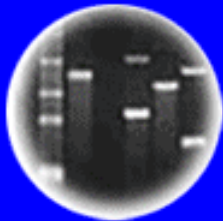


DNA  
Genetic Code of Life



Entire Genetic Code  
of a Bacteria



DNA Fingerprinting



Cloning: Ethical Issues  
and Future Consequences



Plants of Tomorrow

# HC70A Winter 2008 Genetic Engineering in Medicine, Agriculture, and Law Professor Bob Goldberg

## Lecture 9 Science & The Constitution: Who Owns Your Genes?



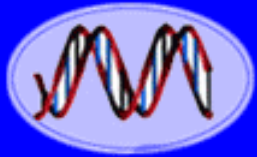
**No One, Of Course-Just Listen and Wait!**

# **TEXT READING**

**Chapter 12**  
**Focus on Pages 279-284**

## SELECTED REFERENCES

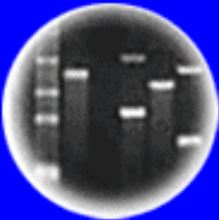
- 1. A Practical Companion To The Constitution,*  
By J.K. Lieberman (1999)
- 2. Patent, Copyright, & Trademark, By R.*  
*Stim, 9th Edition (2007)*
- 3. Biotechnology and The Law, By H.B.*  
Wellons et al. (2007)
4. United States Patent and Trademark  
Office ([www.uspto.gov](http://www.uspto.gov))



