

Intellectual Property and Its Protection

UCC
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Overview of Drug Development Scheme

	Preclinical Testing	Phase I	Phase II	Phase III	FDA	Phase IV
Years	3-6	1	2	3	2-5	12 Total
Population	Laboratory and animal studies	20 to 80 healthy volunteers	100 to 300 patient volunteers	1000 to 3000 patient volunteers	File NDA	Additional Post marketing testing required by FDA
Purpose	Access safety and to prove activity	Determine safety and dosage	Establish effectiveness look for side effects	Verify effectiveness address reactions from long-term use	Review and approval	
Success Rate	8,000 compounds evaluated	5 into trials			1 approved	

Research & D → Years? ↑

Disclaimer

- The content of this presentation on intellectual property is solely as an introduction, and not intended to provide legal advice, or to serve as the latest legal interpretation of patent, trademark or copyright law.



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What is the Origin/Intent of a Patent?

- Congress enacted patent laws to provide (1) an incentive to inventors to invent, (2) to make their inventions public, and (3) to protect patented invention from unauthorized use.

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What Government Entity Issues Patents?

- A patent for an invention is the grant of a property right to the inventor, issued by the United States Patent and Trademark Office.
- Federal patent law wholly preempts the area (i.e. states cannot regulate patents).
- U.S. patent grants are effective only within the United States, U.S. territories, and U.S. possessions.

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What is conferred by the patent?

- The right conferred by the United States or "importing" the invention into the United States.
- What is granted is not the right to make, use, offer for sale, or sell. In the language of the statute and of the grant itself, "the right to exclude others from making, using, offering for sale, or selling."
- Once a patent is issued, the patentee may enforce the patent, but without aid from the USPTO.

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What types of patents are available?

- There are three types of patents:
 - Utility patents may be granted to anyone who invents or discovers any new and useful process, machine, article of manufacture, or compositions of matters, or any new useful improvement thereof;
 - Design patents may be granted to anyone who invents a new, original, and ornamental design for an article of manufacture; and
 - Plant patents may be granted to anyone who invents or discovers and asexually reproduces any distinct and new variety of plants.

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How does one apply for a patent?

- Application for a patent
 - the inventor or his representative must file an application for a patent with the patent and trademark office
 - generally, the application must be filed within one year of the "public use" or publication" of the invention
 - the application must contain "a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise and exact terms as to enable any person skilled in the art to which it pertains to make and use the same
 - the application must conclude with one or more claims "pointing out and distinctly claiming the subject matter" that constitutes the invention, and no more.

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How long does patent protection last?

- Utility and plant patents are granted for a term which begins with the date of the grant and usually ends 20 years from the date you first applied* for the patent subject**.
- Design patents last 14 years from the date you are granted the patent.

* Please read about provisional patent applications in a subsequent slide
**This applies to utility and plant patents applications filed on or after June 8, 1995.

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Provisional Application

- The provisional application is a *patent application*
- Establishes an official US patent application *filing date* for the invention
- Permits the term "*Patent Pending*" to be applied in connection with the invention. However,
 - A foreign application may claim priority to a provisional application.
 - Automatically becomes abandoned when its pendency expires (12 months after the filing date)
 - Applicants must file a non-provisional application before the pendency period expires

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Benefits of Provisional Application

- Lower-cost first patent filing in the US
- TA future regular (non-provisional) application would benefit in several ways:
 - Patentability would be evaluated as though filed on the earlier provisional application filing date
 - The twenty-year patent term would be measured from the later non-provisional application filing date.
 - Domestic applicants are placed on equal footing with foreign applicants with respect to the patent term.

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Disclosure Document

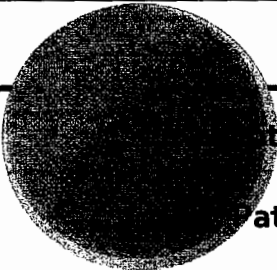
- Not a patent application.
- Does not permit the term "*Patent Pending*" to be applied to the invention.
- Date of receipt will not become the *effective filing date* of related application filed.
- However, the date the DD is received in the USPTO does provide evidence of a date of conception (if referenced in a related patent application within two years of such receipt.)

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What if some person/entity is infringing on my patent?

- There are remedies for patent infringement
- Injunction precluding use of the patent
- Damages measured as the "reasonable royalty" that the patent holder should have received for the use of the patent by the defendant, together with interest and costs of the suit
- Any other monies that the patent holder would have made had there been no patent infringement (e.g. Profits from "lost sales" that the plaintiff patent holder was able and willing to make but that defendant infringer made)
- Reasonable attorney fees

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**Intellectual Property
Part 2
Patent Requirements**

What are Statutory requirements?

- In addition to the requirement of a patentable subject matter, there are four other statutory requirements that must be met before an invention can be granted a patent
- 1. an invention or discovery must be "original"
 - cannot substitute new material for old material
 - cannot change the size or dimensions of article or machine
 - cannot make an article portable
 - cannot multiply or combine parts
 - cannot reverse the position of parts
 - cannot convert a batch method to a continuous method

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Statutory Requirements (cont'd)

- 2. An invention or discovery must be "novel"
 - a. if invention or discovery was actually known in the prior art, it is not "novel" and not patentable
- 3. The invention must have "utility". The invention must be able to accomplish some beneficial purpose in a practical manner
- 4. The invention or discovery must be "non-obvious."

