

PATENTS IN TWO HOURS OR LESS

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- What is a patent?
- Who is an inventor?
- What can be patented?
- What are the requirements for obtaining a patent?
- What about patent protection beyond the US?
- When is a patent infringed?
- What happens in a lawsuit? (Brenda Pomerance)
- When is freedom of operation a concern and how should it be addressed?

What is a patent?

- Is an intangible property right/asset
- Awarded to a person who invents or discovers any new, useful and nonobvious article of manufacture, machine, process, compositions of matter and improvements thereof.
- A patent is granted to the inventor(s).
- Only covers the United States

Parts of a Patent

- Field of the Invention
- Summary of the Invention
- Brief Description of Figures
- Detailed Description
- Claims
 - Most important section
 - Analogous to a deed to a house
 - Defines the metes and bounds of an invention
- Figures

Method for the Cultivation of Filamentous Fungi

(1) United States Patent
We et al.

(18) Patent No.: US 6,746,862 B1
(21) Date of Patent: Jun. 8, 2004

(51) Int. Cl. Class. No. C12N 1/20
(52) U.S. Cl. Class. No. 435/252

(54) Method for Cultivation of Filamentous Fungi

(57) Abstract: A method for cultivation of filamentous fungi comprising the steps of: (a) preparing a medium for submerged culture comprising rice particles that receive said filamentous fungi, wherein the rice particles are husked, cooked, and sterilized before being added to said medium; and (b) inoculating said medium with said filamentous fungi in a bioreactor to carry out fermentation wherein the mycelia of said filamentous fungi are attached to said rice particles.

Method for the Cultivation of Filamentous Fungi

- U.S. Patent No. 6,746,862
 - Independent Claim
 - A method for cultivation of filamentous fungi comprising the steps of: (a) preparing a medium for submerged culture comprising rice particles that receive said filamentous fungi, wherein the rice particles are husked, cooked, and sterilized before being added to said medium; and (b) inoculating said medium with said filamentous fungi in a bioreactor to carry out fermentation wherein the mycelia of said filamentous fungi are attached to said rice particles.
 - Dependent Claim
 - The method as claimed in claim 1, wherein said filamentous fungi comprise *Monascus*, *Penicillium* or *Aspergillus*.

Rights of a Patent Holder

- A patentee has the right to prevent others from making using, selling, offering to sell or importing into the United States the claimed invention from the time of issuance until for the most part 20 years after the patent application was filed.
- A patentee may obtain from an infringer royalties, lost profits and/or obtain an injunction against an infringer.

Who is the patent holder?

- The inventor(s) of the subject matter claimed.
- Can have different inventors for different claims

Importance of Naming the Correct Inventors

- In the U.S., only the inventor can obtain the patent. Therefore, if the correct inventors are not named, the patent will be deemed invalid.
- It may be important in establishing dates of conception.
- The identification of inventors may determine the assignees of the invention.

Assignment of Rights

- Each inventor may assign the subject matter claimed to a person, non-profit institution or domestic or foreign
- Unless agreed otherwise, each assignee is a joint owner-this means that each assignee has equal rights and can license and/or assign rights in the invention.
- Assignee is generally listed on the patent
- Assignment records are publicly available and may be obtained from <http://assignments.uspto.gov/assignments/>

Who is an Inventor?

- An invention involves both conception of an idea or what needs to be accomplished to solve a problem and reduction to practice.
- Conception must be accomplished by the inventor(s) while actual reduction to practice can be accomplished by almost anyone.

What is Required for Conception?

- Conception requires both the idea of the invention's structure and possession of an operative method of making it.
- Conception requires that the idea involves a specific approach to the particular problem at hand. It must be specifically precise so that one of skill in the art could carry out the invention without undue experimentation.
- Conception requires conceiving of or appreciation for a utility of the invention.
- Conception must be supported by clear and convincing corroborating evidence-signed and witnessed lab notebooks

Examples of Conception

- Results of preliminary tests suggesting that a given compound may be used for a given purpose, though further tests are performed by a collaborator.
- Construction of a prototype of a device even though improvements are later made.

