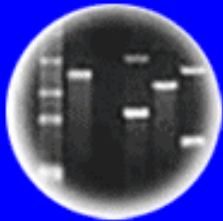


DNA  
Genetic Code of Life



Entire Genetic Code  
of a Bacteria



DNA Fingerprinting



Cloning: Ethical Issues  
and Future Consequences



Plants of Tomorrow



# HC70A & SAS70A Winter 2015 Genetic Engineering in Medicine, Agriculture, and Law

Professors Bob Goldberg & John  
Harada

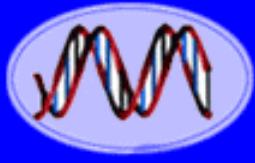
## Lecture 10 Science & The Constitution: Who Owns Your Genes?

UCLA



UC DAVIS  
UNIVERSITY OF CALIFORNIA

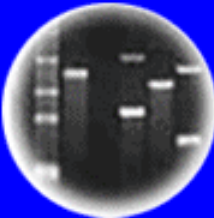
**No One, Of Course-Just Listen and Wait!**



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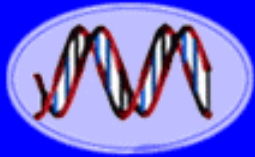
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# THEMES

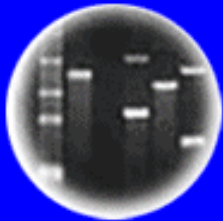
1. The Constitution & Intellectual Property
2. A History of Patents
3. Who Makes and Interprets Patent Laws?
4. Questions Dealing With Patents
5. Is the US Patent System Morally Neutral?
6. Life Is Patentable-Landmark Chakrabarty Case
7. Landmark Genetic Engineering Patent Cases
8. What is Intellectual Property?
9. What Are the Different Forms of Intellectual Property?
10. When Are Different Forms of Intellectual Property Used? In General? In Genetic Engineering?
11. What Are Trademarks and Service Marks?
12. What Are Copyrights?
13. What Are Trade Secrets?
14. What Are Patents?
15. What Are the Criteria to Obtain a Patent?
16. Can Genes and Life Be Patented?
17. The Patent Process



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# TEXT READING

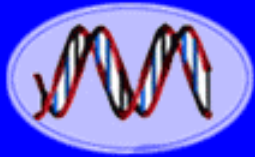
## Chapter 12

Pages 314-317



## SELECTED REFERENCES

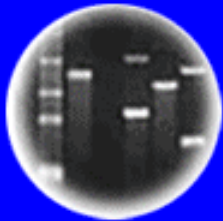
1. *United States Patent and Trademark Office* ([www.uspto.gov](http://www.uspto.gov))
2. *A Practical Companion To The Constitution*, By J.K. Lieberman (1999)
3. *Patent, Copyright, & Trademark*, By R. Stim, 12th Edition (2012)
4. *Federal Register, USPTO Gene Utility Guidelines*, Volume 66 (4), January 5, pages 1092-1099 (2001)
5. *United States Patent and Trademark Office, Guidance For Subject Matter Eligibility Analysis For Claims Involving Laws of Nature and/or Natural Products (e.g., genes)*. ([www.uspto.gov](http://www.uspto.gov)), March 4, (2014) (New Myriad Case Rules)
6. *United States Patent and Trademark Office, Interim Guidance on Patent Subject Eligibility*. *Federal Register*, Volume 79 (241), December 16, 2014
7. *A Patent Perspective on US Human Stem Cell Research*. *Nature Biotech.* 32, 633-637 (2014)
8. *Mayo vs. Prometheus, Supreme Court Decision*, March 12 (2012)
9. *Association For Molecular Pathology vs. Myriad Genetics, Supreme Court Decision*, June 13 (2013)
10. *Bowman vs. Monsanto, Supreme Court Decision*, June 13 (2013)



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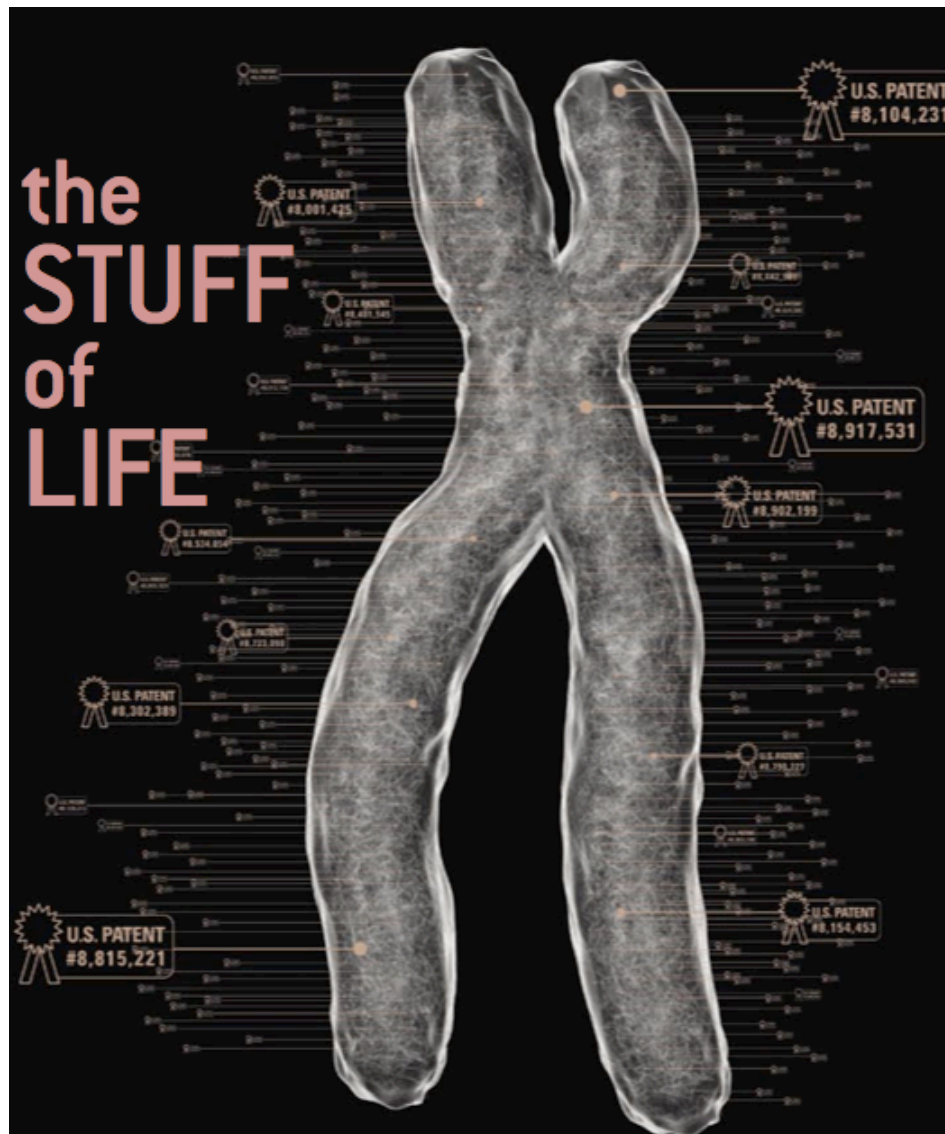


Plants of Tomorrow

# Patent Questions Relevant to Genes, Genetic Engineering, & Biotechnology



# OWNING



# MAJOR Gene and Genetic Engineering Patent Cases Decided Recently by the US Supreme Court



INTELLECTUAL PROPERTY

**Supreme Court to Review the Scope  
Of Monsanto's Seed Patents**

## **Monsanto Wins Case on Genetically Altered Soybeans**

**Gene Patents Draw High Court Review in Biotechnology  
Test**



PROMETHEUS®  
Therapeutics & Diagnostics



## **Justices, 9-0, Bar Patenting Human Genes**

# 1. Article I - Section 8.8

The Congress shall have the Power:

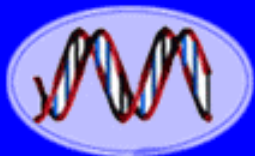
[8] “To Promote the Progress of Science and the useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their Writings and Discoveries”

Keywords: Authors & Inventors.

Key Concepts: Patent & Copyright Laws Are Guaranteed By the Constitution, Legislated By Congress, and Adjudicated in Federal Courts

*Proposed By James Madison (Federalist Papers) and Charles Pickney in 1787  
to a Committee Drafting Constitution*

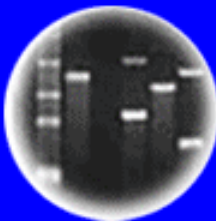




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# History

# What Does Stained Glass Have To Do With United States Patents?



# The United States Can Trace Its Patent Roots Back ~600 Years

1. *Letter Patents Marked By King's Great Seal Were the First Patents in the 15th Century in Great Britain*
2. *Current Patent System Originated in 1449 in Great Britain*
  - a. First Patent to John Utynam of Flanders by King Henry VI
  - b. Method For Cambridge Kings and Eton College Stained Glass Windows
  - c. Method Not Previously Known in England (Flanders is in Belgium)
  - d. King Gave a 20-Year Monopoly to John Utynam in Exchange For Knowledge of His Stained Glass Method
3. *Inventor (John Utynam) Gave Knowledge & Know How to Society in Exchange For a 20-Year Monopoly to His Invention*
  - a. He Taught Others in England How to Make Stained Glass
  - b. In Exchange Other People Could Not Use His Method Without His Permission-KEY CONCEPT-BENEFIT TO SOCIETY
4. *United States Patent System Follows Tradition Established in Great Britain and Passed on the US Colonies*
  - a. In US Constitution
  - b. Patent Act of 1793 Written and Administered by Thomas Jefferson Laid the Foundation For a Patent System That Exists to this Day
    - ii. What is Patentable Subject Matter ("Any New or Useful Art, Machine, Manufacture, or Composition of Matter")
    - iii. What Invention Must be Written in Patent (e.g., Written Description)-KEY CONCEPT-OTHERS CAN KNOW WHAT THE INVENTION IS AND BUILD UPON IT-SOCIETY CAN PROGRESS



# The First United States Patent Issued-*Notice Signature*

Approved By The Secretary of State (Thomas Jefferson), Secretary of War (Henry Knox), and Attorney General( Edmond Randolph) who were the First Patent Board!



*The United States.*

*To all to whom these Presents shall come. Greeting.*

*Whereas Samuel Hopkins of the City of Philadelphia and State of Pennsylvania hath discovered an Improvement, not known or used before, such Discovery, in the making of Pot. ash and Pearl. ash by a new Apparatus and Procefs; that is to say, in the making of Pearl. ash 1<sup>st</sup> by burning the raw Ashes in a Furnace, 2<sup>d</sup> by dissolving and boiling them when so burnt in Water, 3<sup>rd</sup> by drawing off and settling the ley, and 4<sup>th</sup> by boiling the ley into Salts which then are the true Pearl. ash; and also in the making of Pot. ash by fluxing the Pearl. ash so made as aforesaid; which Operations of burning the raw Ashes in a Furnace, preparatory to their Dissolution and boiling in Water, is new, leaves little Residuum; and produces a much greater Quantity of Salt: These are therefore in pursuance of the Act, entitled "An Act to promote the Progress of useful Arts", to grant to the said Samuel Hopkins, his Heirs, Administrators and Assigns, for the Term of fourteen Years, the sole and exclusive Right and Liberty of using, and vending to others the said Discovery, of burning the raw Ashes previous to their being dissolved and boiled in Water, according to the true Intent and meaning, of the Act aforesaid. In Testimony whereof I have caused these Letters to be made patent, and the Seal of the United States to be hereunto affixed. Given under my Hand at the City of New York this thirty first Day of July in the Year of our Lord one thousand seven hundred & Ninety.*

*G. Washington*

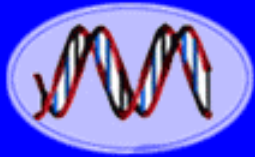
*City of New York July 31<sup>st</sup> 1790. -*

*I do hereby Certify that the foregoing Letters patent were delivered to me in pursuance of the Act, entitled "An Act to promote the Progress of useful Arts"; that I have examined the same, and find them conformable to the said Act.*

*Edm. Randolph* Attorney General for the United States. -

**To Samuel Hopkins for a new process for making potash,  
or salts of potassium - one of the largest US industries in 1790.**

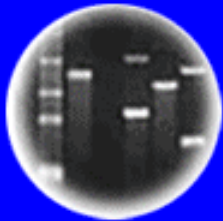




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Plants of Tomorrow

# What Is Intellectual Property?



# What Are the Different Types of Intellectual Property?

Form of Property Rights That Can Be Sold,  
Bought, Traded, or Licensed  
Laws Are Country Specific!

1. Patent

2. Copyright

3. Trademark or Service Mark

4. Trade Secret



# What Are Patents?



1. A patent is the grant of a property right to the inventor, issued by the USPTO, that allows the patent owner to maintain a monopoly for a limited period of time on the use and development of the invention.
2. The right to EXCLUDE OTHERS from making, using, offering for sale, or selling, the invention in the United States or “importing” the invention into the United States (e.g., can’t make in another country & import back to United States)
3. What is granted is not the right to make, use, offer for sale, sell or import, but the right to EXCLUDE OTHERS from making, using, selling, or importing the invention.  
*Term=20 years from filing date. File today, then lasts until 2032.*

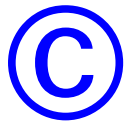
*“How to Make bobg” US patent No. 7,989,755, March 8, 2011*

# What Does Invention and Inventor Mean?

**Invention n.** The creation of something in the mind, such as a new device or process, resulting from study and experimentation

**Inventor n.** One who contrives a previously unknown device, method, or process

**Inventions that Accelerated Human Evolution:** speech/vocabulary; tool making/chipped stones-knives (flint chippers); agriculture (domestication of plants & animals); writing



# What Are Copyrights?



1. A form of protection provided to authors of “original works of authorship” that are tangibly expressed - including literary, dramatic, musical, artistic, and certain intellectual works, both published and unpublished.
2. Protects the form of expression and not the subject matter of the writing. Must be original, have some form of creativity, and be fixed in tangible medium.
3. A copyright gives the owner of a creative work the right to KEEP OTHERS from unauthorized use of the work.
4. Gives the owner the **EXCLUSIVE RIGHT** to reproduce the copyrighted work, to distribute copies of the copyrighted work, to perform the copyrighted work publicly, or display the copyrighted work publicly. Term = 70 years after death of the author, or 95 years if corporate authorship, or 120 years from time of creation, whichever expires first. Created today, then operative until 2134!

