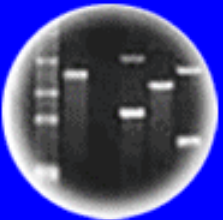




DNA
Genetic Code of Life



Entire Genetic Code
of a Bacteria



DNA Fingerprinting



Cloning: Ethical Issues
and Future Consequences



Plants of Tomorrow

HC70A & SAS70A Winter 2012 Genetic Engineering in Medicine, Agriculture, and Law

Professors Bob Goldberg & John Harada

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



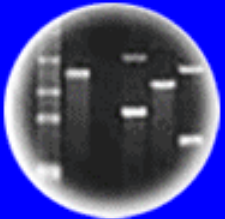
No One, Of Course-Just Listen and Wait!



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Entire Genetic Code
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DNA Fingerprinting



Cloning: Ethical Issues
and Future Consequences



Plants of Tomorrow

TEXT READING

Chapter 12

Focus on Pages 279-284

SELECTED REFERENCES

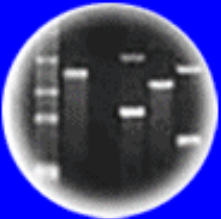
1. *A Practical Companion To The Constitution*, By J.K. Lieberman (1999)
2. *Biotechnology and The Law*, By H.B. Wellons et al. (2007)
3. United States Patent and Trademark Office (www.uspto.gov)
4. *Patent, Copyright, & Trademark*, By R. Stim, 11th Edition (2010)
5. Nature Biotech. 28, 230-233 (2010)
6. *Patents in Genomics and Human Genetics*, By Robert Cook-Deegan & Christopher Heaney, *Annu. Rev. Human Genetics*, 11, 383-425 (2010)



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Cloning: Ethical Issues
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Plants of Tomorrow

THEMES

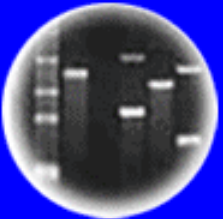
1. The Constitution & Intellectual Property
2. A History of Patents
3. Who Makes and Interprets Patent Laws?
4. Questions Dealing With Patents
5. Is the US Patent System Morally Neutral?
6. Life Is Patentable-Landmark Chakrabarty Case
7. Landmark Genetic Engineering Patent Cases
8. What is Intellectual 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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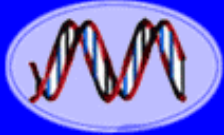


Plants of Tomorrow

Patent Questions Relevant to Genes, Genetic Engineering, & Biotechnology



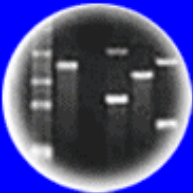
DNA Patent Questions



DNA
Genetic Code of Life



Entire Genetic Code
of a Bacteria



DNA Fingerprinting

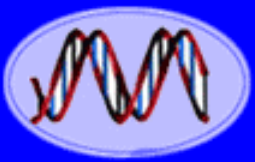


Cloning: Ethical Issues
and Future Consequences



Plants of Tomorrow

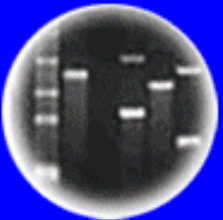
- 1. Is One of "Your" Genes Patentable?**
 - a. In Your Chromosomes?
 - b. In a Plasmid?
- 2. Is a "Switch" Patentable?**
 - a. In Your Chromosomes?
 - b. In a Plasmid?
- 3. Is a Cell Line (e.g., Stem Cell) Patentable?**
 - a. In Your Body?
 - b. In a Test Tube?
- 4. Is a Genetic Engineering Procedure 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? 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?**



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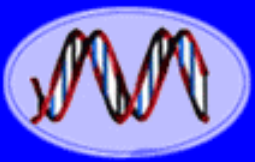
Cloning: Ethical Issues
and Future Consequences



Plants of Tomorrow

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

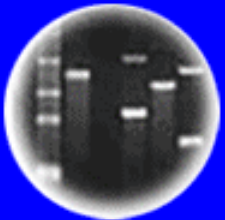
- a. Yes
- b. No



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DNA Fingerprinting



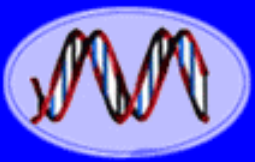
Cloning: Ethical Issues
and Future Consequences



Plants of Tomorrow

Should Transgenic Organisms Be Patentable?

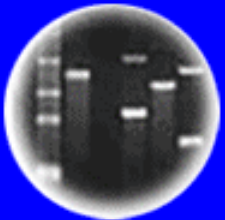
- a. Yes
- b. No



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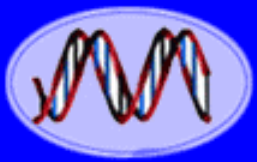
Cloning: Ethical Issues
and Future Consequences



Plants of Tomorrow

Are There World-Wide Patents?

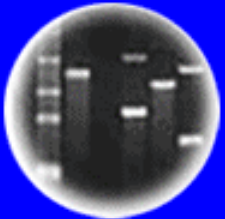
- a. Yes
- b. No



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Plants of Tomorrow

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

- a. Yes
- b. No

1. Article I - Section 8.8

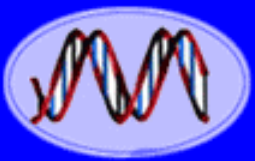
The Congress shall have the Power:

[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

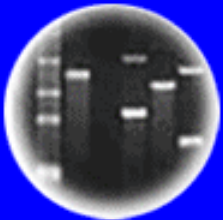
*Proposed By James Madison (Federalist Papers) and Charles Pickney in 1787
to a Committee Drafting Constitution*



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Plants of Tomorrow



History

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 Process; that is to say, in the making of Pearl. ash 1st by burning the raw Ashes in a Furnace, 2^d by dissolving and boiling them when so burnt in Water, 3^d by drawing off and settling the ley, and 4th 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 31st 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.



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



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

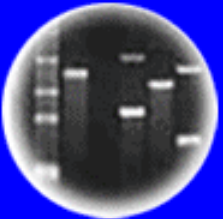
1. *Letter Patents Marked By King's Great Seal Were the First Patents in the 15th Century in Great Britain*
2. *Current Patent System Originated in 1449 in Great Britain*
 - a. First Patent to John Utynam of Flanders by King Henry VI
 - b. Method For Cambridge Kings and Eton College Stained Glass Windows
 - 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



