Case Law Developments
and Resulting Litigation Issues**

Presentation to SDIPLA

November 19, 2009

PRESENTER

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Building a Formidable Patent Fortress

- Four Cornerstones of a Solid IP Foundation
 - Scope and Quality of Science
 - People and Resources to Execute
 - Well-Conceived Strategy and Alignment
 - External Environment (X Factor)

**Unprecedented
Assault on Patents**

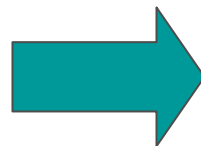




External Environment (X-Factor)

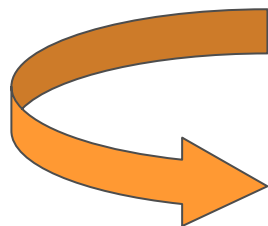
Then

Unified Industry Approach
Pro-Patent Legislative Environment
Non-Activist USPTO
Pro-Patent Court System



Now

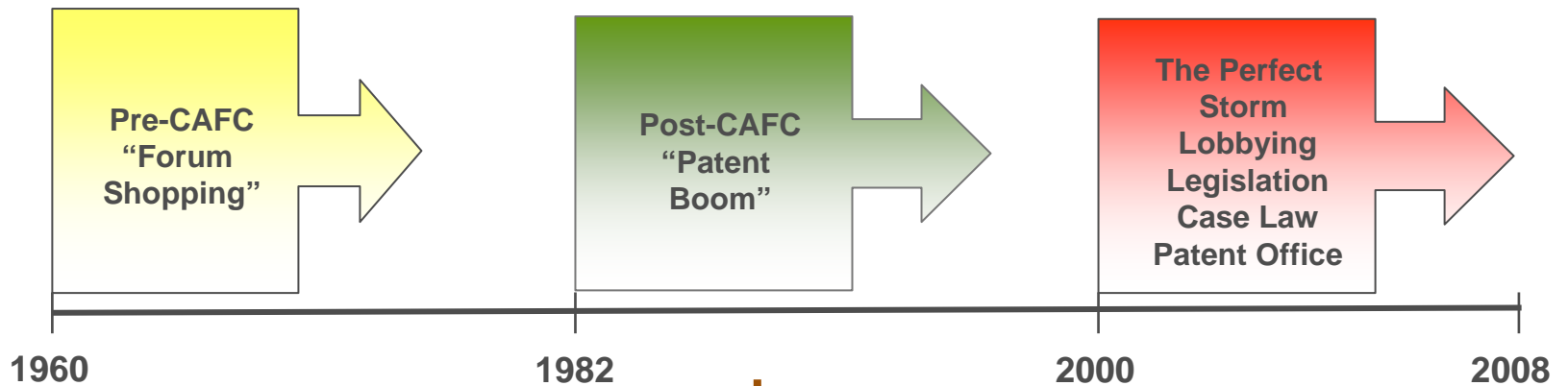
Partisan Lobbying by High Tech
Comprehensive Legislative Reform
Activist USPTO
Significant Case Law Erosion



The Rise . . .

and Fall of the Patent Empire . . .

The Rise and Fall of the Patent Empire



The Pendulum



The Rise and Fall of the Patent Empire

- **Impact of the Court of Appeals for the Federal Circuit (“CAFC”) on Patentee’s Rights**
 - Established in 1982
 - Nationwide jurisdiction for all Federal District Court patent appeals
 - Single forum for evolution of a unified more predictable body of law
 - In the 25 years preceding the CAFC, the number of patents increased by ~25%
 - In the 25 years after the CAFC, the number of patents increased by ~400%
 - Obviated “Forum Shopping”



The Rise and Fall of the Patent Empire

PATENTEE WINS

	Patentee Wins in Lower Court (Valid & Infringed)	Affirmed on Appeal
Pre-CAFC	30%	62%
Post-CAFC	60 – 65%	80 – 90 %