DNA  
Genetic Code of Life



Entire Genetic Code  
of a Bacteria



DNA Fingerprinting



Cloning: Ethical Issues  
and Future Consequences



Plants of Tomorrow

## THEMES

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

# 1. Article I - Section 8.8

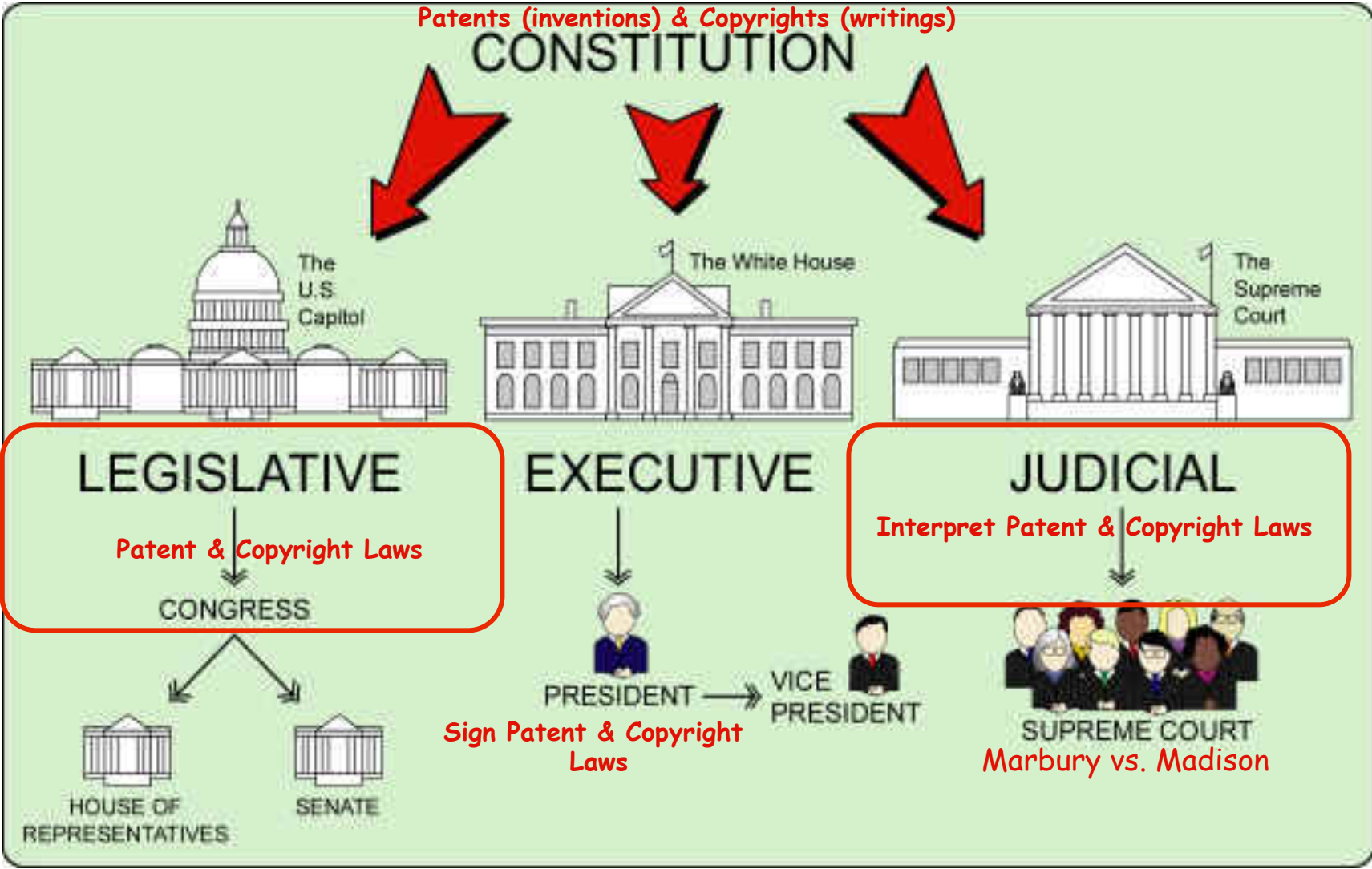
**The Congress shall have the Power:**

**[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**

# Intellectual Property and The United States Government



# The First United States Patent Issued-Notice Signature



X000001  
July 31, 1790

*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 Process; 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>d</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 Operation 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.*



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



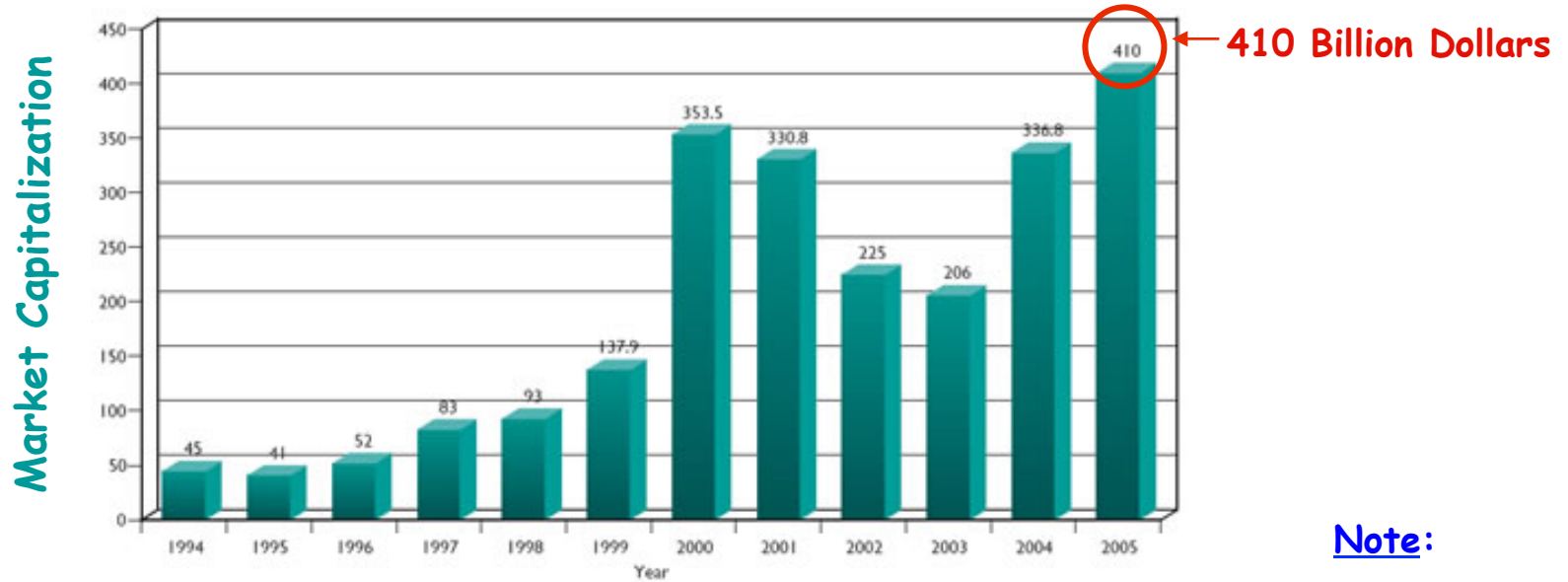
# The United States Can Trace Its Patent Roots Back ~600 Years

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 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 Is Must Written In Patent (e.g., Written Description)-KEY CONCEPT-OTHERS CAN KNOW WHAT THE INVENTION IS AND BUILD UPON IT-SOCIETY CAN PROGRESS

