

The background of the slide features a low-angle, perspective view of several modern skyscrapers with glass facades, reaching towards the top of the frame. The buildings are rendered in a light, semi-transparent style, creating a sense of depth and architectural grandeur.

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**Recent Changes in the United States
Patent System and Their Effects**

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Introduction

- Significant changes have occurred in patent procurement and patent enforcement in the United States that may affect you and which shed light on how a patent system can and should (or should not) work
 - Problems that needed to be solved will be identified, as well as the solutions attempted by the United States Congress and Courts
 - Comments will be offered on the various solutions

Who Has Made the Changes?

- **United States Congress (makes the laws)**
 - After heavy lobbying by interest groups and several years of changes in proposed bills, the patent reform bill (*Leahy Smith America Invents Act*, AIA) was passed in September of 2011
- **United States Supreme Court (highest court)**
 - Perceiving problems in the system and inconsistencies with its prior precedent
- **Court of Appeals for the Federal Circuit (second highest court re patents)**
 - Continuing efforts on consistency and making clear, black letter rules
 - Has undergone significant criticism including significant reversals from United States Supreme Court
- **The Press**
 - Significant amounts of criticism by the press focused on “patent trolls” and Non-Practicing Entities (“NPE”); little discussion of importance of patents to certain industries, such as the pharmaceutical industry

Problem: What Should Be Patentable?

- **Attempted Solution:** Supreme Court and Federal Circuit adjusting boundaries of what is patentable under § 101 of the Patent Statute.
 - *In re Bilski* (S. Ct.)
 - Federal Circuit’s long-used machine-or-transformation (“MoT”) test is an “investigative tool,” not the only test for determining patentable subject matter
 - Only 3 exceptions to broad patent-eligibility principles: “laws of nature, physical phenomena, and abstract ideas”
 - *Research Corp. Technologies Inc. v. Microsoft Corp.* (Fed. Cir.)
 - § 101 is “coarse eligibility filter,” not substitute for “patentability analysis related to prior art, adequate disclosure, or other conditions and requirements of Title 35”
 - No “rigid formula or definition” for measuring “abstractness”
 - Abstractness should be so “manifest” that it overrides broad statutory categories of eligible subject matter and focuses on patentability criteria

Problem: What Should Be Patentable? (cont'd)

- *Prometheus Labs. Inc. v. Mayo Collaborative Services* (Fed. Cir. 2010)
 - Federal Circuit held that claims directed to application of naturally occurring correlations between metabolite levels and efficacy or toxicity are patentable because they do not preempt use of any natural phenomenon and they also meet MoT test
 - On appeal, the Supreme Court justices focused on whether § 101 is merely a “coarse filter” to pass through before analysis under the remaining patentability inquiries, or whether it has a strong “gatekeeper” role to stop inventions undeserving of patents early in the examination process
- Types of claims Federal Circuit has found patentable/unpatentable in last several years

Problem: What Should Be Patentable? (cont'd)

Case	Type of Claim	Patentable?
<i>Research Corp. Technologies v. Microsoft</i> (Fed. Cir. 2010)	Digital imaging process claims	Yes – functional applications in computer technology
<i>Prometheus Labs. v. Mayo Collaborative Services</i> (Fed. Cir. 2010) (On appeal to Supreme Court)	Methods for calibrating proper dosage of drug for treating autoimmune disease	Yes – passed transformation prong of MoT test. Also did not preempt all uses of correlations between test results and toxicity and efficacy of drug dosage
<i>Classen Immunotherapies v. Biogen</i> (Fed. Cir. 2011)	Method of immunization	Yes – 2 claims including physical step of immunization directed to “specific tangible application”; no – patent claiming abstract idea unfettered to any physical steps
<i>CyberSource v. Retail Decisions</i> (Fed. Cir. 2011)	Beauregard claims for patents that cite a “computer readable medium	No – method that can be performed purely mentally
<i>DealerTrack v. Huber</i> (Fed. Cir. 2012)	Computer-aided method of managing a credit application	No – “computer aided” preamble language did not specify particular programming for computer or exactly what aspect of claims actually used computer

Problem: What Should Be Patentable? (cont'd)