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Statutory requirements in the "claims" section of the patent application?

- In order to meet the statutory requirements of "particularity" and "distinctiveness," the claims must distinguish that which is claimed from that which went before in the art, and clearly describe what is foreclosed from future use by the claim
- Claims often fail as being too broad, vague, or ambiguous
- Any fraudulent statement made to the patent office with regard to an application for a patent results in the invalidation of the patent

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What is patentable?

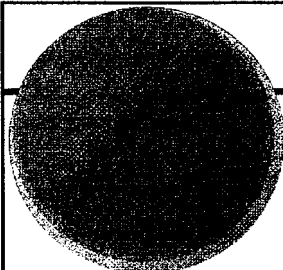
- Patentable subject matter. The invention must fall within one of the statutory clauses of invention:
 - A process (e.g. a unique method of extracting a curative compound from plants)
 - A machine
 - A manufacture (i.e. not a process, machine, or composition or matter; for example, a drive-in movie theater)
 - A composition of matter (i.e. a mixture of two or more ingredients)
 - An improvement (i.e., an addition, simplification, or variance) to an existing machine, process, manufacture, or composition of matter

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What is patentable (Cont'd)?

- An asexually reproduced plant (i.e. mutant hybrid, variety, etc.)
- A design for an article of manufacture (i.e. a design by means of lines, images, and configuration that makes an impression on the mind of the observer through the eyes
- Are ideas patentable?
 - *A mere idea, abstraction, scientific principle, or natural process cannot be patented, unless it is part of a tangible environment*

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Part 3 Inventions and the Employer/Employee Relationship

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Inventions and the Employer/Employee Relationship

- How am I affected if I invent something, and I work for a biotech company, for example?



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**Employer-Employee Relationship
(Scenario 1)**

Generally,
where an employee is hired by an employer
to invent, the employer may enforce
employment agreements assigning all
inventions by the employee to the
employer, whether made on company
time or not, and whether made on
company property or not

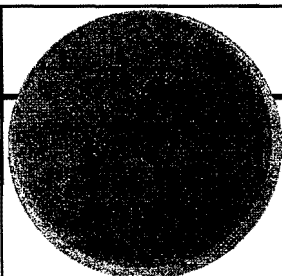
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**Employer-Employee Relation
(Scenario 2)**

Generally,
● If hired in non-inventive position, the employer has no
right of assignment to any invention of the employee
made by the employee on his or her own time and not
using the employer's place of business or equipment

However,
● If invention occurs during hours of employment, or
using the employer's equipment and materials, the
employer is given a common-law "shop right" license to
the invention even absent an employment agreement

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**Part 4
Other IP
Protections**

What are Trademarks and Servicemarks

- A trademark is a word, name, symbol, or device used in trade with goods to indicate the source of the goods and to distinguish them from the goods of others.
- A servicemark is the same as a trademark except that it identifies and distinguishes the source of a service rather than a product.
- The terms “trademark” and “mark” are commonly used to refer to both...

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What is a Copyright?

- Copyright is a form of protection provided to the authors of “original works of authorship” including literary, dramatic, musical, artistic, and certain other intellectual works, both published and unpublished.
- The 1976 Copyright Act generally gives the owner of copyright the exclusive right to reproduce the copyrighted work, to prepare derivative works, to distribute copies or photo-records of the copyrighted work, to perform the copyrighted work publicly, or to display the copyrighted work publicly.

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What are Trade Secrets?

- Processes, procedures used in a business or manufacture that gives advantage to that company and sets them apart from the rest
- Trade secrets may consist of a product formula, pattern, customer list, or other device or compilation of information.
- Trade secrets that do not qualify for patent, copyright, or trademark protection are thereby accorded limited protection by state unfair competition laws (generally misappropriation).

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What is "actionable misappropriation of trade secrets?"

- Actionable misappropriation of a trade secret usually requires that the competitor discover the trade secret through espionage, bribery, theft or some other form of unlawful activity
- Further, the plaintiff in a misappropriation of a trade secret case must have taken all reasonable precautions to protect its trade secret from discovery (fences, guards, locks, etc.)

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Non-Disclosure Agreements And Protection Of Trade Secrets

- An NDA is a contract in which parties promise to protect the confidentiality of secret information disclosed during employment or another type of business transaction.
- Can be used to protect any type of trade secret
- The purpose of is to create a confidential relationship between a person who has a trade secret and the person to whom the secret is disclosed.
- People who have such a confidential relationship are legally bound to keep the information a secret.

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Other types of intellectual property

Biological Material refers to unpatented or non-patentable biological materials including organisms, cells lines, proteins, RNA/DNA, antibodies and other cellular components and their derivatives.

- Research and development of biological materials (and their possession) is an important issue, therefore possession and controlled rights should be governed by contract with or without patent rights.

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Other types of intellectual property

- **Tangible Research Property** refers to those research results which may or may not be patentable or copyrightable and are in a tangible form as distinct from intangible (intellectual) property.
- Examples include research notebooks, prototypes, engineering drawings, clinical data, databases and other property that can be physically distributed.
- Possession and controlled rights of such property can be governed by contract.

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