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DNA Fingerprinting



Cloning: Ethical Issues
and Future Consequences



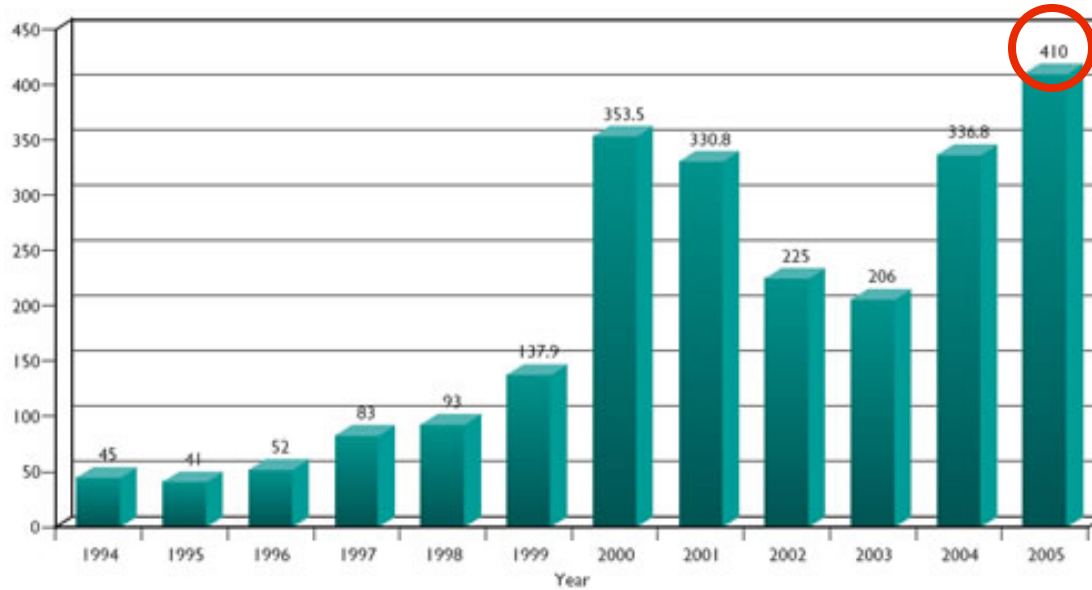
Plants of Tomorrow

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

Market Capitalization



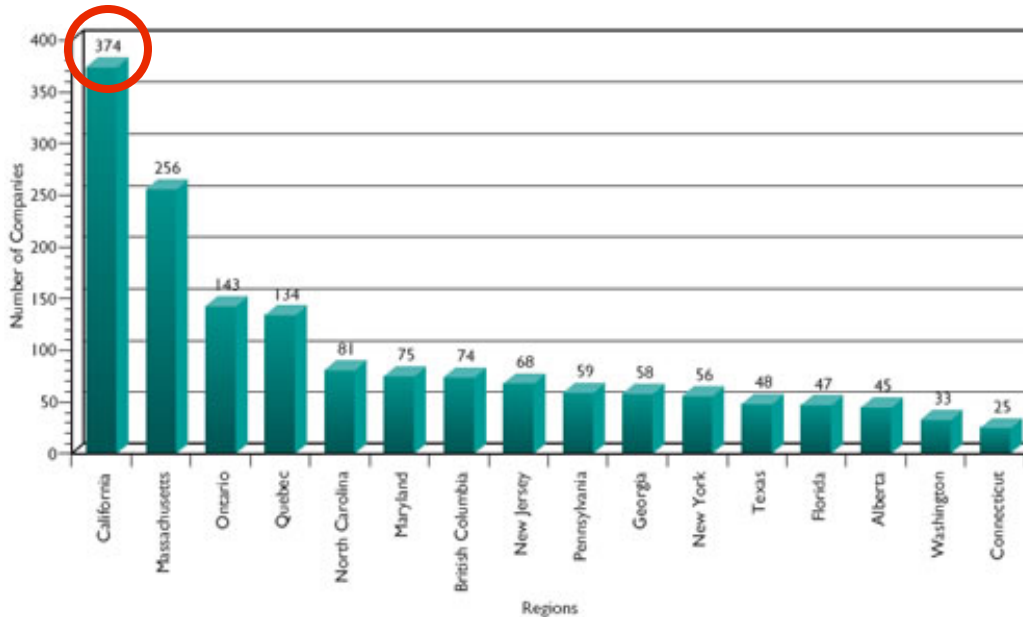
350 Billion Dollars
In 2011

Note:

There Was No
Biotech Industry
Before 1976

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

No. of Companies



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
5. Human Embryonic Stem Cell Lines

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

Life **Is** Patentable (In USA)

**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

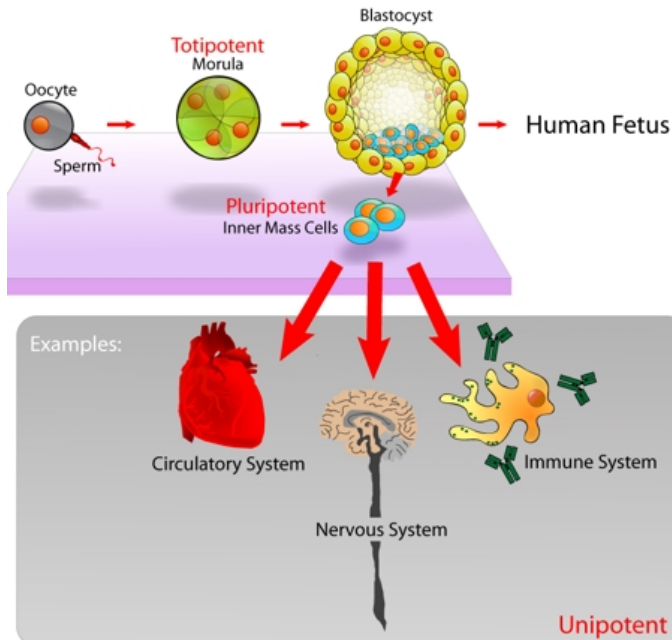
Harvard Mouse



1988

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

Including Human Embryonic Stem Cells!!



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

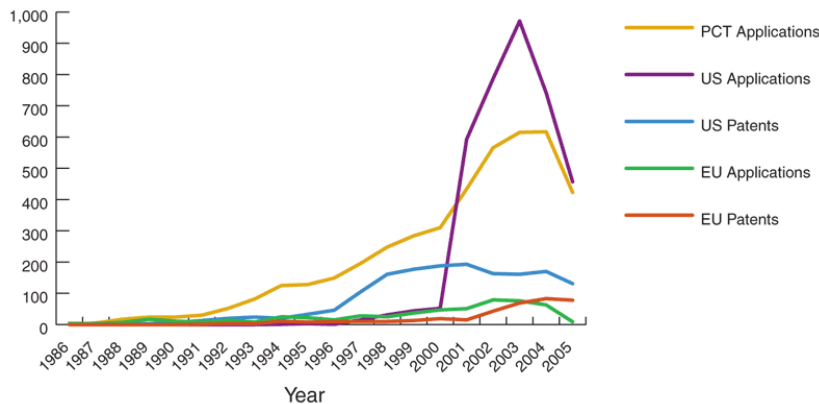
Abstract

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.