ACCUSED INFRINGER WINS

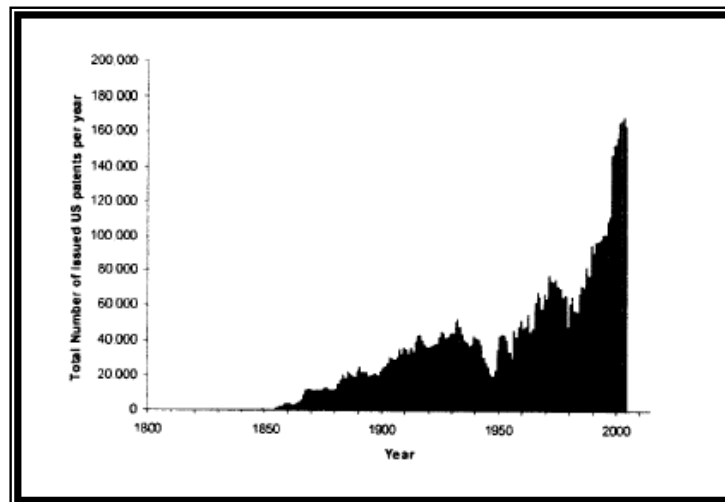
	Accused Infringer Wins in Lower Court (Invalid and/or not infringed)	Affirmed on Appeal
Pre-CAFC	70%	88%
Post-CAFC	35 – 40%	72 %

Unprecedented Number of Patent Filings

“USPTO 2007 Fiscal Year-End Results Demonstrate Trend of Improved Patent and Trademark Quality”

“Production at All-time Record Levels”

- 362,227 applications examined in 2007 – highest number in history
- In 2000, a record high of 72% of all patent applications matured into patents





Unprecedented Number of Patent Lawsuits

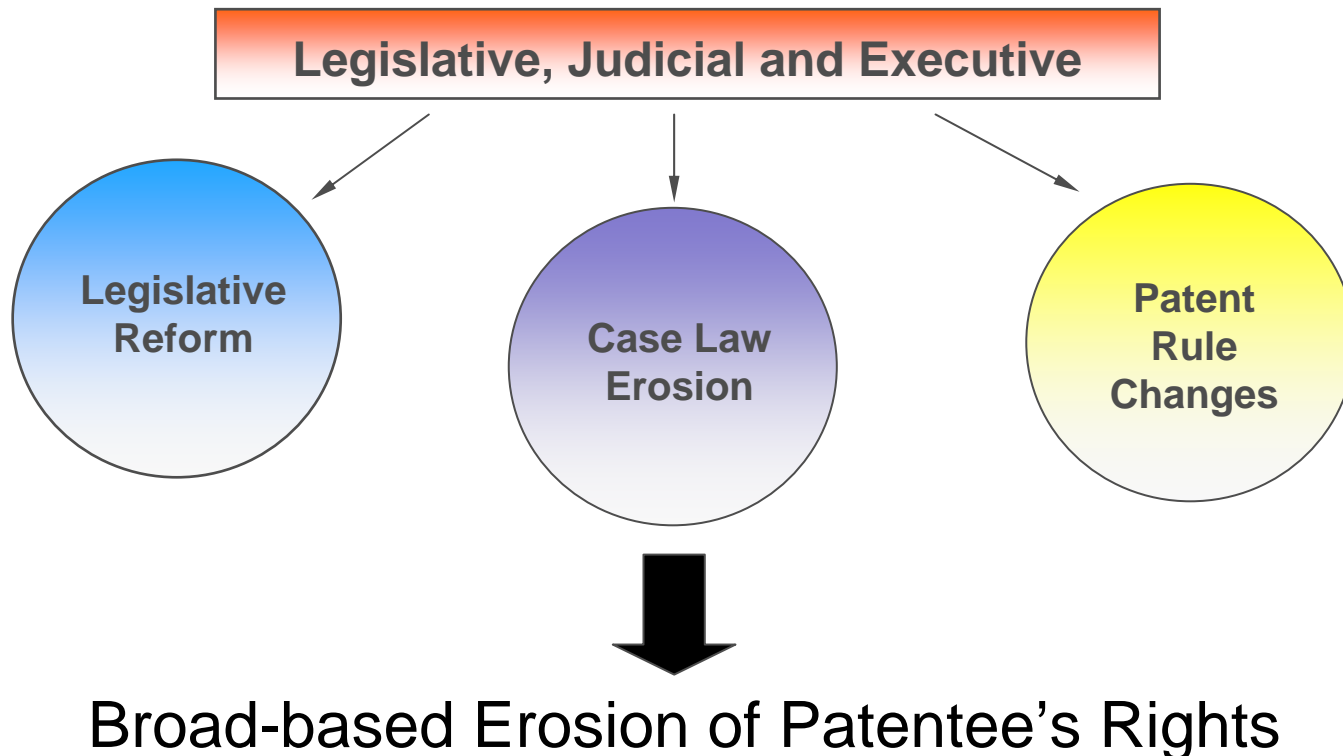
- U.S. Intellectual Property collectively valued at > \$5 trillion
- “Patent Thickets” – multiple sets of patents in same technology area
 - > Particularly in High Tech
- Multiple licenses leading to royalty stacking concerns
 - > Cost / Benefit Analysis
- The number of patent lawsuits has tripled between 1991 and 2004
- Patent cases can cost \$5-30 million through trial depending on complexity / economic importance
- These factors have combined and led to an overtaxed system creating the conditions for . . .