# What Can and Cannot Be Copyrighted?

What Can Be Copyrighted?	What Cannot Be Copyrighted?
Literary Works	Works Not In Tangible Form (e.g., spontaneous speech)
Scientific Publications (Including Figures, Tables, & Graphs)	Titles, Names, Phrases, Slogans, Lettering
Musical Works	Ideas, Procedures, Methods, Processes, Concepts, Principles, Devices
Dramatic Works	Common Information With No Authorship (e.g., Calendar, Ruler, Height & Weight chart)
Picture, Graphic, Sculpture, Architecture, and Design Works	Human Genome Sequence
Motion Pictures and Other Audiovisual Works (e.g., HC70A Taped Lectures)	Works With No Creativity (e.g., Phone Book, List of Names)
Video Games	Facts and Ideas in Databases
Computer Program (Software)	Software Elements and Algorithms
Factual Databases	

# What Can and Cannot Be Copyrighted?

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Musical Works	Ideas, Procedures, Methods, Processes, Concepts, Principles, Devices
Dramatic Works	Common Information With No Authorship (e.g., Calendar, Ruler, Height & Weight chart)
Picture, Graphic, and Sculpture Works	Human Genome Sequence
Motion Pictures and Other Audiovisual Works	Works With No Creativity (e.g., Phone Book, List of Names)
Video Games	Facts and Ideas in Databases
Computer Program	Software Elements and Algorithms
Architectural and Design Works	



# Global analysis of gene activity during *Arabidopsis* seed development and identification of seed-specific transcription factors

Brandon H. Le<sup>a,1</sup>, Chen Cheng<sup>a,1</sup>, Anhthu Q. Bui<sup>a,1</sup>, Javier A. Wagmaister<sup>a,2</sup>, Kelli F. Henry<sup>a</sup>, Julie Pelletier<sup>b</sup>, Linda Kwong<sup>b</sup>, Mark Belmonte<sup>b</sup>, Ryan Kirkbride<sup>b</sup>, Steve Horvath<sup>c</sup>, Gary N. Drews<sup>d</sup>, Robert L. Fischer<sup>e</sup>, Jack K. Okamuro<sup>f</sup>, John J. Harada<sup>b</sup>, and Robert B. Goldberg<sup>a,3</sup>

<sup>a</sup>Department of Molecular, Cell, and Developmental Biology, and <sup>c</sup>Department of Human Genetics, David Geffen School of Medicine, University of California, Los Angeles, CA 90095; <sup>b</sup>Section of Plant Biology, Division of Biological Sciences, University of California, Davis, CA 95616; <sup>d</sup>Department of Biology, University of Utah, Salt Lake City, UT 84112; <sup>e</sup>Department of Plant and Microbial Biology, University of California, Berkeley, CA 94720; and <sup>f</sup>United States Department of Agriculture, Agricultural Research Service, Beltsville, MD 20705

This contribution is part of the special series of Inaugural Articles by members of the National Academy of Sciences elected in 2001.

PNAS, May, 2010

# Comprehensive developmental profiles of gene activity in regions and subregions of the *Arabidopsis* seed

Mark F. Belmonte<sup>a,1,2</sup>, Ryan C. Kirkbride<sup>a,1</sup>, Sandra L. Stone<sup>a,3</sup>, Julie M. Pelletier<sup>a</sup>, Anhthu Q. Bui<sup>b,4</sup>, Edward C. Yeung<sup>c</sup>, Meryl Hashimoto<sup>a</sup>, Jiong Fei<sup>a</sup>, Corey M. Harada<sup>a</sup>, Matthew D. Munoz<sup>a,5</sup>, Brandon H. Le<sup>b</sup>, Gary N. Drews<sup>d</sup>, Siobhan M. Brady<sup>a,e</sup>, Robert B. Goldberg<sup>b,6</sup>, and John J. Harada<sup>a,6</sup>

<sup>a</sup>Department of Plant Biology and <sup>e</sup>Genome Center, University of California, Davis, CA 95616; <sup>b</sup>Department of Molecular, Cell, and Developmental Biology, University of California, Los Angeles, CA 90095; <sup>c</sup>Department of Biological Sciences, University of Calgary, Calgary, AB, Canada T2N 1N4; and <sup>d</sup>Department of Biology, University of Utah, Salt Lake City, UT 84112

Contributed by Robert B. Goldberg, December 20, 2012 (sent for review December 7, 2012)

PNAS, January, 2013

# ® What Are Trademarks & Service Marks? TM

1. **Protects a word, phrase, name, symbol (logo), sounds, or colors that distinguish the source of goods and services** (e.g., shape of Coca Cola bottle, name Coca Cola, roar of MGM lion, Apple logo, Microsoft name). Term = indefinite, as long as mark is used continuously. Must be re-registered every 10 years.
2. **A service mark is the same as a trademark-except that trademarks promote products and service marks promote services** (e.g., FedEx, MTV, McDonald's, Yahoo, Google, Amazon.com).
3. **Trademark law-decisions of state and federal courts + US statutes-is applied to resolve disputes when competing businesses adopt similar product names or logos** (Lanham Act).
4. Not in Constitution.



# What Are Trade Secrets?



1. Information that companies keep secret to give them an advantage over their competitors.
2. Any information that has commercial value, that has been maintained in confidence by a business, and that is not known to competitors
3. For example, formula for Coca Cola, gene sequence database, genome sequences, software, cell lines, unpatented inventions, etc.
4. Trade Secret Law-decisions of state and federal courts + US statutes-plus-criminal anti-theft statutes.
5. Not in Constitution.

Designer Seed Thought to Be Latest Target by Chinese

By JOHN ELIGON and PATRICK ZUO FEB. 4, 2014

## Patents vs. Trade Secrets?

Patents	Trade Secrets
<ul style="list-style-type: none"><li>1. Society Gains Knowledge</li><li>2. Patents Published 18 Months After Filing (Patent Pending Status)</li><li>3. Patent Expires After 20 Years</li></ul>	<ul style="list-style-type: none"><li>1. Prevent Competitors From Gaining Proprietary Information</li><li>2. Society Does Not Get Access to Trade Secret Knowledge</li><li>3. Limited Protection</li></ul>

## Patents vs. Trade Secrets?

Patents	Trade Secrets
<ol style="list-style-type: none"><li>1. Society Gains Knowledge</li><li>2. Patents Published 18 Months After Filing (Patent Pending Status)</li><li>3. Patent Expires After 20 Years-Society Can Use</li><li>4. Patent Law Protection</li></ol>	<ol style="list-style-type: none"><li>1. Prevent Competitors From Gaining Proprietary Information</li><li>2. Society Does Not Get Access to Trade Secret Knowledge</li><li>3. Limited Protection</li></ol>

# Summary of Intellectual Property Characteristics

Patent	<ul style="list-style-type: none"><li>• Constitutional Right</li><li>• Protects Inventions</li><li>• Right to Exclude Others From Using Invention</li><li>• No Right to Make \$</li></ul>
Copyright	<ul style="list-style-type: none"><li>• Constitutional Right</li><li>• Protects Original Works of Authorship &amp; Expression</li><li>• Right to Exclude Others From Copying + Using + Performing</li><li>• No Right to Exclude Others From Using Ideas in Work</li></ul>
Trademark	<ul style="list-style-type: none"><li>• Legislated Right</li><li>• Protects Symbol or Name Indicating Source of Goods/Services</li><li>• Right to Exclude Others From Using Same Mark</li><li>• No Right to Prevent Same Business</li></ul>
Trade Secret	<ul style="list-style-type: none"><li>• Legislated Right</li><li>• Protects Anything By Virtue of Secrecy/Confidentiality/Privacy</li></ul>



# Examples of Intellectual Property Protections

## General & Genetic Engineering

©    ™    ®

An Act

To amend title 35, United States Code, to provide for patent reform.  
*Be it enacted by the Senate and House of Representatives of  
the United States of America in Congress assembled,*  
SECTION 1. SHORT TITLE; TABLE OF CONTENTS.  
(a) SHORT TITLE.—This Act may be cited as the “Leahy-Smith  
America Invents Act”.  
(b) TABLE OF CONTENTS.—The table of contents for this Act  
is as follows:

# American Invents Acts of 2011



President Barack Obama signs the America Invents Act September 16, 2011, at Thomas Jefferson High School for Science and Technology in Alexandria, VA.

- Biggest Change in US Patent System in 60 Years
- To Make US Patents Consistent With Those of Other Countries
  - First To File
  - Patent Runs For 20 Years
- Requires USPTO To Issue a Report on Second Opinion Gene Diagnostic Tests
  - Started on March 16, 2013



# Patents

1. Exclusive Rights **Granted To an Inventor For a Limited Period of Time (20 years) to Exclude Others From Making, Using, Offering For Sale, Selling, or Importing the Invention**
2. Country Specific
  - a. **Can't Block Someone From Making. Using, or Selling Invention In Another Country If Not Patented in That Country**
  - b. **Can't Be Imported, However, Into The Patent Country**
  - c. **Can File a PCT Application**
3. Claims in Invention Set Nature of Protection-What is Claimed in the Invention? **READ CLAIMS!!!**
4. **Can Be Sold, Traded, Assigned to Others Like Any Property Right**
5. **Patent Property Right is Owned For Only a Limited Period of Time-Time-Dependent Monopoly (20 Years)**
  - a. **Invention Ultimately Belongs to Society**
6. **Lasts 20 years From Time of Filing**
7. **Governed By Constitution and Federal Laws**

# What is a Patentable Invention?

35 U.S.C. 101 (Note: United States Code)

“Whoever Invents or Discovers Any New and Useful Process, Machine, Manufacture, or Composition of Matter, or Any New and Useful Improvement Thereof, May Obtain a Patent Subject to the Conditions of the Title”

Key Words: New & Useful

*Process, Machine, Manufacture, or Composition of Matter*

## What Can Be Patented?

1. **Process or Method** (Recombinant DNA)
2. **Machine or Apparatus** (PCR or Sequencing Machine)
3. **Article of Manufacture** (Transgenic Organism)
4. **Composition of Matter** (Engineered DNA Sequence)
5. **Plant Varieties** (Sexual or Asexual)
6. **Improvements to Any of the Above**

# What Are the Different Types of Patents?

## 1. Utility Patents (Most Common)

### a. Process or Method

#### i. Recombinant DNA or Stem Cell

### b. Machine or Apparatus

#### i. PCR or Sequencing Machine

### c. Article of Manufacture

#### i. Transgenic Organism

### d. Composition of Matter

#### i. DNA Sequence

### e. Improvements to Any of the Above

## 2. Design Patents

### a. Must Ornament a Manufactured Article

#### i. New Shape of Car Fender

## 3. Plant Patents (Least Common)

### a. Asexually or Sexually Reproducing Plants

# What Are the Criteria For Granting a Patent?

1. Must Be Patent-Eligible Material (or Subject Matter)
2. Must Have Specific, Substantial, and Credible Utility (Claims)
3. Must Be Novel and New (No Prior Art)
4. Must Be Non-Obvious
5. Must Have a Written Description of the Invention
6. Must Describe the Best Mode of Making and Using, or Practicing, the Invention (Enablement)

- These Criteria Are Set Forth in Title 35 of US Code - Sections 101, 102, 103, & 112. and Must Be Satisfied In Order For a Patent To Be Granted. The Written Description and Best Mode of Practice, Collectively Known As the Specification, Must Be Set Forth in Clear, Concise, and Exact Terms.

- A Patent Is Only Valid in Country Where Issued. Each Country Has Its Own Set of Criteria

- A Contract Between Inventor and Society. Inventor Publishes Invention and Tells Society How to Use It. Society Grants Inventor a 20-year Monopoly to Exclude Others From Practicing Invention

# What Are the Criteria For Granting a Patent?

1. Must Be Patent-Eligible Material
2. Must Have Specific, Substantial, and Credible Utility
3. Must Be Novel and New
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5. Must Have a Written Description of the Invention
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- These Criteria Are Set Forth in Title 35 of US Code - Sections 101, 102, 103, & 112. and Must Be Satisfied In Order For a Patent To Be Granted. The Written Description and Best Mode of Practice, Collectively Known As the Specification, Must Be Set Forth in Clear, Concise, and Exact Terms.
- A Patent Is Only Valid in Country Where Issued. Each Country Has Its Own Set of Criteria
- A Contract Between Inventor and Society. Inventor Publishes Invention and Tells Society How to Use It. Society Grants Inventor a 20-year Monopoly to Exclude Others From Practicing Invention



# What Is Not Patent-Eligible Subject Matter?

1. Laws of Nature-Including Algorithms and Mathematical Formulas [*Including Software-Unless Leads to Physical Result/Transformation (Currently Before Supreme Court)*]
2. Abstract Ideas
3. Naturally Occurring Phenomena
4. Naturally Occurring Substances That Exist in Nature-Including Cells, Chromosomes, and Genes (including sequences) - *Now "Up in the Air"*

∴ YOUR GENES IN YOUR BODY ARE  
NOT PATENT ELIGIBLE!