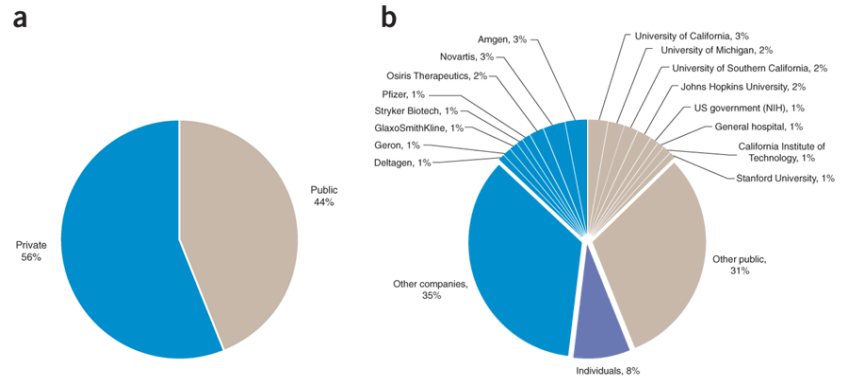
Inventors: Thomson; James A. (Madison, WI)
Assignee: Wisconsin Alumni Research Foundation (Madison, WI)
Appl. No.: 09/106,390
Filed: June 26, 1998

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

Stem Cell Patent Applications



Stem Cell Patents in USA

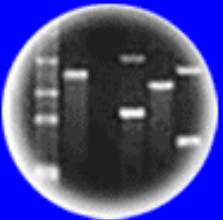




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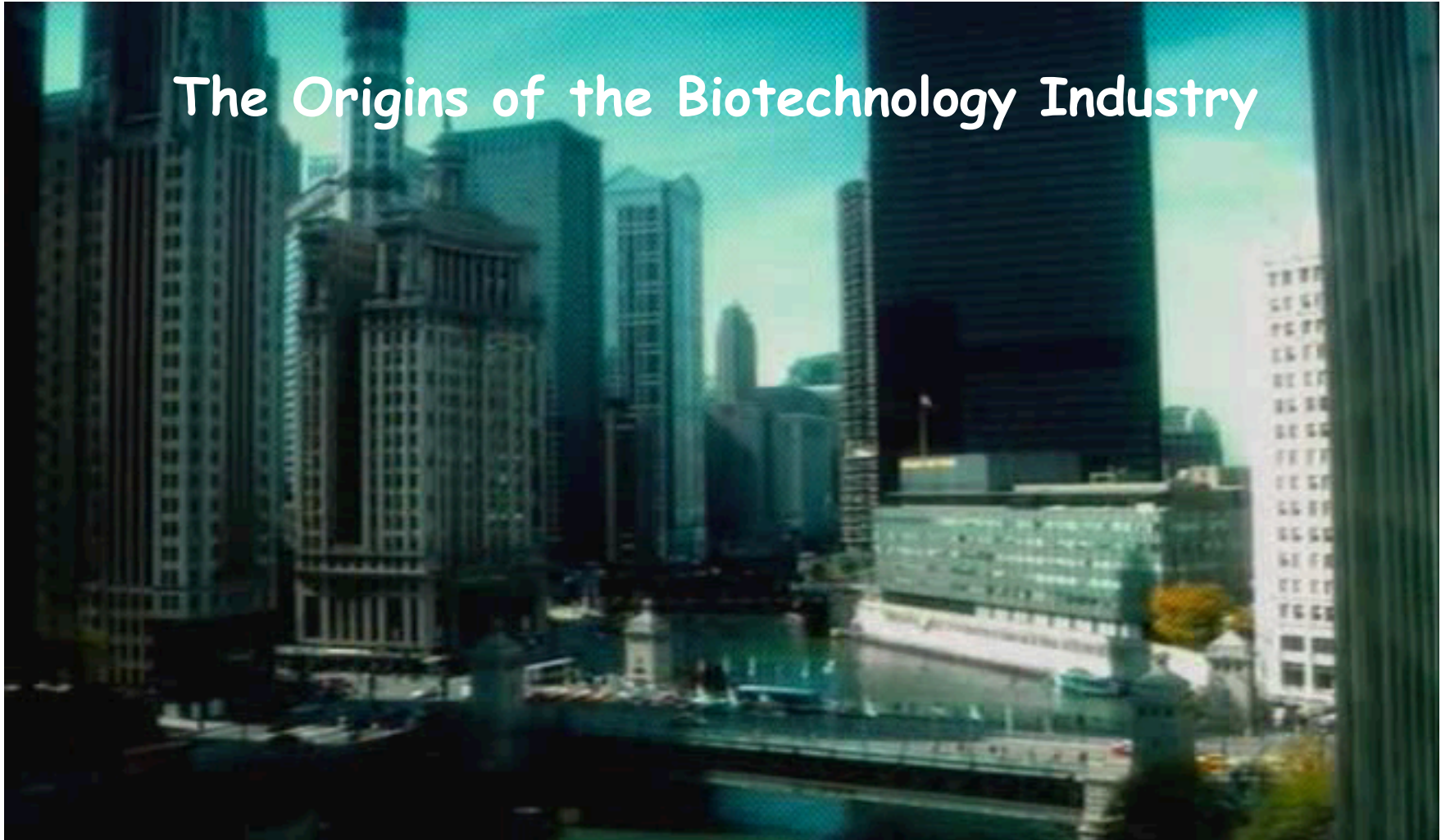


Plants of Tomorrow

Can Genetically Engineered Organisms Be Patented?



The Origins of the Biotechnology Industry



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!

Genetically Engineered Bacteria!

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.³ **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.

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: **Jan. 7, 1972**

[51] Int. Cl.³ **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.

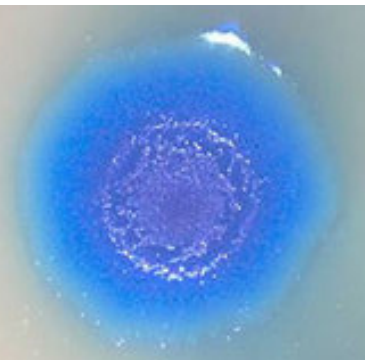
20110045592
A1
February 24, 2011

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.

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 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.
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 2132!*

Copyrights©

1. A Form of Protection For “Original Works of Authorship-Expression,” Including Literary, Drama, Musical, Artistic, Scientific and Other Intellectual Works-Both Published and Unpublished - including software. ONLY FOR EXPRESSED MATERIAL - NOT IDEAS IN MATERIAL. For example, Apple vs. Microsoft, 1992 (only expression of code protected, not code’s ideas and individual elements of graphics user interface).
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
 - b. Elements of Software Code or Ideas in a Database
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
 - a. EXCEPT FOR FAIR USE (education, criticism, research, scholarship, news reporting)
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, or 95 years if Corporate Authorship, or 120 Years Maximum.

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	

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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^{a,1}, Chen Cheng^{a,1}, Anhthu Q. Bui^{a,1}, Javier A. Wagmaister^{a,2}, Kelli F. Henry^a, Julie Pelletier^b, Linda Kwong^b, Mark Belmonte^b, Ryan Kirkbride^b, Steve Horvath^c, Gary N. Drews^d, Robert L. Fischer^e, Jack K. Okamoto^f, John J. Harada^b, and Robert B. Goldberg^{a,3}

^aDepartment of Molecular, Cell, and Developmental Biology, and ^cDepartment of Human Genetics, David Geffen School of Medicine, University of California, Los Angeles, CA 90095; ^bSection of Plant Biology, Division of Biological Sciences, University of California, Davis, CA 95616; ^dDepartment of Biology, University of Utah, Salt Lake City, UT 84112; ^eDepartment of Plant and Microbial Biology, University of California, Berkeley, CA 94720; and ^fUnited 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

Identification of *cis*-regulatory sequences that activate transcription in the suspensor of plant embryos

© 2009 by The National Academy of Sciences of the USA

Tomokazu Kawashima, Xingjun Wang¹, Kelli F. Henry, Yuping Bi¹, Koen Weterings², and Robert B. Goldberg³

Department of Molecular, Cell, and Developmental Biology, University of California, Los Angeles, CA 90095-1606

Contributed by Robert B. Goldberg, December 27, 2008 (sent for review December 12, 2008) PNAS, February, 2009

