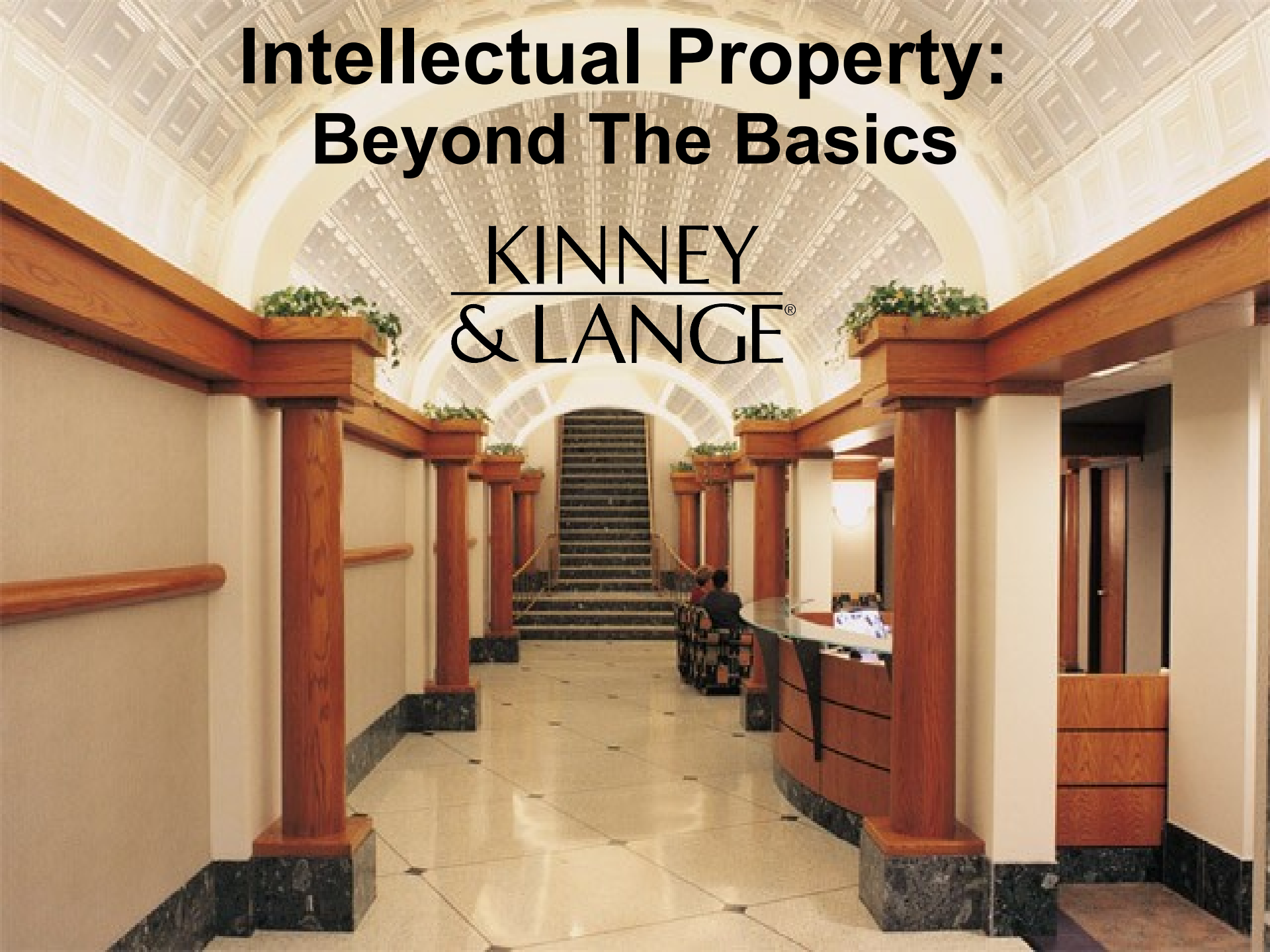


Intellectual Property: Beyond The Basics

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INTELLECTUAL PROPERTY AND INDUSTRY STANDARDS

Alan M. Koenck

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Syllabus

- What is an industry standard?
- How does intellectual property interact with industry standards?
- Fujitsu Ltd. v. Netgear – can patent infringement be proved by showing compliance with an industry standard?

What is an industry standard?

- Technical specification of operating requirements
- Allows devices from different manufacturers to operate together
- Upon compliance with standard, devices may be marked/certified with the standard name

How are industry standards established?

- Standards developing organizations (SDOs)
- Voluntary consensus standard development process
- ANSI (American National Standards Institute) accredits SDOs that follow a set of guidelines designed to ensure fairness in the process of developing voluntary consensus standards

Voluntary consensus standard setting process

- Open
- Balance of interests
- Notification
- Consensus
- Patent policy

Voluntary consensus standard – patent policy

- If standard utilizes technology covered by a patent held by a participant in the standard development group, that participant must:
 - Provide assurance that the patent is not held and will not be held, or
 - Provide assurance that a license will be made available under reasonable conditions or for no compensation

Examples of industry standards

- IEEE

- ▶ 802.11 wireless networking (Wi-Fi)
- ▶ Hundreds of other standards

- ISO

- ▶ 9000 quality management/assurance

- ASTM

- ▶ Material content and qualities

Also CD, DVD, MP3, MPEG, AAC, ATSC...