Case	Type of Claim	Patentable?
<i>FuzzySharpTechnologies v. 3D Labs</i> (Fed. Cir. 2011)	Method of reducing visibility computations in 3D computer graphics	Not patentable under MoT, but remanded to District Court for claim construction
<i>Ultramercial v. Hulu</i> (Fed. Cir. 2012)	Methods of displaying advertisements in exchange for access to copyrighted media	Yes -- focusing on programming complexity required to carry out claimed elements, court determined claimed invention was patentable application, not unpatentable abstract idea

■ Comments:

- Leaves unanswered how to assess whether a claim is too “abstract” to get past the “coarse eligibility filter” of § 101 of the patent statute

Problem: One Obviousness Standard?

- **Attempted Solution:** Supreme Court criticized Federal Circuit's allowing "teaching-motivation-suggestion" ("TSM") test for obviousness to become "rigid and mandatory" formula (*KSR v. Teleflex*)
 - Approach to obviousness should be "expansive and flexible"
 - When a work is available in one field of endeavor, design incentives and other market forces can prompt variations of it, either in same field or different one
 - Factors to be considered in determining whether there was reason to combine known elements in fashion claimed by patent: interrelated teachings of multiple patents, market demands, and the background knowledge possessed by person of ordinary skill in the art
 - Apply "common sense" and recognize that "combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results"
 - "When there is design need or market pressure to solve a problem, and there are a finite number of identified, predictable solutions, which a person of ordinary skill would have good reason to pursue, and when pursued lead to the anticipated success,"" obvious to try may be enough to invalidate

Problem: One Obviousness Standard?

■ Comments:

- Significant impact on obviousness findings by courts and PTO
- Immediately after *KSR* was decided percentage of patentees prevailing in patent litigation decisions decided on obviousness grounds declined by nearly 30%
- PTO's Board of Patent Appeals and Interferences has cited *KSR* in more than 2,000 decisions, many affirming patent examiners' rejections of patent applications
- Within year of Supreme Court's ruling, Federal Circuit cited *KSR* in 18 precedential decisions, 12 holding patents obvious
- Mechanical and electrical patents more susceptible to *KSR* challenges than pharmaceutical or biopharma patents, where unpredictability is an important factor
- Patents claiming improvement in physical form of known drug molecules, and those claiming dosage amounts or regimens, are more susceptible to *KSR* challenges
- Obvious-to-try rationale for finding obviousness revived by *KSR*
- Since *KSR*, it may be necessary to review broader cross-section of prior art, or to consider filing evidence of unexpected results earlier rather than later in the course of prosecution
- TSM test remains as useful tool in obviousness analysis

Problem: Who Should Get The Patent?

- **Attempted Solution:** United States' present first-to-invent system is not followed by most other countries, so America Invents Act ("AIA") switches United States to first-to-file system.
 - Applies to patent applications filed on or after March 16, 2013
 - Derivation of invention addressed by implementation of derivation proceedings
- **Comments:**
 - AIA may create first-to-disclose system instead of first-to-invent – provides one-year "grace period" to file patent application following certain disclosures
 - Unresolved problems:
 - To whom must disclosure be made and what information must disclosure contain?
 - Prior user rights
 - What is prior art? (*e.g.*, if inventor A discloses invention before filing patent application, and inventor B discloses *slight variation* of Inventor A's invention in interim, is inventor B's disclosure prior art to Inventor A's claimed invention?)
 - How to address stealing invention
 - Critical for businesses to identify their inventions and file provisional applications

Problem: Difficulty Obtaining Inventor's Cooperation on Patent Application

■ **Attempted Solution:** AIA allows

- Substituted inventor's oath or declaration when inventor deceased, incapacitated, cannot be found or reached after diligent effort, or is under obligation to assign the invention but has refused to cooperate
- Assignee may file patent application without first seeking inventor's execution of the application

■ **Comments:**

- Makes it easier for corporation to file substitute inventor's oath when inventor cannot be reached or is uncooperative – especially important where companies have significant employee turnover