Who is not an Inventor?

- One who suggests a desired end but not the means that would sufficiently enable one of ordinary skill to e.g., obtain a product.
- One who merely follows instructions of the person who conceived the invention (Stern v. Trustees of Columbia University, 434 F.3d 1375 (Fed. Cir. 2006))
- One who merely uses ordinary skill in the art to reduce to practice the idea conceived by the inventor.
- A person who supplies background data or general information to an inventor.

Joint Inventorship

- Each joint inventor must contribute to the conception.
- Joint inventors must be aware of each other.
- Joint inventors must collaborate with each other. It is necessary that each of the inventors work on the same subject matter and make some contribution to the inventive thought and to the final result.
- Inventors may apply for a patent jointly even though
 - They did not physically work together or at the same time,
 - Each did not make the same type or amount of contributions, or
 - Each did not make a contribution to the subject matter of every claim of the patent.

Hypothetical #1

- Scientist has isolated a number of substances which according to a preliminary screen kill fungi.
- Scientist requests that collaborator screen the substances for various activities (specific fungi, antibacterial activity).
- Two compounds are found possessing one of the activities tested for.

■ **WHO IS THE INVENTOR?**

Hypothetical #2

- Scientist has isolated a substance with antifungal activity.
- Scientist requests that collaborator screen the substance for various activities (specific fungi, antibacterial, etc.). Collaborator suggests an additional screen (activating immune response).
- The compound is found to possess the activity detected by the screen suggested by the collaborator.

■ **WHO IS THE INVENTOR?**

Hypothetical #3

- Project manager has come up for new idea for a new antiseptic mouthwash which does not contain alcohol
- Scientist comes up with a possible solvent. No direction is given by project manager regarding solvents to try.

■ **WHO IS THE INVENTOR?**

What Can Be Patented?

- Machines and methods of using the machine
- Chemical compounds, formulations and methods for obtaining and using such compounds
- Biotechnology
 - Isolated genetic material (DNA/RNA)
 - Genetically modified organisms (transgenic plants, animals)
 - Methods for obtaining isolated genetic material, genetically modified organism
 - Nanotechnology
 - Stem Cells
 - Asexual reproduction methods of organisms

What Can Be Patented?

- Computer software-computer configured into a special-purpose machine by software (e.g., system claim), the computer program itself, the software product itself, hardware containing the computer software
- Business methods (automated business data processing)-as long as mathematical algorithm is applied in a practical manner to produce a useful result. Includes the business method itself as well as systems for implementing the business method.

Other Patentability Requirements

- Adequate written description
- Must disclose best mode
- Enabling to one of skill in the art
- Novel-no previous oral or written disclosure
- Nonobvious
- Useful

Procedures for Obtaining Patent Protection

- File provisional patent application (optional)
- File regular patent application (within one year of filing provisional application) with the U.S. Patent and Trademark Office which contains
 - Written/enabling description of the invention
 - Description of best mode for carrying out the invention
 - Claims-legally define the invention protected by the patent
 - May also contain drawings
- Examination of application by Patent Examiner to determine if all requirements have been met
- Response by applicant

Procedures for Obtaining Patent Protection

- Further action by U.S. Patent and Trademark Office or issuance of patent
 - Further action includes a second Office Action
 - After that, may refile the application, abandon or file an appeal
- Average pendency-3-4 years
- Costs for obtaining patent protection \$20,000 minimum

What About Patent Protection Beyond the US?

- A US patent only provides protection in the US
- It is necessary to file an application in each country where protection is desired
- An application must be filed within 1 year of the initial US application
- Each country has its own laws with respect to what constitutes patentable subject matter and requirements for patentability

Rights of a Patent Holder

- A patentee has the right to prevent others from making using, selling, offering to sell or importing into the United States the claimed invention from the time of issuance until for the most part 20 years after the patent application was filed.
- A patentee may obtain from an infringer royalties, lost profits and/or obtain an injunction against an infringer.

