



## Does Your Company Have an Effective Corporate IP Program?

### An Integrated Approach

#### Profiting From Intellectual Property

##### Why Is IP Protection Important?

- Companies with good IP protection have 20-30 percent valuation over those that don't.
- One third of clients we meet for the first time have lost IP already, typically due to one year bar.
- Many companies won't accept technology for evaluation without patent protection, even with a non-disclosure agreement in place.

##### Six Basic Components of Effective Corporate IP Programs

- Evaluation of IP
- Patents
- Trademarks
- Copyrights
- Trade Secrets
- Physical Security
  - Internal
  - External

##### Evaluation of Intellectual Property

- Create standing IP Committee to:
  - Review new invention disclosures
  - Define patent strategies
  - Make decisions on where to foreign file
  - Make decisions re maintenance fees
  - Review entire IP portfolio
  - Monitor competition for new developments and potential infringers
- Appoint key individual to head IP Committee
  - Make sure individual has decision-making authority
- Meet at least quarterly
- Encourage employee disclosures
  - Record ideas in notebook to establish early date



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- Establish formal “Invention Disclosure” form
- Establish policies and standards for maintaining lab notebooks that can be used as evidence
  - Hand-written, hard-bound lab notebooks, e.g., Chicago Bindery No. B 100P
  - Sign and date every entry
  - Witness (read and understood) and sign at least weekly by an individual not actively involved in work but who has the technical background to understand the work or idea
  - Electronic notebooks - standards not yet agreed upon
- Corporate recognition as motivation
  - Plaques
  - Annual recognition banquet for inventors
  - Cash awards for inventions that are commercialized
- Re-evaluate IP portfolio every year - weed out dead wood

## Patents

### What Are They?

- Grant from federal government
- Patent owner has an exclusive right to prevent others from:
  - Making
  - Using
  - Offering for sale
  - Selling
  - Importing the patented invention
- Limited period of grant in exchange for full and complete disclosure of invention
- Not an absolute right to practice the invention

### Criteria for Patentability

- Patentable subject matter if
  - New (35 U.S.C. §102)
  - Useful (35 U.S.C. §101)
  - Non-obvious (35 U.S.C. §103)



### What Can Be Patented?

- Statutory classes - 35 U.S.C. §101
  - Process (method)
  - Machine
  - Article of manufacture
  - Composition
  - A “new use” of one of the above
  - Certain “Business Model” patents

### Examples of Patentable Pharma Subject Matter

- Compounds
- Intermediates
- Compositions
- Diagnostic kits
- Methods for making compounds
- Methods for making intermediates
- Methods for making compositions
- Methods for isolation/purification of compounds
- Methods for analysis
- Methods for treatment/use
- Screening methods
- Improvements to known compositions
- Improvements to known methods
- Combination of active ingredients

### Examples of Patentable Biotech Subject Matter

- Microorganisms
- Cell lines
- Cellular compositions
- Viral isolates
- Vectors or cloning/expression vectors
- DNA/RNA
  - Promoters
  - Synthetic oligonucleotides
  - Signal sequences



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- Expressed sequence tags (ESTs)
- Proteins
  - Recombinant
  - Purified from biological samples
  - Active fragments
  - Modified known protein
  - Receptors
- Monoclonal antibodies/hybridomas
- Isolated antigens/vaccine compositions
- Methods for isolation/purification of biological materials
- Methods for cloning/protein production
- Methods for diagnosis
- Methods for treatment/use
- Screening methods
- Transgenic animals/plants

#### Types of U.S. Patent – Pre-1995

- Utility – Protect concept
- Design – Protect ornamental appearance
- Plant – Protect certain types of asexually reproduced plants

#### New Patent Laws – Implementation of GATT TRIPPS Accord, June 8, 1995

- Provisional patent application
  - Option became available June 8, 1995
  - Get early priority date
  - File often and early
  - Must be converted to non-provisional (traditional utility) patent within 12 months or it goes abandoned
- Term of 20 years from date of filing



### New Patent Laws – American Inventor’s Protection Act (AIPA) of 1999

- Electronic filing is an option
- Publication of non-provisional applications 18 months after priority date
- Provisional applications will not be published
- Patent Term Adjustments

### Foreign Filing

- The cost of filing and maintaining foreign applications can be high
- Need to be selective
- Choice tied in with where product will be manufactured and sold
- PCT filing is attractive option
- Get specific price quotes from foreign associates