Ⓡ 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.**



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. Abandoned after three years of disuse.
4. Can Register with USPTO As Long As Product or Service Crosses State, National, and/or Territorial Boundaries (Lanham Act, 1946).
 - a. Registration Lasts Ten Years With Ten Year Renewals for indefinite period of time.
 - b. Official Registration and Better Protection From Use
 - c. Can Only Use ® If Registered. Can Use TM If Not Registered, But Not Necessary As Use of Mark Confers Rights
 - d. If used only within one state, can follow state registration, but must be used first.
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 if Used a Business (e.g., Amazon.com). No Need to Trademark as each domain name unique website address.
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

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.**

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 (i.e., to prevent everything being reversed engineered)
9. Lasts As Long as Information Kept Confidential





Examples of Intellectual Property Protections General & Genetic Engineering

© ™ ®

Creative Work	Patent	Copyright	Trademark	Trade Secret
Biological Invention	✓			
Idea				✓
Database		✓		✓
Computer Design	✓			✓
Drawing		✓		
Advertisement		✓	✓	
Formula	✓			✓
Logo			✓	
Movie Script		✓		✓
Movie Film		✓		
Writings		✓		
Photograph		✓		
Song		✓		
Web Page		✓	✓	
Web Domain Name *Only if Used as Business			✓*	

Creative Work	Patent	Copyright	Trademark	Trade Secret
Gene in Plasmid	✓			✓
Gene Sequence (*Upheld By Appeals Court in July, 2011)	✓*			✓
Gene Database		✓		✓
Software (*If Part of A Machine/ Technical/Physical Result)	✓*	✓		✓
Transgenic Organism	✓			✓
Biotech Co. Logo			✓	
DNA Perfume	✓		✓	✓
Knome Website (*as a business)		✓	✓*	
DNA Test to Detect CF (*being challenged)	✓*			✓
Research Article		✓		
Stem Cell Line	✓			✓
PCR Technique	✓			✓
Genome Project Website		✓	*Not a Business	
Genes in Human Cell				
Antisense or RNAi Drug	✓		✓	✓

Summary of Intellectual Property Characteristics

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

Patents vs. Trade Secrets?

Patents

1. Society Gains Knowledge
2. Patents Published 18 Months After Filing (Patent Pending Status)
3. Patent Expires After 20 Years

Trade Secrets

1. Prevent Competitors From Gaining Proprietary Information
2. Society Does Not Get Access to Trade Secret Knowledge
3. Limited Protection

Patents vs. Trade Secrets?

Patents

1. Society Gains Knowledge
2. Patents Published 18 Months After Filing (Patent Pending Status)
3. Patent Expires After 20 Years-Society Can Use
4. Patent Law Protection

Trade Secrets

1. Prevent Competitors From Gaining Proprietary Information
2. Society Does Not Get Access to Trade Secret Knowledge
3. Limited Protection

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? 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** (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 (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

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- 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) In Their Natural State

∴ YOUR GENES IN YOUR BODY ARE NOT PATENT ELIGIBLE!

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**∴ THE 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, 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
 - a. Purified Genes (*Just Upheld in the Myriad Case - 2011*)
 - 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. Non-Obvious Improvements on Any of the Above (Different Patent)

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

Utility	<ol style="list-style-type: none">1. Must Have a Practical or Real World Benefit2. Specific and Substantial Utility Credible By Person of Ordinary Skill in The Art3. Commercial Development is NOT Required to Establish Usefulness
Novel	<ol style="list-style-type: none">1. New and Not Anticipated By Prior Art (published works regarding invention-including literature, lectures, and published patents)2. Never Publish or Discuss Your invention Prior to Filing a Patent. If You Do, It is Prior Art and in the Public Domain
Non-Obvious	<ol style="list-style-type: none">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)
Written Description & Best Mode of Practice (Specification & Enabling)	<ol style="list-style-type: none">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)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)3. Must Provide in the Written Description the Best Way (mode) to Use and Practice the Invention4. Written Description and Best Mode of Practice are Part of the <u>Patent Specification</u> Which Includes the Claims (What the Invention is)

Specific Examples

<p>Utility</p>	<ol style="list-style-type: none"> 1. A Purified DNA Molecule With Sequence 5' ACGT3' (composition of matter) - <u>Not Patentable</u>-No Utility 2. A Purified DNA Molecule With Sequence 5' ACGT3' To Be Used As a Diagnostic Marker For Cystic Fibrosis - Patentable-<u>Specific Utility</u>
<p>Novel & New</p>	<ol style="list-style-type: none"> 1. A Method of Producing Recombinant DNA Molecules - <u>Patentable</u> 2. Never Before in Prior Art and not Anticipated By Prior Art (Being Restricted More & More - In re Gleave, 560 F. 3rd 1331 (Fed Cir. 2009))
<p>Non-Obvious</p>	<ol style="list-style-type: none"> 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 2. A Non-Radioactive Probe to Detect DNA Molecules - <u>Patentable</u> Because Not Obvious and Not In Prior Art
<p>Written Description & Best Mode of Practice</p>	<ol style="list-style-type: none"> 1. UC Patent on Rat Insulin cDNA Clone and Sequence 2. Eli Lilly Patent on Human Insulin cDNA to Make Insulin in Bacteria Cells (From Genentech®) 3. UC Sued Eli Lilly For Patent Infringement & Lost 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> 5. UC Patent Written Description <u>Could Not Instruct Others How To Translate Rat cDNA Sequence Into Human Protein Sequence Because of Degeneracy in Genetic Code</u>

US Courts Applying Central Dogma More & More To Biotech Patents

1. Novelty - *In re Gleave* - 2009

If sense oligonucleotide known, anti-sense sequence for probe is not novel as a person having ordinary skill in the art would know what antisense sequence is, and, thus NOT NOVEL.

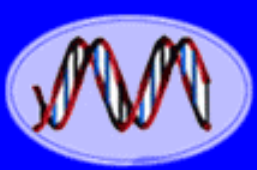
2. Non-Obviousness - *In re Kubin* - 2009

If protein sequence known, DNA coding sequence not novel as a person having ordinary skill in the art would know what coding sequence is, and, thus NOT OBVIOUS.

∴ Courts Applying a More Stringent Test To What is Novel and Not Obvious to a “Central Dogma-Related” Patent Application

How Does The Patent Process Work?

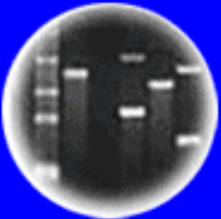
1. Patent Application Filed At USPTO in Washington and/or in Other Countries (e.g., EPO or European Patent Office)
 - a. Filing Date Critical
 - b. Time Period For Patent Starts When Patent Application Filed (20 Years)
 - c. Europe and Japan-Invention Priority-First To File
 - d. US-First to File Too-*American Invents Law of 2011*
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., *Diamond vs. Chakrabarty Case*)
5. Challenge (Very Expensive)
 - a. Infringement-Someone Illegally Practicing Invention (Country Specific)



DNA
Genetic Code of Life



Entire Genetic Code
of a Bacteria



DNA Fingerprinting



Cloning: Ethical Issues
and Future Consequences



Plants of Tomorrow



THE AMERICA INVENTS ACT:



One Hundred Twelfth Congress of the United States of America

AT THE FIRST SESSION

*Begun and held at the City of Washington on Wednesday,
the fifth day of January, two thousand and eleven*

2011

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.