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



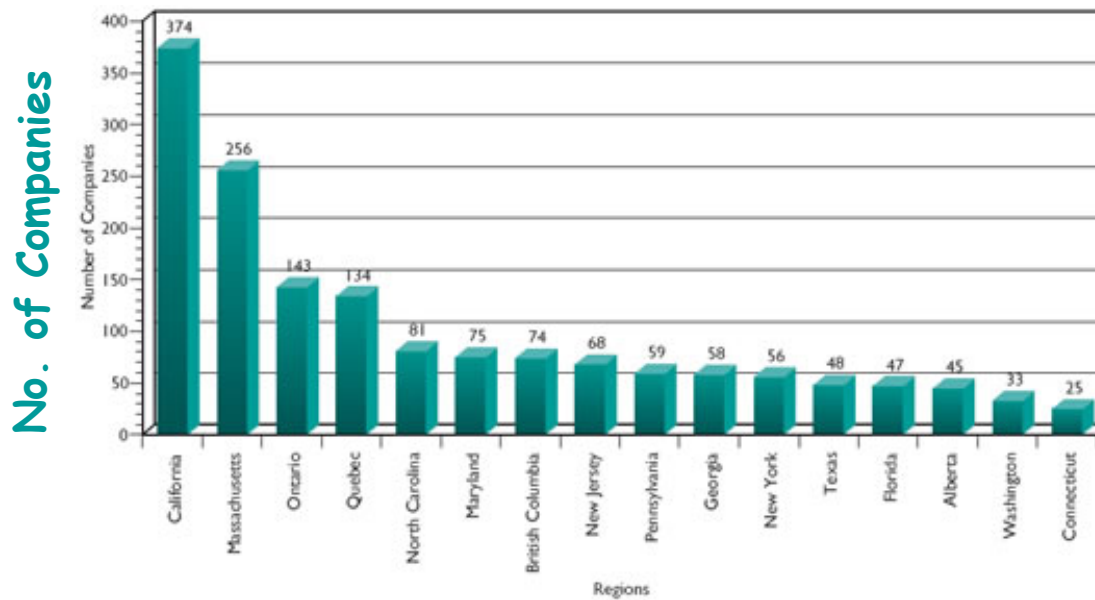
# Biotech in the United States is a Huge Success and a Big Business



Note:

There Was No  
Biotech Industry  
Before 1976

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



# Patent Questions Relevant To Genes & Genetic Engineering

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?
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? Copyrighted?
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?



# The United States Patent System Is “Morally Neutral”

1. Bypasses Public Debate on Social Issues Related To Technology Innovation
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 Policy or Morality.”



## 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, Including the Sequence or Partial Sequence of a Human Gene Cannot Be Patented

# Life **Is** 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



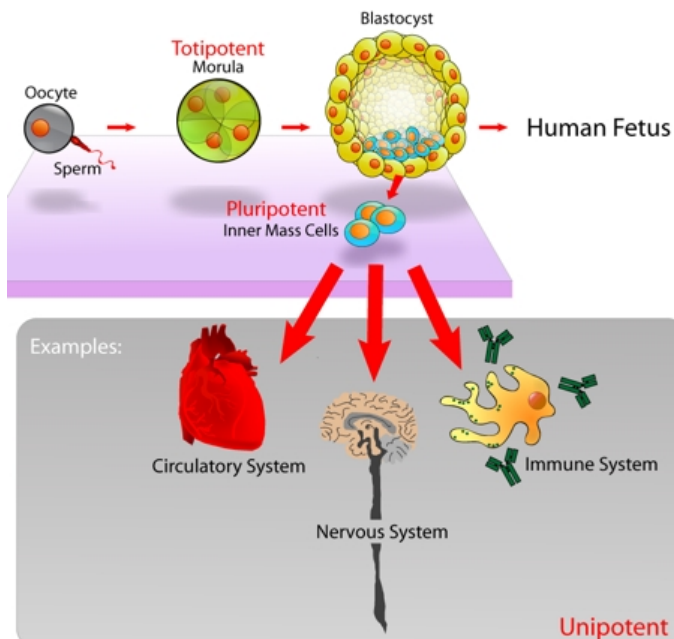
**1980**

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

6/17/1980



# Including Human Embryonic Stem Cells!!



(6 of 7)

United States Patent  
Thomson

## Human Stem Cells (US Patent)

6,200,806  
March 13, 2001

Primate embryonic stem cells

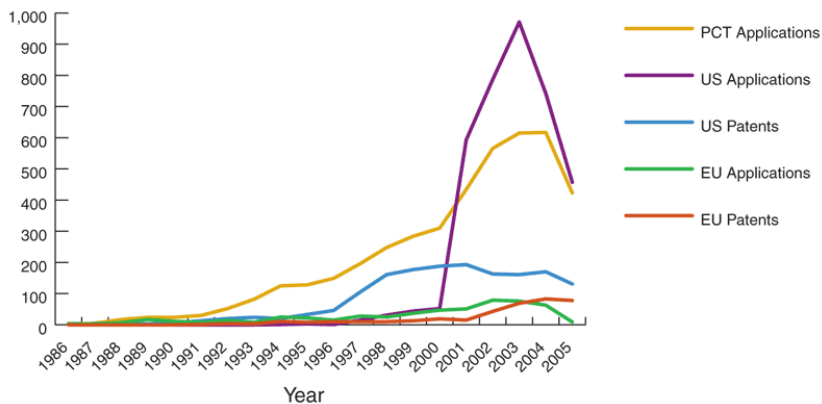
### Abstract

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.

