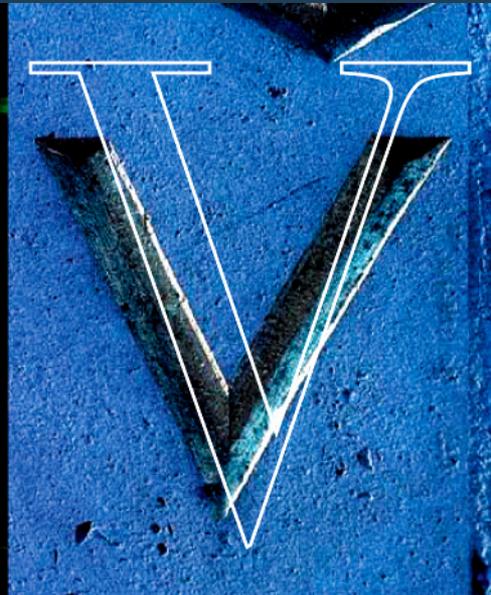
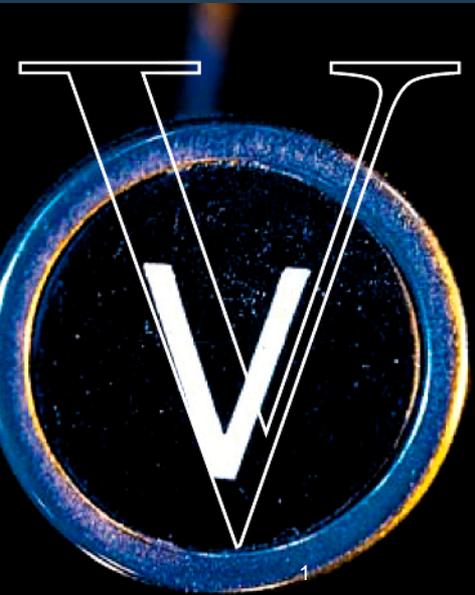


PATENT REFORM MARCHES ON

Clifton E. McCann, Esq.

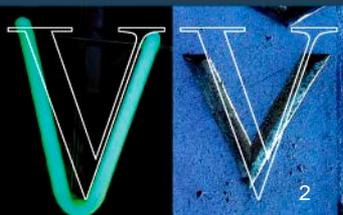
Lars H. Genieser, Esq., Ph.D.

Venable LLP



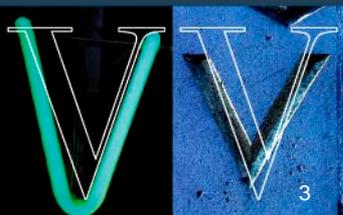
Tumultuous times in patent law

- Supreme Court reviewing patent decisions at historically high rate
 - 1982-2004: One decision every 3 years
 - 2005-2012: One decision every 7 months
- America Invents Act continues to phase in
 - Enacted in 2011, phasing in through 2013
 - Biggest changes since 1952
- Patents continue to attract capital



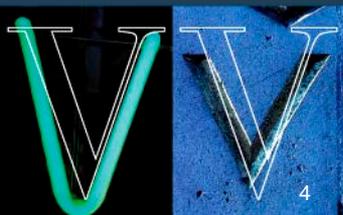
Kappos v. Hyatt (S.Ct. 2012)

- Patent applicants who disagree with PTO's rejection of applications can appeal to the U.S. District Court in VA.
- At issue: Can the disgruntled patentees add new evidence of patentability when they appeal to the Court?
- Why litigated?: Some thought the answer should be “no” because otherwise patentees get extra bite at apple.
- Supreme Court's holding: New evidence can be added.
- Significance of holding:
 - Some inventions represent small technological advance, but evidence can show that the small advance was deserving of a patent
 - Sometimes such evidence is unavailable during prosecution
 - *Kappos* decision allows patentees more time to acquire and present evidence of patentability



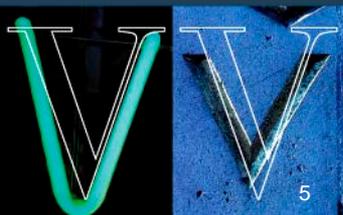
Mayo v. Prometheus (S.Ct. 2012)

