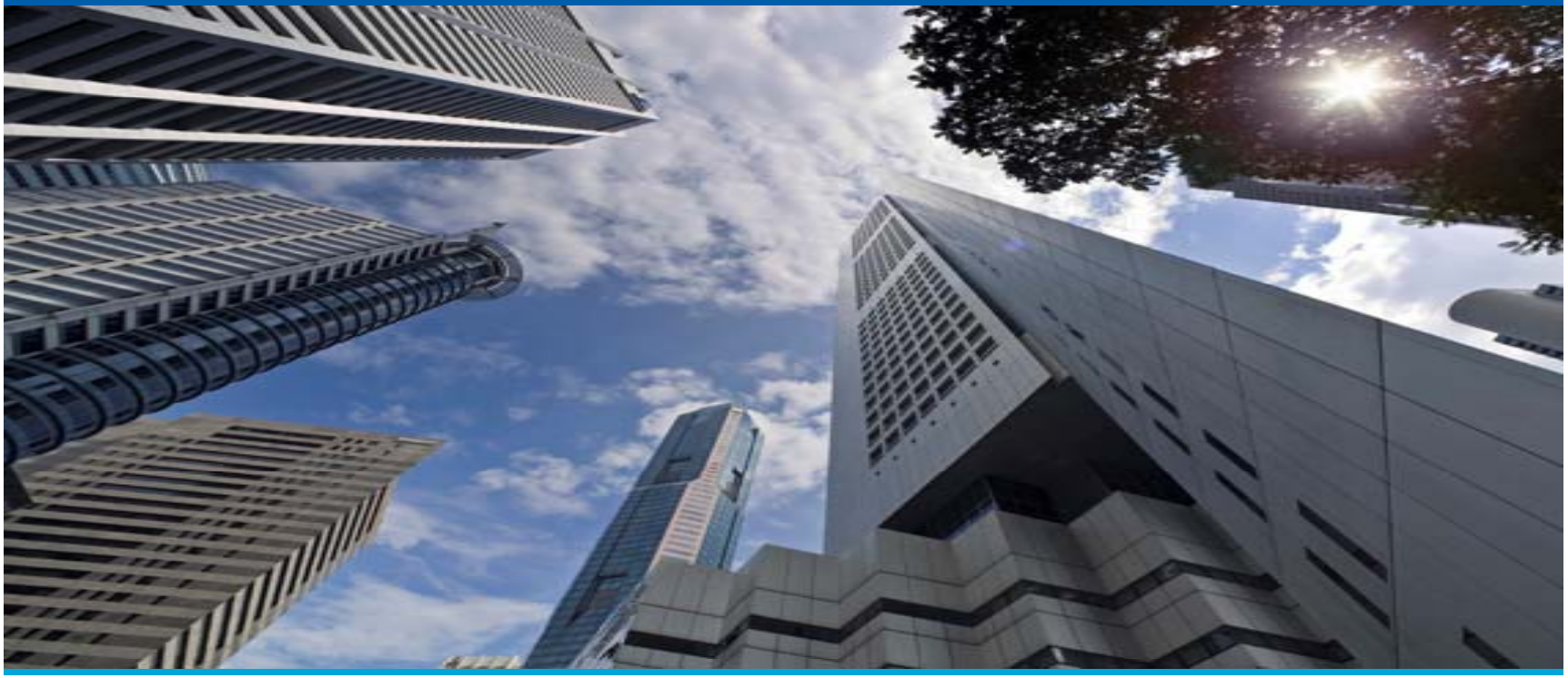
WHITE & CASE



Current Developments in U.S. Patent Law

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Developments: 2011-2012

- **Legislation: America Invents Act (*signed into law on Sept. 16, 2011*)**
- **Supreme Court: remains active in reviewing patent cases**
- **Federal Circuit: *en banc* review to address significant issues**

America Invents Act – Highlights

- **Effective Sept. 16, 2011: litigation reform**
  - Prior Commercial Use defense – expanded beyond business method patents (*process or product used in commercial process)*
  - Best mode (35 U.S.C. § 282) – no longer a defense (but still required for patentability)
  - False marking reform
  - Joinder – permissible if infringement of same accused product or process; joint & several liability; common question
  - Tax strategies within prior art
  - Ban on claims covering human organism

America Invents Act – Highlights

- **Effective Sept. 16, 2012:**
  - Pre-issuance submissions by third parties – *patents, published applications, printed publications*
  - Supplemental examination (available to patentee) – *limit inequitable conduct charges*
  - Inter-partes review (replaces inter-partes reexamination) – *102 & 103 grounds only, patents and printed publications only (estoppel effect)*
    - Reasonable likelihood that requester would prevail on at least one of the claims challenged