Fujitsu Ltd. v. Netgear, Inc.

610 F.3d 1321 (Fed. Cir. 2010)

- Issue: Whether patent infringement may be proved by virtue of an accused product complying with an industry standard (IEEE 802.11 wireless networking standard)
- Questions:
 - How did someone manage to hold a patent that covers the 802.11 standard?
 - What is the theory of patent infringement?

Fujitsu Ltd. v. Netgear, Inc.

- Patents of Fujitsu, Philips and LG were accessible via a patent licensing pool called “Via Licensing”
- Via Licensing is a subsidiary of Dolby Corporation
- Offers a mechanism for satisfying the licensing requirements for participating in a standard setting organization (RAND)

Fujitsu Ltd. v. Netgear, Inc.

- Via Licensing offered a license to Netgear
 - \$\$.05 to \$.55 fee per product
- Netgear declined the license
- The patent holders (Philips & Fujitsu) sued Netgear for patent infringement

Fujitsu Ltd. v. Netgear, Inc.

- Theory of patent infringement: indirect infringement (contributory/inducement)
 - Using Netgear products was alleged to be the act of infringement
 - Required a showing of actual infringement
 - Sale of the products by Netgear was alleged to be contributing to or inducing infringement

Fujitsu Ltd. v. Netgear, Inc.

- The Federal Circuit analyzed whether the compliance of Netgear products with the 802.11 standard was sufficient evidence to show that use of the products would result in actual infringement
- Outcome: compliance with a standard can be sufficient evidence, if (and only if) the patent covers all implementations of the standard

Fujitsu Ltd. v. Netgear, Inc.

- In this particular case, the feature of the asserted patent was an optional portion of the 802.11 standard, which was available on the Netgear devices but turned off by default
- The Federal Circuit held that the plaintiff must prove that customers actually used the patent feature in the Netgear products

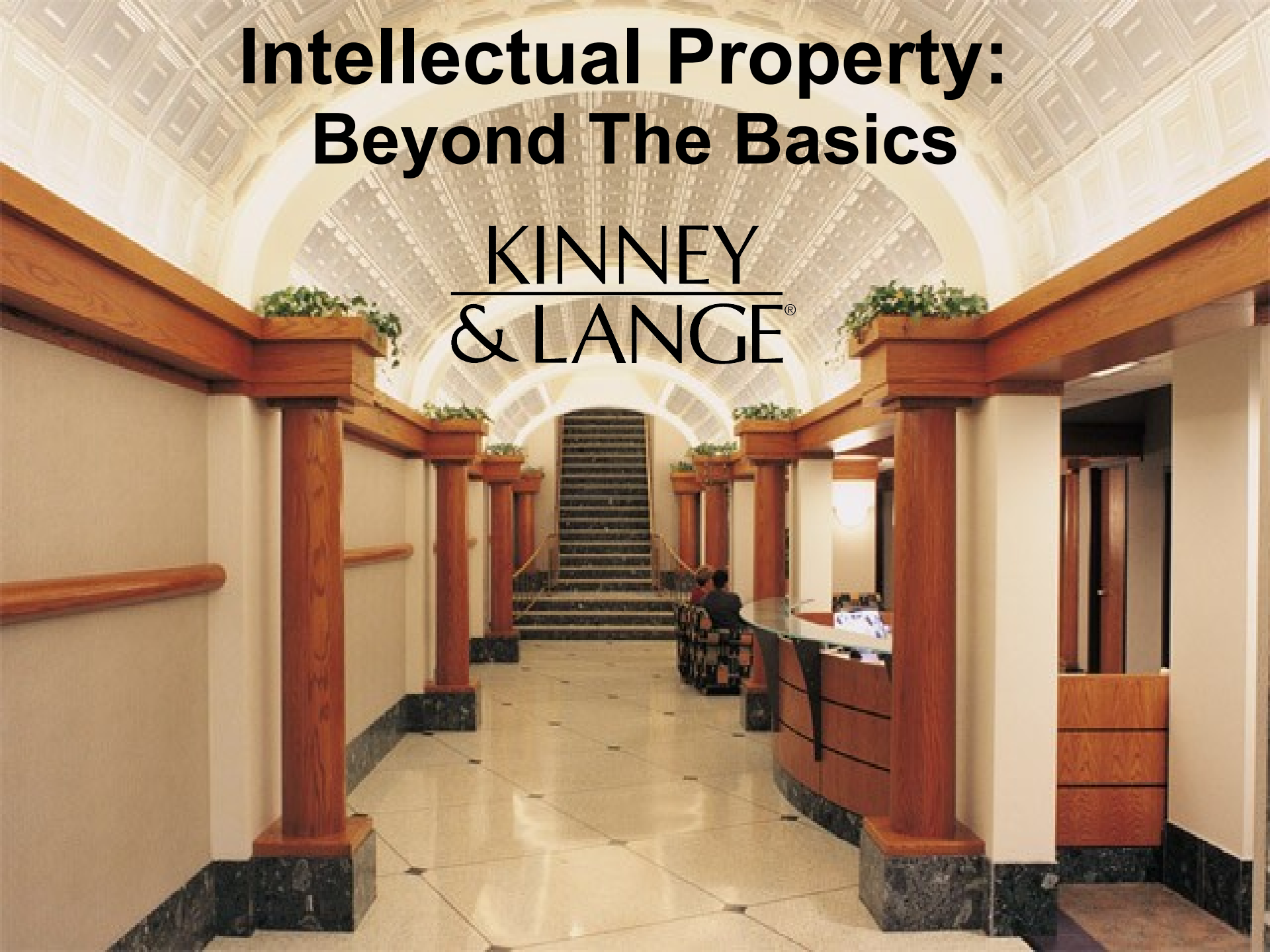
Intellectual Property and Industry Standards