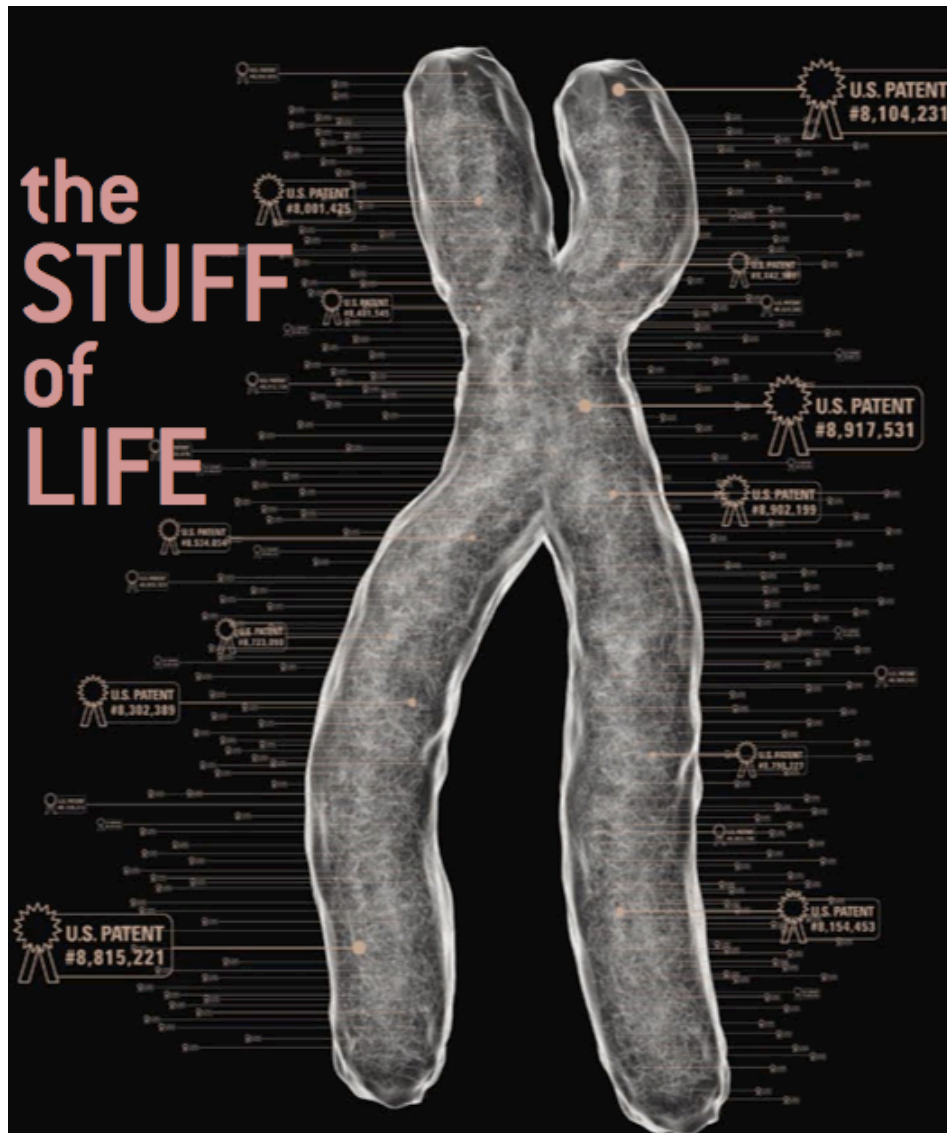
(a) SHORT TITLE.—This Act may be cited as the “Leahy-Smith
America Invents Act”.

(b) TABLE OF CONTENTS.—The table of contents for this Act
is as follows:



UNITED STATES PATENT
AND
TRADEMARK OFFICE

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. If Arrested (in CA) for a Felony - Required to give Cheek Swab for DNA Testing

However...What About Purified Genes?

Purified Genes And Their Sequences Are Patent-Eligible Material in the United States

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
 - iv. 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