# What **Is Not** Patent-Eligible Subject Matter?

1. Laws of Nature-Including Algorithms and Mathematical Formulas
2. Abstract Ideas
3. Naturally Occurring Phenomena
4. Naturally Occurring Substances That Exist in Nature-Including Cells, Chromosomes, and Genes (including sequences) in Their Natural State

**∴ YOUR GENES ARE **NOT** PATENT  
ELIGIBLE SUBJECT MATTER!**

**WHAT ABOUT IN A PLASMID?**

# What **Is** Patent-Eligible Subject Matter?

1. Machine or Apparatus
  - a. PCR Machine
  - b. Sequencing Machine
  - c. GeneChip
  - d. Gel Electrophoresis Apparatus
  - e. Computer (including software algorithms that tell machine how to run)
2. Process or Method of Use
  - a. Gene Splicing-Recombinant DNA
  - b. Making Human Insulin in E. coli
  - c. Making a Transgenic Organism (e.g., goat)
  - d. PCR
  - e. DNA Sequencing
  - f. Sequence of Software Algorithms That Tell a Machine How to Run
3. Article of Manufacture
  - a. A Genetically Engineered Organism (e.g, GloFish, Insect Resistant Plant)
4. Composition of Matter-Including Chemical Compounds and Physical Mixtures-As Long As Claimed in Form Not In Nature-Because "Isolated and Purified" Materials Do Not Exist In Nature Making Them Novel and Patent Eligible  
*(UNCERTAIN NOW DUE TO MYRIAD CASE)*
  - a. Purified Proteins (e.g., adrenaline-epinephrine-Parke-Davis vs. Mulford & Co., 1912-Judge Learned Hand)
  - b. Purified Natural Substances (e.g., aspirin-salicylic acid, strawberry flavoring-In Re Katz-1979)
  - c. Purified Microorganisms (e.g., pure culture of antibiotic-producing bacteria-In Re Bergy-1977)
  - d. NOT DNA Sequences Identical to What is in Chromosomes (Myriad, 2013)
5. Non-Obvious Improvements on Any of the Above (Different Patent)

## ALL of The Following Criteria Must Also Be Met to Be Granted a Patent

<b>Utility (Claims)</b>	<ol style="list-style-type: none"> <li>1. Must Have a Practical or Real World Benefit</li> <li>2. Specific and Substantial Utility Credible By Person of Ordinary Skill in The Art</li> <li>3. Commercial Development is NOT Required to Establish Usefulness</li> </ol>
<b>Novel</b>	<ol style="list-style-type: none"> <li>1. New and Not Anticipated By Prior Art (published works regarding invention-including literature, lectures, and published patents)</li> <li>2. Never Publish or Discuss Your invention Prior to Filing a Patent. If You Do, It is Prior Art and in the Public Domain</li> </ol>
<b>Non-Obvious</b>	<ol style="list-style-type: none"> <li>1. A Person of Ordinary Skill in the Art Cannot Bridge the Gap Between Prior Art and Claimed Invention (e.g., gene splicing and PCR)</li> </ol>
<b>Written Description &amp; Best Mode of Practice (<u>Specification &amp; Enabling</u>)</b>	<ol style="list-style-type: none"> <li>1. Concept: Social Compact Between Inventor and Society-Patents Promote the Progress of Science (Article I, Section 8.8) By Securing Complete Disclosure of Invention in Exchange For Inventor's Right to Exclude Others For a Limited Time (e.g., recombinant DNA)</li> <li>2. Must Provide Written Description So That People With Adequate Skill in Art Will Know How the Invention Was Made and How to Reproduce the Invention When Paten Expires (e.g., generic drugs)</li> <li>3. Must Provide in the Written Description the Best Way (mode) to Use and Practice the Invention</li> <li>4. Written Description and Best Mode of Practice are Part of the <u>Patent Specification</u> Which Includes the Claims (What the Invention is)</li> </ol>

# Specific Examples

Utility	<ol style="list-style-type: none"> <li>1. A Purified DNA Molecule With Sequence 5' ACGT3' (composition of matter) - <u>Not Patentable</u>-No Utility</li> <li>2. A Purified DNA Molecule With Sequence 5' ACGT3' To Be Used As a Diagnostic Marker For Cystic Fibrosis - <u>Patentable</u>-<u>Specific Utility</u></li> </ol>
Novel & New	<ol style="list-style-type: none"> <li>1. A Method of Producing Recombinant DNA Molecules - <u>Patentable</u></li> <li>2. Never Before in Prior Art and not Anticipated By Prior Art</li> </ol>
Non-Obvious	<ol style="list-style-type: none"> <li>1. A New Type of Radioactive probe to Detect DNA - <u>Not Patentable</u>-Obvious Because Radioactivity Has Been used For a Long Time to Detect Biological Molecules and in Prior Art</li> <li>2. A Non-Radioactive Probe to Detect DNA Molecules - <u>Patentable</u> Because Not Obvious and Not In Prior Art</li> </ol>
Written Description & Best Mode of Practice	<ol style="list-style-type: none"> <li>1. <u>UC Patent on Rat Insulin cDNA Clone and Sequence</u></li> <li>2. Eli Lilly Patent on Human Insulin cDNA to Make Insulin in Bacteria Cells (From Genentech®)</li> <li>3. UC Sued Eli Lilly For Patent Infringement &amp; Lost</li> <li>4. Court Said That UC Rat Insulin DNA Sequence Patent's Written Description Could not Instruct Others How To Make Human Insulin In Bacteria-UC's Patent <u>Violated Written Description Provision</u></li> <li>5. UC Patent Written Description <u>Could Not Instruct Others How To Translate Rat cDNA Sequence Into Human Protein Sequence</u> Because of Degeneracy in Genetic Code</li> </ol>

# How Does The Patent Process Work?

1. Patent Application Filed At USPTO in Washington and/or in Other Countries (e.g. European Patent Office - *Unitary EU Patent*). Can also File a PCT (Patent Cooperation Treaty) Application to Get Filing Date In Other Countries and Opinion on Patentability. Goes to US in 30 Months.
  - a. Filing Date Critical
  - b. Time Period For Patent Starts When Patent Application Filed (20 Years)
  - c. Europe and Japan-Invention Priority-First To File
  - d. US-First to File Too-*American Invents Act of 2011*
2. Patent Application Published After 18 Months and Becomes Prior Art - But Have a One-Year "Grace Period" To Publish Your Own Patent Research Prior to Filing Patent
3. Patent Examiners At USPTO Examine Patent Application
  - a. Patent Examiners-At Least a Bachelor's Degree in Technical Field-46% Have PhD. Degrees-Must Work at Least Four years Before given Authority To Review Patent Applications
  - b. Review: Patent Eligible? Prior Art? Novel and New? Utility? Non-Obvious? Written Description? Best Mode of Practice? Claims?
4. Review Process (Average of 25 Months)
  - a. Send Official Letter Accepting or Rejecting Claims-Some or All
  - b. Applicant Can Respond
  - c. Final Letter Granting or Rejecting patent Application
  - d. Applicant Can Appeal to Federal Court (e.g., *Diamond vs. Chakrabarty Case*)
5. Challenge (Very Expensive)
  - a. Infringement-Someone Illegally Practicing Invention (Country Specific)



# The United States Patent System Is “Morally Neutral”

1. **Bypasses Public Debate on Social Issues Related To Technology Innovation** - *laissez faire* attitude - does not make judgments about what is “good” for society. Courts allow the market to decide which inventions are morally acceptable
2. **Patent Can Be Issued Even If Device Is Not In Public Interest** (e.g., Car That Pollutes)
3. **Congress Makes Laws on What Is Patentable and What Is Not-If You Don’t Like It, Write Your Representatives**
  - a. **Specific Criteria For Issuing a Patent Governed By Laws of Congress**
  - b. **Patent Laws Are Administered By the USPTO**
  - c. **Interpreted By the Federal Courts**
  - d. **Example**
    - i. No patents on any invention or discovery useful solely in utilization of nuclear weapons
    - ii. 42 USC 2181
4. **European Union (EU) Patents Differ (1998)-“Inventions Are Considered Unpatentable If Their Commercial Exploitation Would Be Contrary to Public “Order” (Policy) or “Morality.”**

# US Law Banning Patents on Atomic Weapons

## 42 U.S. CODE

US Code

Notes

Updates

Authorities (CFR)

Current through Pub. L. [113-52](#). (See [Public Laws for the current Congress](#).)

### **(a) Denial of patent; revocation of prior patents**

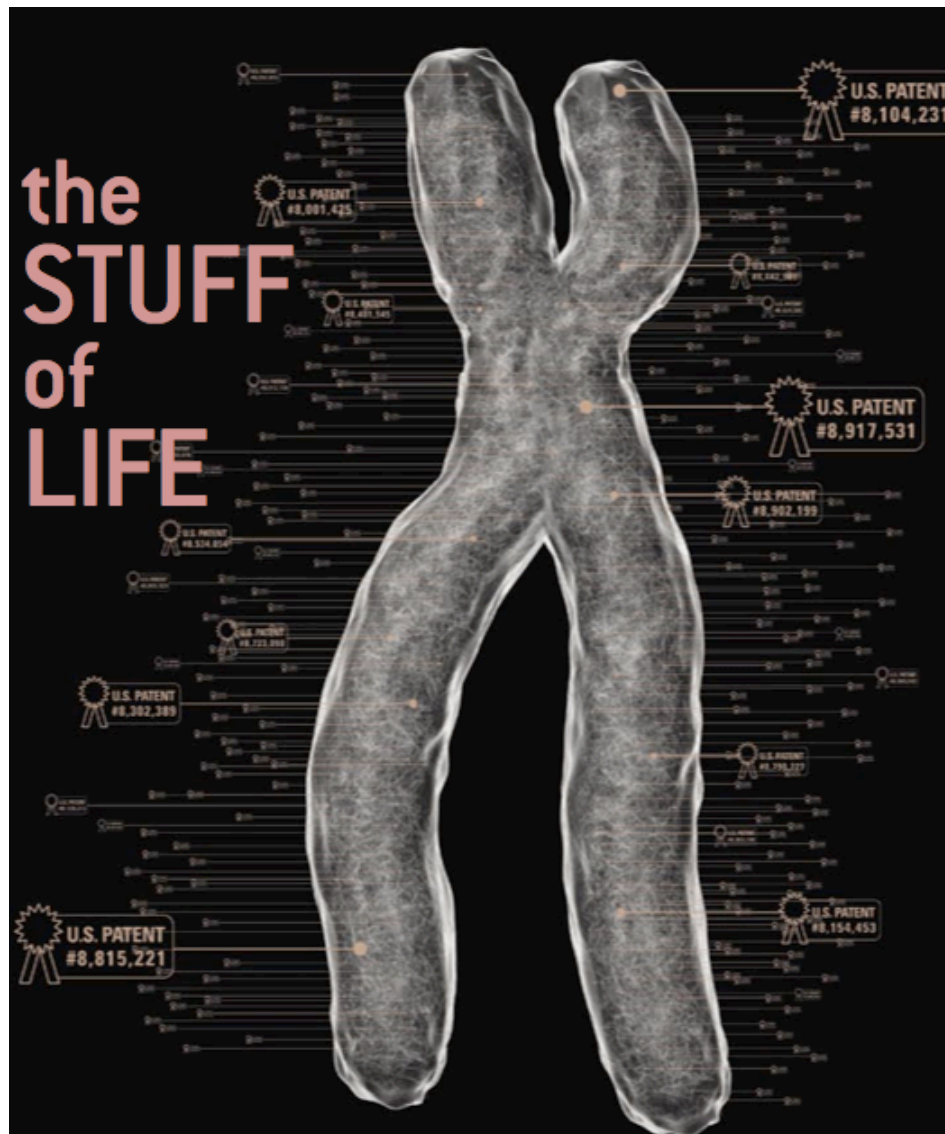
No patent shall hereafter be granted for any invention or discovery which is useful solely in the utilization of special nuclear material or atomic energy in an atomic weapon. Any patent granted for any such invention or discovery is revoked, and just compensation shall be made therefor.

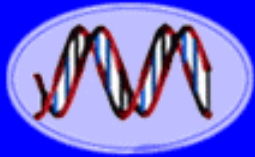
### **(b) Denial of rights; revocation of prior rights**

No patent hereafter granted shall confer any rights with respect to any invention or discovery to the extent that such invention or discovery is used in the utilization of special nuclear material or atomic energy in atomic weapons. Any rights conferred by any patent heretofore granted for any invention or discovery are revoked to the extent that such invention or discovery is so used, and just compensation shall be made therefor.

*Key - Congress Decides What is Patentable Subject Material*

# OWNING

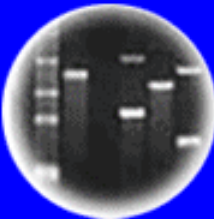




DNA  
Genetic Code of Life



Entire Genetic Code  
of a Bacteria



DNA Fingerprinting



Cloning: Ethical Issues  
and Future Consequences



Plants of Tomorrow

# Can Genetically Engineered Organisms & Genes Be Patented?

**Yes-But...!!! When Did This Begin?**



# In The US Life **Is** Patentable...

***SCIENCE MAY PATENT  
NEW FORMS OF LIFE,  
JUSTICES RULE, 5 TO 4***

## *Diamond vs. Chakrabarty*

6/17/1980

**1980**

The Supreme Court rules that Ananda Chakrabarty's bacterium is not a "product of nature" and so can be patented; other living things "made by man" are declared patentable as well



Ananda Chakrabarty

## *Harvard Mouse*



**1988**

Harvard University gets a patent for the OncoMouse, a rodent with a gene inserted that predisposes it to cancer



# Landmark Genetic Engineering Patents

United States Patent  
**Cohen , et al.**

4,237,224  
December 2, 1980

## Recombinant DNA!

Process for producing biologically functional molecular chimeras

### Abstract

Method and compositions are provided for replication and expression of exogenous genes in microorganisms. Plasmids or virus DNA are cleaved to provide linear DNA having ligatable termini to which is inserted a gene having complementary termini, to provide a biologically functional replicon with a desired phenotypical property. The replicon is inserted into a microorganism cell by transformation. Isolation of the transformants provides cells for replication and expression of the DNA molecules present in the modified plasmid. The method provides a convenient and efficient way to introduce genetic capability into microorganisms for the production of nucleic acids and proteins, such as medically or commercially useful enzymes, which may have direct usefulness, or may find expression in the production of drugs, such as hormones, antibiotics, or the like, fixation of nitrogen, fermentation, utilization of specific feedstocks, or the like.