When is a Patent Infringed?

- Direct Infringement
- Third Party Liability
- Importation
- Defenses

Direct Literal Infringement

- Law of Exactness-infringing product or process must contain the exact elements recited
- Law of Addition-addition of an element to claimed elements would still constitute infringement
- Law of Omission-omission of a claimed element would not constitute infringement

Hypothetical-Law of Omission

- Patent Claim recites
 - A beverage comprising sucrose, glucose, water, lemon juice.
- Third party makes a beverage containing sucrose, water and lemon juice.
- Does third party infringe?

Hypothetical-Law of Addition

- Patent Claim recites
 - A beverage comprising sucrose, glucose, water, lemon juice.
 - Third party makes a beverage containing sucrose, glucose, water, lemon juice and pink food coloring.
- Does third party infringe?

Infringement Inquiry

- Does the accused product or process literally infringe the claimed product or process?
- If no, does the accused product or process infringe the claimed product or process under the Doctrine of Equivalents?
- If yes, would prosecution history estoppel limit the scope of the claims?

Doctrine of Equivalents

- An element of an accused product or process is equivalent if the differences between the element and the claim limitation are “insubstantial” to one of ordinary skill in the art.

Hypothetical-Doctrine of Equivalents

- Patent Claim recites
 - A beverage comprising sucrose, glucose, water, lemon juice.
- Third party makes a beverage containing sucrose, glucose, water and lemon extract.
- Does third party infringe?

Third Party Liability

- Inducement of Infringement-35 USC §271(b)
- Contributory Infringement-35 USC §271(c)

Inducement of Infringement

- 35 U.S.C. §271(b) occurs where a party is “actively and knowingly aiding and abetting another’s direct infringement.”
Elements-Plaintiff must show
 - (1) the defendant possessed the specific intent to cause the acts which constitute the infringement and
 - (2) that he knew or should have known his actions would induce actual infringement.

Inducing Infringement

- Manufacturer of typhoid vaccine is not liable for inducing infringement of claim to a method of treating a human patient to effect the remission of AIDS even though the typhoid vaccine boosts immune response.
- Caution on packaging not to use blood glucose test strips on particular meter identified by trademark and patent marking “until this legal matter is settled in the courts” did not preclude liability on summary judgment.

Requirements of 35 USC §271(c) Contributory Infringement

- There must be a sale of a component part for a patented item.
- The component must be a material part of the patented item.
- There must be knowledge by the seller that the component is especially made for use in an infringement of the patent.
- The component must not be a staple article suitable for a substantial noninfringing use.

Hypothetical

- A has a patent containing a claim to a method for ultrasonic assisted liposuction. B manufactures a machine that can be used in the patented method as well as other surgical applications. B markets the machine to physicians performing liposuction and was aware of patent. The machine has not been used for any other purposes.
- What is B's liability under 35 USC §271(b) (inducing infringement) and 35 USC §271(c) (contributory infringement)?

Exporting Components Used in a Patent Process-35 USC 271(f)

- Imposes liability for supplying "components of a patented invention where such components are uncombined... in such manner as to actively induce the combination of such components outside of the United States."
- Exporting catalysts used in a patented process where the process was conducted abroad constitutes infringement. *Union Carbide Chemicals & Plastics Tech. Corp. v. Shell Oil Co.* 425 F.3e 1366 (Fed. Cir. 2005)

Importation-35 U.S.C. §271(g)

- Imposes liability for infringement by importation, sale or use in the US of a product made abroad by a process patented in the US.
- Process must be patented when product is made (*Mycogen Plant Science, Inc. v. Monsanto Co.* 252 F.3d 1306, 58 USPQ2d 1891 (Fed. Cir. 2001))
- Extends to immediate product of the process and "downstream" products subject to two limitations:
 - (1) "materially changed" by subsequent processes or
 - (2) it becomes a "trivial and nonessential component of another product"
- Process must be for manufacturing a physical article ("the product")-a "product" is not research data produced by identification method; does not cover "wireless electronic mail" specifically formatted by a patented process (NTP v. RIM-blackberry case)