- Members of standards organizations commonly form patent pools to handle licensing of patents implicated by use of industry standards
- In some cases, making a case of patent infringement may be streamlined by showing that the patent covers all implementations of the standard
- This is the “entry fee” into industry

Intellectual Property: Beyond The Basics

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Trademark Myths

Jo M. Fairbairn

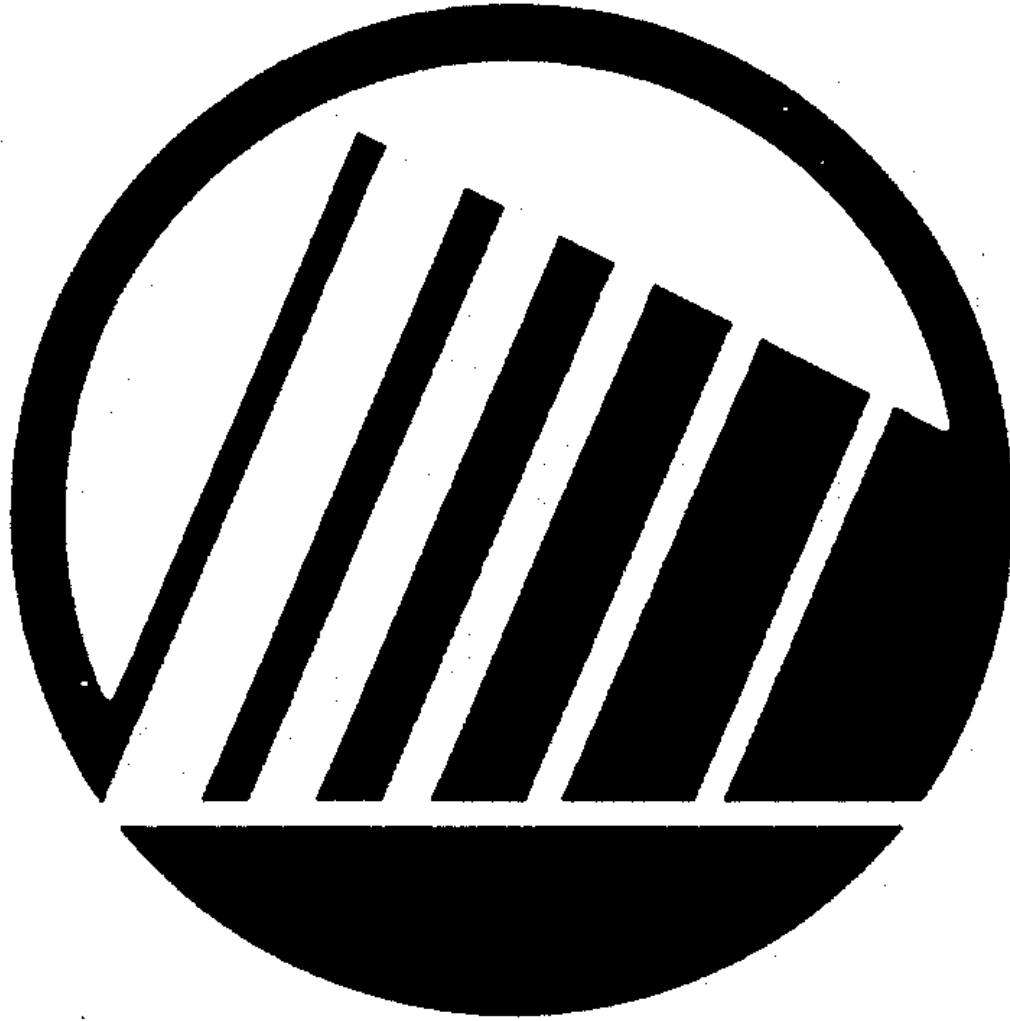
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Trademarks are only words





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The Secretary of State approved
the mark, so I'm OK

Anyone can use their own name

The best trademarks describe
your product

I am not infringing because my
mark is not the same as yours.