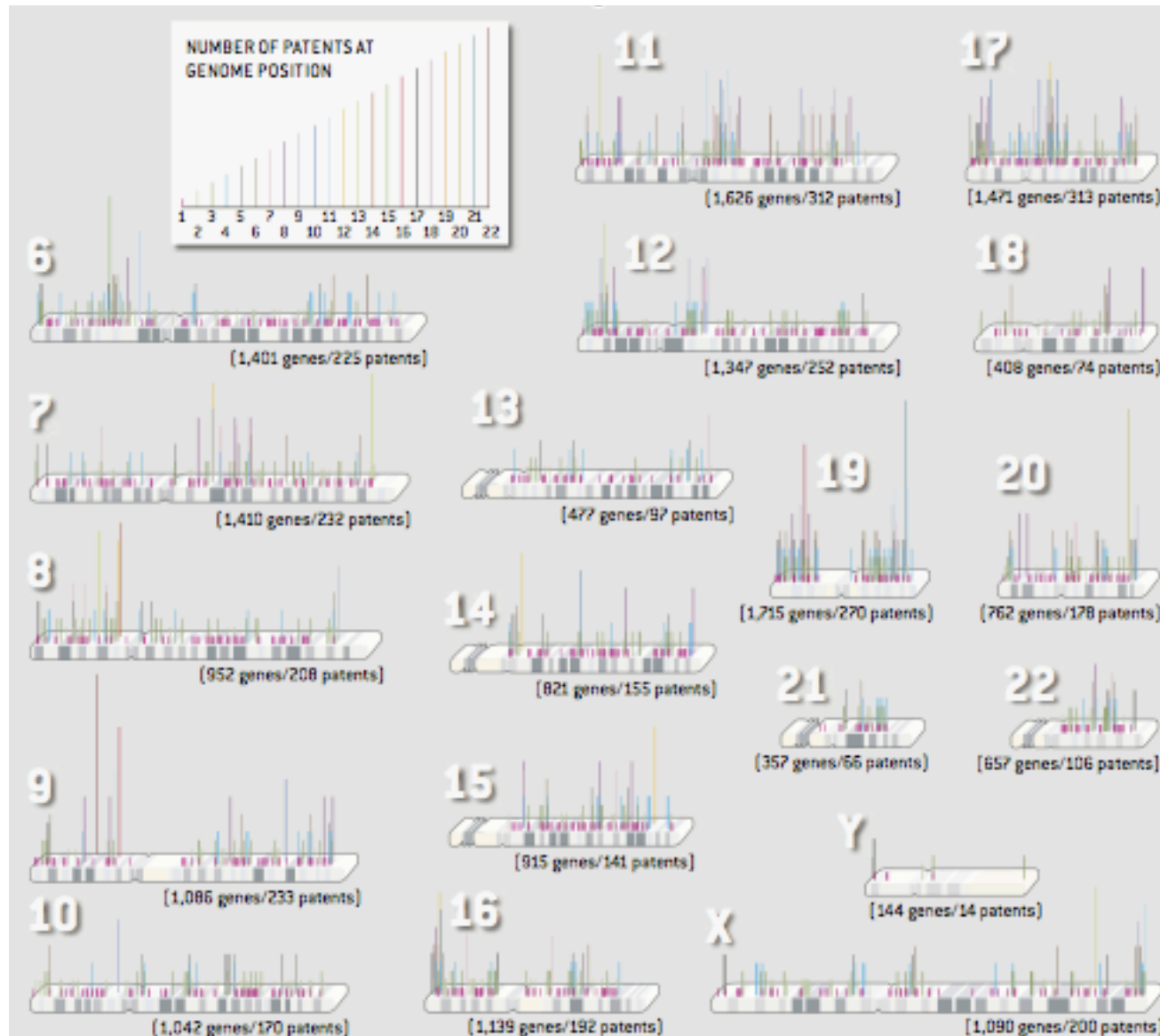
Abstract

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

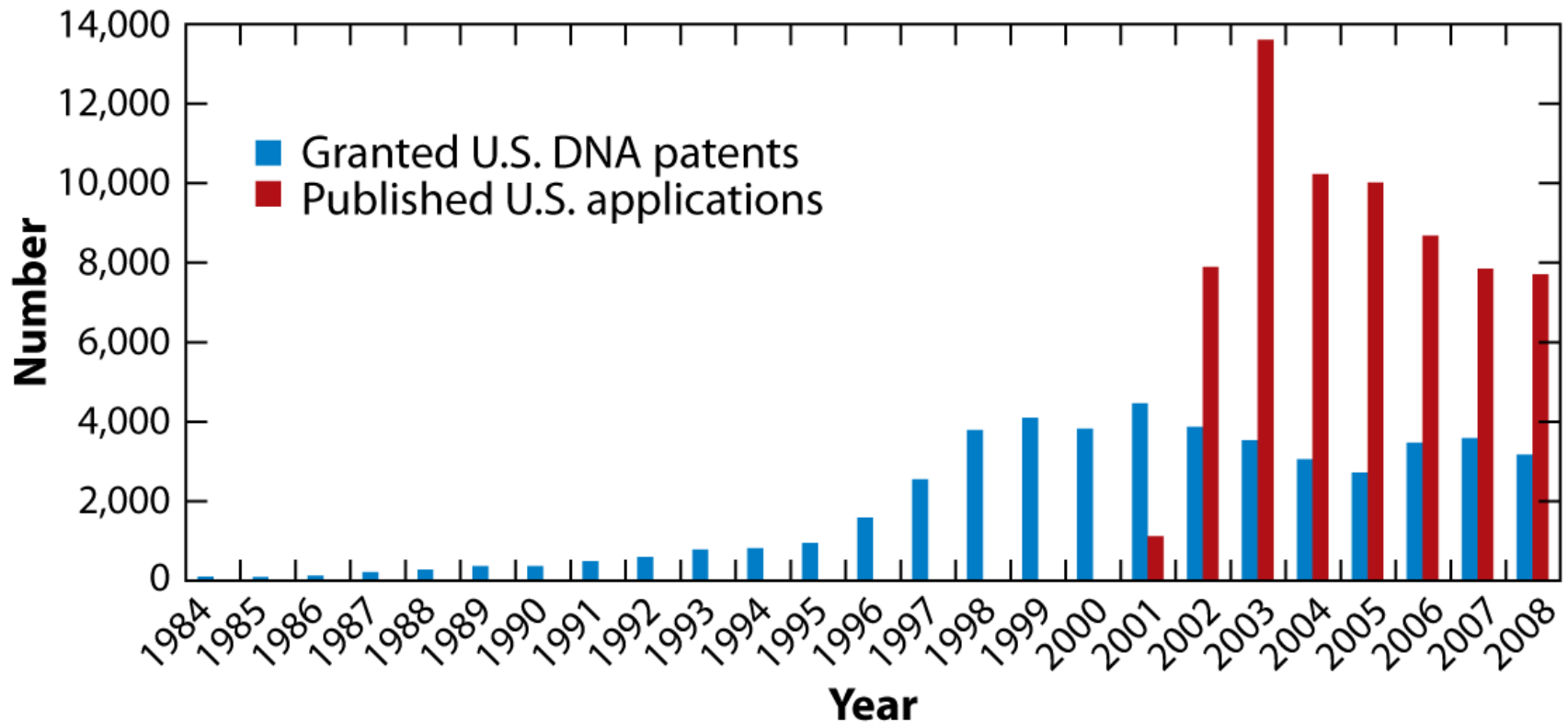
Inventors: **Weterings; Koen** (Nijmegen, NL), **Apuya; Nestor R.** (Culver City, CA), **Goldberg; Robert B.** (Topanga, CA)
Assignee: **The Regents of the University of California** (Oakland, CA)
Appl. No.: **09/724,857**
Filed: **November 28, 2000**



Who Owns Your Genes: Human Gene Patents



Gene and DNA Patents

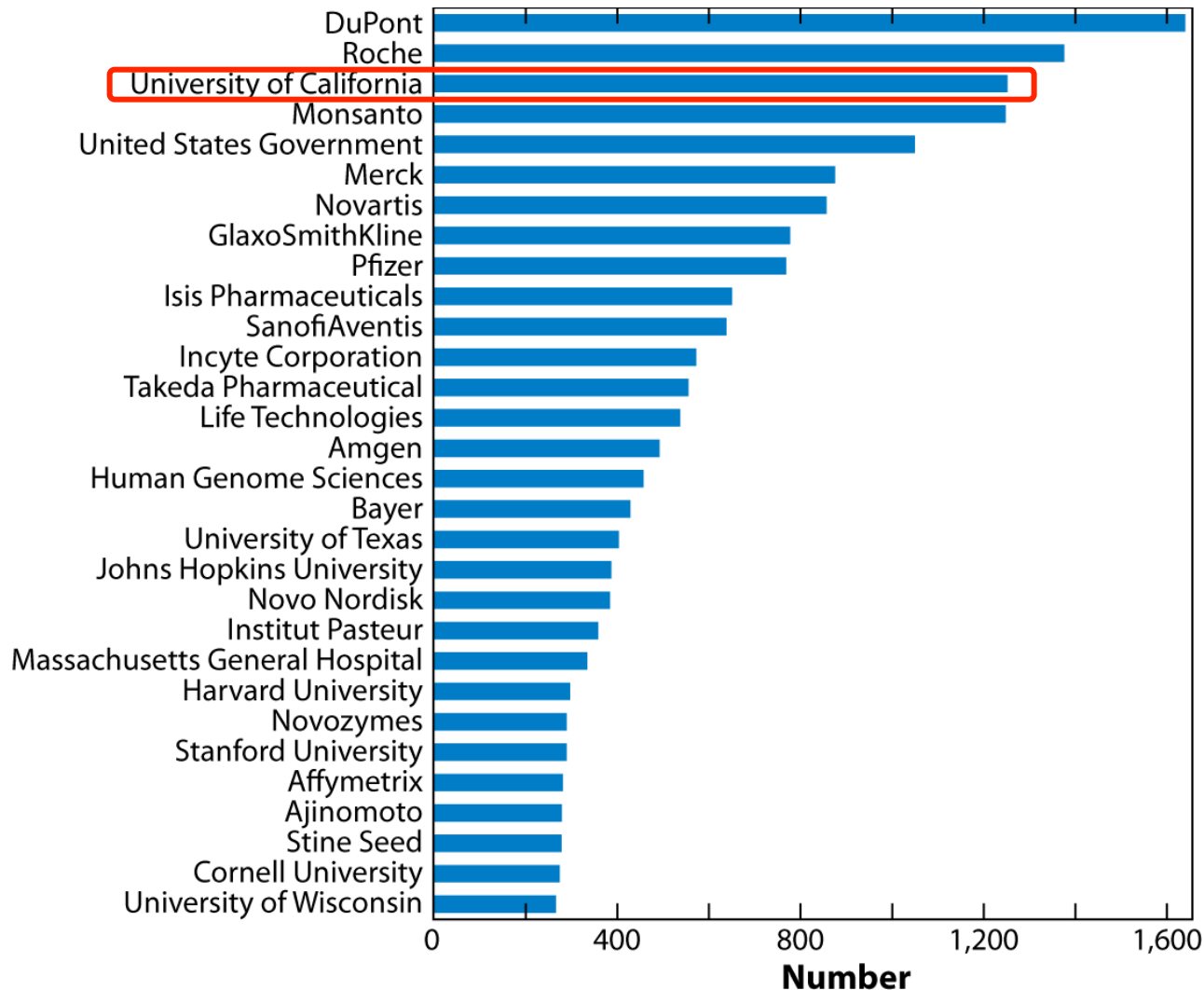


AR

Cook-Deegan R, Heaney C. 2010.

