

# Protecting & Monetizing Your Intellectual Property

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Presented by:

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## Agenda

- What Is IP?
- The Economics of IP
- Developing a Strategy and IP Program
- Transactions

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## Intellectual Property

- *Difficult (and expensive) to create – easy to knock-off*
- There are four main types of IP:
  - **Patents** (Protects rights in useful inventions and discoveries, like machines and processes)
  - **Copyrights** (Protects expressive works, like art, music, dance, and literature, and also software)
  - **Trademarks** (Protects product, service, and company identifiers, like brands, logos and package designs)
  - **Trade Secrets** (Protects commercially valuable confidential information, like business and financial plans, formulas, recipes and customer information)

## Patents

- A patent is a right granted by the U.S. government to *an inventor* for a limited time to exclude others from:
  - Making, using, offering for sale, or selling the invention in the U.S.
  - Importing the invention into the US
- Limited time = 20 years from filing
- Does not grant freedom-to-operate
- Average cost to procure = \$60,000<sup>1</sup>
- Average value (mostly EE) = \$375K (\$54K - \$1.6M)<sup>2</sup>

<sup>1</sup> AIPLA (2015)

<sup>2</sup> IP Offerings, LLC (2012)

## Trademarks

- A trademark identifies source goods and services
- Distinguishes the goods and services from those made or sold by others
- Embodies value and goodwill
- Trademarks may take the form of:
  - Names (GEORGE FOREMAN® grills)
  - Brands (APPLE® computers)
  - Designs and symbols (Nike's "Swoosh")
  - Slogans (Wendy's WHERE'S THE BEEF®)
  - Color (Owens-Corning's pink fiberglass)
  - Sound (Yahoo! Inc.'s yodel)
  - Package, product or store design (the shape of a fragrance bottle)

## Trademark Registration

- In the U.S. trademark rights arise from use, not registration
- However, federal trademark registration in the USPTO gives the trademark owner many benefits, including:
  - The exclusive right to use the mark nationwide in connection with the goods or services covered by the registration
  - The right to use the registered trademark symbol ® to discourage infringement

## Copyrights

- Copyright protects original works of authorship that are:
  - Fixed in any tangible form or medium of expression
  - Original in the sense that they are:
    - Independently created by the author (or authors)
    - At least minimally creative
- The “author” may be one person, or two or more persons (in which case the work is jointly owned by its authors)
- For a “work made for hire,” the employer or party that commissions the work is the initial owner of the copyright in that work, unless either of these parties and the creator of the work agree differently in a signed writing

## Works Protected by Copyright

- Copyright original works of authorship, including:
  - Literary works (*e.g.*, books, periodicals, manuscripts, film, tapes and computer programs)
  - Musical works, including accompanying words
  - Dramatic works, including accompanying music (*e.g.*, scripts and screenplays)
  - Pantomimes and choreographic works
  - Pictorial, graphic and sculptural works (*e.g.*, fine, graphic, and applied art and art reproductions, photographs, prints, maps, models and technical drawings)
  - Motion pictures, video games and other audiovisual works
  - Sound recordings
  - Architectural works

## Copyright Registration

- Registration is not required to establish federal copyright ownership
- However, registration in the U.S. Copyright Office provides substantial benefits:
  - The ability to bring an action for copyright infringement
  - Recovery of attorneys' fees and special categories of damages not otherwise available in an infringement action

## Trade Secrets

- A trade secret is:
  - Business, financial and technical *information*
  - Kept confidential by its owner through reasonable efforts
  - Economically valuable because the information is not generally known
- For example, Coca-Cola's soda formula, KFC's fried chicken recipe and the source code of Adobe's PHOTOSHOP<sup>®</sup> software are trade secrets

## Trade Secret Protection

- Trade secrets are not registered like patents, trademarks and copyrights
- Instead, trade secrets are protected by making reasonable efforts to keep information confidential, for example, by:
  - Never giving your passwords to anyone
  - Keeping hard copies of trade secret information in locked files or cabinets
  - Never giving confidential information to customers or other individuals outside of the company unless:
    - Authorized by management
    - The recipient has signed a written Non-Disclosure Agreement
- Define in NDA/CDA with no expiration term for the information
- Employee training and company documentation
- Marking documents as trade secret/confidential