They'll never sue; we are a church

IHOP



INTERNATIONAL HOUSE OF PANCAKES

INTERNATIONAL HOUSE OF PRAYER

You can't sue me because your
Trademark isn't registered

**You can't sue me because someone
else is using the mark**

I registered first and I own it

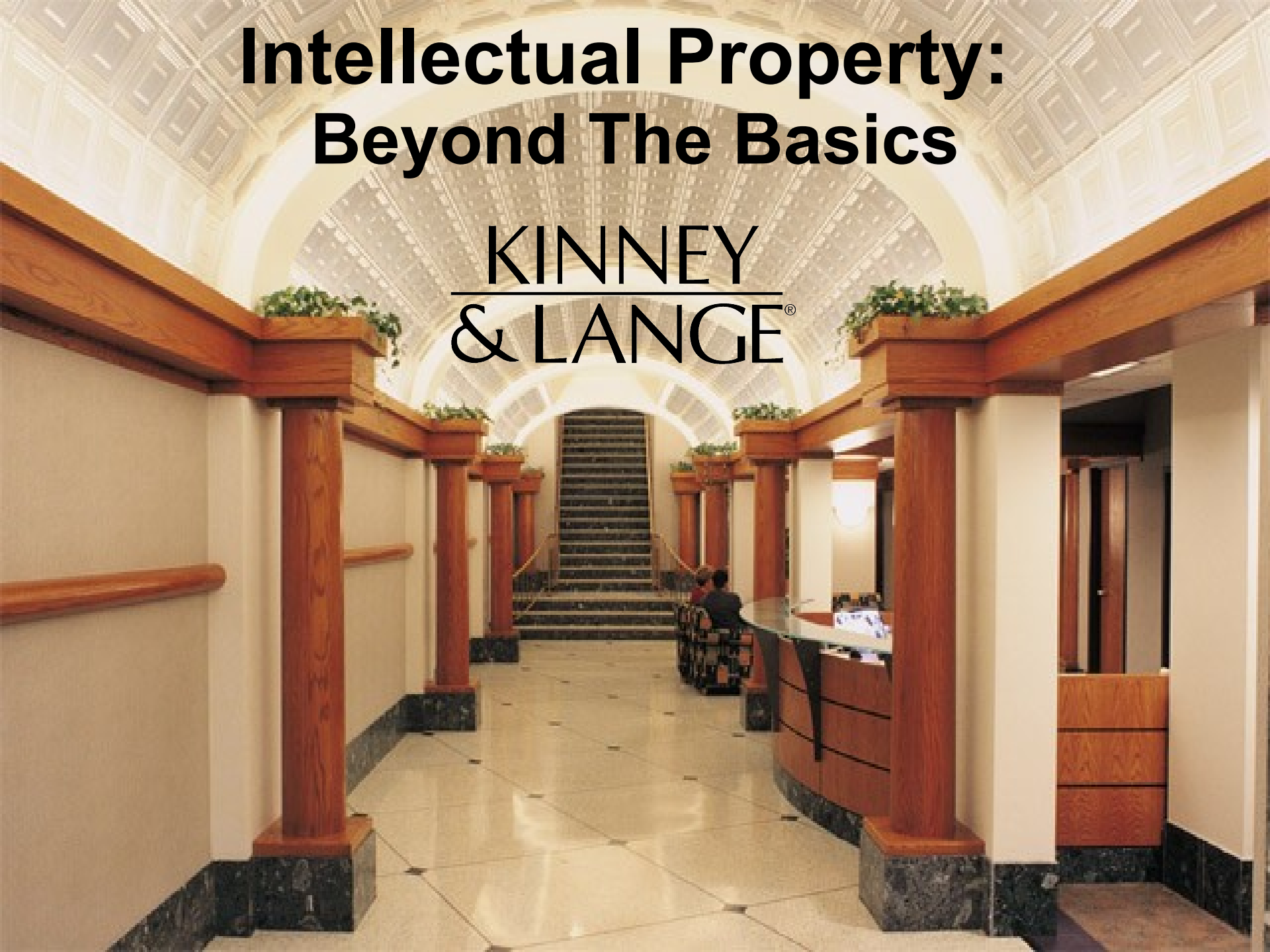




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The Legal Standing of Reverse Payments

Matthew J. DeRuyter

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Louisiana Wholesale Drug Co. v. Bayer AG

- April 29, 2010: Second Circuit publishes decision
- September 7, 2010: petition for rehearing *en banc* denied
 - Numerous *amicus* briefs recommending *certiorari* to the Supreme Court of the U.S.
- March 7, 2011: petition for *certiorari* to the Supreme Court denied
 - The Supreme Court declined to determine whether “reverse payments” from a pharmaceutical patent holder to a generic manufacturer are unlawful *per se*

Overview

- Background
 - Terminology
 - Hatch-Waxman Act
- Reverse payments
- Court decisions
- Reasons why *certiorari* was denied
- Predictions

Hatch-Waxman Act

- Drug Price Competition and Patent Term Restoration Act (1984)
 - ♦ “[M]ake available more low cost generic drugs...”
 - ♦ Established our current system of branded and generic pharmaceuticals
 - ♦ Provisions for
 - Generic drug manufacturers
 - Branded drug manufacturers (i.e. innovators/patent owners)

A Little Terminology

- New Chemical Entity (NCE)
 - Molecule developed in early drug discovery
 - Not approved by FDA in any other application
- Investigational New Drug (IND)
 - Application requesting an experimental drug be shipped across state lines, presumably for clinical trials
 - Generally based on preclinical studies that show the drug is believed safe for human tests

A Little More

- New Drug Application
 - Application requesting FDA approval of a new pharmaceutical for sale and marketing
 - Safety and efficacy
 - Appropriate labeling
 - Adequate manufacturing methods and controls
 - Often not an NCE, but a modified drug
- Approved Drug
 - Pharmaceutical having an approved NDA

ANDA

- Abbreviated New Drug Application
 - ▶ Application for generic drug approval for an existing approved drug
 - ▶ Submitted to special branch of FDA
 - ▶ Comparable to innovator drug in
 - Dosage form
 - Strength
 - Route of administration
 - Quality
 - Intended use