Inventors: **Cohen; Stanley N.** (Portola Valley, CA), **Boyer; Herbert W.** (Mill Valley, CA)  
Assignee: **Board of Trustees of the Leland Stanford Jr. University** (Stanford, CA)  
Appl. No.: **06/001,021**  
Filed: **January 4, 1979**

## PCR!

United States Patent  
**Mullis**

[19] Patent Number: **4,683,202**  
[45] Date of Patent: **\* Jul. 28, 1987**

[54] **PROCESS FOR AMPLIFYING NUCLEIC ACID SEQUENCES**  
[75] Inventor: **Kary B. Mullis**, Kensington, Calif.  
[73] Assignee: **Cetus Corporation**, Emeryville, Calif.  
[\*] Notice: The portion of the term of this patent subsequent to Jul. 28, 2004 has been disclaimed.  
[21] Appl. No.: **791,308**  
[22] Filed: **Oct. 25, 1985**

### Related U.S. Application Data

[63] Continuation-in-part of Ser. No. 716,975, Mar. 28, 1985, abandoned.  
[51] Int. Cl.<sup>3</sup> ..... **C12P 19/34; C12N 15/00; C12N 1/00; C07H 21/04; C07H 21/02**  
[52] U.S. Cl. .... **435/91; 435/177.3; 435/317; 536/27; 536/28; 536/29; 935/17; 935/18; 935/16**  
[58] Field of Search ..... **435/91, 172.3, 317; 536/27, 28, 29; 935/17, 18**

[56] **References Cited**  
**PUBLICATIONS**

mentary DNA for Cloning", *J. Theor. Biol.* 95: 679 (1982).  
Caton and Robertson, *Nucleic Acids Research*, vol. 7, pp. 1445-1456 (1979).  
Rossi et al., *J. Biol. Chem.*, 257, 9226-9229 (1982).

*Primary Examiner*—James Martinelli  
*Attorney, Agent, or Firm*—Janet E. Hasak; Albert P. Halluin

### [57] ABSTRACT

The present invention is directed to a process for amplifying any desired specific nucleic acid sequence contained in a nucleic acid or mixture thereof. The process comprises treating separate complementary strands of the nucleic acid with a molar excess of two oligonucleotide primers, and extending the primers to form complementary primer extension products which act as templates for synthesizing the desired nucleic acid sequence. The steps of the reaction may be carried out stepwise or simultaneously and can be repeated as often as desired.

## Genetically Engineered Bacteria!

United States Patent  
**Chakrabarty**

[19] Patent Number: **4,259,444**  
[45] Date of Patent: **Mar. 31, 1981**

[54] **MICROORGANISMS HAVING MULTIPLE COMPATIBLE DEGRADATIVE ENERGY-GENERATING PLASMIDS AND PREPARATION THEREOF**

[75] Inventor: **Ananda M. Chakrabarty**, Latham, N.Y.  
[73] Assignee: **General Electric Company**, Schenectady, N.Y.  
[21] Appl. No.: **260,563**  
[22] Filed: **Jun. 7, 1972**

[51] Int. Cl.<sup>3</sup> ..... **C12N 15/00**  
[52] U.S. Cl. .... **435/172; 435/253; 435/264; 435/281; 435/820; 435/875; 435/877**  
[58] Field of Search ..... **195/28 R, 1, 3 H, 3 R, 195/96, 78, 79, 112; 435/172, 253, 264, 820, 281, 875, 877**

### [56] References Cited

**PUBLICATIONS**

Annual Review of Microbiology vol. 26 Annual Review Inc. 1972 pp. 362-368.  
*Journal of Bacteriology* vol. 106 pp. 468-478 (1971).  
*Bacteriological Reviews* vol. 33 pp. 210-263 (1969).

*Primary Examiner*—R. B. Penland

*Attorney, Agent, or Firm*—Leo I. MaLossi; James C. Davis, Jr.

### [57] ABSTRACT

Unique microorganisms have been developed by the application of genetic engineering techniques. These microorganisms contain at least two stable (compatible) energy-generating plasmids, these plasmids specifying separate degradative pathways. The techniques for preparing such multi-plasmid strains from bacteria of the genus *Pseudomonas* are described. Living cultures of two strains of *Pseudomonas* (*P. aeruginosa* [NRRL B-5472] and *P. putida* [NRRL B-5473]) have been deposited with the United States Department of Agriculture, Agricultural Research Service, Northern Marketing and Nutrient Research Division, Peoria, Ill. The *P. aeruginosa* NRRL B-5472 was derived from *Pseudomonas aeruginosa* strain 1c by the genetic transfer thereto, and containment therein, of camphor, octane, salicylate and naphthalene degradative pathways in the form of plasmids. The *P. putida* NRRL B-5473 was derived from *Pseudomonas putida* strain FpG1 by genetic transfer thereto, and containment therein, of camphor, salicylate and naphthalene degradative pathways and drug resistance factor RP-1, all in the form of plasmids.

**18 Claims, 2 Drawing Figures**



# And Now Synthetic Life Patents!!

United States Patent Application  
Kind Code  
Benders; Gwynedd A.; et al.

20110053273  
A1  
March 3, 2011

## METHODS FOR CLONING AND MANIPULATING GENOMES

### Abstract

Compositions and methods are disclosed herein for cloning a synthetic or a semi-synthetic donor genome in a heterologous host cell. In one embodiment, the donor genome can be further modified within a host cell. Modified or unmodified genomes can be further isolated from the host cell and transferred to a recipient cell. Methods disclosed herein can be used to alter donor genomes from intractable donor cells in more tractable host cells.

Inventors: **Benders; Gwynedd A.**; (Portland, OR) ; **Glass; John I.**; (Germantown, MD) ; **Hutchison; Clyde A.**; (La Jolla, CA) ; **Lartigue; Carole**; (Des Arenes Bayonne, FR) ; **Vashee; Sanjay**; (Boys, MD) ; **Algire; Mikkel A.**; (Jessup, MD) ; **Smith; Hamilton O.**; (San Diego, CA) ; **Merryman; Charles E.**; (Sykesville, MD) ; **Noskov; Vladimir N.**; (Montgomery Village, MD) ; **Chuang; Ray-Yuan**; (Rockville, MD) ; **Gibson; Daniel G.**; (Crofton, MD) ; **Venter; J. Craig**; (La Jolla, CA)

Assignee: **Synthetic Genomics, Inc.**  
La Jolla  
CA



United States Patent Application  
Kind Code  
Glass; John I.; et al.

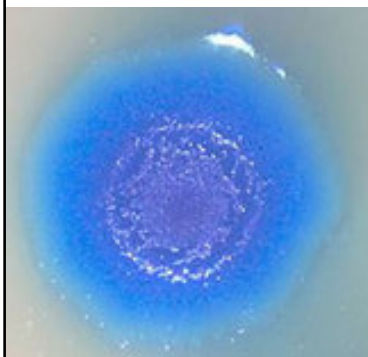
20110045592  
A1  
February 24, 2011

## METHODS OF GENOME INSTALLATION IN A RECIPIENT HOST CELL

### Abstract

The presently disclosed invention relates to methods of installing a genome isolated from one species (the donor) into suitably prepared cells of a second species (the recipient). Introduction of the donor genetic material into the recipient host cell effectively converts the recipient host cell into a new cell that, as a result of the operation of the donated genetic material, is functionally classified as belonging to the genus and species of the donor genetic material.

Inventors: **Glass; John I.**; (Germantown, MD) ; **Alperovich; Nina**; (Germantown, MD) ; **Hutchison, III; Clyde A.**; (La Jolla, CA) ; **Lartigue; Carole**; (Gaithersburg, MD) ; **Merryman; Charles E.**; (Sykesville, MD) ; **Vashee; Sanjay**; (Boys, MD) ; **Venter; J. Craig**; (La Jolla, CA)



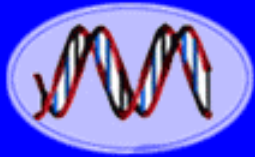
United States Patent Application  
Kind Code  
Venter; J. Craig ; et al.

20070264688  
A1  
November 15, 2007

## Synthetic genomes

### Abstract

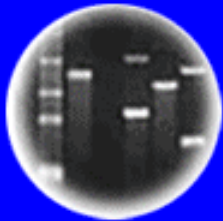
Methods are provided for constructing a synthetic genome, comprising generating and assembling nucleic acid cassettes comprising portions of the genome, wherein at least one of the nucleic acid cassettes is constructed from nucleic acid components that have been chemically synthesized, or from copies of the chemically synthesized nucleic acid components. In one embodiment, the entire synthetic genome is constructed from nucleic acid components that have been chemically synthesized, or from copies of the chemically synthesized nucleic acid components. Rational methods may be used to design the synthetic genome (e.g., to establish a minimal genome and/or to optimize the function of genes within a genome, such as by mutating or rearranging the order of the genes). *Synthetic genomes* of the invention may be introduced into vesicles (e.g., bacterial cells from which part or all of the resident genome has been removed, or synthetic vesicles) to generate synthetic cells. *Synthetic genomes* or synthetic cells may be used for a variety of purposes, including the generation of synthetic fuels, such as hydrogen or ethanol.