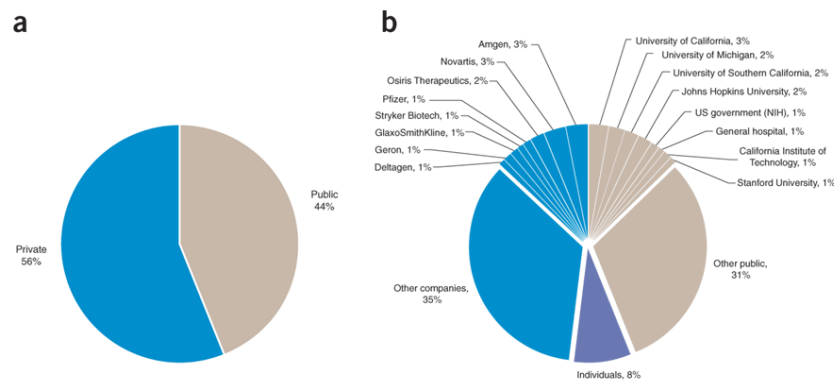
Inventors: Thomson, James A. (Madison, WI)  
Assignee: Wisconsin Alumni Research Foundation (Madison, WI)  
Appl. No.: 09/106,390  
Filed: June 26, 1998

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

## Stem Cell Patent Applications



## Stem Cell Patents in USA





# Landmark Genetic Engineering Patents

United States Patent  
Cohen, et al.

4,237,224

December 2, 1980

Process for producing biologically functional molecular chimeras

## Recombinant DNA!

### 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]

[11] 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 Martinell  
 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]

[11] **4,259,444**  
 [45] **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: **Jan. 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

# What Is Intellectual Property?

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

What Are the Different Types of Intellectual Property?

1. Patent

2. Copyright

3. Trademark or Servicemark

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.
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.

“How to Make bobg” US patent No. 7,989,755, March 11, 2008



# 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



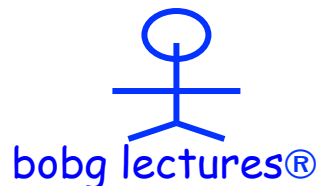
# What Are Copyrights?



1. A form of protection provided to authors of “original works of authorship,” 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.
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.

# What Are Trademarks & Service Marks?

1. Protects words, names, symbols (logos), sounds, or colors that distinguish goods and services (e.g., shape of Coca Cola bottle, name Coca Cola, roar of MGM lion, Apple logo, Microsoft name).
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).
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.
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.**

# Examples of Intellectual Property Protections



<b>Creative Work</b>	<b>Patent</b>	<b>Copyright</b>	<b>Trademark</b>	<b>Trade Secret</b>
<b>Biological Invention</b>	✓			
<b>Idea</b>				✓
<b>Database</b>		✓		✓
<b>Computer Design</b>	✓			✓
<b>Drawing</b>		✓		
<b>Advertisement</b>		✓	✓	
<b>Formula</b>	✓			✓
<b>Logo</b>			✓	
<b>Movie Script</b>		✓		✓
<b>Movie Film</b>		✓		
<b>Writings</b>		✓		
<b>Photograph</b>		✓		
<b>Song</b>		✓		
<b>Web Page</b>		✓	✓	
<b>Web Domain Name</b>			✓	

Creative Work	Patent	Copyright	Trademark	Trade Secret
Gene in Plasmid	√			√
Gene Sequence	√			√
Gene Database		√		√
Software (*If Part of A Machine)	√*	√		√
Transgenic Organism	√			
Biotech Co. Logo			√	
DNA Perfume	√		√	
Knome Website		√	√	
ASOs to Detect CF	√			√
Research Article		√		
Stem Cell Line	√			√
PCR Technique	√			√
Genome Project Website		√	√	
Genes in Human Cell				
Antisense Drug	√		√	√

## Summary of Intellectual Property Characteristics

<b>Patent</b>	<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>
<b>Copyright</b>	<ul style="list-style-type: none"><li>• Constitutional Right</li><li>• Protects Original Works of 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>
<b>Trademark</b>	<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>
<b>Trade Secret</b>	<ul style="list-style-type: none"><li>• Legislated Right</li><li>• Protects Anything By Virtue of Secrecy/Confidentiality/Privacy</li></ul>