More ANDA

- Preclinical (animal) and clinical (human) data not usually needed
 - Rely instead on bioequivalence
 - Performs in the same manner as the innovator
 - Bioavailability
 - Testing can be performed prior to patent expiration

ANDA Certifications

- Certification required
 - I: Drug is not patented
 - II: Drug's patent has expired
 - III: Generic will not go on market until patent expires
 - IV: Patent is not infringed or invalid
 - 45-day period for innovator to sue for infringement
 - Triggers 30-month waiting period before FDA will approve generic

Generic Drug Manufacturers

- Expedites the availability of generic drugs
 - ▶ Authorizes ANDAs
 - Prohibits FDA from requiring more than bioavailability data
 - ▶ Provides 180-day exclusivity to the first ANDA filer
 - ▶ Allows generic drug manufacturers the ability to challenge the validity of the innovator patent without risk of entry
 - Liability exposure: litigation costs

Branded Drug Manufacturers

- No generic approval within 5 years of NCE approval
- Three-year data exclusivity for approved drugs
- Patent term restoration
 - ◆ Extension up to 5 years depending on length of the IND and NDA review periods
 - But term cannot exceed 14 years

“Reverse Payments”

- Agreement where a company holding a patent on a drug pays a generic manufacturer to delay the launch of its generic version
 - Also known as a “pay-for-delay” agreement
- Generally delays both generic entry and validity challenges, allowing continued sales of higher-priced branded drugs

Why Agree?

- Differences in valuation
 - Patent owners
 - Can continue selling branded drugs at higher prices
 - Generic manufacturers
 - Reverse payment amount generally equivalent or greater than revenue from actually selling a generic
 - Reduced risk

Sherman Act (15 U.S.C. §1)

- “Every contract...in restraint of trade or commerce...is declared to be illegal.”
 - ▶ “Every” = “only unreasonable restraints” *State Oil Co. v. Kahn*, 522 U.S. 3, 10 (1997).
 - ▶ “[P]redictable and pernicious anticompetitive effect, and...limited potential for procompetitive benefit”
- *per se* unlawful
 - ▶ Most conduct subject to “rule of reason” analysis
 - ▶ Patent settlements are subject to antitrust scrutiny

Recent Cases

- Reverse payments not legal
 - ▶ *In re Cardizem CD Antitrust Litigation*, 332 F.3d 896 (6th Cir. 2003)
- Reverse payments legal
 - ▶ *Schering-Plough Corp. v. FTC*, 402 F.3d 1056 (11th Cir. 2005)
 - ▶ *In re Tamoxifen Citrate Antitrust Litigation*, 466 F.3d 187 (2d Cir. 2006)
 - ▶ *In re Ciprofloxacin Antitrust Litigation*, 544 F.3d 1323 (Fed. Cir. 2008)

In re Cardizem

- Facts

- ▶ Pat. No. 5,470,584: Cardizem CD (diltiazem)
 - Angina and hypertension treatment
 - Patent owner: Hoechst Marion Roussel
- ▶ Andrx filed ANDA (1995) – ¶ IV certification
- ▶ HMR sued Andrx for patent infringement
- ▶ Andrx filed antitrust and unfair competition counterclaims

In re Cardizem

- Facts (con'd)
 - In September 1997, FDA tentatively approved Andrx's ANDA
 - Official approval once the 30-month period ended or the patent was deemed not infringed
 - Nine days later...agreement
 - HMR agrees to pay Andrx \$10 million per quarter
 - Andrx agrees to drop antitrust and unfair competition claims
 - Andrx agrees not to relinquish its 180-day exclusivity

In re Cardizem

- Facts (con'd)
 - ▶ 30-month waiting period ends (July 1998)
 - FDA approves Andrx's generic
 - No launch
 - ▶ Andrx reformulates
 - FDA approval (June 1999)
 - ▶ HMR and Andrx settle patent litigation
 - \$50.7 million
 - Andrx begins marketing its generic, initiating its 180-day exclusivity

In re Cardizem

- Plaintiffs sued HMR and Andrx
- District court found agreement “a naked, horizontal restraint of trade” and *per se* illegal
 - ▶ Granted partial summary judgment to plaintiffs
- Sixth Circuit
 - ▶ Affirmed district court
- Led to 2003 Medicare Act
 - ▶ 180-day exclusivity: use it or lose it

In re Tamoxifen

- Facts

- ▶ Pat. No. 4,536,516: Tamoxifen
 - Breast cancer treatment
 - Patent owner: Imperial Chemical Industries (ICI)
- ▶ Barr filed ANDA (1985) – ¶ IV certification (1987)
- ▶ ICI sued Barr and raw material supplier
- ▶ District court found ICI's patent invalid (1992)
 - Safety/effectiveness data deliberately withheld
- ▶ ICI appealed to the Federal Circuit

In re Tamoxifen

- Parties settle while appeal is pending
 - Zeneca paid Barr \$21 million and gave Barr a non-exclusive license to sell under Barr's label
 - Drug purchased directly from Zeneca
 - Zeneca paid raw material supplier \$45 million
 - Barr agreed to change its ANDA certification from IV to III, but Barr could revert to IV if the patent was later declared invalid