- “Anything under the sun that is made by man” is patentable; But not “laws of nature, natural phenomena, and abstract ideas”.
- At issue: Is a method that requires measuring the concentration of a metabolite in a sample taken from a patient and, based on the metabolite concentration, adjusting the amount of an administered drug, patentable?
- Why litigated?: Medical experts and other groups believed that patentability of such claims would constrain the availability of scientific data required for physicians to provide sound medical care.
- Supreme Court’s holding: A method that only requires applying a law of nature (in this case, the range of metabolite concentrations associated with a beneficial dose of the drug) with minimally specific claim elements setting forth the application is not patentable.
- Significance of holding:
 - Constrains the patenting of diagnostic claims.
 - Patent applicants should ensure that claims contain sufficiently specific limitations on how physiological measurements and critical values are applied to effect a desired change.
 - S.Ct. subsequently ordered Fed. Cir. to reconsider 2011 decision upholding Myriad patent claims to isolated DNA associated with breast and ovarian cancer.



Stanford Univ. v. Roche (S.Ct. 2011)

- This case decided who gets ownership of patents for government-sponsored research.
- At issue: Absent an agreement, does the inventor own, or research institution?
- Why litigated?: Research institutions believed inventor ownership interferes with patent licensing and enforcement.
- Supreme Court's holding: An inventor is entitled to the ownership and the Bayh-Dole Act did not change that fundamental principle.
- Significance of holding:
 - Some institutions will need to pay individual inventors for rights to their inventions.
 - In future, institutions must be more careful to ensure agreements are in place.



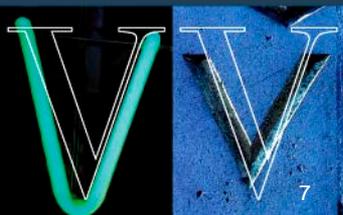
Microsoft v. i4i (S.Ct. 2011)

- Determines the standard an alleged infringer must meet when challenging a U.S. patent on prior art grounds.
- At issue: When the PTO examiner did not consider the best prior art, should the presumption of validity be diminished?
- Why litigated?: Some felt a patent should not be presumed valid when the best art not considered.
- Supreme Court's holding:
 - Notwithstanding new and better art, the patent should still be presumed valid
 - A preponderance of evidence is not enough to overcome the presumption ... the presumption can only be overcome by **clear and convincing** evidence of invalidity
- Significance of holding:
 - Favors patent owners. Maintains strong presumption of validity.



Global-Tech v. SEB (S.Ct. 2011)

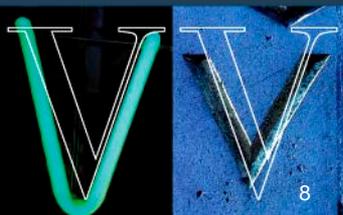
- Redefines test for liability when a company does not infringe itself, but encourages its customers to infringe.
- At issue: Is a company liable for patent infringement if it does not know about the infringed patent?
- Why litigated?: Some believed it was too easy for companies to avoid liability through carelessness.
- Supreme Court's holding: Inducement to infringe liability requires knowledge that the induced conduct infringes, but this knowledge requirement can be met by if **WILLFUL BLINDNESS** is shown, namely:
 - Company subjectively believes there is high probability of patent infringement, and
 - Company takes deliberate actions to avoid learning that fact.
- Significance of holding:
 - Easier to avoid infringement by inducement
 - “Deliberate indifference,” “recklessness” or negligence“ not enough.



Next AIA phase: September 16, 2012

5 new provisions become effective:

- Easier to cite prior art against a competitor's patent application in PTO
- Patent owner can remove cloud of possible inequitable conduct charge via new procedure
- Method patents directed to finance industry become subject to new type of PTO challenge
- New pro-challenger procedures become available in reexamination proceedings
- Willfulness becomes more difficult for patentees to prove across the board



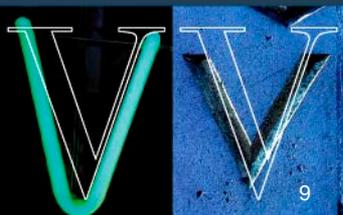
Battling over new procedures ...