DNA  
Genetic Code of Life



Entire Genetic Code  
of a Bacteria



DNA Fingerprinting



Cloning: Ethical Issues  
and Future Consequences

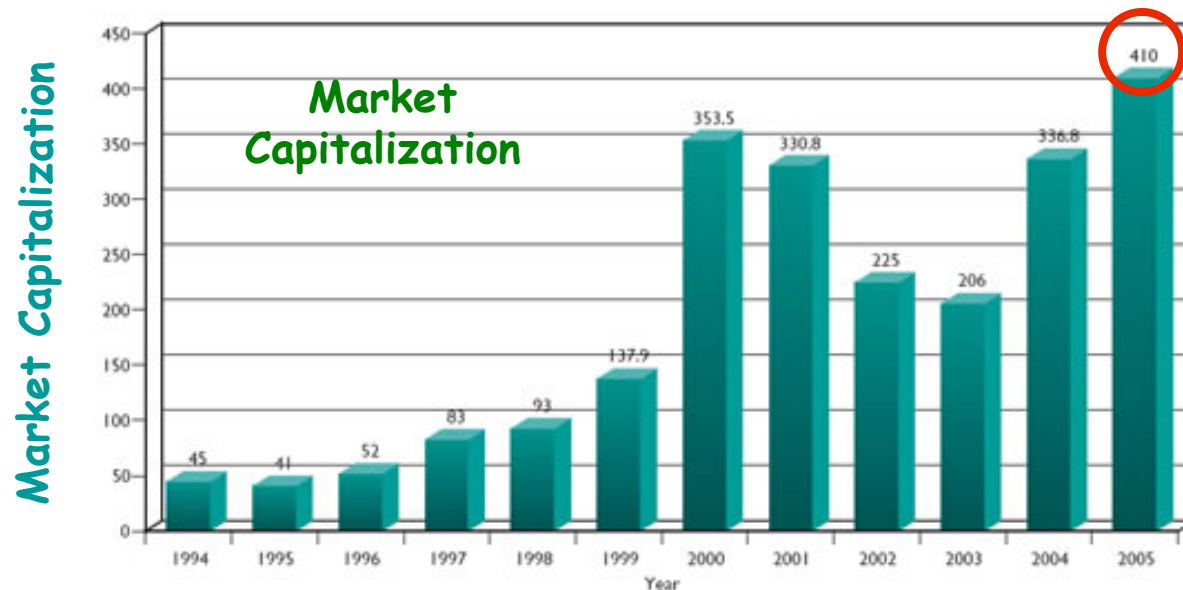


Plants of Tomorrow

# Patents Affect How Science is Carried Out and How Basic Science is Translated Into Business



# Biotech in the United States is a Huge Success and a Big Business



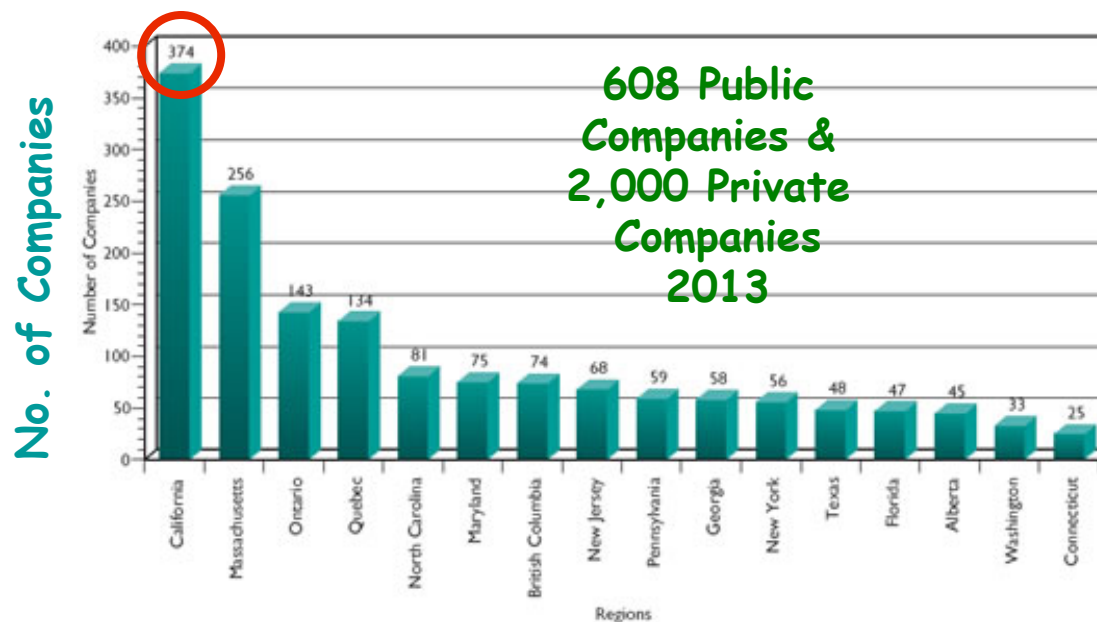
**\$100B**  
Net Revenue in  
2013

**\$404B**  
Market Cap as of  
April 27, 2015

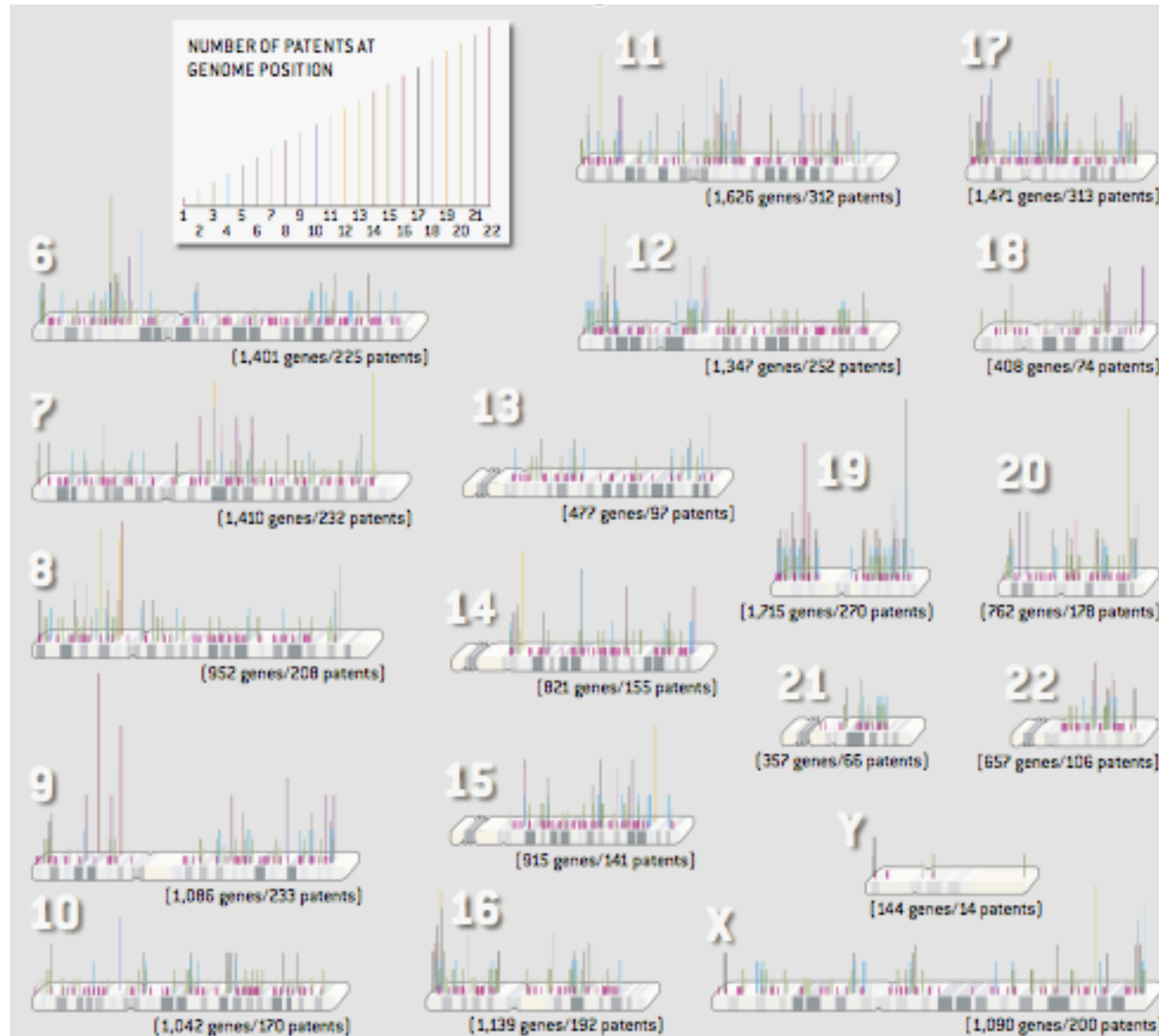
Note:

There Was No  
Biotech Industry  
Before 1976

With No Gene  
Patent Protection  
There Would Be no  
Biotech Industry!!



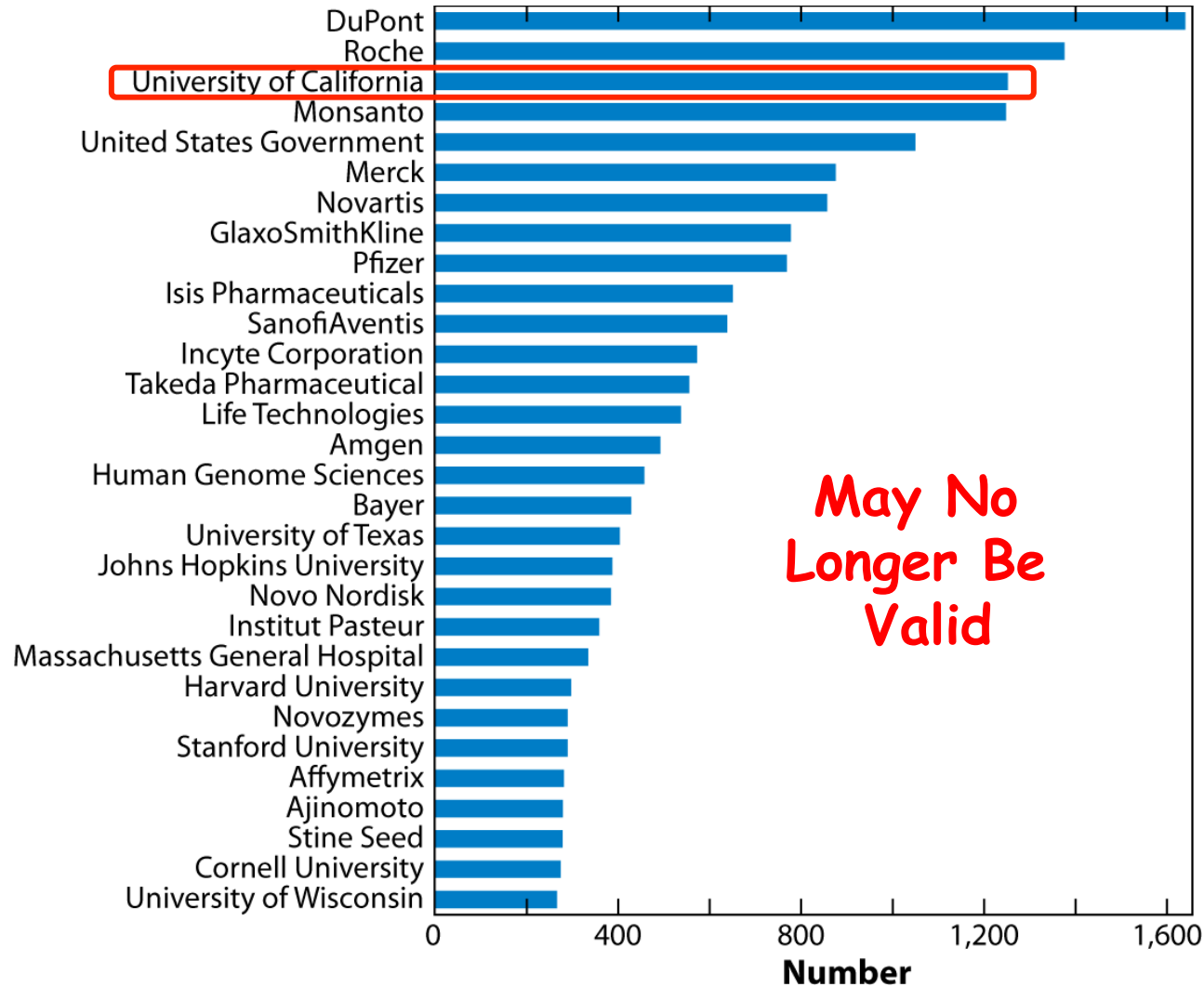
# Who Owns Your Genes: Human Gene Patents



*Scientific American, February 2006*

*20% of Human Genes Have Been Patented (2006)*

# Top US DNA Patent Holders



Cook-Deegan R, Heaney C. 2010.

Annu. Rev. Genomics Hum. Genet. 11:383–425

## The Original Question- Who Owns Your Genes?

1. Genes in Your Body Exist in Nature and Are NOT Patent-Eligible Material or Patentable
2. ∴ NO ONE OWNS the Intellectual Property Associated With Your Genes In Your Body-There is None!
3. YOU “Own” the Genes In Your Body

However...What About Purified Genes?

*Central Question - Are Genes Patent-Eligible Material?*





United States Patent [19]  
Chakrabarty

[11] 4,259,444  
[45] Mar. 31, 1981

## Purified Genes (e.g., Human Genes) And Their Sequences **Were** Patent-Eligible Material in the United States *Prior to 2013*

1. **Genes (and Cells, Living Organisms, and Natural Substances) ARE Patent-Eligible** As Long As They Are Claimed in a Form That Does Not Occur in Nature and Altered In Some Way By the “Hands of Man”
2. **Purifying or Isolating Genes Makes Them Novel** Because “Isolated and Purified” Materials Do Not Exist in Nature
3. **∴ Genes Are Patent-Eligible If They Meet ALL of These Criteria: Invention Must Be:** Novel, Useful, Non-Obvious, Have a Clear Written Description, and Document the Best Mode of Practice
  - a. **A “Switch” To Turn On Genes In Goat Mammary Glands (e.g., chimeric gene)**
  - b. **A Gene Sequence to Produce Insulin in Bacteria Cells**
  - c. **A Vector To Propagate Genes In Yeast Cells**
  - d. **Diagnostic Test (Probe for Specific Disease-Breast Cancer)**

# A Gene Switch Patent

United States Patent  
*Weterings*, et al.

6,855,866  
February 15, 2005

Polynucleotides useful for modulating transcription

## Abstract

The invention provides polynucleotides for expression of genes in suspensor cells in plants and methods for using such polynucleotides.

Inventors: **Weterings; Koen** (Nijmegen, NL), **Apuya; Nestor R.** (Culver City, CA), **Goldberg; Robert B.** (Topanga, CA)  
Assignee: **The Regents of the University of California** (Oakland, CA)  
Appl. No.: **09/724,857**  
Filed: **November 28, 2000**



# MYRIAD

GENE PATENT LITIGATION



After 2013.....

## SUPREME COURT OF THE UNITED STATES

Syllabus

ASSOCIATION FOR MOLECULAR PATHOLOGY ET AL.  
v. MYRIAD GENETICS, INC., ET AL.

CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR  
THE FEDERAL CIRCUIT

No. 12-398. Argued April 15, 2013—Decided June 13, 2013



UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents  
United States Patent and Trademark Office  
P.O. Box 1450  
Alexandria, VA 22313-1450  
[www.uspto.gov](http://www.uspto.gov)

### MEMORANDUM

**DATE:** March 4, 2014

**TO:** Patent Examining Corps

**FROM:** Andrew H. Hirshfeld  
Deputy Commissioner  
For Patent Examination Policy

**SUBJECT:** 2014 Procedure For Subject Matter Eligibility Analysis Of Claims Reciting Or  
Involving Laws Of Nature/Natural Principles, Natural Phenomena, And/Or  
Natural Products

# This Case Has Changed the Gene Patent Landscape

MYRIAD

United States Patent  
Shattuck-Eidens, et al.

5,693,473  
December 2, 1997

Linked breast and ovarian cancer susceptibility gene

## Abstract

The present invention relates generally to the field of human genetics. Specifically, the present invention relates to methods and materials used to isolate and detect a human breast and ovarian cancer predisposing gene (*BRCA1*), some mutant alleles of which cause susceptibility to cancer, in particular breast and ovarian cancer. More specifically, the invention relates to germline mutations in the *BRCA1* gene and their use in the diagnosis of predisposition to breast and ovarian cancer. The present invention further relates to somatic mutations in the *BRCA1* gene in human breast and ovarian cancer and their use in the diagnosis and prognosis of human breast and ovarian cancer. Additionally, the invention relates to somatic mutations in the *BRCA1* gene in other human cancers and their use in the diagnosis and prognosis of human cancers. The invention also relates to the therapy of human cancers which have a mutation in the *BRCA1* gene, including gene therapy, protein replacement therapy and protein mimetics. The invention further relates to the screening of drugs for cancer therapy. Finally, the invention relates to the screening of the *BRCA1* gene for mutations, which are useful for diagnosing the predisposition to breast and ovarian cancer.



## What is claimed is:

1. An isolated DNA comprising an altered *BRCA1* DNA having at least one of the alterations set forth in Tables 12A, 14, 18 or 19 with the proviso that the alteration is not a deletion of four nucleotides corresponding to base numbers 4184-4187 in SEQ. ID. NO:1.
2. An isolated DNA comprising an altered *BRCA1* DNA having one of the alterations set forth in Tables 12A or 14 with the provision that the alteration is not a deletion of four nucleotides corresponding to base numbers 4184-4187 in SEQ. ID. NO:1.
3. An isolated DNA comprising an altered *BRCA1* DNA having one of the alterations set forth in Tables 18 or 19.
4. A nucleic acid probe specifically hybridizable to a human altered *BRCA1* DNA and not to wild-type *BRCA1* DNA, said altered *BRCA1* DNA having one of the alterations set forth in Tables, 12A, 14, 18 or 19.

United States Patent  
Shattuck-Eidens, et al.

5,709,999  
January 20, 1998

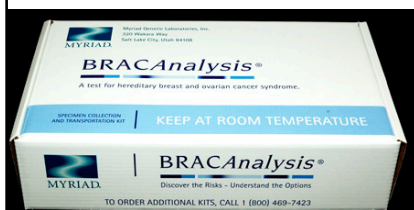
Linked breast and ovarian cancer susceptibility gene

## Abstract

The present invention relates generally to the field of human genetics. Specifically, the present invention relates to methods and materials used to isolate and detect a human breast and ovarian cancer predisposing gene (*BRCA1*), some mutant alleles of which cause susceptibility to cancer, in particular breast and ovarian cancer. More specifically, the invention relates to germline mutations in the *BRCA1* gene and their use in the diagnosis of predisposition to breast and ovarian cancer. The present invention further relates to somatic mutations in the *BRCA1* gene in human breast and ovarian cancer and their use in the diagnosis and prognosis of human breast and ovarian cancer. Additionally, the invention relates to somatic mutations in the *BRCA1* gene in other human cancers and their use in the diagnosis and prognosis of human cancers. The invention also relates to the therapy of human cancers which have a mutation in the *BRCA1* gene, including gene therapy, protein replacement therapy and protein mimetics. The invention further relates to the screening of drugs for cancer therapy. Finally, the invention relates to the screening of the *BRCA1* gene for mutations, which are useful for diagnosing the predisposition to breast and ovarian cancer.