In re Tamoxifen

- Agreement contingent on *vacatur* of district court judgment
 - ♦ Federal Circuit vacated (1993)
 - Then considered valid, such a *vacatur* is now invalid in nearly all circumstances after *U.S. Bancorp Mortg. Co. v. Bonner Mall Pshp.*, 513 U.S. 18 (1994).
 - ♦ Three other generic manufacturers filed ANDAs attempting to rely on the vacated judgment
 - None succeed

In re Tamoxifen

- Over 30 lawsuits filed
- Plaintiffs allege the agreement
 - ▶ Allowed Zeneca and Barr to resuscitate a patent held invalid and unenforceable
 - ▶ Facilitated Zeneca's continuing market monopolization
 - ▶ Provided for the sharing of unlawful monopoly profits
 - ▶ Maintained an artificially high price for Tamoxifen
 - ▶ Prevented competition from other generic manufacturers

In re Tamoxifen

- District court granted defendants' rule 12(b)(6) motion and dismissed the case
 - While market-division agreements between monopolist and competitor ordinarily violate the Sherman Act, they are not necessarily unlawful when the monopolist is a patent holder
 - Patent owner may settle litigation by entering into a license agreement with an alleged infringer as long as they do not act in bad faith “beyond the limits of the patent monopoly” to restrain or monopolize trade

In re Tamoxifen

- Second Circuit
 - ♦ Timing of settlement “of little moment”
 - Risk of loss in all appeals gives rise to a desire to settle
 - ♦ That a patent holder is paying to protect its patent monopoly, without more, does not establish a Sherman Act violation
 - Hatch-Waxman Act encourages reverse payments
 - ♦ “Excessive” payments arguments unpersuasive

In re Tamoxifen

- Second Circuit
 - ◆ Exclusionary effects of the agreement did not exceed the scope of the patent's protection
 - Did not restrain unrelated or non-infringing products
 - Opened the Tamoxifen patent to challenge by others
 - Did not entirely foreclose competition in the market
 - ◆ 180-day issue did not rise to the level of an antitrust violation

In re Cipro

- Facts

- ▶ Pat. No. 4,670,444: ciprofloxacin hydrochloride
 - Antibiotic
 - Patent owner: Bayer
- ▶ Barr filed ANDA (1991) – ¶ IV certification
- ▶ Bayer sued Barr for patent infringement
- ▶ Parties settle two weeks before trial (1997)

In re Cipro

- Settlement agreement
 - ▶ \$49.1 million
 - ▶ Quarterly payments of \$12.5-17.125 million for duration of patent except the last 6 months
 - ▶ Bayer provides Barr a guaranteed license to sell brand-name Cipro at reduced rates for the last 6 months of the patent's life
 - ▶ Barr concedes validity and agrees not to market a generic before the patent expires

In re Cipro

- Over 30 antitrust lawsuits filed alleging
 - Agreement exceeded scope of patent rights
 - Agreement unlawful because Barr was permitted to reclaim its 180-day exclusivity if a subsequent challenger succeeded in invalidating the patent

In re Cipro

- District court
 - Summary judgment for defendants
 - Patents have an adverse effect on competition
 - *Post hoc* determination of validity would undermine patents' presumption of validity
 - No precedent for a requirement that parties to a settlement are required to preserve the public's interest
 - Undermine settled principles of patent law
 - Discourage settlement

In re Cipro

- Second Circuit (direct purchasers)
 - ▶ Noted split in authorities
 - FTC, U.S., academic commentators
 - Most courts (including the Second Circuit)
 - ▶ Affirmed relying on Tamoxifen precedent
 - ▶ Invited appellants to petition for *in banc* rehearing
 - Rehearing *in banc* denied
 - Pooler dissent: up to the Supreme Court or Congress

In re Cipro

- Federal Circuit (indirect purchasers)
 - Affirmed district court
 - No anticompetitive effect beyond what the patent permitted
 - Agreement excluded Barr from profiting from the patented invention
 - Within Bayer's right as patentee
 - Long-standing policy in favor of settlements

Reasons Why *Certiorari* was Denied

- A *per se* rule is not proper
 - Patents provide a right to exclude
 - Patents are presumed valid
 - Courts favor settlement
 - Agreements do not prevent 3rd party challenges
- Proper to look at agreements on a case-by-case basis

Reasons why *Certiorari* was Denied

- The Court is signaling Congress to take action
 - Preserve Access to Affordable Generics Act
 - First introduced in 2010
 - Introduced again in January
 - Referred to Committee on the Judiciary