- New provisions come with new questions and new battles between differing interest groups.

- Current rulemaking addresses four new procedures:
 - Post-Grant Review
 - Inter Partes Review
 - Transitional Proceeding for challenging finance-related method patents
 - Derivation Proceedings

- PTO has proposed new rules that will determine how patents are challenged in the PTO.

- Debate is now raging between patent owner and patent user groups as to whether draft rules make it too hard or too easy for patent rights to be challenged in the PTO.



Wall Street continues to value patents

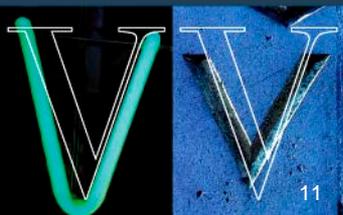
- 2009 spate of pharmaceutical acquisitions driven in part by expiring “blockbuster drug” patents (Pfizer (Lipitor; Protonix) acquires Wyeth; Roche acquires Genentech; Merck (Singulair) acquires Schering-Plough)
- 4/2011 Sanofi (Plavix) acquires Genzyme for \$20 bil.
- 4/2011 J&J (Levaquin; Concerta) intends to acquire Synthes for \$21 bil.
- 5/2011 Microsoft acquires Skype for \$8.5 bil. (VOIP patents)
- 8/2011 Google acquires Motorola Mobility for \$12.5 bil.
- 8/2011 Ecolab acquires Nalco for \$8 bil.
- 2/2012 Baxter acquires Synovis for \$0.26 bil.
- 4/2012 Microsoft acquires 925 AOL patents for \$1 bil. (with subsequent sale of 650 patents to Facebook for \$0.55 bil.)
- 4/2012 GSK bids \$2.6 bil. for Human Genome Sciences (Benlysta) (rejected)
- 4/2012 AstraZeneca acquires Ardea Biosciences for \$1.3 bil. (lesinurad)



Clifton E. McCann

(cemccann@venable.com; 202.344.8162)

- Mr. McCann is an AV-rated patent attorney and a partner at Venable LLP in Washington, DC. He has 30 years of experience helping clients plan patent strategies, obtain patents, and license and defend patent rights.
- Water technology has been a primary focus of Mr. McCann's career. In water tech he has obtained and licensed U.S. and foreign patents and has an undefeated record as first-chair trial counsel in three federal district courts and the U.S. Court of Appeals for the Federal Circuit, with awards and settlements reaching eight figures.
- Mr. McCann has chaired the Patent Section of the Bar Association of the District of Columbia and the American Bar Association's Committee on Intellectual Property Litigation. He is a member of the American Intellectual Property Law Association, the Intellectual Property Owners Group, the Licensing Executives Society, and the American Chemical Society.
- Mr. McCann received an LL.M. in patent law from George Washington University, a J.D. from Catholic University of America, and a bachelor's from Northern Illinois University, where he studied chemistry and biology. He frequently speaks and writes on patents.



Lars H. Genieser (lhgenieser@venable.com; 202.344.8234)

- As a registered patent attorney in Venable's Technology Division, Lars Genieser advises clients in managing complex international intellectual property portfolios, licensing intellectual property, and prosecuting patents before the USPTO.
- Dr. Genieser counsels clients in the chemical process, pharmaceutical, and environmental remediation sectors, and has prosecuted patents pertaining to, for example, high purity water electrodeionization treatment, protective polymer coatings, plasma processing, small molecule drug therapies, and quantum-dot-based medical and biological analysis.
- Dr. Genieser received a J.D. from Georgetown University, a Ph.D. in Chemical Engineering from the Massachusetts Institute of Technology, and a B.S.E. from Princeton University.
- He is a member of the American Intellectual Property Law Association, the ABA, the American Chemical Society, and the Sigma Xi Scientific Research Society. He writes articles and speaks on developments in patent law.