America Invents Act – Highlights

- **Effective March 16, 2013:**
  - Shift to **"First-Inventor-to-File"** system
  - Prior art determination based on "effective filing date" (*but one-year grace period exists for inventor "disclosures"*)
  - Derivation proceedings (*replaces interference*)
  - Post-Grant Review (full implementation) – *first 9 months after issue; any grounds of invalidity (except best mode), any prior art (estoppel effect)*

Supreme Court: Burden of Proof Invalidity

- **Microsoft Corp. v. i4i Limited Partnership, 131 S. Ct. 2238 (June 9, 2011)**
  - Affirms Federal Circuit on burden of proof for establishing invalidity (*i4i Limited Partnership v. Microsoft Corp.*, 598 F.3d 831 (Fed. Cir. 2010)

- **Holding (8-0): 35 U.S.C. § 282 requires an invalidity defense to be proved by clear and convincing evidence**
  - **Clear and convincing standard applies to all prior art arguments**
  - **However, "if the PTO did not have all material facts before it…the challenger's burden to persuade the jury of its invalidity defense by clear and convincing evidence may be easier to sustain"**
    - **Jury instructions may be given instructing that PTO did not evaluate the new evidence**

Supreme Court: Knowledge Requirement for Inducing Infringement

- **Global-Tech Appliances, Inc. v. SEB S.A., 131 S. Ct. 2060 (May 31, 2011)**
  - Affirms Federal Circuit, *SEB S.A. v. Montgomery Ward & Co.*, 594 F.3d 1360 (Fed. Cir. 2010), on standard for finding active inducement of infringement

- **Holding (8-1): inducement under 35 U.S.C. § 271(b) requires knowledge that the induced acts constitute patent infringement**
  - **Same knowledge requirement as for contributory infringement under § 271(c)**
  - **"Deliberate indifference" to known risk that patent exists is insufficient**
  - **Knowledge can be satisfied by "willful blindness"**
    - ***Subjective belief that there is a high probability that a fact exists; and***
    - ***Deliberate actions taken to avoid learning that fact***
  - **J. Kennedy dissent: willful blindness is not a substitute for "knowledge"**

Supreme Court: Limitations on Bayh-Dole Act

- ***Board of Trustees of the Leland Stanford Junior University v. Roche Molecular Systems, Inc., et al.*, 131 S. Ct. 2188 (June 6, 2011) – affirms Federal Circuit decision, 583 F.3d 832 (Fed. Cir. 2010)**
  - Stanford researcher visits Roche to conduct research
  - Separate assignment agreements at each institution
    - Stanford: "I agree to assign"
    - Roche: "I hereby assign"
  - Stanford sues Roche for patent infringement in 2005; Roche asserts co-ownership
  - Bayh–Dole Act provides that contractors may "elect to retain title to any subject invention." *35 U.S.C. § 202(a)*
  - **Holding:** Bayh-Dole does not deprive inventors of their rights in the invention – must expressly grant their rights to their employers

Supreme Court: Patentable Subject Matter

- **Mayo Collaborative Services v. Prometheus Labs., Inc., 566 U.S. ___ (March 20, 2012)**
  - **Reverses Federal Circuit decision in Prometheus Labs., Inc. *v.* Mayo Collaborative Services, 628 F.3d 1347 (Fed. Cir. Dec. 17, 2010)**
    - Federal Circuit held that claims are patentable under "machine-or-transformation" test (on remand, post-*Bilski*)

Supreme Court: Patentable Subject Matter (*cont'd*)

- **Supreme Court (9-0) reverses Federal Circuit**
  - Laws of nature not patentable
  - Application of laws of nature, etc. may be patentable – *but not in this instance*
  - Additional steps that consist of "well-understood, routine conventional activity" will not transform natural phenomena into patentable subject matter
    - "administering" step – long known and practiced in the prior art
    - "determining" step – also well known in prior art
    - "wherein" clause – merely describes law of nature
  - Court's concern: "improperly tying up the future use of law of nature"
  - Machine-or-transformation test does not trump law of nature exclusion

Supreme Court: Patentable Subject Matter (*cont'd*)

Claim 1:

A method of optimizing therapeutic efficacy for treatment of an immune mediated gastrointestinal disorder, comprising:

(a) **administering** a drug providing 6-thioguanine to a subject having said immune-mediated gastrointestinal disorder; and

(b) **determining** the level of 6-thioguanine in said subject having said immune-mediated gastrointestinal disorder,

wherein the level of 6-thioguanine less than about 230 pmol per 8x108 red blood cells indicates a need to <u>increase</u> the amount of said drug subsequently administered to said subject and

wherein the level of 6-thioguanine greater than about 400 pmol per 8x108 red blood cells indicates a need to <u>decrease</u> the amount of said drug subsequently administered to said subject.