Problem: Low Patent Quality

- **Attempted Solution:** AIA provides for
 - **Pre-Issuance Submissions:** Third parties may submit and explain relevance of any patent, published application, or printed publication in connection with examination of pending application
 - Submissions must be made before the earlier of: (1) notice of allowance or (2) later of (i) 6 months after application's publication or (ii) date of examiner's first rejection of application's claim(s)
 - Doesn't go into effect until September 16, 2012

- **Comments:**
 - Requires closely monitoring potential competitors' patent applications because window for submission of materials is relatively narrow

Problem: Patent Process Takes Too Long

■ Attempted Solution:

- **Track I: Prioritized examination:** allows applicants to request accelerated examination in exchange for payment of additional fee – new procedure intended to result in notice of allowance or final rejection within 12 months
 - Available for (1) original utility or plant applications filed on or after Sept. 26, 2011; (2) continuation or divisional of pending application; (3) application in which Request for Continued Examination filed before, on or after Dec. 19, 2011; and (4) continuation application claiming priority to PCT application which designates US.
 - Not available to national stage entry of PCT application
- **Satellite PTO Offices:** AIA authorizes PTO to establish satellite offices – 1st will open in Detroit in July 2012

■ Comments:

- Limitations: (1) only 10,000 Track I requests/year allowed; (2) Application cannot contain (i) more than 4 independent claims; (ii) more than 30 total claims; or (iii) multiple dependent claims.
- First patent issued to Google Jan. 10, 2012 on application filed Sept. 30, 2011.

Problem: Should Fraud on PTO Be Punished?

■ Attempted Solution:

- Federal Circuit's new standards:
 - For proving patentee engaged in inequitable conduct in procuring patent (*Therasense v. Becton, Dickinson*)
 - **Materiality:** “But for” patentee’s misrepresentations or omissions, PTO would not have issued patent EXCEPT affirmative acts of “egregious misconduct” deemed material
 - **Intent:** Patentee must have acted with specific intent to deceive or made deliberate decision to withhold information from PTO. Intent to deceive must be single, most reasonable inference.
 - For pleading claim (*Exergen Corp. v. Wal-Mart Stores*)
 - Materiality requires “identification of the specific who, what, when, where, and how of the material misrepresentation or omission committed before the PTO”
 - Intent requires “sufficient underlying facts from which a court may reasonably infer that a party acted with the requisite state of mind”

Problem: Should Fraud on PTO Be Punished?

- **Supplemental Examination:** post-patent issuance proceeding established by AIA to consider information inadequately considered, not considered or incorrect during prosecution of patent application
 - Information considered generally can't be used in court to argue inequitable conduct EXCEPT such information can be considered if there was fraud on PTO or case is brought before supplemental examination is concluded

■ Comments:

- More difficult for alleged infringers to establish inequitable conduct as infringement defense, which may allow patentees who concealed information from PTO to enforce their patents
- *Therasense* standard likely to evolve in course of judicial interpretation
- What are parameters of “egregious conduct”?

Problem: Who Should Get An Injunction?

- **Attempted Solution:** Under *eBay v. MercExchange*, patent holders are no longer presumptively entitled to a permanent injunction after proving infringement. Instead, patentees must meet traditional four-factor test: (1) irreparable injury; (2) remedies available at law, such as monetary damages, inadequate to compensate injury; (3) considering balance of hardships, equitable remedy warranted; and (4) public interest not disserved by permanent injunction.

- **Comments:**
 - May create need for compulsory licensing system that was not provided for by AIA or the courts.

Problem: Cost of Patent Challenges Too High

- **Attempted Solution:** AIA's new post-grant review procedures
 - **Post-Grant Review:** may be sought on any invalidity ground
 - Only available within first 9 months after patent issues or reissues
 - “More likely than not” that at least 1 challenged claim is unpatentable
 - ***Inter Partes* Review:** limited to patents and printed publications
 - Replaces *Inter Partes* Examination
 - Available any time after the later of: (i) termination of post-grant review or (ii) 9 months after issuance of patent
 - Traditional “substantial new question of patentability” standard replaced by requirement that “there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition”
- **Comments:**
 - Limitations: (1) Can't be initiated if petitioner or real party in interest has filed civil action challenging validity of patent; and (2) Petitioner/real party in interest estopped from asserting any ground for invalidity raised in petition in later civil action