## What is claimed is:

1. A method for detecting a germline alteration in a *BRCA1* gene, said alteration selected from the group consisting of the alterations set forth in Tables 12A, 14, 18 or 19 in a human which comprises analyzing a sequence of a *BRCA1* gene or *BRCA1* RNA from a human sample or analyzing a sequence of *BRCA1* cDNA made from mRNA from said human sample with the proviso that said germline alteration is not a deletion of 4 nucleotides corresponding to base numbers 4184-4187 of SEQ. ID. NO:1.
2. The method of claim 1 which comprises analyzing *BRCA1* RNA from the subject.
3. The method of claim 2 wherein a germline alteration is detected by hybridizing a *BRCA1* gene probe which specifically hybridizes to nucleic acids containing at least one of said alterations and not to wild-type *BRCA1* sequences to RNA isolated from said human sample and detecting the presence of a hybridization product, wherein the presence of said product indicates the presence of said alteration in said RNA and thereby the presence of said germline alteration in said sample.





# SUPREME COURT OF THE UNITED STATES

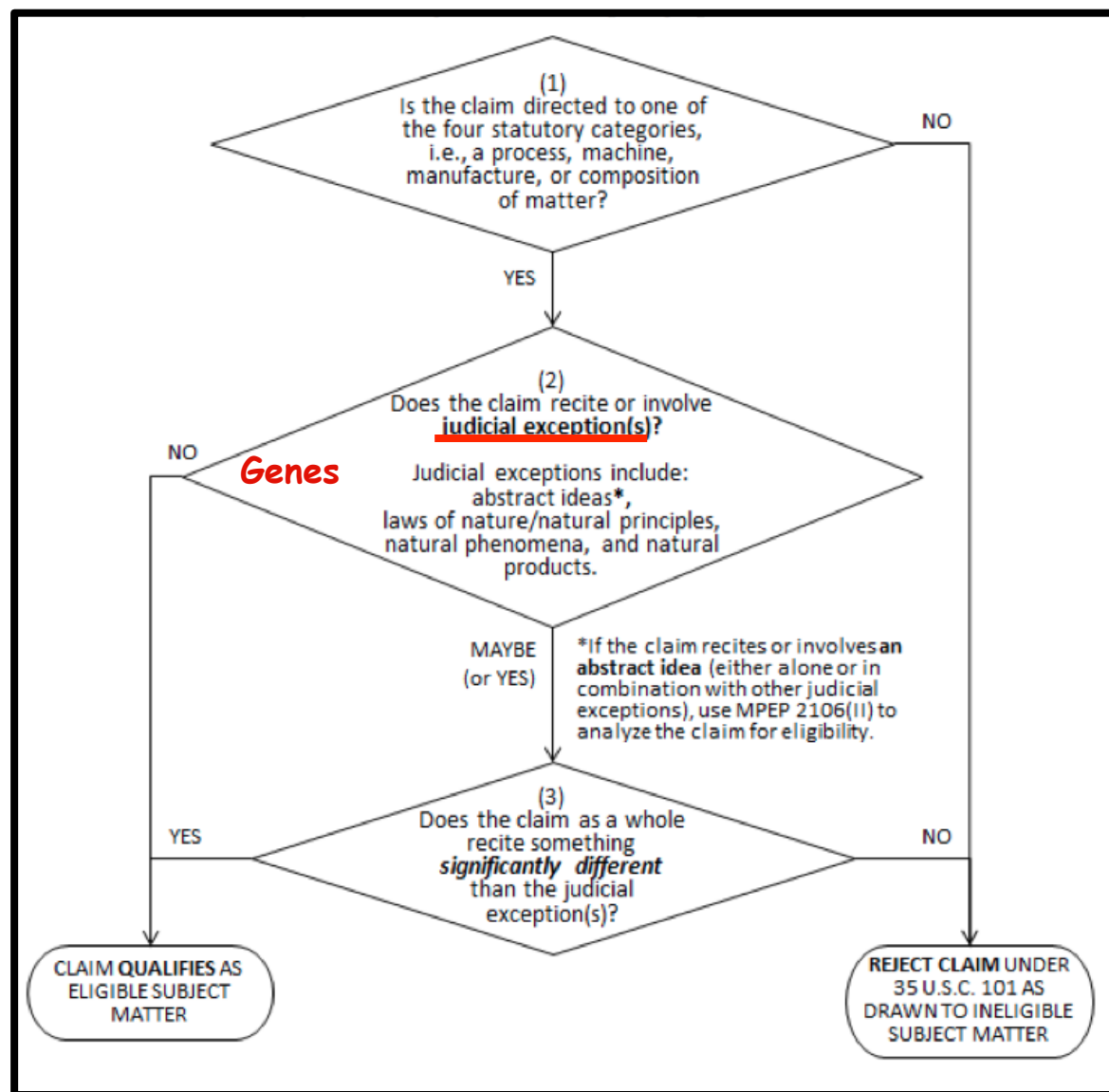
## Syllabus

ASSOCIATION FOR MOLECULAR PATHOLOGY ET AL.  
v. MYRIAD GENETICS, INC., ET AL.

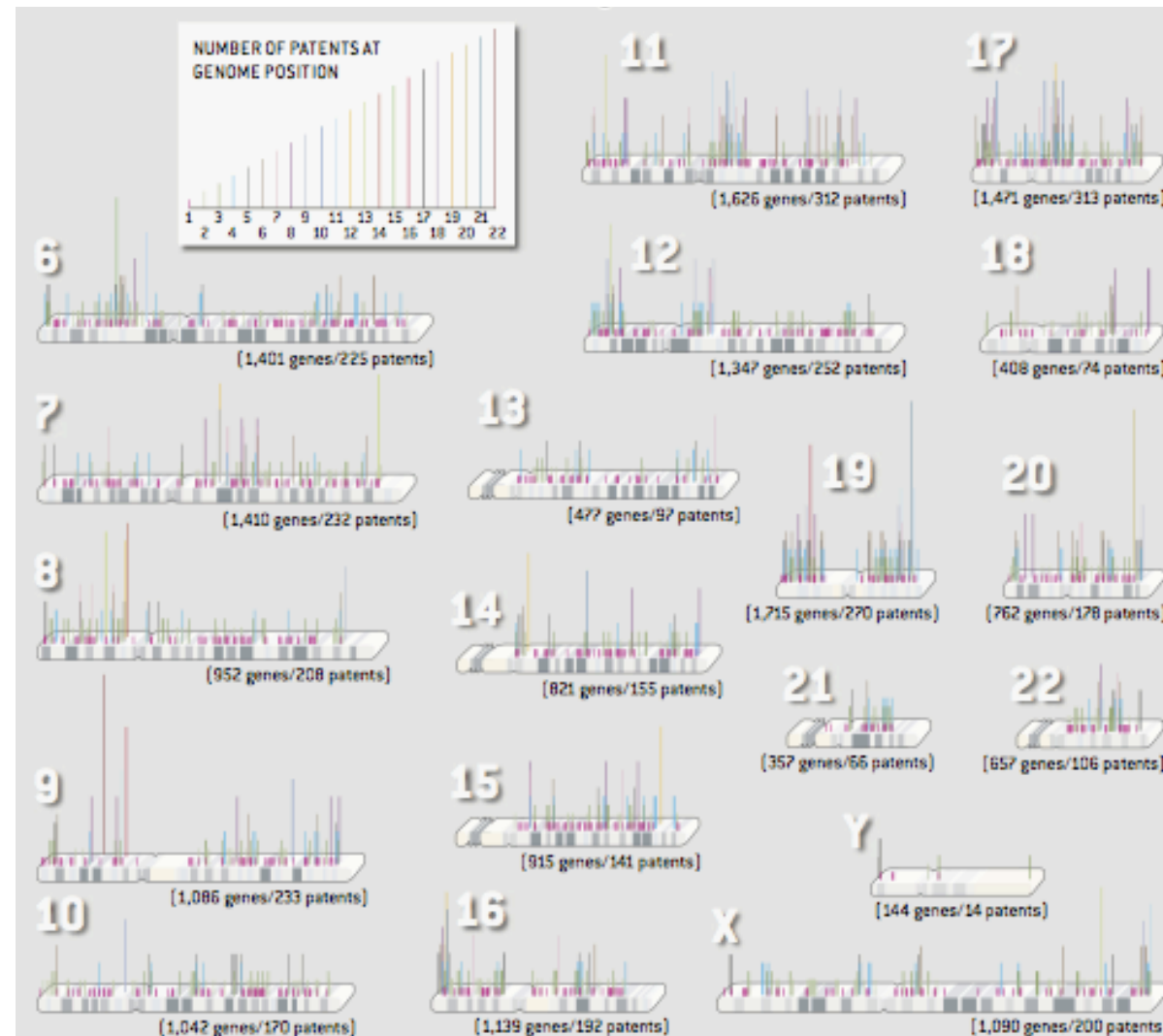
Myriad recognizes that our decision in *Chakrabarty* is central to this inquiry. Brief for Respondents 14, 23–27. In *Chakrabarty*, scientists added four plasmids to a bacterium, which enabled it to break down various components of crude oil. 447 U. S., at 305, and n. 1. The Court held that the modified bacterium was patentable. It explained that the patent claim was “not to a hitherto unknown natural phenomenon, but to a nonnaturally occurring manufacture or composition of matter—a product of human ingenuity ‘having a distinctive name, character [and] use.’” *Id.*, at 309–310 (quoting *Hartranft v. Wiegmann*, 121 U. S. 609, 615 (1887); alteration in original). The *Chakrabarty* bacterium was new “with markedly different characteristics from any found in nature.” 447 U. S., at 310, due to the additional plasmids and resultant “capacity for degrading oil.” *Id.*, at 305, n. 1. In this case, by contrast, Myriad did not create anything. To be sure, it found an important and useful gene, but separating that gene from its surrounding genetic material is not an act of invention.

**SUBJECT:** 2014 Procedure For Subject Matter Eligibility Analysis Of Claims Reciting Or Involving Laws Of Nature/Natural Principles, Natural Phenomena, And/Or Natural Products *Do the Claims Involve Patent-Eligible Subject Matter?*

**Myriad Case Ruled That Genes Are Natural Products That Don't Differ From What Exists in Chromosomes/Nature and, Therefore, Are NOT Patent-Eligible Subject Matter**



# Under New Myriad Rule - None of These Genes Would Have Been Patent-Eligible





# Nor Would This Switch Have Been Patent-Eligible.....

United States Patent  
Weterings, et al.

6,855,866  
February 15, 2005

Polynucleotides useful for modulating transcription

## Abstract

The invention provides polynucleotides for expression of genes in suspensor cells in plants and methods for using such polynucleotides.

Inventors: Weterings; Koen (Nijmegen, NL), Apuya; Nestor R. (Culver City, CA), **Goldberg; Robert B. (Topanga, CA)**  
Assignee: The Regents of the University of California (Oakland, CA)  
Appl. No.: 09/724,857  
Filed: November 28, 2000

## What Is No Longer Patent-Eligible Subject Matter?

- Genes
- Switches
- Oris
- PCR Primers

Any Nucleic Acid That Is Identical in Sequence To  
What is Found in Chromosomes

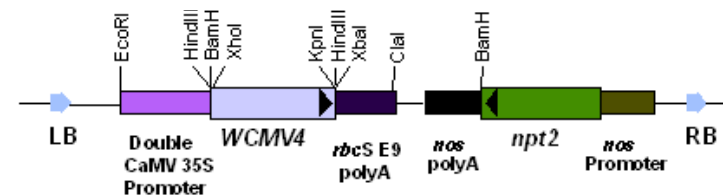


## What Is Patent-Eligible Subject Matter After Myriad?

Any Nucleic Acid That Substantially Different From  
What is Found in Chromosomes

- cDNAs
- Chimeric Genes (e.g., Mouse Switch + GFP)
- Synthetic Genes or Chromosomes With Engineered Difference From Nature

Or Any Nucleic Acid That Has Been “Altered  
Significantly With the Hands of Man”





PROMETHEUS®  
Therapeutics & Diagnostics

# What is Patent-Eligible Subject Matter?

## MAYO CLINIC —VS.— PROMETHEUS

Mayo Clinic fought the eight-year legal battle against Prometheus Labs because of our strong belief in our primary value: *the needs of the patient come first.*

The lawsuit centered on a blood test that measures metabolites in an individual's system when they are taking the drug Azathioprine.

The metabolite level would tell the physician if they needed to increase or decrease the patient's dosage.

## MAYO CLINIC —VS.— PROMETHEUS

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The metabolite level would tell the physician if they needed to increase or decrease the patient's dosage.

2004

The arguments centers on Section 101 of the Patent Act. Section 101 lays out what can and what cannot be patented. What cannot be patented is anything that is a law of nature. In other words, no one can own the rights over the body's nature response to illness or a medical treatment.

June 2004 - Prometheus Labs learns of the new test and sues for patent infringement.

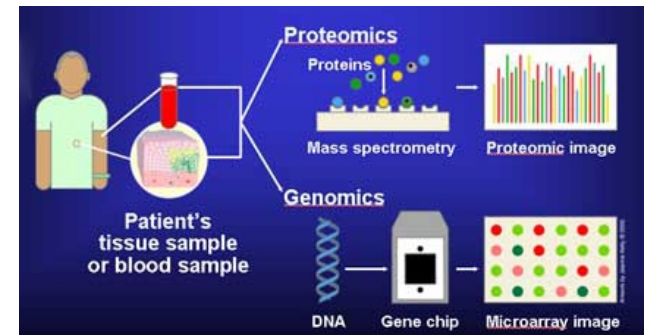
2005 - 2008

March 2008 - The journey starts in Federal District Court in San Diego, California, where the court rules in favor of Mayo, that Prometheus' patent claims are too broad and invalid.



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## Genetic Diagnostic Tests?



### SUPREME COURT OF THE UNITED STATES

No. 10–1150

MAYO COLLABORATIVE SERVICES, DBA MAYO  
MEDICAL LABORATORIES, ET AL., PETITION-  
ERS *v.* PROMETHEUS LABORATORIES, INC.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF  
APPEALS FOR THE FEDERAL CIRCUIT

[March 20, 2012]

JUSTICE BREYER delivered the opinion of the Court.

Section 101 of the Patent Act defines patentable subject matter. It says:

“Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.” 35 U. S. C. §101.