# Trademarks and Service Marks®™

1. A Word, Name, Symbol, or Device to Indicate a Specific Source of Goods or Services and Distinguish Them From Others.
2. Owned By Business That is First to Use It in Commercial Context
3. Can Last Indefinitely With Continued Use
4. Can Register with USPTO As Long As Product or Service Crosses State, National, and/or Territorial Boundaries
  - a. Registration Lasts Ten Years With Ten Year Renewals
  - b. Official Registration and Better Protection From Use
  - c. Only Can Use ® If Registered. Can Use ™ If Not Registered, But Not Necessary As Use of Mark Confers Rights
5. Can Prevent Others From Using the Same Mark-But Not From Selling and/or Trading the Same Goods and/or Services
6. Can Be Transferred, Sold, Traded, and/or Acquired Like Any Other Property Right
7. Domain Names For Websites Fall Within Trademark System
8. Must Be Distinctive-McDonald's, Coca Cola, Kinkos, FedEx, Amazon.com
9. A Trademark For Goods is Not Necessarily Infringed By the Same Trademark For Different Goods-Except in Certain Cases Known as "Dilution"
  - a. The mark is "famous" or well known (e.g., Microsoft)
  - b. The unrelated mark would dilute the famous mark's strength; that is, impair or tarnish its reputation for quality or render it common through overuse in different contexts
10. Trademark Law Does Not Prohibit Use of Another Company's Trademark For Purposes of Commentary or Criticism and For Comparative Advertising

# Copyrights©

1. A Form of Protection For “Original Works of Expression,” Including Literary, Drama, Musical, Artistic, Scientific, and Other Intellectual Works-Both Published and Unpublished.
2. Does Not Protect Ideas, or Facts-Only Unique Way In Which Ideas Or facts Are Expressed
  - a. For Example, Ideas In Scientific Paper-Only the Way They Were Written or Graphically Displayed
3. Requirements For a Copyright
  - a. Must Be Original
  - b. Have Some Creativity; That is, Produced By An Exercise of Human Intellect (e.g., a list of names cannot be copyrighted)
  - c. Must Be Fixed In Tangible Medium or Expression (e.g, recorded, expressed on paper, computer disk, dvd)
4. Gives Owner the Exclusive Right To Reproduce, Prepare Derivative Works, Distribute Copies, Perform Work,and/or Display Work, and Authorize Others To Do So As Well.
5. Can Prevent Others From Unauthorized Use
6. Copyright Protect Starts When Work Is Created In Fixed Form
  - a. Tangible Medium For Expression: Paper, DVD, Computer Disk
7. Non-Registered Right-Starts Automatically
  - a. Official Registration and Better Protection From Use
  - b. Can Register With U.S. Copyright Office, but Not Necessary.
  - c. Can Use The bobg HC70A Lectures© To Prevent Others From Claiming That They Didn't Know Work Was Copyrighted
8. Lasts For Life of Author Plus 70 Years (Works Created After 1978)

# What Can and Cannot Be Copyrighted?

<b>What Can Be Copyrighted?</b>	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, 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	
Computer Program (Software)	
Architectural and Design Works	



# 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, 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	
Computer Program	
Architectural and Design Works	

# Copyright on a Scientific Paper

The Plant Cell, Vol. 13, 2409–2425, November 2001, www.plantcell.org © 2001 American Society of Plant Biologists

## Regional Localization of Suspensor mRNAs during Early Embryo Development

**Koen Weterings,<sup>a,1,2</sup> Nestor R. Apuya,<sup>a,1,3</sup> Yuping Bi,<sup>a</sup> Robert L. Fischer,<sup>b</sup> John J. Harada,<sup>c</sup> and Robert B. Goldberg<sup>a,4</sup>**

<sup>a</sup> Department of Molecular, Cell, and Developmental Biology, University of California, Los Angeles, California 90095-1606

<sup>b</sup> Department of Plant and Microbial Biology, University of California, Berkeley, California 94720

<sup>c</sup> Section of Plant Biology, Division of Biological Sciences, University of California, Davis, California 95616

## Trade Secrets

1. “Unprotected” Form of Intellectual Property.
2. Information of Any Sort That is Valuable To the Owner, Not Generally Known, and Has Been Kept Secret by the Owner
3. What Can Be “Protected” as Trade Secrets?
  - a. Customer Lists
  - b. Formulas (e.g., Coca Cola)
  - c. Designs
  - d. Processes
  - e. DNA Sequences and Databases (Never Publish!)
  - f. Idea
4. Federal-Economic Espionage Act of 1996
5. States-Uniform Trade Secret Act-Adopted By 43 States and Washington, D.C.
6. Can Be Transferred, Sold, Traded, and/or Acquired Like Any Other Property Right
7. Trade Secret Owner Has Right to Keep Others From Stealing and Using Trade Secret
  - a. Employees Leaving and Going to Another Company (Confidentiality and Non-Compete Clauses)
  - b. Theft
8. Information Learned Through Independent Research or Reverse Engineering of Product is Considered to be in the Public Domain and No Longer a Trade Secret and Covered By Trade Secret Laws (Does Not Affect Patents)
  - a. Must Be On a Legitimate Copy (Not stolen One)
  - b. Could Be Prohibited Through End-User License Agreement-That is, prohibits Reverse Engineering as Condition of Use
9. Lasts As Long as Information Kept Confidential

