

# L'importance des brevets pour protéger les inventions

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## Goals of this Presentation

- **Provide a broad overview of:**
  - **U.S. Patents and Patent Rights**
  - **The United States Patent and Trademark Office (USPTO)**
  - **The Major Requirements for a Patentable Invention**
  - **How Protéus has taken advantage of the patent system**

## What Is A U.S. Patent?

- **Agreement between U.S. Government and Inventor**
  - Inventor is given property rights in his invention
  - Government (and the public) is given information on how to make and use the invention
- **Property rights in patent last for term of 20 years from the date the patent application was filed**
  - These patent rights are only effective in the U.S.

## What Rights are Created by a Patent?

- **A U.S. Patent gives the right to exclude others from:<sup>1</sup>**
  - **Making** the invention
  - **Using** the invention
  - **Offering to sell** the invention
  - **Selling** the invention
  - **Importing** the invention into the U.S.
- **It does not give the patent holder the right to practice the invention.**

<sup>1</sup> 35 U.S.C. §271(a)

## What is the Basis for the Patent System?

### U.S. Constitution, Article I, § 8, clause 8

- **The Congress shall have the power to...**

“promote the progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries.”

# Who is Responsible for Issuing U.S. Patents?

- **U.S. Patent & Trademark Office**
  - Agency of the U.S. Federal Government
  - Responsible for issuing patents in accordance with the United States patent laws
- **USPTO is Divided into Art Units**
  - Each art unit determines the patentability of inventions based on different types of technology
  - Example: Art Unit 1637 examines many types of biotechnology patent applications like those submitted by Proteus
- **USPTO is Located in Alexandria, Virginia**
  - Just outside of Washington, DC

## What Gets Examined At the USPTO?

- **Patent applications include:**
  - **Specification**
    - **Description of the invention**
    - **Claims that define the invention such that a person in the field is apprised of the scope of the claimed invention**
  - **Drawings**
  - **Fees and Oath or Declaration of Inventor**

# What is Required Before the USPTO Grants a Patent?

- **The Examiners must determine whether the invention is:**
  - **Useful and Patentable Subject Matter** under 35 U.S.C. § 101
  - **Novel** under 35 U.S.C. § 102
  - **Nonobvious** under 35 U.S.C. § 103
  - **Described and Enabled** with Disclosure of the **Best Mode** under 35 U.S.C. § 112, ¶ 1

## What Type of Inventions are Patentable Subject Matter Under § 101?

- **35 U.S.C. § 101 allows patents for these types of inventions:**
  - Processes (including business methods)
  - Machines
  - Articles of Manufacture
  - Compositions of Matter (including life forms)
- U.S. Supreme Court: “[A]nything under the sun that is made by man.”<sup>1</sup>

<sup>1</sup> *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980).

## What Types of Inventions are “Useful” Under § 101?

- **To be patentable, the invention must have at least one operable use that is credible to a person of ordinary skill in the art**
  - Can NOT be something that does not work, like a “perpetual motion machine”<sup>1</sup>
  - Can NOT be a chemical compound that does not serve any known purpose<sup>2</sup>

<sup>1</sup> See M.P.E.P. § 2107

<sup>2</sup> *Brenner v. Manson*, 383 U.S. 519 (1966).

# What is NOT Patentable Subject Matter Under § 101 ?

- **35 U.S.C. § 101 excludes the following from patentability:**
  - Laws of Nature/Abstract Ideas/Mathematical Formulas
    - Examples:  $E=mc^2$ ,  $d/dx \sin(x) = \cos(x)$ , etc.
  - Scientific Principles
    - Examples: Theory of relativity, gravity, etc.
  - Products of Nature (unpurified or unmodified)
    - Examples:  $H_2O$ , Fe, Si, etc.

- **However, 35 U.S.C. § 101 includes products of nature when they are in a novel form:**
- **For example:**
  - Purified forms of known compounds
    - Examples: vitamin C in purified form.
  - Life forms
    - Examples: Recombinant microorganisms, plants or animals (excluding humans).

## What is Required for an Invention to be Novel Under § 102?

- **To be novel, a claimed invention must NOT be disclosed by “prior art”**
  - “Prior art” can be: patents, scientific publications, or evidence of actual knowledge, use or sale of the invention or prior invention by another within the United States
  - If a single source of prior art discloses all of the claimed limitations of an invention, the claimed invention will be unpatentable for lack of novelty.

## What is Required for an Invention to be Novel Under § 102?

- o Unlike Europe and Japan, the U.S. provides inventors with a one year “grace period” from the time the invention is made public until a patent application must be filed.