Problem: Declaratory Judgment Cases Too Hard to Challenge Patents

- **Attempted Solution:** Supreme Court rejected Federal Circuit’s long-standing “reasonable apprehension of suit” test for determining whether court had subject matter jurisdiction of a case seeking a declaratory judgment (“DJ”), holding that standard should be “whether the facts alleged, under all the circumstances, show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality” (*MedImmune v. Genentech*)

- **Comments:**
 - Open issues: (1) Licensee estoppel – Court did not express opinion as to whether nonrepudiating licensee is entitled to take advantage of *Lear* doctrine (*i.e.*, repudiation of licensee estoppel only applies when licensee renounces license, stops paying royalties and opens itself to risk of infringement suit with potential imposition of injunction and treble damages); (2) effect on jurisdiction of DJ actions; and (3) discretionary dismissal of DJ actions

Problem: Declaratory Judgment Cases Too Hard to Challenge Patents (cont'd)

- **Federal Circuit's post-*Medimmune* guidance regarding DJ jurisdiction:**
 - Found sufficient case or controversy when patentee asserted rights based on certain identified ongoing or planned activity of another party, and where other party contended that it had right to engage in the accused activity without a license (*SanDisk v. STMicroelectronics*)
 - Held that whether there has been “meaningful preparation to conduct potentially infringing activity” remains important element in totality of circumstances to be considered in determining whether DJ is appropriate (*Cat Tech v. TubeMaster*)
 - No DJ jurisdiction where counterclaimant had been granted covenant not to sue and its activities fell within the exception of § 271(e)(1) as interpreted by the Supreme Court in *Merck v. Integra Life Sciences* since counterclaimant had not filed NDA application for its work (*Benitec Australia v. Nucleonics*)
 - Federal Circuit decisions increase uncertainty as to where a court will draw the line in any specific case

Problem: Declaratory Judgment Cases Too Hard to Challenge Patents (cont'd)

- Patent licensing negotiations – can now form basis for DJ jurisdiction
 - Pre-licensing considerations: (1) know business value of patent(s) – protect core technologies vs. limited interest in enforcing patent(s); (2) analyze strengths and weaknesses of patent(s); (3) monitor activities of potential licensees and competitors
 - Some examples of additional clauses for patent licenses:
 - “No challenge” clause reserving licensor’s right to terminate license agreement in event of licensee patent challenge
 - Licensee termination clause conditioning licensee’s right to challenge patent validity/enforceability on its termination of license
 - Licensee’s acknowledgement and agreement that licensed subject matter falls within scope of licensed patent
 - Nonrefundable, non-creditable, upfront licensee fee payments minimizing amount of earned royalties that may be contested, deferred or, ultimately unpaid by licensee
 - Higher, front-loaded royalty rates to offset risk of licensee patent challenge

Problem: Proliferation of Nuisance False Marking Suits

- **Attempted Solution:** Because two relatively recent Federal Circuit decisions (one allowing individuals to sue; the other allowing individual initiating suit to retain 50% of penalties imposed) led to proliferation of lawsuits against corporations for false marking, AIA virtually eliminated false marking lawsuits
 - As of Sept. 16, 2011, only US can sue for penalty authorized by false marking statute
 - Civil cause of action if can prove competitive injury resulting from false marking
 - Product marked with expired patent doesn't constitute false marking violation
 - Products with fixed internet address to website providing status of patents covering product is sufficient notice for purposes of recovering damages during infringement action

- **Comments:**
 - Some courts have sua sponte dismissed false marking claim lawsuits
 - One West District of Virginia court ruled that enactment of AIA doesn't preclude claimants from continuing to assert false patent marking violates state consumer protection laws, such as state laws of false advertising and unfair competition
 - A Southern District of California district court rejected challenge to constitutionality of AIA's false marking provision

Problem: Multidefendant Lawsuits to Complex to be Fair

- **Attempted Solution:** Suing multiple defendants in a single lawsuit barred if only justification for joinder is that all defendants alleged to have infringed same patent(s)
 - Joinder still possible, but only if right to relief against all parties (1) arises out of same transaction, occurrence, or series of transactions or occurrences relating to same accused product or process and (2) is based on common questions of fact