Patentable Subject Matter

- ***Cert*. granted on March 26, 2012 in *Assn. for Molecular Pathology v. Myriad Genetics, et al.*, No. 11-725**
  - Federal Circuit judgment is vacated and case is remanded for further considerations consistent with Mayo v. Prometheus
- **Association for Molecular Pathology et al. v. Myriad Genetics, Inc., 653 F.3d 1329 (Fed. Cir. July 29, 2011)**
  - Composition claims covering ***isolated DNA sequences*** were patent **eligible**
    - Distinctive chemical structure from native DNA, despite same nucleotide sequence
  - Method claims for ***screening*** potential cancer therapeutics were patent **eligible**
    - Includes transformative steps ("growing" host cells), not just abstract mental steps
  - Method claims for ***comparing or analyzing*** isolated DNA sequences **ineligible**
    - Covered only abstract mental processes

Other 101 Cases – Will They Be Revisited?

- **Classen Immunotherapies, Inc. v. Biogen IDEC et al. 659 F.3d 1057 (Fed. Cir. Aug. 31, 2011), rehearing *en banc* denied Nov. 30, 2011**
  - **Procedural History:**
    - *Classen Immnunotherapies, Inc. v. Biogen IDEC*, 304 Fed. Appx. 866 (Fed. Cir. 2008), vacated and remanded by Supreme Court in view of *Bilski v. Kappos, 130 S.Ct. 3218 (2010)*
  - **Holdings:**
    - Method claims that include a physical step of immunization (after screening/comparing steps) are patent eligible
      - "*Presence of a mental step is not of itself fatal to § 101 eligibility*"
    - Method claim directed to merely collecting and comparing data (immunization results) is ineligible
      - *Does not include further step of immunization*
  - **Status:**
    - Remanded to district court for further proceedings

Novo Nordisk v. Caraco, Supreme Court No. 10-844
Hatch-Waxman Litigation Patent Listings

- ***Cert.* granted (June 27, 2011); argued on Dec. 5, 2011 (awaiting decision)**
  - Novo patent covers only one of three approved uses of Prandin®
  - Caraco amends ANDA to "carve out" patented use from label
  - Novo amends use code description in Orange Book – *encompasses all three uses*
  - Caraco files Counterclaim under Hatch-Waxman Act

- **Novo Nordisk v. Caraco Pharm. Labs., 601 F.3d 1359 (Fed. Cir. 2010)**
  - Hatch-Waxman Act provides a limited counterclaim for generic manufacturers in infringement actions - o*nly available where the drug patent does not claim any approved methods of using the listed drug*

- **Issue on Appeal:**

  Does the counterclaim provision of the Hatch-Waxman Act authorize a generic drug manufacturer in a patent infringement suit to assert a counterclaim compelling the patent holder to modify an overly broad description of its patent?

Kappos v. Hyatt, Supreme Court No. 10-1219
Introduction of New Evidence Post-PTO Proceedings

- ***Cert*. granted June 27, 2011; argued on Jan. 9, 2012 (awaiting decision)**
- **Hyatt v. Kappos, 625 F.3d 1320 (Fed. Cir. Nov. 8. 2010):**
  - 35 U.S.C. § 145 "imposes no limitation" on a patent applicant's right to introduce new evidence before a federal district court that was not previously submitted to the PTO
- **Questions Presented:**
  - Whether the plaintiff in a § 145 action may introduce new evidence that could have been presented to the agency in the first instance
  - Whether, when new evidence is introduced under § 145, the district court may decide *de novo* the factual questions to which the evidence pertains, without giving deference to the prior decision of the PTO

Pending *Cert*. Petitions – Solicitor General Invited to Submit Brief (CVSG)

- ***Saint-Gobain Ceramics & Plastics, Inc. v. Siemens Medical Solutions USA, Inc.*, No. 11-301**
  - *Cert*. filed Sept. 6, 2011
  - Solicitor General invited to file brief (Nov. 7, 2011) – *awaiting brief*
  - Question presented:
    - **Whether the PTO's presumptively valid finding that an invention is not obvious and is thus patentable over a prior art patent is impermissibly nullified or undermined when a jury is allowed to find, by a mere preponderance of the evidence, that the patented invention is "insubstantially different" from the very same prior art patent, and thus infringes that prior art patent under the "doctrine of equivalents."**