Remedies for Infringement

- Injunction preventing infringer from producing, using or selling claimed product, making product using claimed method, or using a product applying claimed use
- Royalties
- Lost profits
- Exceptional cases-attorney fees

Willful Infringement

- Court may award treble damages and/or attorney fees (exceptional circumstances)
- Factors
 - Copying-whether infringer deliberately copied ideas, methods or designs of an another
 - Investigation-whether on learning of patent's existence, infringer investigated patent's scope and formed a good faith belief of its noninfringement and/or invalidity
 - Litigation conduct-whether infringer conducted itself inappropriately during litigation

Defenses to Infringement

- Do not infringe
- Patent is invalid-obvious, not novel, does not provide an adequate disclosure, fails to disclose best mode
- Inequitable conduct-if prevail, patent is unenforceable
 - Failure to disclose prior art
 - Deceptive intent in naming inventor

Defenses to Infringement

- Experimental Use
 - 271(e)(1)-activity associated with clinical trials or preclinical data ultimately submitted to the FDA (Merck v. Integra, 125 S. Ct. 2372 (2005))
 - Other experimental uses-solely for amusement, to satisfy idle curiosity, or for strictly limited philosophical inquiry. The profit or non-profit status of the user is not determinative. (*Madey v. Duke University*, 307 F.3d 1351, 64 USPQ2d 1737 (Fed. Cir. 2002))

Freedom of Operation

- Before investing substantial resources in developing a new product or process, a search of currently issued U.S. and pending applications should be undertaken to determine if your proposed process would potentially infringe claims of U.S. patents or pending application.

What to Search

- Potential competitors
- Search terms encompassing the proposed product or process

Where to Perform a Search

- Online
- USPTO
- Patent Depository Library (Sunnyvale, CA and College Station, Texas)

Online Patent Resources

- www.uspto.gov
 - Can search issued US patents and published US applications
- <http://ep.espacenet.com>-European Patent Office (contains published applications filed worldwide)
- www.wipo.int - international patent applns.
- <http://patent1.ic.gc.ca>-Canadian Patent application
- Commercial services (e.g., Dialog, micropatent, STN (from ACS), Delphion, Derwent)

Who can conduct a patent search

- Inventors
- Those familiar with search engines and/or technology
- Professional Patent Researchers
- Patent Attorneys and Agents

Other Patent Related Searches

- Assignment searches to determine assignor and assignee-
<http://assignments.uspto.gov/assignments/>
- Inventor search-check patent databases
- Maintenance fee to determine if maintenance fee has been paid-maintenance fees are due 4, 8 and 12 years post issuance-if not paid, patent is no longer enforceable-
<https://ramps.uspto.gov/eram/patentMaintenance.do>

When to Consult an Attorney

- It is not necessary to be an attorney to conduct searches
- However, only a patent attorney may render an opinion as to whether your product or process infringes a claims in a patent document
- If there is any question as to whether there is infringement, an opinion of an attorney is necessary to avoid willful infringement

To Patent or Not to Patent

- Is the product or process patentable?
search patent and nonpatent literature
- If so, would it be easy for a third party to design around a patent?
- Weighing the question of public disclosure v. keeping invention as a trade secret

So, What IP issues do I need to consider when I have developed a new product or process?

- Does the product/process infringe third party patent documents?
 - To find out, conduct patent search of potential competitors or use search terms containing your product/process
 - Search competitors website
 - Set up competitive intelligence program
- If so, look into licensing or determine if patent is invalid and/or enforceable (Is the patent still in force?)
- Is my product/process patentable?
- Even if it is patentable, is it worth patenting?

THANK YOU!

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