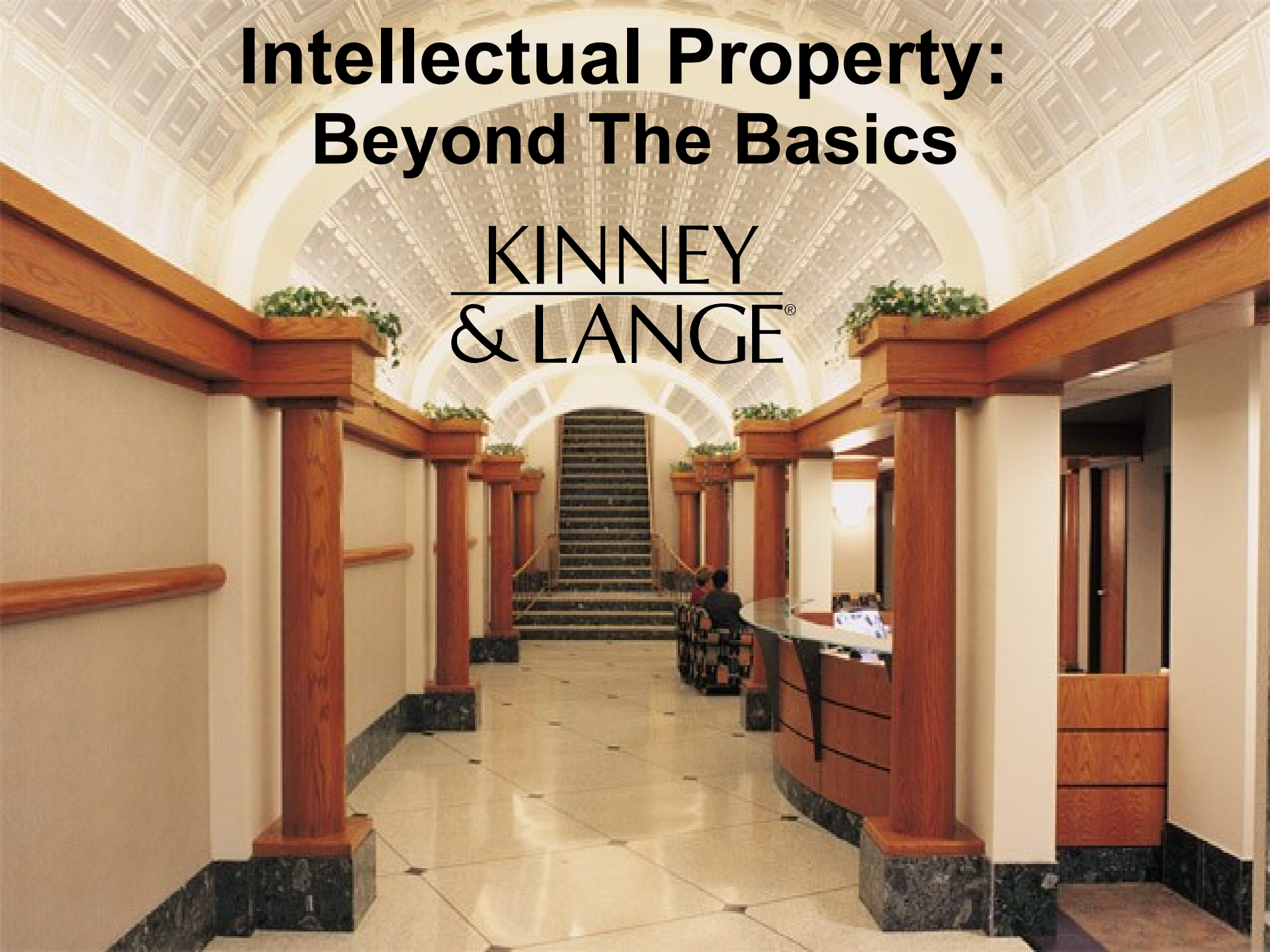
Predictions

- Reverse payment agreements will continue to be upheld by the courts
- The Supreme Court will not grant *certiorari* for a challenge asserting that these agreements are *per se* violations
- Legislative action will introduce additional conditions for reverse payment agreements

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Intellectual Property Ownership

David L. Buck

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Overview

- Types of Ownership
- Federal Preemption of State Law
 - ▶ *B.T. Leland Stanford Jr. University v. Roche* (U.S., No. 09-1159)
 - ▶ *Abraxis BioScience v. Navinta* (Fed. Cir. 2011) (denial of petition for en Banc opinion)
- Security Interests

Ownership

- Assignment

- Transfers substantially all commercial rights
 - Patent-must transfer right to make, use, sell the invention
 - Trademark-must include the goodwill associated with the mark
 - Copyright-15 U.S.C.A. § 1060 owner can assign one or more exclusive rights

Ownership

- Assignment

- General requirements:

- Written per federal law 35 U.S.C § 261
- Consideration
- Term: finite time period for copyright and patent
- Recorded per federal law 35 U.S.C § 261 (or other form of notice-otherwise subsequent purchaser can claim they are bona fide purchaser)
 - Patent and Trademark-within three months of execution or prior to sub. transfer must record
 - Copyright-within one month of execution or before recordation of a sub. transfer must record

Ownership

- License
 - Transfers less than substantially all commercial rights
 - Rights transferred must be identified with particularity
 - Rights can be restricted by duration, manufacture, use, sale, field of use, geography and quantity

Ownership

- License

- General requirements:

- Written per individual state statute of frauds
- Consideration
- Term: finite time period for copyright and patent
- No recording requirement
- Cannot violate antitrust laws

Federal Preemption

- Source: Supremacy Clause, Art. VI Clause 2
 - ◆ Issue: When is state law preempted by federal law? Issue is closely tied to question of standing
 - *Abraxis BioScience v. Navinta* (Fed. Cir. 2011) (en Banc opinion)

Facts: Plaintiff Abraxis had an IP assignment agreement as part of an asset purchase agreement from patent owner AstraZeneca. However, AstraZeneca had not actually obtained title to the patents from its subsidiaries by the date of execution of the asset purchase agreement. Abraxis did not gain title until after the suit was filed.