- **Comments:**
 - Since mid-September 2011, NPEs have filed more than 400 cases against individual defendants and asked courts if they could add defendants to existing cases
 - Extra lawsuits increase burdens on defendants, NPEs and courts
 - Strategic advantage -- defendants in slower-moving cases can learn from faster-moving cases involving same patent(s)
 - May increase reliance on multidistrict litigation
 - Such suits may focus on forums such as D. Delaware and ITC

Problem: Too Easy To File Case Without Merit

- **Attempted Solution:** New pleading requirements from Supreme Court
 - Complaints must state enough facts that the claim is “plausible on its face” (*Bell Atlantic Corp. v. Twombly*)
 - Judges should use their common sense and judicial experience to make the plausibility determination
 - A distinction must be made between conclusory statements, which need not be accepted as true, and factual allegations, which are accepted as true (*Ashcroft v. Iqbal*)

- **Comments:**
 - Increased likelihood of filing motion to dismiss under Rule 12(b)(6)
 - Less predictability as to whether claim “plausible on its face” because plausibility determination depends on different experiences and common sense of individual judges

Problem: High Litigation Costs

- **Attempted Solution:** Federal Circuit , regional circuit and district courts are dealing with issues that raise the cost of litigation, such as inconvenient fora, drawn-out litigation process for patents, and litigants are finding ways to reduce discovery costs
 - **Discourage Forum Shopping:** Initially, patent reform bills contained venue provisions governing where plaintiffs could commence patent litigation
 - Numerous Federal Circuit decisions, beginning with Kramer Levin's success in transferring *In re Tech* from the E.D. Texas to a more convenient forum, granted defendants' petitions for mandamus requiring district courts to transfer lawsuits to more suitable jurisdictions
 - Recently, even the District Court of Delaware, known for rarely granting transfer motions, especially where Delaware corporations are involved, was found to have abused its discretion in denying a transfer of venue
 - Venue provisions dropped from AIA on grounds that Federal Circuit and district courts were dealing with the venue issue

Problem: High Litigation Costs (cont'd)

- **Establish Rules Governing Patent Cases:** govern when patent owner must serve its asserted claims and infringement contentions, and when alleged infringer must serve its invalidity and noninfringement contentions
 - 21 states now have such local rules
 - 5 states having such local rules also have rules applicable only to pharmaceutical cases brought under the Hatch-Waxman Act – shortens time frame for serving various contentions and puts pressure on defendants to serve noninfringement contentions and produce ANDA early in case
- **Rocket Dockets:** Refers to court noted for speedy disposition of cases, often by maintaining strict adherence to filing deadlines
 - 8 states considered to have rocket dockets
 - Favored by patentees because (1) average time from filing-to-trial shorter; (2) decreases litigation costs; and (3) puts pressure on accused infringer to develop noninfringement, validity and other defenses under tight time constraints
- **Reduce Discovery Costs:** non-traditional methods of document review, such as key word filtering, hiring contract attorneys or outsourcing document review (*e.g.*, to India) can substantially reduce costs

Problem: High Litigation Costs (cont'd)

■ Comments:

- No one jurisdiction favors patentees or alleged infringers on every measure (*e.g.*, plaintiff win percentage, percentages of cases going to trial, time to trial)
- Study trends in various fora (*e.g.*, pro-patentee, granting summary judgment motions, time to trial)

Problem: Spoliation of Evidence

- **Attempted Solution:** Development of document retention and destruction policy and imposition of litigation hold once litigation “reasonably anticipated”
 - “**Spoliation** is the destruction or significant alteration of evidence, or the failure to preserve property for another’s use as evidence in pending or reasonable foreseeable litigation” (*Zubulake v. UBS Warburg*)
 - U.S. law forbids spoliation of evidence, which may lead to monetary fines, exclusion of evidence, negative inference, and even a judgment against the party without any consideration of the merits
 - **Document Retention/Destruction Policy:** should be compatible with business needs, litigation readiness, e-discovery and regulatory compliance, and knowledge management
 - Purchase e-discovery tools
 - Identify vendors to be used if litigation arises