The “Perfect Storm”

The intensifying policy issues have caused:

- A significant increase in lobbying efforts by High Tech
- Involvement of all three branches of Government





Patent Reform Lobbying Efforts

Legislative Branch - Articulated Reasons for Reform

- Pro-Patent CAFC
- Patent Office overtaxed
 - > Number of Examiners per 1000 applications – down 20% over last few years
 - > High turnover rate
 - > Increased patent complexity
- Issuance of Questionable Patents
 - > Patent to Smuckers for its peanut butter and jelly sandwich
 - > Patent to Amazon for “one-click”



Patent Reform Lobbying Efforts

Real Reasons for Reform – Follow the Money . . .

- “Patent Trolls” and resulting economic damage to High Tech Industry
- Assertion of “submarine” patents years after technology has developed and markets have matured
- Pitched as Patent Reform, but really about Litigation Reform
- Pitched as High Tech vs. Biotech, but really about Global Competitiveness



The Eye of the Storm

Legislative Branch - Legislative Amendments Proposed

- **Abandonment of presumption of validity**
- **Revamp system from first to invent to first to file**
- **Pre-grant oppositions**
- **Post-grant reexamination**
- **Limitations on damages to the economic value of the improvement**
- **Limitation on when damages may be trebled for willful infringement**
- **Third party submission of prior art**
- **Modifying definition of Inequitable Conduct**
- **Requirement for search reports by patentee**
- **Requirement for applicant to analyze and distinguish all prior art**
- **Delegation of substantive rulemaking authority to USPTO**
- **Counterpart generics legislation for Generic Biopharmaceuticals (“Biogenerics”)**



Patent Reform Act of 2009

- S.515 (Senate Judiciary Committee passed the Bill in April)
- H.R. 1260 (has not advanced)
- Latest Developments

CQ TODAY ONLINE NEWS – LEGAL AFFAIRS

Oct. 30, 2009 – 2:34 p.m.

Commerce Dept., Judiciary Chairmen Negotiating Patent Law Revision

By Keith Perine, CQ Staff

Senate and House lawmakers are negotiating a major rewrite of federal patent law with the Obama administration, in the hope of producing a bill that can quickly be cleared for the president's signature this year.

U.S. Patent and Trademark Office (USPTO) Director David Kappos, a former lawyer for IBM Corp., is leading talks that involve the chairmen and ranking members of the Senate and House Judiciary committees. . .

Negotiations are focusing on the way patents are reviewed once they are granted. In an Oct. 15 letter to Senate leaders, 12 Republican senators said the relevant language in the committee-approved version of Leahy's bill was "quite problematic" because it would allow serial challenges to patents at the USPTO and in U.S. courts.