### Why PCT Filing?

- Use to control costs
- Initially more expensive route, but long term much less expensive
- Adds 18 months to the convention year, affording a total of 30 months from the priority date in which to make an informed decision regarding foreign filing

### Best Value for PCT Filing

- US
- Canada
- Brazil
- Australia
- India
- Japan
- France
- UK
- Germany
- South Africa

### Typical Patent Strategies

- Initial U.S. provisional filing, followed by U.S. non-provisional filing at end of convention year and no foreign filing
- Initial U.S. provisional filing, followed by U.S. non-provisional and PCT filing at end of convention year designating all countries, except U.S.
- Initial U.S. provisional filing, followed by PCT filing at end of convention year designating all countries, including U.S.



## Trademarks

### What Is a Trademark?

- A trademark is any word, symbol or device used to identify one's product and distinguish it from the products of others
- Old way – pre-1989
- ITU – 1989
- Careful selection and checking is the key
- Consider both:
  - Availability
  - Enforceability
- Need to police marks

### Trademark Hierarchy

- Fictitious or coined marks = Best
- Arbitrary = Very Good
- Suggestive = So-So
- Descriptive = Poor
  - geographic
  - surnames
  - attributes
- Generic = Bad

## Copyrights

### What Is a Copyright?

- A copyright is the right that the government gives an author of any original work of expression to exclude others from copying or commercially using the work of expression without proper authorization.
- Examples: books, poetry, plays, songs, catalogs, photographs, computer programs, advertisements, labels, movies, maps, drawings, sculpture, prints and art reproductions, game boards and rules, recordings
- Relatively easy



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- Put correct copyright in right location, e.g., “Copyright © 2009 Fox Rothschild LLP” or “© 2009 Fox Rothschild LLP”
- Register with U.S. Copyright Office

## Trade Secrets

### What Is a Trade Secret?

- Any information, design, device, process, composition, technique or formula that is not known generally and that affords its owner a competitive business advantage.
- Reasonable measures to maintain the secret must be made so that relief against those who wrongfully obtain the information can be obtained.

## Internal Security

- Vetting potential employees
  - Look at non-competes
  - Ask for representations about IP carved out before employment
- Employment agreements
  - Non-competes limited to two years in New Jersey
  - Make sure signed before employment
- Other agreements – licenses
  - Should be carefully crafted

## Licensing

### Key Issues

- Foreign
  - Always review with foreign legal counsel
  - Can be hard to discontinue
  - Terrorism exclusion?
  - Include provision to get paid in hard U.S. dollars if possible
- Exclusive
  - Always include minimum royalty requirements



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### External Security

- Front desk / security guards
- Sign-in book and visitor badges
- Limit access of public to secure areas
- Remove confidential material, erase blackboards, etc., when visitors are in secure areas
- Establish policy with regard to incoming calls from competitors, recruiters, etc.

### The Top Seven Internet Vulnerabilities\*

1. Default software installations
2. Accounts with no passwords
3. Inadequate back-ups
4. Too many open doors
5. False addresses
6. Bad record-keeping
7. Vulnerable web programs

\*Adapted from *The Wall Street Journal*, Wednesday, Oct. 10, 2001

### Non-Disclosure Agreement

#### What Is a Non-Disclosure Agreement?

- Confidentiality agreement/secretcy agreement
- Confidential information disclosed pursuant to the agreement is maintained in confidence in accordance with the provisions of the agreement for a length of time set forth in the agreement
- Not difficult to do right and not expensive
- Disastrous if done wrong
- Due diligence more important

#### Obligation To Maintain Disclosed Information in Confidence Ordinarily Terminated in Event That:

- Information becomes publicly available through no fault of the receiving party
- Information was already known to the receiving party or is given to the receiving party by another party without any obligations



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- Information was independently developed by the receiving party

### Three Types of Non-Disclosure Agreements

- Incoming – Confidential info disclosed into company by third party and no company confidential information disclosed out
- Outgoing – Company confidential info is disclosed to a third party and none of the third party's confidential info is disclosed to the company
- Mutual – Company and third party exchange confidential info pertaining to a particular subject

### External Security

- Establish policy with regard to proper use of e-mail
- Erase e-mail on a regular basis

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