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

Top US DNA Patent Holders



Cook-Deegan R, Heaney C. 2010.

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

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.

A Case To
Test the
Patent
Eligibility of
Isolated
Genes!

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.

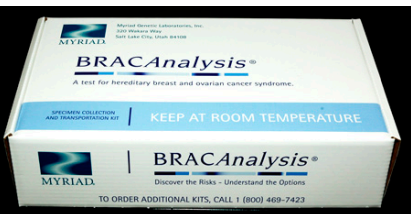
Linked breast and ovarian cancer susceptibility gene

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.



**Myriad Breast Cancer Gene Patent Challenge
2009-2011**

Was Challenged in Federal Courts

Europe revokes controversial gene patent

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

A controversial patent on a breast cancer gene has been revoked by the European Patent Office, paving the way for cheaper screening across the continent. The verdict reflects the transatlantic disparities that make gene patents much tougher to uphold in Europe than in the US.

May 13, 2009

Cancer Patients Challenge the Patenting of a Gene *BRCA1 & BRCA2*

By [JOHN SCHWARTZ](#)

When Genae Girard received a diagnosis of [breast cancer](#) in 2006, she knew she would be facing medical challenges and high expenses. But she did not expect to run into patent problems.

Ms. Girard took a genetic test to see if her genes also put her at increased risk for [ovarian cancer](#), which might require the removal of her ovaries. The test came back positive, so she wanted a second opinion from another test. But there can be no second opinion. A decision by the government more than 10 years ago allowed a single company, [Myriad Genetics](#), to own the patent on two genes that are closely associated with increased risk for breast cancer and ovarian cancer, and on the testing that measures that risk.

On Tuesday, Ms. Girard, 39, who lives in the Austin, Tex., area, filed [a lawsuit](#) against Myriad and the Patent Office, challenging the decision to grant a patent on gene to Myriad and companies like it. She was joined by four other cancer patients, by professional organizations of pathologists with more than 100,000 members and by several individual pathologists and genetic researchers.

**Only Gene Patents
Challenged, Not
cDNA Patents**

- a. Not Patentable Subject Matter - Natural Substance-Not Made By "Hands of Man"
- b. First Amendment - Freedom of Thought - Restricts Freedom to Think/Inquire

ACLU CHALLENGE & CANCER PATENT CLASS ACTION

Court upholds patenting of genes in Myriad case

Fri, Jul 29 2011

By Julie Steenhuysen

CHICAGO (Reuters) - A federal appeals court affirmed the right of Myriad Genetics to patent two genes linked to breast cancer, overturning a lower court ruling that threatened a key element of the biotech business.

July 29, 2011

Ruling Upholds Gene Patent in Cancer Test

By ANDREW POLLACK

The court ruled that DNA isolated from the body was eligible for patents because it was “markedly different” in its chemical structure from DNA that exists inside the chromosomes in the body. As a result, the isolated DNA is not simply a product of nature, which would not be eligible for a patent.

March 29, 2010

Judge Invalidates Human Gene Patent

By JOHN SCHWARTZ and ANDREW POLLACK

A federal judge on Monday struck down patents on two genes linked to breast and ovarian cancer. The decision, if upheld, could throw into doubt the patents covering thousands of human genes and reshape the law of intellectual property.

United States District Court Judge Robert W. Sweet issued the 152-page decision, which invalidated seven patents related to the genes BRCA1 and BRCA2, whose mutations have been associated with cancer.

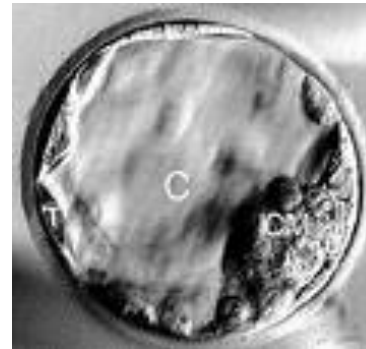
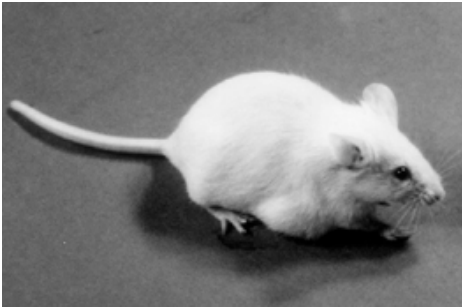
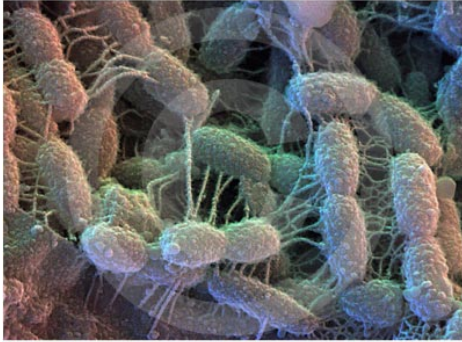
Oct 30, 2010

US Government Argues in Court that Isolated Genes are Unpatentable

AMP v. Myriad (Fed. Cir. 2010)

In March, 2010, District Court Judge Robert Sweet held Myriad's gene patent claims invalid for failing to satisfy the subject matter eligibility requirements of 35 U.S.C. 101. The ruling was directed toward claims that cover particular isolated DNA molecules (genes) and processes of detecting and screening for those genes, but was written broadly enough to essentially invalidate all patents covering genes that were isolated from an organism.

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

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. Streptocmyces velosus producing antibiotics-In Re Bergy (1977)
 - b. Purified Yeast Free of Organic Germs 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

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

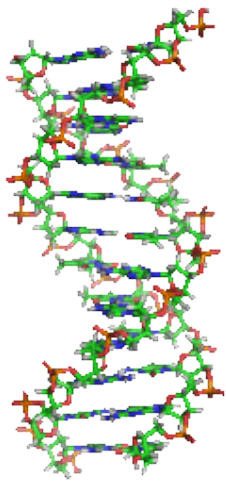
Patent Laws in US Guided By Constitution and US Statutes. Can Be Changed By Congress. Morally Neutral System That Has 600 Years of Tradition. Fed. Reg. 66, January 5, 2001

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

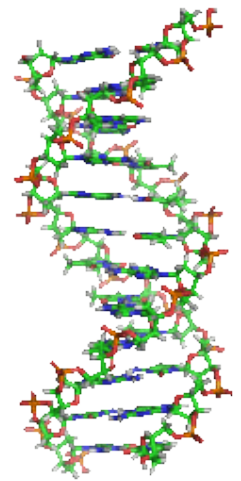
To the Contrary.....Patent Laws REQUIRE Disclosure of the Invention (Written Description & Best Mode of Practice) And ARE PUBLISHED 18 Months After Filing Application. *Alternative Would be Trade Secrets!*

∴ 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!