Patent Reform Act of 2009

- Different Feel From Prior Years
- Components Remaining in Bill
 - > First to File System – “First Inventor to File”
 - > Damages Assessment
 - Codification of Georgia Pacific standard rejected
 - Compromised on “Gatekeeper” Role of Judge
 - > PTO Cancellation Proceedings
 - Third-Party Reexamination Already Permitted
 - Post Grant Opposition
 - Single Window vs. Double Window
 - No Presumption of Validity
 - Lower Burden of Proof
 - Estoppel Effect Under Debate
 - > Venue – Requires Transfer if Clearly More Convenient
 - > Fee Setting Authority
 - > Rule Making Authority



Patent Reform Act of 2009

- Critics have raised concerns over two former high-level executives at IBM and Microsoft for their key roles in patent reform efforts

David Kappos

- > Former Vice President and Assistant General Counsel at IBM
- > Director of USPTO
- > As one of the Obama administration's chief negotiators on the bill and the main adviser to Commerce Secretary Gary Locke on patent issues, Kappos is a central figure in formulating the administration's policy

Critics Raise Concerns at Commerce

By Michael Falcone

POLITICO

November 2, 2009

At Kappos's July confirmation hearing for the Commerce post, Sen. Arlen Specter (D-Pa.) grilled him on his ties to IBM. He pledged to steer clear of any issues that involved the company.

"To me, it's extraordinarily important that I have absolutely nothing to do with any particular decision that involves my former employer if I am confirmed for this job," Kappos said at the time.

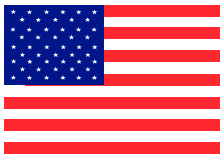
He added: "Like other people who are in private industry and move to the government, I will put my previous role behind me and focus entirely on doing the right thing for the United States of America."



Patent Reform Act of 2009

Marc Berejka

- > Held Senior Government Affairs/Lobbyist roles at Microsoft
- > Now Senior Policy Advisor to Obama Administration
- > Berejka has helped coordinate the department's efforts to reach out to stakeholders involved in the debate and has been involved with the department's patent reform messaging efforts
- > Berejka's job at the Commerce Department did not require Senate confirmation



On his first full day in office, President Barack Obama issued an executive order banning appointees of his administration from working on any matter “involving specific parties that is directly and substantially related” to their former employers for a period of two years. Former lobbyists entering government are subject to even stricter ethics rules. Still, a number of appointees who did not meet the guidelines managed to find their way into the executive branch; some were issued waivers allowing them to serve in key roles

Neither Kappos or Berejka sought or obtained waivers



Patent Reform Act of 2009

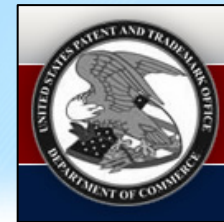
- Melanie Sloan, executive director of Citizens for Responsibility and Ethics in Washington, an organization that monitors ethics in government, said that, at the very least, Kappos should have recused himself from the patent reform matter

“I don’t understand why someone who testified on this issue for IBM is working on the exact issue in Commerce,” Sloan said. “It’s completely in violation of the rules.”

She added: “Even if you get past your technical ethics problem, you can’t get past your appearance problem. Appearance counts.”



New USPTO Rules



Executive Branch – USPTO Rule Changes

Further Erosion of Patentee's Rights

- Objective
 - > Stated objective is to improve patent office efficiencies
- Most Sweeping Set of Rule Changes in History
 - > Rules to apply retroactively to all applications pending as of November 1, 2007 and all applications must be brought into compliance with new rules by February 1, 2008



Proposed USPTO Rule Changes



Rule Changes to Patent Claims

- > **Current rules have no limitation on the number of claims which may be filed in an Application**
- > **Proposed rules provide significant limitations on number of claims which may be filed for each Application**
 - Maximum of 5 independent claims per Application
 - Maximum of 25 total claims per Application
 - Maximum of 15 independent claims per Application family
 - Maximum of 75 total claims per Application family

Rule Changes to Continuation Applications

- > **Current rules have no limitation on number of Continuation Applications which may be filed**
- > **Proposed rules allow only 3 Continuation Applications**



Judiciary - Tafas v. Doll (Fed. Cir. 2009)