Problem: Spoliation of Evidence (cont'd)

- **Litigation Hold:** document preservation duties triggered once litigation “reasonably anticipated” (*e.g.*, when complaint received)
 - Suspend automated computer system deletion of electronic documents
 - Suspend overwriting of backup tapes
 - Cancel routine hardware, software or data storage device upgrades
 - Do not reconfigure employees’ hard drives to erase data stored locally

■ Comments:

- Reiterate document retention/destruction policies and litigation hold requirements periodically after litigation commenced
- Revisit document retention/destruction policies periodically in light of developing case law

Problem: Ambiguous Standards

- **Attempted Solution:** Supreme Court and Federal Circuit have clarified ambiguous standards for proving induced infringement, willful infringement, and invalidity with respect to evidence not considered by the PTO when it granted a patent.
 - **Induced Infringement:** Federal Circuit's "deliberate indifference" standard made it difficult to determine whether induced acts constituted patent infringement. Supreme Court sought to eliminate ambiguity by requiring knowledge that induced acts constitute patent infringement, and by holding that "willful blindness" can support knowledge finding (*Global-Tech Appliances v. SEB*)
 - **Standard of Proof for Invalidity:** Rejecting argument that standard for proving invalidity of patent, particularly for evidence not considered by PTO when it granted patent, should be preponderance of the evidence, Supreme Court affirmed Federal Circuit's clear-and-convincing standard

Problem: Ambiguous Standards (cont'd)

- **Willful Infringement:** Overruling its “affirmative duty of care” standard, the Federal Circuit established a 2-prong test for determining willfulness: (1) whether the accused infringer “acted despite an objectively high likelihood that its actions constituted infringement of a valid patent”; and (2) patentee must show that objectively defined risk was “either known or so obvious that it should have been known to the accused infringer” (*In re Seagate Technology*)
 - No affirmative obligation to obtain opinion of counsel
 - Asserting advice of counsel defense and disclosing opinions of counsel do not result in waiver of attorney-client privilege with respect to communications with trial counsel

■ Comments:

- Unanswered questions regarding induced infringement: (1) whether “knowledge of the patent” means knowledge of specific patent or knowledge of high likelihood that a patent exists; (2) possible chilling effect upon potential infringers seeking opinions of counsel

Problem: Ambiguous Standards (cont'd)

- Induced infringement important doctrine because:
 - Often only direct acts of patent infringement for increasing number of products made overseas and imported into U.S. through complex distribution channels are by retailers that sell an infringing product and by end-users of product
 - Patents covering method of performing tasks, particularly in software, consumer electronics and financial fields, unlike patents covering devices, are only infringed when patented method is performed, often only by end-user. Steps of patented method are often performed by multiple parties, creating joint infringement problem
- Federal Circuit now looking at standards for finding two parties jointly liable for infringement of patent method claim
 - Should joint liability include standards taken from joint tortfeasor doctrines instead of limiting liability for joint infringement to cases where the accused infringer exerts “direction or control” over the other party (*i.e.*, the defendant’s customer)? (*Akamai Technologies v. Limelight Networks*)
 - Can multiple parties be liable for direct infringement, at least for inducement analysis, even if no one party individually infringed all elements of the claim? (*McKesson Technologies v. Epic Systems*)

Problem: Ambiguous Standards (cont'd)

- Willfulness findings dropped from 63.8% of cases before 1999 down to 37.4% after *Seagate* decision
 - After willfulness established, and district court is considering whether enhanced damages should be awarded, court can take whether defendant had obtained opinion of counsel into account
 - Other factors courts take into account: evidence of copying, design-around evidence, substantial defense of noninfringement or patent invalidity, and reexamination evidence

Problem: Narrowly Construed Experimental Use Safe Harbor for Drugs

- **Attempted Solution:** Supreme Court held that “§ 271(e)(1)’s exemption from infringement extends to all uses of patented inventions that are reasonably related to the development and submission of *any* information under the FDCA [Food, Drug and Cosmetic Act].” (*Merck v. Integra Life Sciences*)
 - Research “reasonably related” (1) if research was conducted after biological mechanism and physiological effect of candidate drug are reasonably recognized; and (2) if research if successful would appropriately be included in a submission to the FDA
 - Includes (1) clinical and preclinical studies of patented compounds that are appropriate for submission to FDA; (2) studies intended to generate pharmacological, toxicological, pharmacokinetic, and biological qualities of the drug in animals; (3) studies intended to generate information regarding “risk-benefit assessment of the appropriateness of [a proposed clinical] trial”; and (4) safety-related tests even if not compliant with FDA regulations

