



INTERNATIONAL
TRADE
ADMINISTRATION

Intellectual Property in the Life Sciences

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Session Objectives

At the end of this session, you will be able to:

- Understand the basics of obtaining and enforcing intellectual property (IP) rights in the life sciences industries.
- Start assessing how IP rights may be critical for research institutions and businesses and why counterfeiting and piracy is a problem.
- Learn how to protect and enforce intellectual property and resources that are available to help.



Part I

WHAT IS INTELLECTUAL PROPERTY?

What is Intellectual Property

Intellectual property can be broadly defined as creations of the mind.

- **PATENTS:** protect an invention
- **TRADEMARKS:** word/phrase/symbol identifies and distinguishes the source of the goods
- **COPYRIGHTS:** protects original artistic or literary work
- **TRADE SECRETS:** confidential information.



What are common forms of intellectual property in the life sciences industries?

- You may have a scientific tool, medical device, technique, molecule, which may be patented with a process or product patent.
- You may make a product that bears your company's trademark.
- The instructional manual that is sold with that product may be protected by copyright.
- Scientific publications and dissertations may also be protected by copyright.



Part II

PROTECTING INTELLECTUAL PROPERTY

How can you protect yourself from IP theft?

- Step 1: **Conduct an IP audit.** Examine your business to see what might be eligible for a patent, trademark, copyright or trade secret status.
- Step 2: Review your options for protecting that property, at home and abroad.

How can you protect your business from IP theft?

- **Step 3: Obtain your IP rights in the United States by filing a patent application or registering your trademark or copyright with the proper U.S. Government Agencies.**
- **Step 4: Do your due diligence on your business partners. Do not assume that your business partner is looking out for your company's best interest. Remember your intellectual property may be quite valuable.**

Am I Eligible to Obtain Intellectual Property?

- Bayh-Dole Act: University and Small Business Patent Protection Act
 - Gave U.S. universities, small businesses and non-profits IP control of their inventions of IP that resulted from such funding.
 - Reversed the presumption of title: Permits pursuit of an invention in preference of the government.

Obtaining IPR Protection in the U.S.

- Apply for a Patent or Register for a Trademark
 - U.S. Patent and Trademark Office
 - www.uspto.gov; 1-800-786-9199
 - Patent \$110-850
 - Trademark \$275-\$375
- Register a Copyright
 - U.S. Copyright Office
 - www.copyright.gov
 - \$35 (Electronic Filing)



Protecting Your Intellectual Property in Foreign Markets

- Questions: Are my U.S. patents or trademarks valid in other markets?
- Answer: **No!** Intellectual property rights are generally territorial. This means that a U.S. patent or trademark offers you no protection abroad. You must apply for patents and trademarks in every market where you are seek protection.

Protecting Your Intellectual Property in Foreign Markets (Continued)

- ***A Special Note About Copyrights:*** There is no such thing as an “international copyright” that will automatically protect a work throughout the world. Protection against unauthorized use in a particular country depends on the national laws of that country.
- Most countries offer protection to foreign works under certain conditions that have been greatly simplified by international copyright treaties and conventions such as the Berne Convention.

Register in Current and Potential Markets

- Trademarks: The Madrid Protocol
 - File international application with USPTO
 - 84 countries
 - www.WIPO.int
 - www.USPTO.gov
- Patents: The Patent Cooperation Treaty
 - File a PCT application with the U.S. Receiving Office of the USPTO
 - 142 countries

In which countries should I seek IP Protection?

- **Business Decision:** You must decide for yourself in which countries to seek intellectual property protection.
- **When to consider:** Prior to new product development; prior to export.
- You may wish to ask yourself a series of questions in determining your priorities:
 - Where do I currently sell my product?
 - Where do I want to sell my product in the future?
 - Where are my products or components of my product produced?
 - What are some of the more likely countries where infringement may occur?



Part III

MONETIZING INTELLECTUAL PROPERTY

Licensing & Assignments

Licensing

- **Benefits for the licensee:** Licensing facilitates commercialization; provides access to intellectual property that would not otherwise be obtainable.
- **Benefits for licensor:** Licensing generates cash, can enhance your reputation.
- **Owner of intellectual property is responsible for payment of maintenance fees, may be subject to litigation.**

Licensing & Assignments

Assignments

- Sell IP rights
- Can sell outright or pursue other forms of revenue such as a percentage of sales
- Purchaser is responsible for maintenance of IP rights and future ensuing litigation

Manufacture and Sale

- **Your intellectual property could be incorporated into end product that you manufacture and sell.**



Part II

THE PROBLEM OF INTELLECTUAL PROPERTY INFRINGEMENT

Why should you protect your Intellectual Property?

- Piracy, counterfeiting and the theft of intellectual property assets pose a serious threat to all American businesses. Exporters face unfair competition abroad, non-exporters face counterfeit imports at home and all businesses face legal, health and safety risks from the threat of counterfeit goods entering their supply chains.