Abraxis BioScience v. Navinta

- ◆ Facts con't: The agreements spelled-out that New York state law should be the source of contract interpretation for IP transfers and contained *nunc pro tunc* clauses.
- District court applied New York state law to prior agreements between AstraZeneca and Abraxis to give *nunc pro tunc* effect in order to cure defect in ownership.
- Federal Circuit panel finds 35 U.S.C. § 261 requires a written assignment between parties to effect transfer of title. Thus, Abraxis does not have standing to sue.

Abraxis BioScience v. Navinta

- Federal Circuit panel applies “promise to assign” line of cases based upon wording of asset purchase agreement between AstraZeneca and Abraxis
 - “[C]ontracts that obligate the owner to grant rights in the future do not vest legal title to the patents in the assignee.” *Bd. of Trs. of Leland Stanford Junior Univ. v. Roche Molecular Sys., Inc.*, 583 F.3d 832, 841-42 (Fed. Cir. 2009).
- Dissent-majority creates a new and unique rule to the patent aspects of commercial transactions that diverges from the governing state law selected by the parties to the transaction

Bayh-Dole Act

- Adopted in 1980, Bayh-Dole is codified in 35 U.S.C. § 200-212[1],
- Gives U.S. universities, small businesses and non-profits intellectual property control of their inventions and other intellectual property that resulted from support with government funding.
- Reversed the existing presumption of title (which had previously been presumed to rest with the government) to allow institution to elect to pursue ownership of an invention in preference to the government

B.T. Leland Stanford Jr. University v. Roche

- Issue: Whether patents subject to Bayh-Dole are subject to traditional rules of title (title vests first with the inventor) or whether instead title vests directly with the contractor?
- Facts: Inventors from Stanford University and Cetus (purchased by Roche) collaborated in HIV/AIDS research. Stanford U. receives federal funding for HIV/AIDS research from NIH. Inventor at issue moves back and forth from Cetus to Stanford and utilizes facilities and conducts research at both.

B.T. Leland Stanford Jr. University v. Roche

Facts Cont'd: Inventor signs employment agreements with Stanford U. and Cetus. Cetus agreement states “I will assign and do hereby assign” while Stanford U. agreement states “I agree to assign.” Inventor conceived of invention while working with Cetus but returns to Stanford U. and reduces invention to practice. Stanford after several years of further research eventually applies for patent rights in researcher’s invention. Roche commercializes patented invention and refuses license from Stanford who then files suit for infringement.

B.T. Leland Stanford Jr. University v. Roche

- District Court: Roche's defense of ownership based on employment agreement is dismissed as barred by California statute of limitations, as well as by Bayh-Dole which acts to automatically vest title in the contracting entity.
- Federal Circuit: "Agree to assign" is mere promise in future. Thus, Cetus's legal title vested first, negating inventor's subsequent assignment during prosecution. Stanford was not bona fide purchaser because had constructive notice of inventor's work with Cetus.

B.T. Leland Stanford Jr. University v. Roche

- Federal Circuit on Bayh-Dole's applicability: “Nothing in the statute, regulations, or our caselaw indicates that title (of the inventor) is automatically forfeited.”
- Federal Circuit dismisses 35 USC § 202(d)
 - Inventor had transferred his rights to Cetus more than 6 years before Stanford elected title
 - Stanford's own policy “allowed all rights to remain with the inventor if possible.”
- Federal Circuit also dismisses Roche's counter claim for declaratory judgment of ownership as time barred by state statute of limitations

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Supreme Court

- Arguments conducted February 28th
Opinion issued June 6th 7-2 ruling in favor of Roche
 - Roche's had textual support in § 101 of the Patent Act
 - Contrast § 101 to § 201 of the Copyright Act
 - Pervasive use of contracts assigning inventions from employees to employers
 - If Stanford had chosen more stringent automatic assignment language for its employment contract, it would have title

Supreme Court

- Justice Breyer in dissent criticizes the Federal Circuit's line of cases distinguishing between “promise to assign” and “automatic assignment.”
 - ♦ J. Breyer would have found that the initial contract created equitable title in the invention. Old decisions (pre-Fed. Circuit) historically did not enforce contracts to automatically transfer legal title to patent rights.

Security Interest in IP Basics

- Is created by a written agreement signed by the debtor expressing an intent to create a security interest and describing the collateral subject to the security interest
 - ▶ Patents, trademarks, copyrights, mask work registrations, trade secrets, know how are classified as “general intangibles” by UCC

Security Interest in IP Basics

- Security interests must be perfected to give other parties notice-generally perfection should occur in the jurisdiction of principle place of business or residence of the debtor according to the U.C.C. However...
 - ▶ USPTO accepts security interests for recording
 - ▶ Copyright Office and Plant Variety Office do as well

Perfection Continued...

- Is a state U.C.C. filing necessary? Answer:
Is the U.C.C. preempted by federal recording statutes?
 - Copyright-*In re Peregrine* holds that U.C.C. is preempted for recording security interests in registered copyrights
 - Patent and Trademark-U.C.C. is not preempted, need to perfect under the U.C.C.
 - Trade secrets, know-how, rights of publicity, etc. must be perfected under the U.C.C.

THANK YOU!

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