Issue – Power of the PTO to make new rules

- > Upheld power of PTO to make many of new Claims and Continuations Rules
 - New rules procedural, not substantive
 - New rules on Claims, RCE's and ESD's within PTO power, remanded to review additional arguments
 - New rules on continuations invalidated (substantive)
- > Dissent – PTO lacked power because new rules substantive
- > **Appealed** – Briefing schedule suspended pending discussions with new PTO Commissioner, John Kappos
- > **Rescinded** – On October 8, PTO Commissioner rescinds proposed rules and pending litigation to be vacated
- > **But...** Kappos is pushing for fee-setting and rulemaking authority in the Patent Reform Bill



Case-Based Limitations on Patent Rights

- **Obviousness Expanded**
- **Safe Harbor Provision Expanded**
- **Injunctions Harder to Obtain**
- **Willful Infringement Harder to Prove**
- **Business Method Patentability (Bilski)**



Obviousness

“A patent may not be obtained . . . if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made”

35 U.S.C. § 103(a)



KSR Int'l Co. v. Teleflex Inc.

Issues:

- > Is “teaching, suggestion, motivation” test proper standard for determining § 103 obviousness?

Key Holdings:

- > CAFC’s “rigid” TSM test rejected
- > TSM test “helpful insight” but not exclusive



KSR Int'l Co. v. Teleflex Inc.

Key Quote:

“The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results.”

(at 1739)



Safe Harbor Provision

“It shall not be an act of infringement to make, use, offer to sell, or sell . . . a patented invention . . . solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use or sale of drugs or veterinary biological products.”

35 U.S.C. § 271(e)(1)



Merck KGAA v. Integra Lifesciences I, LTD.

Issue:

“[W]hether uses of patented inventions in preclinical research, the results of which are **not ultimately included in a submission** to the Food and Drug Administration (FDA), are exempted from infringement by **35 U.S.C. § 271(e)(1).**” (at 195) (emphasis added)



Merck KGAA v. Integra Lifesciences I, LTD.

Key Holdings:

- Preclinical studies protected by safe harbor
- Preclinical “general research” protected
- Protection possible without FDA submission
- Research without FDA intent not protected



Injunctions

- **In cases where validity / infringement were proven, high likelihood of obtaining injunctive relief**
- **Injunctions provided significant leverage in settlement negotiations / licensing discussions**



eBay Inc. v. MercExchange, L.L.C.

Issue:

- > Does “general rule” of issuing permanent injunction against infringement hold?

Key Holdings:

- > Court must apply traditional four-factor test before entering permanent injunction



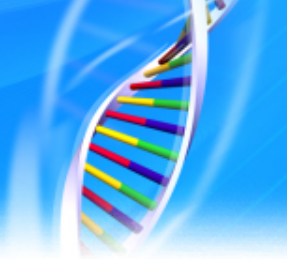
eBay Inc. v. MercExchange, L.L.C.

- “Irreparable Harm” -- injunction more likely if:
 - > Direct competitors
 - > Price erosion
 - > New market
 - > Lost sales, market share, customers
 - > Patent is major component
 - > Patentee has not licensed
- “Adequate Remedy”
- “Balance of Hardships”
- “Public Interest”



Injunctions – Practical Results

- Likelihood of preliminary injunction reduced
- Likelihood of permanent injunction reduced
- Value of litigation reduced
- Litigation strategy altered
- Value of “property” right to exclude reduced
- Prospect of “compulsory license” enhanced
- Value of patents reduced



Willful Infringement – Previous Standard

“Where . . . A potential infringer has actual notice of another’s patent rights, he has an affirmative duty to exercise due care to determine whether or not he is infringing. Such an affirmative duty includes, inter alia, the duty to seek and obtain competent legal advice from counsel before the initiation of any possible infringing activity.”

Underwater Devices, Inc. v. Morrison-Knudsen Co., 717 F.2d 1380, 1389-90



In Re Seagate Technology, LLC, 497 F.3d 1360 (Fed Cir 2007) (En Banc)

New Standard:

“[T]o establish willful infringement, a patentee must show by clear and convincing evidence that the infringer acted despite an objectively high likelihood that its actions constituted infringement of a valid patent.”