## 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?

<b>Patents</b>	Trade Secrets
<ol style="list-style-type: none"><li data-bbox="142 646 877 699">1. Society Gains Knowledge</li><li data-bbox="142 721 993 894">2. Patents Published 18 Months After Filing (Patent Pending Status)</li><li data-bbox="142 915 884 1036">3. Patent Expires After 20 Years-Society Can Use</li><li data-bbox="142 1057 814 1110">4. Patent Law Protection</li></ol>	<ol style="list-style-type: none"><li data-bbox="1056 646 1835 820">1. Prevent Competitors From Gaining Proprietary Information</li><li data-bbox="1056 841 1934 961">2. Society Does Not Get Access to Trade Secret Knowledge</li><li data-bbox="1056 982 1633 1036">3. Limited Protection</li></ol>

# 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
3. Claims in Invention Set Nature of Protection-What is Claimed in the Invention?
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

“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

# 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 (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
2. Must Have Specific, Substantial, and Credible Utility
3. Must Be Novel and New
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

• 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
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

- 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)
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 IN YOUR BODY ARE  
NOT PATENT ELIGIBLE!

# What Is Not Patent-Eligible Subject Matter?

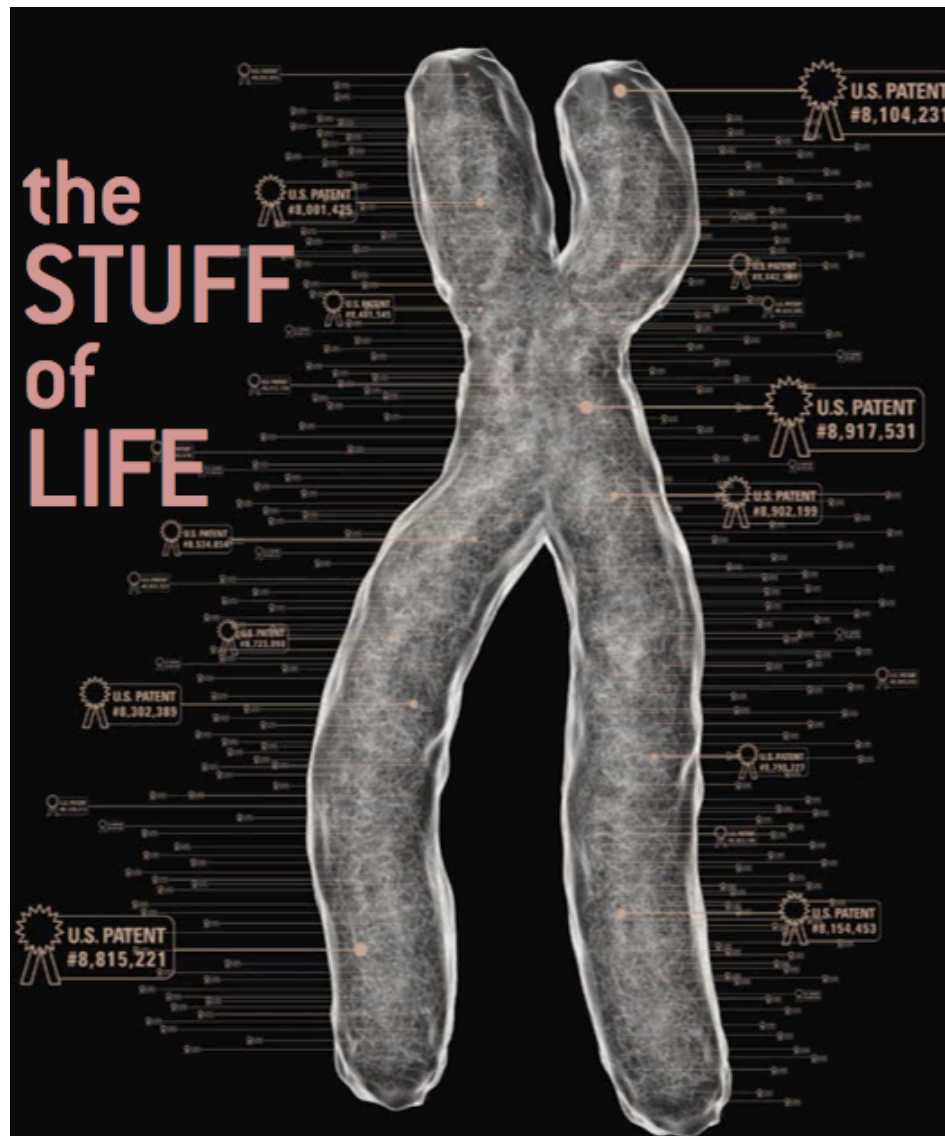
1. Laws of Nature-Including Algorithms and Mathematical Formulas
2. Abstract Ideas
3. Naturally Occurring Phenomena
4. Naturally Occurring Substances That Exist in Nature-Including Cells, Chromosomes, and Genes (including sequences) in Their Natural State