The Court has long held that this provision contains an important implicit exception. “[L]aws of nature, natural phenomena, and abstract ideas” are not patentable. *Dia-*

Still, as the Court has also made clear, to transform an unpatentable law of nature into a patent-eligible *application* of such a law, one must do more than simply state the law of nature while adding the words “apply it.” See, e.g., *Benson, supra*, at 71–72.



# Is Life Patentable!

***SCIENCE MAY PATENT  
NEW FORMS OF LIFE,  
JUSTICES RULE, 5 TO 4***

**1980**

The Supreme Court rules that Ananda Chakrabarty's bacterium is not a "product of nature" and so can be patented; other living things "made by man" are declared patentable as well



Ananda Chakrabarty



**1988**

Harvard University gets a patent for the OncoMouse, a rodent with a gene inserted that predisposes it to cancer

# SUPREME COURT OF THE UNITED STATES

Syllabus

BOWMAN *v.* MONSANTO CO. ET AL.

CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR  
THE FEDERAL CIRCUIT

No. 11–796. Argued February 19, 2013—Decided May 13, 2013

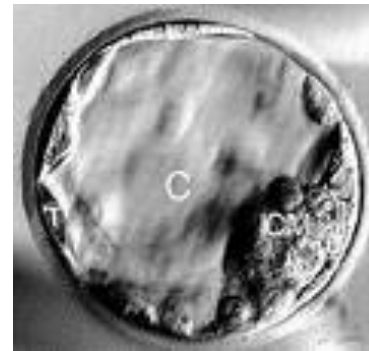
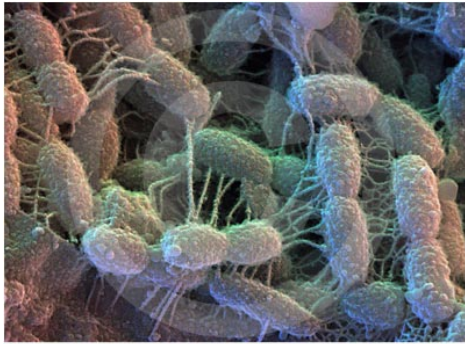
May 13, 2013

## **Monsanto Wins Case on Genetically Altered Soybeans**





# Can Living Organisms Be Patented?



# Many Types of Living Organisms **CAN** be Patented in the United States (Utility Patents)

## 1. Purified Microbial Cultures Do Not Exist In Nature and Are Patent Eligible

- a. Streptococcus velosus producing antibiotics-In Re Bergy (1977)
- b. Purified Yeast Free of Organic Germs or Disease-Louis Pasteur- US patent #141,072 (1873) *May be Re-interpreted under Myriad....*

## 2. Genetically Engineered Microorganisms (Landmark)

- a. Oil-Eating Bacteria-Diamond vs. Chakrabarty (1980)
  - i. "A Human-Made, Non-Natural Microorganism is Patentable
  - ii. "Anything Under the Sun Made by the Hands of Man"

## 3. A Genetically Engineered Mouse (Landmark)

- a. Harvard Mouse Patent-1988
- b. A Mammalian Genetically Engineered Organism Can Be Patented
- c. Not in Canada-Recall-Patents Are Country-Specific (Only "Lower" Forms of Life-Transgenic Bacteria, Yeast, Plant)

## 1. Human Cell Lines *May be Re-interpreted under Myriad....*

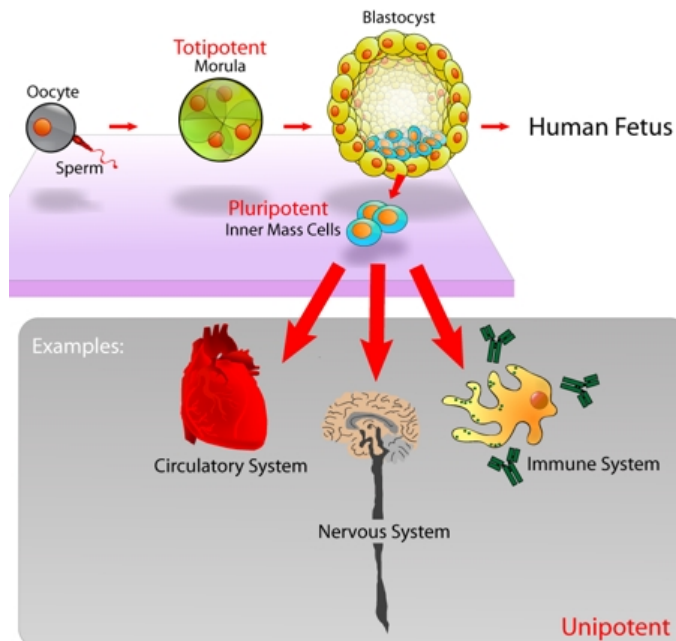
- a. Human Embryonic Stem Cells-Thompson-WARF Patent-1998
- b. Human Cell Line-Moore vs. Regents UC-1990
  - i. Your Cells Can Be Patented By Others If You Voluntarily Give Them To Others (e.g., medical consent)-No Property Rights

## 4. Hybrid Crops-Transgenic Plants (Landmark Utility Patent)

- a. Utility Patent on Method For Producing Hybrid Seeds-J.E.M. Ag Supply vs. Pioneer-Hybrid-2001

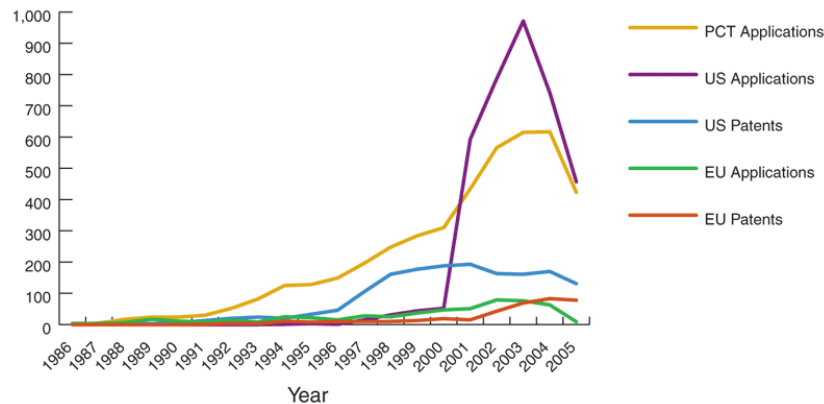


# .....Human Embryonic Stem Cells?



**Rejected in EU in 2004 on Moral Grounds  
Cell 132, 514-516 (2008)**

## Stem Cell Patent Applications



## U.S. office upholds embryonic stem cell patents

**Wisconsin Alumni Research Foundation receives certificates; ruling ends long-fought challenge**

June 27, 2008

(6 of 7)

United States Patent  
Thomson

## Human Stem Cells (US Patent)

6,200,806

March 13, 2001

Primate embryonic stem cells

### Abstract

A purified preparation of primate embryonic *stem cells* is disclosed. This preparation is characterized by the following cell surface markers: SSEA-1 (-); SSEA-4 (+); TRA-1-60 (+); TRA-1-81 (+); and alkaline phosphatase (+). In a particularly advantageous embodiment, the cells of the preparation are human embryonic *stem cells*, have normal karyotypes, and continue to proliferate in an undifferentiated state after continuous culture for eleven months. The embryonic stem cell lines also retain the ability, throughout the culture, to form trophoblast and to differentiate into all tissues derived from all three embryonic germ layers (endoderm, mesoderm and ectoderm). A method for isolating a primate embryonic stem cell line is also disclosed.

Inventors: Thomson; James A. (Madison, WI)  
Assignee: Wisconsin Alumni Research Foundation (Madison, WI)  
Appl. No.: 09/106,390  
Filed: June 26, 1998

**Being Challenged in US by Consumer  
Watchdog on Grounds That Stem  
Cells Are Products of Nature & Not  
Patentable Subject Matter - Up in  
the Air Because of The Myriad  
Decision**

**M<sup>3</sup>RIAD**  
GENE PATENT LITIGATION

**PROMETHEUS®**  
Therapeutics & Diagnostics

iPS Lines??



## Examples of EU Inventions That Are Unpatentable Because They Are Contrary To Public Policy or Morality



1. Processes For Cloning Human Beings
2. Processes For Modifying the Germline Genetic Identity of Human Beings
3. Processes For Modifying the Genetic Identity of Animals Which Are Likely to Cause Suffering Without Substantial Medical Benefit to Man or Animal, and Also Animals Resulting From Such Processes
4. The Human Body At Any Stage in its Formation or Development, Including Germ Cells, and the Simple Discovery of One of Its Elements, or One of Its Products (e.g., Human Genes, DNA Sequences)
5. Human Embryonic Stem Cell Lines
6. Methods For Treatment of Human Body by Surgery or Therapy and Diagnostic Methods

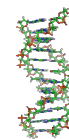
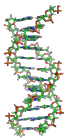
Europe rejects patent governing use of embryonic stem cells

The European Patent Office has turned down a patent that would have governed virtually any use of human embryonic stem cells

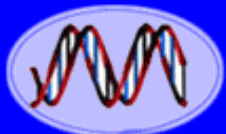
**Europe rejects Wisconsin's key stem-cell patent**

Europe revokes controversial gene patent

› 18:25 19 May 2004 by [Andy Coghlan](#)



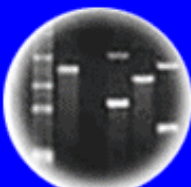
# DNA Patent Questions



DNA  
Genetic Code of Life



Entire Genetic Code  
of a Bacteria



DNA Fingerprinting



Cloning: Ethical Issues  
and Future Consequences



Plants of Tomorrow

1. *Is One of "Your" Genes Patentable?*
  - a. In Your Chromosomes?
  - b. In a Plasmid?
2. *Is a "Switch" Patentable?*
  - a. In Your Chromosomes?
  - b. In a Plasmid?
3. *Is a Cell Line (e.g., Stem Cell) Patentable?*
  - a. In Your Body?
  - b. In a Test Tube?
4. *Is a Genetic Engineering Procedure Patentable?*
  - a. Recombinant DNA (Cohen-Boyer)?
  - b. Plant Genetic Engineering?
  - c. PCR?
5. *Can the Process of Making Human Embryonic Stem Cells Be Patented?*
6. *Can a Living Organism Be Patented?*
  - a. Bacteria?
  - b. Mouse?
  - c. Human Embryo?
7. *Can a DNA Sequence Be Patented?*
8. *Can a DNA Sequence Database Be Copyrighted?*
9. *Can a DNA Analysis Software Program Be Patented? Copyrighted?*
10. *Do Patents Help or Hinder New Knowledge Generation?*
11. *Would There Be a Biotechnology Industry Without Patents?*

Creative Work	Patent	Copyright	Trademark	Trade Secret
Gene in Plasmid (*Only If Different From Natural Sequence)	√*			√
Gene Sequence (*Only If Different From Natural Sequence)	√*			√
Gene Database		√		√
DNA Software (*If Part of A Machine/Technical/Physical Result)	√*	√		√
Transgenic Organism	√			√
Biotech Co. Logo			√	
23 & Me Website (*As a Business)		√	√*	
DNA Test to Detect CF (*Being Challenged Under Prometheus))	√*			√
Research Article		√		
Stem Cell Line (* In USA)	√*			√
PCR Technique	√			√
Genome Project Website		√	*Not a Business	
Antisense or RNAi Drug	√		√	√

## What Concerns Have Been Raised Regarding Patenting Genes and Living Organisms?

Concern	Response
Naturally Occurring Genes Should Not Be Patentable	Your Genes Cannot Be Patented in Your Cells- Only If Outside of Cell and Shown to Have Utility
Patents Should Not Be For Discoveries of Nature-Only Marketable Inventions	Laws of Nature Cannot Be Patented. Patents Do Not Guarantee That The Invention Is Marketable
Patents Delay Research Progress	All Patents Are Published. Therefore, New Innovations Stimulate Scientific Progress. Little Impact on Basic University Research
Life Forms (Including Higher Life Forms) Should Not Be Patented	Life Forms Cannot Be Patented Unless Manufactured by the "Hands of Man." A Transgenic Organism Does Not Exist in Nature. Chakrabarty Case (1980)
Research Tools (Enabling Methods) Should Not Be Patented	Methods Are Patentable Subject Matter According to US Patent Law and Stimulate Scientific Progress (e.g., Gene Splicing, PCR)
Prevent Inventions From Being Used In Third World	Not If Patent Not Issued in Third World. Knowledge In Patent Has Been Published. If Patented in Third World, Can Generally Obtain a Royalty-Free License to Use Technology
Someone Will Own Your Genes	Not In Your Body

Patent Laws in US Guided By Constitution and US Statutes. Can Be Changed By Congress. Morally Neutral System That Has 600 Years of Tradition. Fed. Reg. 66, January 5, 2001

## What Concerns Have Been Raised Regarding Patenting Genes and Living Organisms?

Concern	Response
Naturally Occurring Genes Should Not Be Patentable	<b>Your Genes Cannot Be Patented</b> - Only if Modified or Substantially Different From What is in Nature (Myriad Case, 2013)
Patents Should Not Be For Discoveries of Nature-Only Marketable Inventions	<b>Laws of Nature Cannot Be Patented.</b> Patents Do Not Guarantee That The Invention Is Marketable
Patents Delay Research Progress	<b>All Patents Are Published. Therefore,</b> New Innovations Stimulate Scientific Progress. Little Impact on Basic University Research
Life Forms (Including Higher Life Forms) Should Not Be Patented	<b>Life Forms Cannot Be Patented Unless Manufactured by the "Hands of Man."</b> A Transgenic Organism Does Not Exist in Nature. <b>Chakrabarty Case (1981)</b>
Research Tools (Enabling Methods) Should Not Be Patented	Methods Are Patentable Subject Matter <b>According to US Patent Law and Stimulate Scientific Progress (e.g., Gene Splicing, PCR)</b>
Prevent Inventions From Being Used In Third World	Not If Patent Not Issued in Third World. <b>Knowledge In Patent Has Been Published. If Patented in Third World,</b> Can Generally Obtain a Royalty-Free License to Use Technology
Someone Will Own Your Genes	<b>Not In Your Body or in Isolated Form</b>

Patent Laws in US Guided By Constitution and US Statutes. Can Be Changed By Congress. Morally Neutral System That Has 600 Years of Tradition. Fed. Reg. 66, January 5, 2001

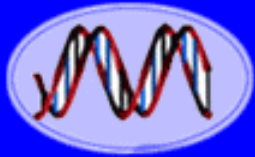
## A Common Misperception.....Patents Inhibit the Free Exchange of Information

To the Contrary.....Patent Laws REQUIRE Disclosure of the Invention (Written Description & Best Mode of Practice) And ARE PUBLISHED 18 Months After Filing Application. *Alternative Would be Trade Secrets!*

∴ Knowledge and Information in Patent Becomes Public Information and Can Stimulate New Innovation and Progress

For Example: Recombinant DNA, Genetic Engineering, PCR and DNA Sequencing!