Business Method Patentability

- **Oral Argument on Bilski vs. Kappos held before U.S. Supreme Court on November 8, 2009**
 - > Did the CAFC err in finding business method claim for a “process” of hedging consumption risk invalid as unpatentable as outside the scope of 35 U.S.C. §101
 - > Bilski has been drawn more intense interest from diverse industries with massive commercial power than any other case
 - **68 amicus briefs in Bilski vs. Kappos**
 - **37 amicus briefs in KSR Int’l Co vs. Teleflex, Inc.**
 - **31 amicus briefs in eBay, Inc. vs MercExchange, L.L.C.**
 - **27 amicus briefs in Festo Corp. vs. Shoketsu**
 - **17 amicus briefs in Medimmune, Inc. vs. Genentech, Inc.**
 - > CAFC (en banc) held that a “process” must be tied to a particular machine or apparatus, or transform a particular article into a different state or thing as the sole and definitive test
 - > Based on Supreme Court comments, CAFC’s “machine or transformation” test as sole test for a patentable process may be invalidated as unduly rigid
 - Justice Sotomayor referred to the CAFC ruling as “extreme”
 - Justice Breyer said he was “nervous about the circuit decision”
 - Justice Ginsburg referred to it as an unnecessary “bold step”



Bilski vs. Kappos

- > The Justices discussed several possible rationales for invalidating the claim
- > The Justices did not appear to reach agreement on a single rationale for invalidating the claim
- > Chief Justice Roberts and Justice Alito emphasized that the claim is an attempt to patent the abstract idea of hedging consumption risk
- > Justice Sotomayor proposed a blanket rule that "patent law does not cover business methods"
- > Justice Scalia proposed "no business methods except those attached to a machine"
- > Justice Ginsburg proposed a "tied to technology" test



Bilski vs. Kappos

- **The Supreme Court appears unlikely to rule on the patentability of software, medical diagnostics, or any other particular type of patent claim**
 - > Justices Breyer and Sotomoyor both expressed awareness of the difficulty of announcing unduly broad exclusions of patentability
 - > Justice Kennedy noted that the United States had urged against further review out of concern the Supreme Court would "mess it up"

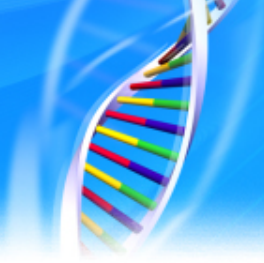


Bilski vs. Kappos

- **One possible outcome:**

- > The Court might issue a short unanimous decision holding the hedging claim invalid because it is unlike any process claim previously approved by the Court and not deal with broader software, diagnostic etc issues
- > Several of the Justices could issue separate concurrences stating more precise views
- > The Court followed this approach in the 2006 *eBay Inc. v. MercExchange LLC* decision

- **An opinion could issue in a few months, and will certainly issue by June 2010**

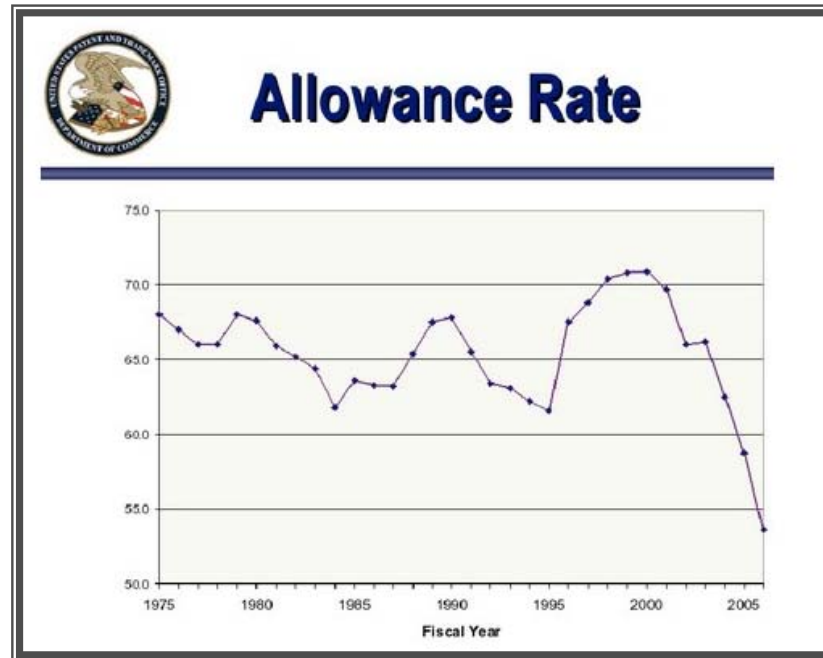


**What is the Practical and Economic
Impact from the Perfect Storm?**

Do we even need Patent Reform?