**∴ YOUR GENES IN YOUR BODY ARE  
NOT PATENT ELIGIBLE!**

# 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)
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**
  - a. Purified Genes
  - b. Purified Proteins (e.g., adrenaline-epinephrine-Parke-Davis vs. Mulford & Co., 1912-Judge Learned Hand)
  - c. Purified Natural Substances (e.g., aspirin-salicylic acid, strawberry flavoring-In Re Katz-1979)
  - d. Purified Microorganisms (e.g., pure culture of antibiotic-producing bacteria-In Re Bergy-1977)
5. **Improvements on Any of the Above (Different Patent)**

# OWNING



## 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
4. YOU Do Not Have To Give a Sample of Your Genes To Anyone Except:
  - a. Voluntarily (But Then Can Be Patented By Others)
  - b. By a Search Warrant (IV Amendment-The Right of People To Be Secure in Their Persons)

However...What About Purified Genes?



## Purified Genes And Their Sequences Are Patent-Eligible

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:
  - a. Invention Must Be Novel, Useful, Non-Obvious, Have a Clear Written Description, and Document the Best Mode of Practice
    - i. A “Switch” To Turn On Genes In Goat Mammary Glands
    - ii. A Gene Sequence to Produce Insulin in Bacteria Cells
    - iii. A Vector To Propagate Genes In Yeast Cells

# A Gene Switch Patent

United States Patent  
*Weterings*, et al.

6,855,866  
February 15, 2005

---

Polynucleotides useful for modulating transcription

## Abstract

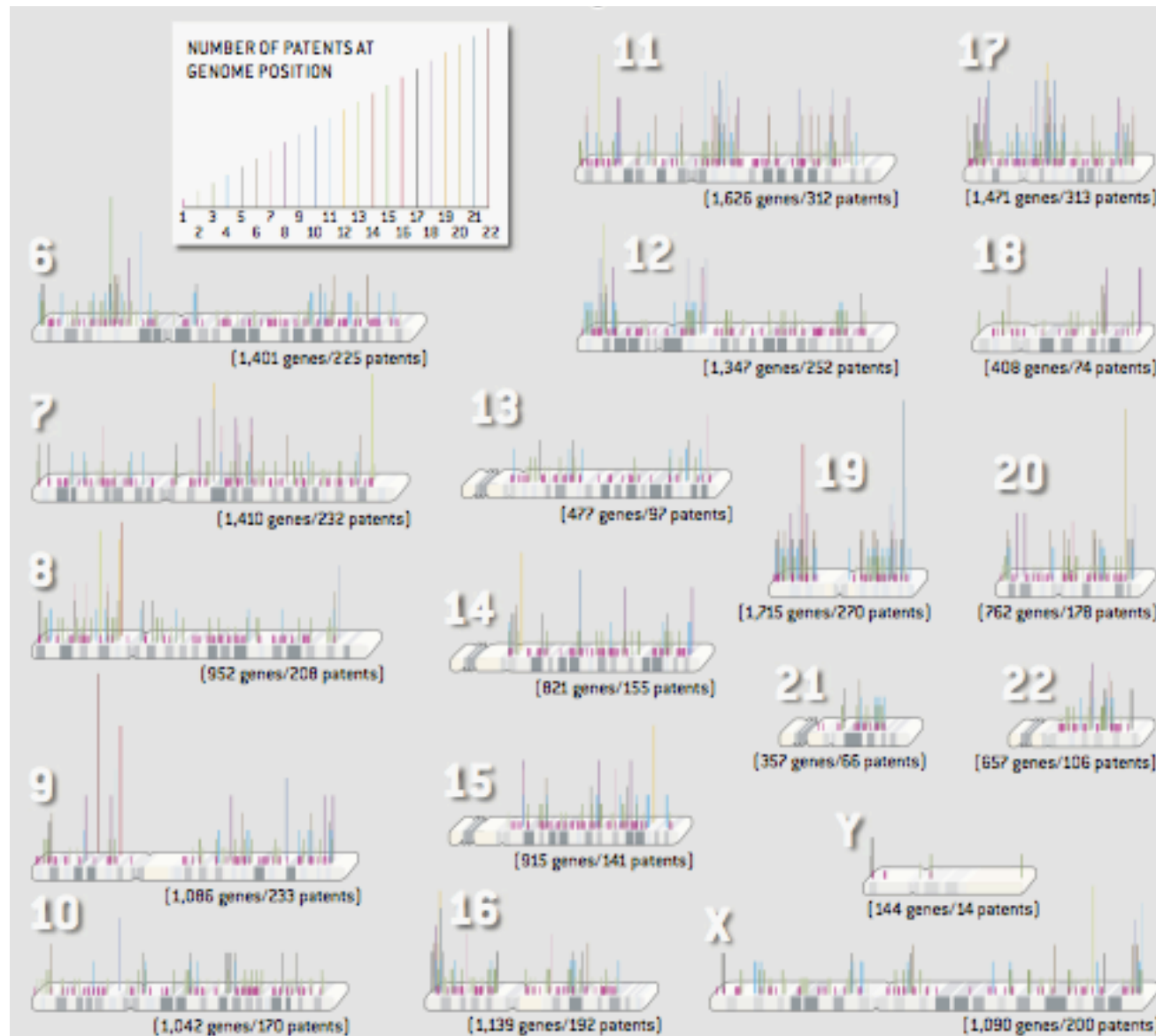
The invention provides polynucleotides for expression of genes in suspensor cells in plants and methods for using such polynucleotides.