# What is Required for an Invention to be Novel Under § 102? (Continued)

- An invention is unpatentable for lack of novelty or “statutory bar” if it is:

<u>What</u>	<u>By</u>	<u>Where</u>	<u>When</u>
Known, Used, or Made	Other than the Inventor	In the U.S.	Before Invention by the Applicant
Patented or Described in a Printed Publication	Other than the Inventor	Anywhere	Before Invention by the Applicant
Patented or Described in a Printed Publication	Anyone	Anywhere	One Year Before the Patent Application
Publicly Used or Sold	Anyone	In the U.S.	One Year Before the Patent Application
Patented	Inventor	Outside the U.S.	One Year Before the U.S. Patent Application
Described in a Patent or Printed Application	Other than the Inventor	In the U.S.	Before Invention by the Applicant

## What is Required for an Invention to be Nonobvious Under § 103?

- **Even if an invention is novel, it may still be unpatentable if the differences between the prior art and the invention would have been obvious to a person of ordinary skill in the art at the time the invention was made;**
  - **Patent Office must establish *prima facie* obviousness based on one or more references;**
  - **If established, applicant may rebut with evidence of “unexpected results,” “long felt need,” “failure of others,” or “commercial success.”**

## What is the Written Description Requirement of § 112, ¶ 1?

- **The description must reasonably convey to a person skilled in the art that the inventor had possession of the claimed subject matter at the time of filing**
- **Rationales:**
  - **Prevents applicants from claiming subject matter that they did not invent**
  - **Requires inventor to disclose the technology of the invention to the public**
  - **Normally for genes, more than the “function” of the gene is required (Applicant must provide some structure).**

## What is the Enablement Requirement of § 112, ¶ 1?

- **Requirement:**
  - **The patent application must enable a person skilled in the art to make and use the invention without undue experimentation**
- **Rationale:**
  - **A patent must meaningfully convey how to make and use the invention in exchange for the monopoly rights granted to the patentee**

## What is the Best Mode Requirement of § 112, ¶ 1?

- **Requirement:**
  - **The patent application must disclose the “preferred embodiment” or best method of practicing the invention known to the inventor at the time of filing**
- **Rationale:**
  - **Prevents inventors from getting patent rights while retaining the best means of using an invention for themselves**

## What Does A Patent Claim Look Like?

The invention claimed is:

1. A method of obtaining polynucleotide fragments for use in polynucleotide shuffling, comprising:
  - (a) obtaining a library of mutant polynucleotides from a parental polynucleotide by mutagenesis;
  - (b) denaturing and hybridizing said mutant polynucleotides to form heteroduplex polynucleotides;
  - (c) cleaving said heteroduplex polynucleotides by using proteins of a polynucleotide repair system which cleave mismatched base pairs;
  - (d) denaturing said cleaved heteroduplex polynucleotides to obtain said polynucleotide fragments; and
  - (e) recovering said polynucleotide fragments,wherein before exposing said heteroduplex polynucleotide to said polynucleotide repair system, formation of said heteroduplex polynucleotide is promoted by increasing the number of the parent polynucleotides in said library relative to other polynucleotides in said library.

# What Does An Issued Patent Look Like?

(12) **United States Patent**  
**Dupret et al.**

(10) **Patent No.:** US 7,303,897 B2  
(45) **Date of Patent:** Dec. 4, 2007

(54) **METHOD OF PREPARING  
POLYNUCLEOTIDE FRAGMENTS FOR USE  
IN SHUFFLING, AND SHUFFLING OF SAME**

5,605,793 A 2/1997 Stemmer  
5,830,721 A 11/1998 Stemmer et al.  
5,965,408 A 10/1999 Short  
6,537,746 B2\* 3/2003 Arnold et al. .... 435/6

(75) Inventors: **Daniel Dupret**, Calvisson (FR);  
**Fabrice Lefevre**, Bajonnette (FR);  
**Laurent Fourage**, Calvisson (FR)

FOREIGN PATENT DOCUMENTS

(73) Assignee: **Proteus S.A.**, Nimes (FR)

WO WO97/21537 A1 6/1997  
WO WO99/29902 A1 6/1999

(\* ) Notice: Subject to any disclaimer, the term of this  
patent is extended or adjusted under 35  
U.S.C. 154(b) by 206 days.

OTHER PUBLICATIONS

(21) Appl. No.: **10/713,006**

Stemmer et al. Proc. Natl. Acad. Sci. 1994; 91: 10747-51.\*  
Tsai-Wu et al. (Analytical Biochemistry, 1999, 275: 127-129).\*  
Dianov et al., "Reconstitution of the DNA base excision-repair  
pathway", *Current Biology* (1994), vol. 4, No. 12, pp. 1069-1078.  
Stemmer, W., "DNA shuffling by random fragmentation for molecu-  
lar evolution", *National Academy of Sciences* (Oct. 1, 1994), vol.  
91, pp. 10747-10751, Washington. XP002087463.

(22) Filed: **Nov. 17, 2003**

(65) **Prior Publication Data**  
US 2004/0214197 A1 Oct. 28, 2004

**Related U.S. Application Data**

(63) Continuation of application No. PCT/IB02/02769,  
filed on May 16, 2002.  
(60) Provisional application No. 60/291,184, filed on May  
17, 2001.

\* cited by examiner

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(51) **Int. Cl.**  
**C12P 19/34** (2006.01)  
**C12N 15/01** (2006.01)

(52) **U.S. Cl.** ..... **435/91.1**; 435/441; 435/442;  
435/443; 435/444; 435/445

(58) **Field of Classification Search** ..... None  
See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

5,556,750 A 9/1996 Modrich et al.

(57) **ABSTRACT**

The invention relates to a fragmentation process that depends on mismatches between two strands of parental polynucleotides. One embodiment, comprises a method for preparing polynucleotide fragments of DNA comprising formation of heteroduplex molecules by hybridizing polynucleotides. The invention also provides a method and process of forming fragments which can be used with any shuffling process or combination of shuffling processes.

**12 Claims, 6 Drawing Sheets**

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**Merci**