USPTO Allowance Rate – Lowest in History

Precipitous
drop in ...



- In 2000, 72% of patent applications matured into patents
- In 2007, down to 51%
- In 2008, down to 44.2%
- In 1Q09, down to 42%



Practical and Economic Repercussions

- More case law arguments to invalidate patents
- Expansion of administrative challenges to invalidate patents in administrative proceedings
- More “shots on goal” by accused infringer
- Potential for abuse from repeated / consecutive challenges
- Estoppel effect unclear
- Lower burden of proof to invalidate patents
- Loss of presumption of validity in certain proceedings
- Pro-infringer bias / No support for Innovation



Practical and Economic Repercussions – (Con't)

- Loss of Venture Capital confidence and financial support
- Slowing of economic engine at worst possible time
- Slower job creation and, in fact, job loss
- Creates a huge additional workload burden on PTO
- More difficult to obtain preliminary / permanent injunctions
- More difficult to prove willful infringement and obtain treble damages
- Less leverage for successful patentee settlement / licensing discussions



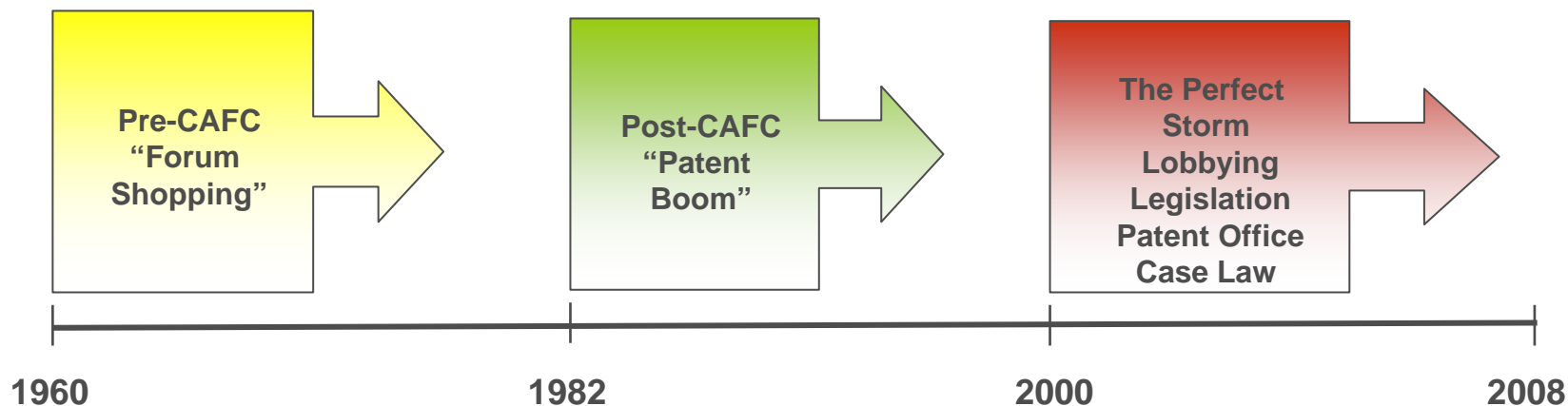
Loss of Global Competitiveness

Loss of Global Competitiveness

Comment regarding U.S. Patent Reforms by former judge in the high court of Beijing:

[I]n general the bill favors infringers and burdens patentees more. It is not bad news for developing countries which have lower technological development and relatively fewer patents. Due to the weak foundation of patents, the Chinese products often encounter trouble in the U.S. market. This bill will provide more mechanisms and flexibilities in making patent challenge strategies, and also lower the cost of infringement, therefore the infringement will become easier...”

The Rise and Fall of the Patent Empire



The Pendulum



has swung . . .

Questions