- ***Bowman v. Monsanto Co. et al.*, No. 11-796**
  - Cert. filed Dec. 20, 2011
  - Solicitor General invited to file brief (April 2, 2012)
  - Question Presented:
    - **Whether the Federal Circuit erred by (1) refusing to find patent exhaustion in patented seeds even after an authorized sale and by (2) creating an exception to the doctrine of patent exhaustion for self-replicating technologies?**

Therasense Inc. v. Becton, Dickinson and Co., 649 F.3d 1276 (Fed. Cir. May 25, 2011) (*en banc*)

- **Federal Circuit *en banc* (6-4) announces new inequitable conduct standard**
  - Must prove by clear and convincing evidence that the applicant: 1) knew of the reference, 2) knew it was material, and 3) made a deliberate decision to withhold it (*no "sliding scale" for proving materiality and intent*)
- **Materiality**
  - The materiality required to establish inequitable conduct is ***but-for materiality***
  - Exception – when the patentee has engaged in affirmative acts of egregious misconduct, materiality may be assumed
- **Intent**
  - Evidence must show that the applicant ***made a deliberate decision*** to withhold a reference *known* to be material
  - Specific intent to deceive must be the single most reasonable inference drawn from the evidence

Inequitable Conduct Post-*Therasense*

- ***Therasense* on remand, 2012 WL 1038715 (N.D. Cal. March 27, 2012)**
  - Briefs submitted by attorney to EPO directly contradict position taken in USPTO that protective membrane in prior art patent was required despite "optional" language
  - Deliberate decision to withhold information known to be "but for" material, lack of credible alternate explanation and witness demeanor demonstrate specific intent
- **Aventis Pharma S.A. v. Hospira, Inc., 2012 WL 1155716 (Fed. Cir. April 9, 2012)**
  - Applied *Therasense* standard in reviewing pre-*Therasense* judgment
  - Prior art references which render pharmaceutical formulation obvious are material
  - Inventor's knowledge of the references and lack of reasonable explanation for withholding them indicates specific intent to deceive
- **Apotex, Inc. v. Cephalon, Inc. et al., 2011 WL 6090696 (E.D.Pa. 2011)**
  - Modafinil batches manufactured by third party and supplied to Cephalon support finding of invalidity – material
  - Complete concealment of company's extensive involvement in claimed invention warrants inference of specific intent to deceive

Marine Polymer Technologies, Inc. v. HemCon, Inc., 2012 WL 858700 (Fed. Cir. March 20, 2012) (*en banc*)

- **In reexam, Examiner initially adopted broad construction of disputed claim term ("biocompatible" polymer) but Marine Polymer persuaded Examiner to adopt narrower construction used during litigation**
  - Cancelled claims but did not amend reissued claims
  - PTO issued reexamination after final judgment by district court in favor of patent holder
- **Panel (2-1): Holds that disclaimer of claim scope during reexam or reissue *even without amendment* can create intervening rights**
  - HemCon is therefore entitled to absolute intervening rights for products made before the reexamination certificate
- ***En banc* court reverses (6-4):**
  - "[W]e cannot agree that a claim can be 'amended' for purposes of 35 U.S.C. § 307(b) without changing the claim language itself"

Joint ("Divided") Infringement – *Akamai* and *McKesson*

- **Rehearing *en banc* granted in two cases:**
  - **Akamai Technologies, Inc. v. Limelight Networks, Inc., 419 Fed. Appx. 989 (Fed. Cir. 2011)**
  - **McKesson Technologies, Inc. v. Epic Systems Corp., 2011 WL 2173401 (Fed. Cir. 2011)**

- **Current standard for joint infringement of method claims:**
  - **Single entity must exercise "direction or control" over all other entities (*i.e.*, the "mastermind") – *Muniauction, Inc. v. Thomson Corp.*, 532 F.3d 1318 (Fed. Cir. 2008)**

- **Questions for the *en banc* court:**
  - **If separate entities each perform separate steps of a method claim, under what circumstances would that claim be directly infringed and to what extent would each of the parties be liable? (*Akamai*)**
  - **If separate entities each perform separate steps of a method claim, under what circumstances, if any, would either entity or any third party be liable for inducing infringement or for contributory infringement? (*McKesson*)**
  - **Does the nature of the relationship between the relevant actors – e.g. service provider/user, doctor/patient – affect the question of direct or indirect infringement liability? (*McKesson*)**

Joint ("Divided") Infringement – *Akamai* and *McKesson*

- **Plaintiffs in *Akamai* and *McKesson* attempting to show infringement by combined actions; want court to reject "single entity" rule**
  - In *McKesson*, defendant (Epic) accused of inducing joint infringement by health care providers and patients by licensing software whose use infringes claimed method
- **Panel decisions in both cases in favor of defendants**
- **Awaiting *en banc* decision**

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