## The Economics of IP

## Why Does IP Matter?

*IP is one of the most valuable business assets.*

- Builds brand awareness and loyalty among consumers
- Establishes protectable legal interests in the goods and services sold by company, and the technology and know-how used to produce them
- Has intrinsic value that may be sold, licensed or leveraged for profit
- Drives innovation and provides a competitive edge
- Enables company to enter new markets and grow market share

## Economics of Intellectual Property

- 40% U.S. GDP attributed to IP intensive industries
- 30% of all employment
- 46% higher wages than non-IP jobs
- IP licensing revenue \$115.2 B (2012)
- Exports \$842 B (2014)

Intellectual Property and the U.S. Economy: 2016 Update, USPTO.gov

## Pharma

- Patent Expiration
  - Lipitor® (atorvastatin)
  - Price per dose on patent = \$5
  - Price per dose off patent = 31¢
- Evergreening
  - Prilosec® (omeprazole) = patent expired April 2001
  - Nexium® (esomeprazole magnesium) = May 2014
- Cabilly
  - General method of making a biotech drug
  - Used by virtually every biopharma company
  - Earns Genentech ~\$300M/year in royalties

## Patent Strategy

- Drug Substance (20 years)
- Drug Product (20 + 5 years)
- Administration and Dosing (20 + 7 years)
- Manufacturing (20 + 10 years)
- New formulations
- New modes of administration



# IP Strategy

## The IP Strategy

- Building a fence – filling the white space
- Assertion and defense philosophy
- Developing a mix of IP
  - Trademark, copyright, utility patent, design patent, trade secret can be used to protect a single product or service (process)
- Balancing trade secrets and patents
- Considerations of product life cycle and development
- Employment agreements/non-compete/affirmative assignment
- Publication policy

## Protect your IP

- Developing best practices for IP protection and training employees on the subject
- Publication and website review
- Mark products and services
- Keeping an eye on the market and competitors' activities.
- Reviewing industry-specific trade papers, magazines and websites
- Enforcing rights against infringers by sending cease and desist letters, and when appropriate, commencing litigation
- Publicizing enforcement victories through targeted press releases

## Minimize the Risk of Infringing

*Obtaining Freedom-to-Operate*

- Conduct a thorough investigation to obtain legal clearance of all IP prior to use
- Closely monitor company disclosures for potential infringing activity before publication
- Conduct a competitive analysis and landscape analysis
- Determine whether infringing (non-infringement opinion)
- In license, Design around, DJ action, *Inter partes* Review
- Defensive publications

# Transacting IP

## Transactions

- The IP Mindset
- Think globally about IP – information, data know-how
- IP is everywhere and in every collaboration
  - MTAs
  - CRADAs
  - JVs
  - Asset purchase
- Ownership vs. inventorship

## Transactions, cont'd

- The IP License
- Patent Exhaustion
- Patent Expiration
- Expanding the patent license
  - Patents, trade secrets, know-how, materials information/data



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Dr. Zahner is a life sciences and biotechnology patent attorney in Kutak Rock's Intellectual Property and Technology Practice Group. Before joining Kutak Rock, Dr. Zahner worked in-house for Regeneron Pharmaceuticals and Wyeth Pharmaceuticals, and directed Saint Louis University's licensing office.

Before working as an intellectual property professional, Dr. Zahner was an assistant professor at Saint Louis University, teaching molecular and developmental biology, and conducting research on cell polarity and stem cell biology. His technical expertise relates to plant and animal genetics, genomics, embryology, developmental biology, cell biology, biochemistry, nanotechnology and biotechnology.

His law practice focuses on technology transfer and commercialization, global patent procurement, intellectual property licensing, portfolio development and due diligence, third-party actions, and freedom-to-operate, infringement/non-infringement, design-around and validity/invalidity opinion work.

Dr. Zahner is registered to practice before the U.S. Patent and Trademark Office (USPTO).