---

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**



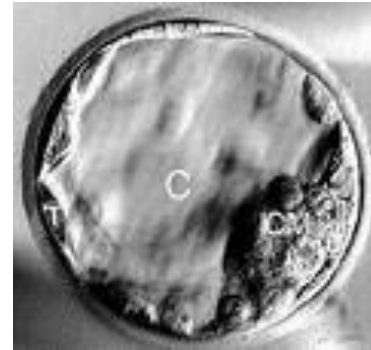
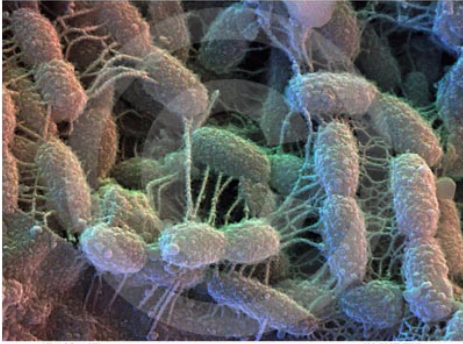
# Who Owns Your Genes: Human Gene Patents



*Scientific American, February 2006*

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

# Can Living Organisms Be Patented?



# Yes-Life **Is** 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

# Living Organisms CAN Be Patented (Utility Patents)

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

- a. Streptocmyces velosus producing antibiotics-In Re Bergy (1977)
- b. Purified Yeast Free of Organic Genrms or Disease-Louis Pasteur- US patent #141,072 (1873)

## 2. Genetically Engineered Microorganisms (Landmark)

- a. Oil-Eating Bacteria-Diamond vs. Chakrabarty (1980)
  - i. "A Human-Made, Non-Natural Microorganism is Patentatble
  - 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)

## 4. Human Cell Lines

- 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

## 5. 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



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

<b>Utility</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 (Specification)</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 Patent Specification Which Includes the Claims (What the Invention is)</li></ol>

## Specific Examples

<p><b>Utility</b></p>	<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 - Patentable-Specific Utility</li> </ol>
<p><b>Novel &amp; New</b></p>	<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>
<p><b>Non-Obvious</b></p>	<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>
<p><b>Written Description &amp; Best Mode of Practice</b></p>	<ol style="list-style-type: none"> <li>1. UC Patent on Rat Insulin cDNA Clone and Sequence</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-<u>Violated Written Description Provision</u></li> <li>5. UC Patent Written Description Could Not Instruct Others How To Translate Rat cDNA Sequence Into Human Protein Sequence 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., EPO or European Patent Office)
  - 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 Invent (Invention Date-Must Have Signed Lab Notebooks)
2. Patent Application Published After 18 Months and Becomes Prior Art
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., Chakrabarty Case)
5. Challenge (Very Expensive)
  - a. Interference-Two Similar Inventions Filed at Same Time (First To Invent in US)
  - b. Infringement-Someone Illegally Practicing Invention (Country Specific)

## 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)
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

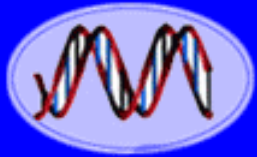
## **A Common Misperception.....Patents Inhibit the Free Exchange of Information**

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

**∴ 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!**

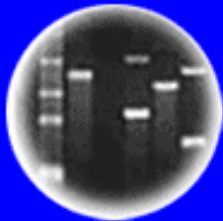




DNA  
Genetic Code of Life



Entire Genetic Code  
of a Bacteria



DNA Fingerprinting



Cloning: Ethical Issues  
and Future Consequences



Plants of Tomorrow

# HC 70A Winter 2008

## The End or Is It the Beginning?