Problem: Narrowly Construed Experimental Use Safe Harbor (cont'd)

■ Comments:

- Court did not address common law experimental use exception or the effect of § 271(e)(1) on “research tools”
- Federal Circuit recently held that § 271(e)(1)’s safe harbor “does not apply to information that may be routinely reported to the FDA, long after marketing approval has been obtained” (*Classen Immunotherapies v. Biogen IDEC*)

Problem: Excessive Jury Damage Awards

- **Attempted Solution:** Initially, patent reform bills contained controversial provisions dealing with calculation of infringement damages
 - Recent Federal Circuit decisions emphasize need for greater precision in presenting, challenging and reviewing patent infringement damage claims
 - **Entire Market Value (“EMV”) Rule:** For EMV to apply in calculating reasonable royalty damages “patentee must prove that ‘the patent-related feature’ is the ‘basis for customer demand’” (*Lucent Technologies v. Gateway*)
 - Can’t consider EMV of accused products for minor patent improvements simply by asserting low enough royalty rate
 - **25% Rule of Thumb** for determining royalty rate inadmissible (*Uniloc v. Microsoft*)
 - **Limitations on introduction of purportedly “comparable licenses”** as basis for damage award:

Problem: Excessive Jury Damage Awards

- Licenses including services unrelated to claimed invention, such as training, maintenance, marketing, and software upgrades, are not “comparable” (*ResQNet.com v. Lansa*)
- Lump-sum licenses not describing “how parties calculated each lump sum, the licensees’ intended products, or how many products each licensee expected to produce” not “comparable licenses.” Further, “some basis for comparison [to the infringing product] must exist in the evidence presented to the jury” for running-royalty licenses (*Wordtech Systems v. Integrated Network Solutions*).
- Damages provisions dropped from AIA on grounds that Federal Circuit and district courts were dealing with issue of excessive damage awards

■ Comments:

- Damages law still evolving
- More difficult to use EMV rule for calculating damages without strong evidence of sound economic and evidentiary basis linking demand for product to patented feature

Problem: Excessive Jury Damage Awards

- District courts insisting on much more evidence than in the past (*e.g.*, econometric studies, customer surveys, regression analysis or other marketplace-wise evidence of demand sensitivities) to make use of EMV rule
- Apportionment method of calculating damages – reasonable royalty damages calculated with reference to portion of overall value to product attributable to patented technology rather than the overall value of the product
 - Problems: (1) using industry-recognized royalty bases only gives “crude” estimate of damages; (2) methodology doesn’t recognize that patented technologies typically create synergies, making value of total greater than sum of parts; and (3) doesn’t adequately address royalty stacking (*i.e.*, single product requiring patent licenses from multiple patent holders, each requiring separate royalty)
- Choose damages experts carefully

Problem: Extraterritorial Application of U.S. Patent Law

- **Attempted Solution:** Refusing to give 35 U.S.C. § 271(f), which provides that infringement occurs when “components of a patented invention” are supplied “from the United States” for “combination outside of the United States,” an expansive interpretation, the Supreme Court signaled that, because § 271(f) is an exception to the general rule that U.S. patent law does not apply extraterritorially, it should be construed narrowly (*Microsoft v. AT&T*) (holding that computer master software disks were not a § 271(f) “component” when sent abroad to be copied and then installed to form what would be infringing system)

- **Comments:**
 - Supreme Court expressly left open whether § 271(f) applies to intangible method and process claims
 - Federal Circuit subsequently ruled that because methods do not have exportable physical components, method claims cannot be infringed under § 271(f) (*Cardiac Pacemaker v. St. Jude*)
 - Decisions benefit U.S. manufacturers who do business overseas, and, therefore, benefits U.S. economy