Enforcing IPR: The Rightholder's Responsibility

- **Civil Remedies**
 - Lawsuit or ADR
 - Licensing Agreement
- **Remedies at the Border**
 - Record with customs
 - ITC, Section 337
- **Criminal Remedies**
 - National Intellectual Property Rights Coordination Center
 - 1-866-IPR-2060; www.ice.gov

Common Pitfalls

- **Not obtaining intellectual property protection**
 - Intellectual property rights are territorial by nature. Rights holders must be diligent about protecting their rights around the world. Just because a company is not in a market does not mean that they should not register their patent, trademark, or copyright in that market. Today's work could avoid tomorrow's headache!
- **Not knowing business partners**
 - Companies should consider using the Commercial Service's International Company Profile Service
 - Develop strong contractual relationships with your business partners as they may be key to protecting your intellectual property.
- **Not enforcing private rights**
 - You should always seek out local legal counsel on how to protect your intellectual property rights in a particular market.

How serious of a problem is IP theft ?

- 2007 OECD Study: “International trade in counterfeit and pirated products could have been up to USD 200 billion”.
- IP theft has a major impact at home: The U.S. Chamber of Commerce estimates that overall intellectual property theft costs 750,000 U.S. jobs a year.
- Sectors most affected: All industry sectors are affected but manufacturing, consumer goods, technology, software, and biotechnology (including pharmaceuticals) tend to have the highest incidences of counterfeiting and piracy.

Do you really need to worry about IP Protection abroad?

- Foreign manufacturers have copied U.S. products, packaging and business plans, even though the U.S. company has never done business abroad.
- Foreign counterfeiters can easily steal your product pictures, brochures and logos from your website and register the material as their own inventions in their country, if you have not registered it there already.
- Some small U.S. companies seek trademark and patent protection in large potential markets well in advance of actually exporting to those markets.

Ensuring Companies Benefit from U.S. Trade Agreements

- **Special 301 Report**

- The Special 301 provisions of the Trade Act of 1974 require USTR to identify foreign countries that deny adequate and effective protection of IPR or fair and equitable market access for U.S. persons that rely on IP protection.

- 3 designations by statute:

- Priority Foreign Country
- Priority Watch List
- Watch List

- Find Report: www.ustr.gov



Part IV

RESOURCES

Resources Available to Assist U.S. Companies



- www.stopfakes.gov
 - Learn more about steps to protect/obtain IPR in the U.S. and abroad
- IPR Toolkits
 - Brazil, Brunei, China, Egypt, European Union, India, Italy, Malaysia, Mexico, Paraguay, Peru, Russia, Taiwan, Thailand and Vietnam
 - How to obtain and enforce IP rights in each country
 - Country contacts

Resources Available to Assist U.S. Companies

- 1-866-999-HALT
 - Speak to trade specialist about company problems
 - File a complaint
 - Request assistance
- www.stopfakes.gov
 - Learn more about steps to protect or obtain IPR in U.S. and overseas

SME Online IP Education Module

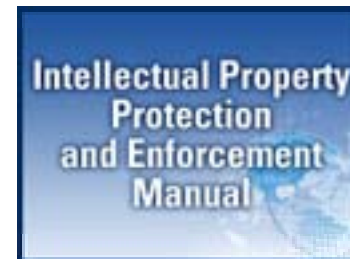


- Allows businesses to educate themselves on a range of important IP issues from basic IP information to more complex analysis.
- Was developed in partnership with the Small Business Administration
- Is available free of charge at:
<http://www.stopfakes.gov/525/menu/index.htm>

U.S. Chamber Global IP Center Resource

Intellectual Property Protection and Enforcement Manual

- Proven strategies companies have used to determine if they have a counterfeiting problem, and combat IPR infringement
- www.thecacp.com



International IPR Advisory Program

- ABA International IPR Advisory Program:
 - One free one-hour consultation
 - China, India, Egypt, Brazil, Russia, Thailand
- Also: ELAN
<http://www.export-legal-assistance.org/>



IP Attaches

IP Experts Posted in U.S. Embassies:

- China – Beijing and Guangzhou
- Bangkok
- Moscow
- New Delhi
- Rio de Janeiro

Ensuring Companies Benefit from U.S. Trade Agreements

- **Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPs)**
- **World Intellectual Property Organization Internet Treaties (WPPT & WCT)**
- **FTAs (17):** Australia, Bahrain, Canada, Chile, Costa Rica, Dominican Republic, El Salvador, Guatemala, Honduras, Israel, Jordan, Mexico, Morocco, Nicaragua, Oman, Peru, Singapore
- Waiting Congressional approval: Colombia, Panama, Korea
- **Trade and Investment Framework Agreements**

Global Partnerships

- Work with our trade partners
 - North America IPR Working Group
 - US-EU
 - US-Japan
- Multilateral Forums
 - OECD, G-8, APEC
- Partnership with SBA and SBDCs



Trade Compliance Center and OIPR

- Ensuring Compliance with U.S. Trade Agreements
- When we identify unfair treatment:
 - Meet with business
 - Form a compliance team
 - Craft an action plan
 - Raise the issue with appropriate authorities

THANK YOU!

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