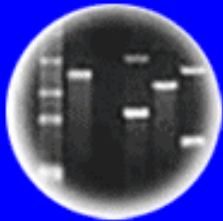




DNA  
Genetic Code of Life



Entire Genetic Code  
of a Bacteria



DNA Fingerprinting



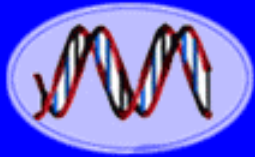
Cloning: Ethical Issues  
and Future Consequences



Plants of Tomorrow

Should You Be Able To Patent Edited Human Genes & Have Intellectual Property Rights?

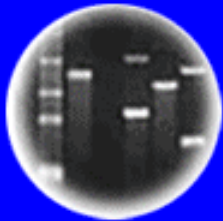
- a. Yes
- b. No



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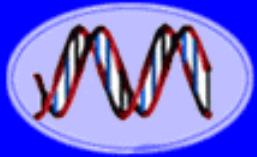
Cloning: Ethical Issues  
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Plants of Tomorrow

Should You Be Able To Patent Diagnostic  
Tests For Human Disease Genes?

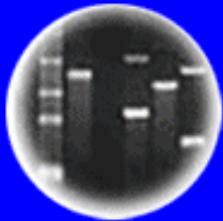
- a. Yes
- b. No



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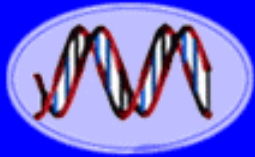
Cloning: Ethical Issues  
and Future Consequences



Plants of Tomorrow

Should Transgenic Organisms Be Patentable  
(e.g., herbicide-resistant soybean)?

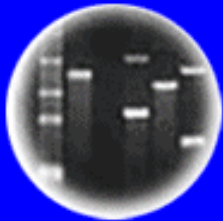
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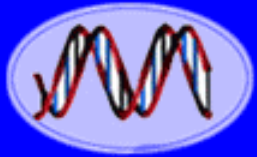
Cloning: Ethical Issues  
and Future Consequences



Plants of Tomorrow

Should Farmers Be Able To Collect Patent-Protected Seeds in Their Fields, and Plant the Next Year Without Paying a Royalty?

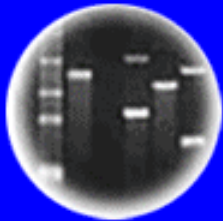
- a. Yes
- b. No



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DNA Fingerprinting



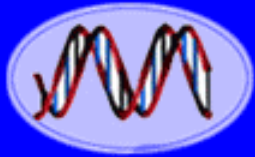
Cloning: Ethical Issues  
and Future Consequences



Plants of Tomorrow

Are There World-Wide Patents?

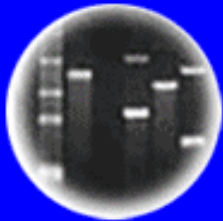
- a. Yes
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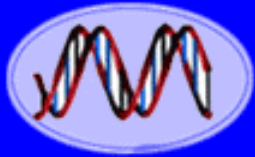
Cloning: Ethical Issues  
and Future Consequences



Plants of Tomorrow

Is Commercial Success a Criterion Used By  
the USPTO For Awarding a Patent?

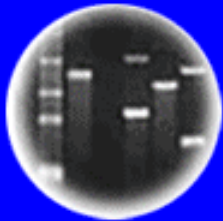
- a. Yes
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DNA Fingerprinting



Cloning: Ethical Issues  
and Future Consequences

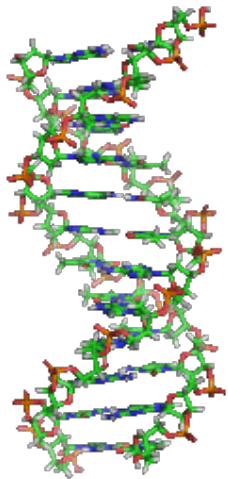


Plants of Tomorrow

Can Your Blood Cells Be Patented by  
UCLA After Being Taken From You By a  
Blood Test?

- a. Yes
- b. No



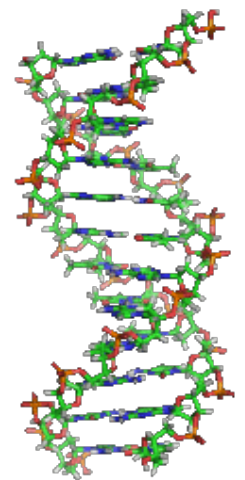
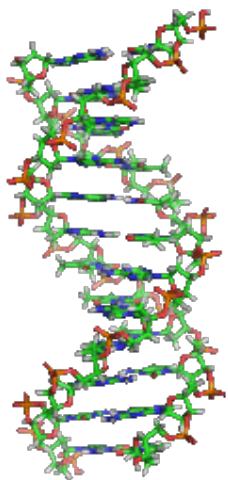


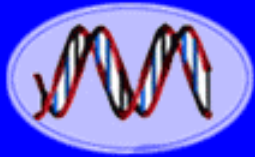
Recall....Way Back in January...



## The Age of DNA!

Genetic Engineering Is  
Manipulating DNA!

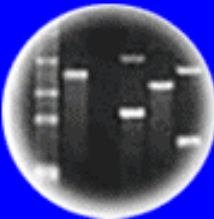




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DNA Fingerprinting



Cloning: Ethical Issues  
and Future Consequences



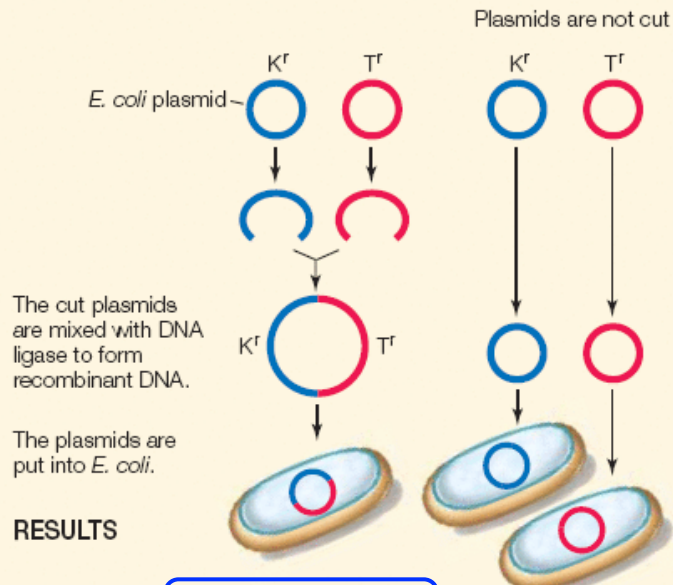
Plants of Tomorrow

# Genetic Engineering Technology Can Combine DNA (Genes) From Different Sources Leading to New Gene Combinations!!

## EXPERIMENT

**HYPOTHESIS:** Biologically functional recombinant chromosomes can be made in the laboratory.

**METHOD** *E. coli* plasmids carrying a gene for resistance to either the antibiotic kanamycin or tetracycline are cut with a restriction enzyme.



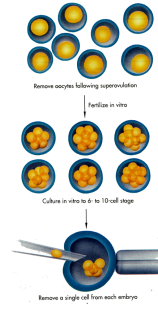
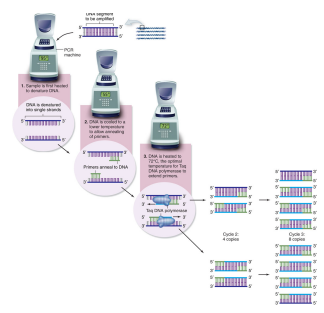
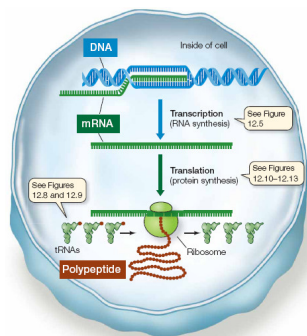
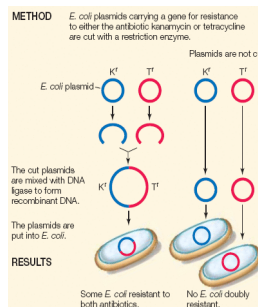
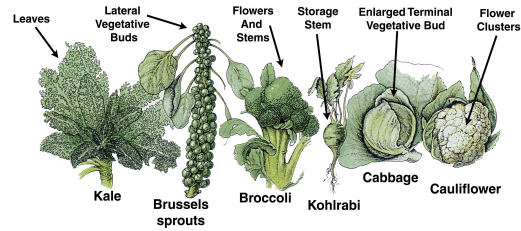
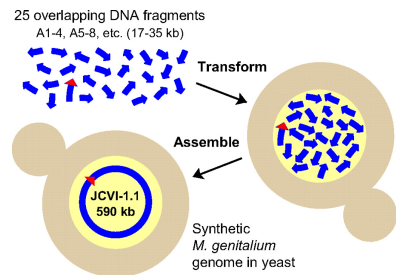
**CONCLUSION:** Two DNA fragments with different genes can be joined to make a recombinant DNA molecule, and the resulting DNA is functional.

Where it all Began  
One Summer in  
1973!

# What's a GMO?

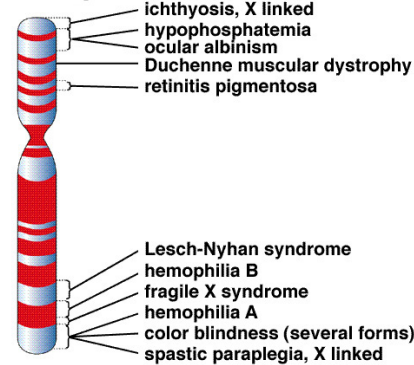
## Analysis of one million base pairs of Neanderthal DNA

Richard E. Green<sup>1</sup>, Johannes Krause<sup>1</sup>, Susan E. Ptak<sup>1</sup>, Adrian W. Briggs<sup>1</sup>, Michael T. Ronan<sup>2</sup>, Jan F. Simons<sup>2</sup>, Lei Du<sup>2</sup>, Michael Egholm<sup>2</sup>, Jonathan M. Rothberg<sup>2</sup>, Maja Paunovic<sup>3</sup> & Svante Pääbo<sup>1</sup>

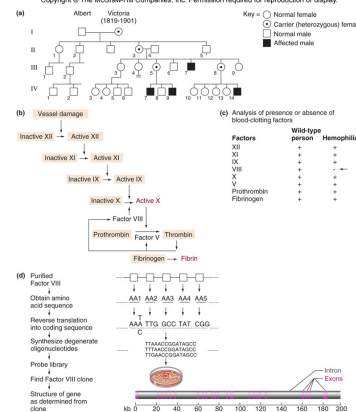


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## Map of chromosome X



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HomeDNA

The New Standard in Home DNA Testing

HomeDNA Home Paternity Testing System

NDIS Statistics

As of October 2007 the profile composition of the National DNA Index System (NDIS) is as follows:

Total number of profiles: 5,265,258

Total Forensic profiles: 196,785

Total Convicted Offender profiles: 5,070,473

DNA Tribes

Genetic Ancestry Analysis

What's Your Tribe?

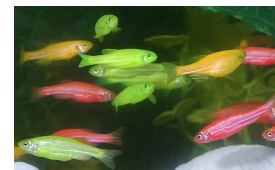
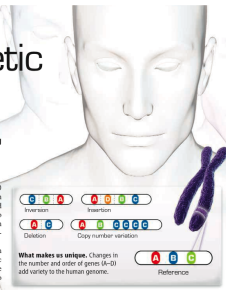
## BREAKTHROUGH OF THE YEAR

## Human Genetic Variation

Equipped with faster, cheaper technologies for sequencing DNA and assessing variation in genomes on scales ranging from one to millions of bases, researchers are finding out how truly different we are from one another.

THE UNVEILING OF THE HUMAN GENOME ALMOST 7 YEARS AGO cast the first light on our complete genetic makeup. Since then, each new genome sequenced and each new individual studied has illuminated our genomic landscape in ever more detail. In 2007, researchers came to appreciate the extent to which our genomes differ from person to person and the implications of this variation for deciphering the genetics of complex diseases and personal traits.

Less than a year ago, the big news was triangulating variation between us and our primate cousins to get a better glimpse on genetic changes along the evolutionary tree that led to humans. Now, we have moved from asking what is our DNA makes us human to striving to know what in my DNA makes me me.



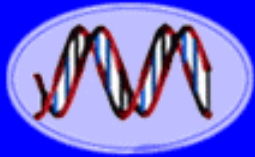
1. Isolate bacterial gene that produces protein toxic against certain insects

2. Insert Bt gene and a "marker" gene into cells

3. Identify cells with Bt and "marker" genes

4. Allow cells to grow into plants. Plants that produce toxin against insect pests

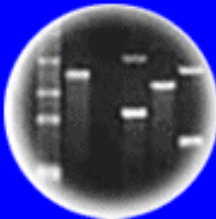
SCIENCE MAY PATENT NEW FORMS OF LIFE, JUSTICES RULE, 5 TO 4



DNA  
Genetic Code of Life



Entire Genetic Code  
of a Bacteria



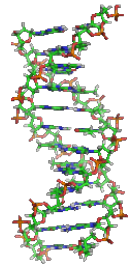
DNA Fingerprinting



Cloning: Ethical Issues  
and Future Consequences



Plants of Tomorrow



Look How Far Science  
& **YOU** Have Come!!!

**HC70A & SAS70A**  
**SPRING 2015**  
**The End!!**

**OR**  
**Is It the Beginning?**