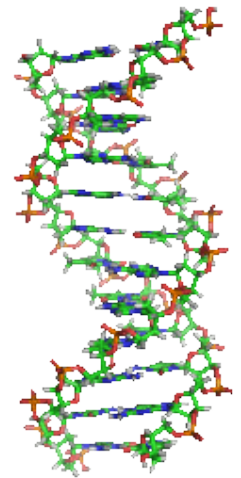
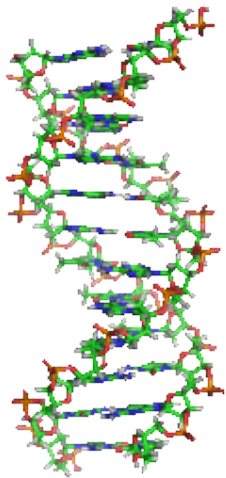


Recall...Way Back in January...



The Age of DNA!

Genetic Engineering Is
Manipulating DNA!

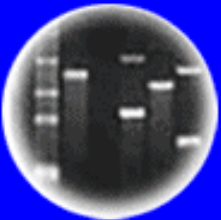




DNA
Genetic Code of Life



Entire Genetic Code
of a Bacteria



DNA Fingerprinting



Cloning: Ethical Issues
and Future Consequences



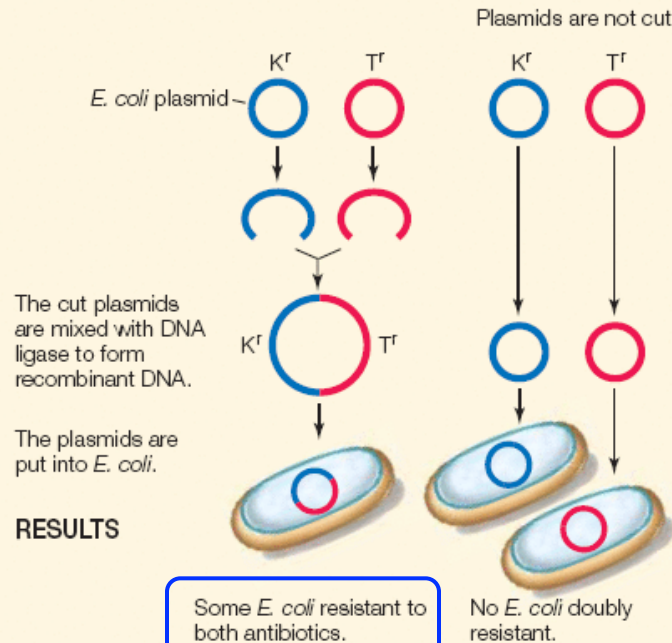
Plants of Tomorrow

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!

Production of healthy cloned mice from bodies frozen at -20°C for 16 years

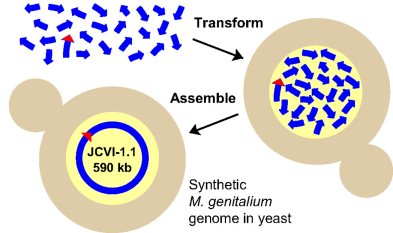
Sayaka Wakayama^a, Hiroshi Ohta^a, Takafusa Hikichi^a, Elji Mizutani^a, Takamasa Iwaki^b, Osami Kanagawa^a, and Teruhiko Wakayama^{a,1}

^aRIKEN, Center for Developmental Biology, 2-2-3 Minatojima-minamimachi, Kobe, 650-0047, Japan; ^bHokkaido University School of Medicine, Tokyo 115-8461, Japan; and ^cRIKEN, Research Center for Allergy and Immunology, 1-7-22, Suihro-cho, Tsurumi-ku, Yokohama, 230-0045, Japan

Analysis of one million base pairs of Neanderthal DNA

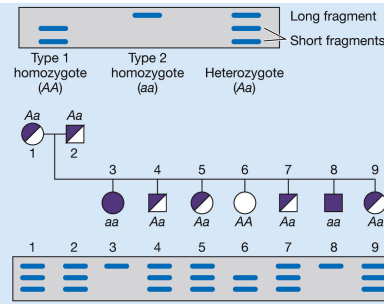
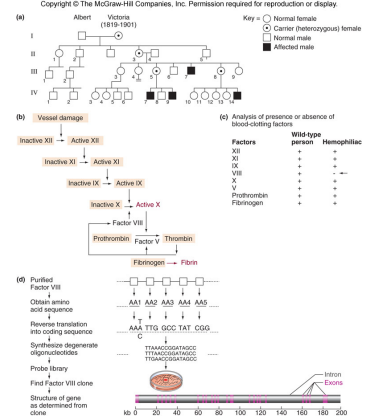
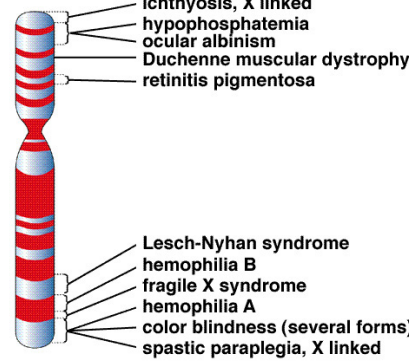
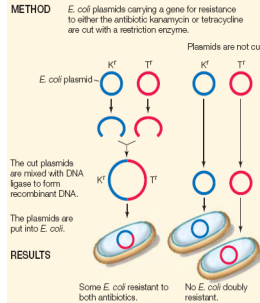
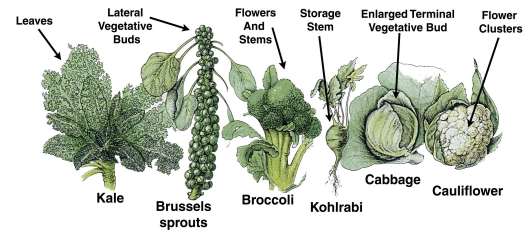
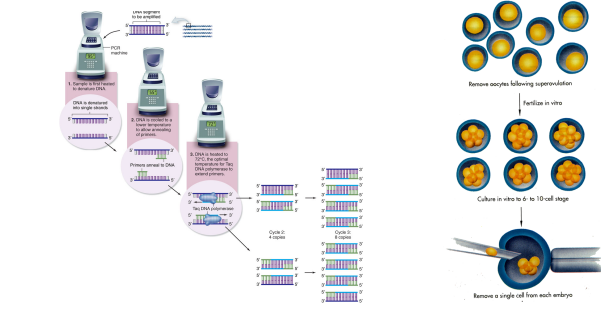
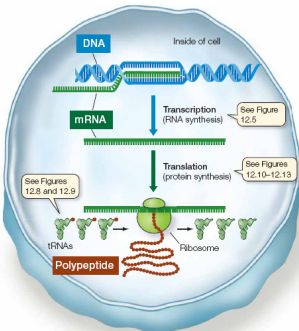
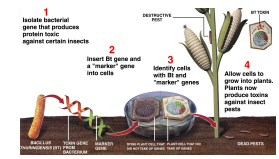
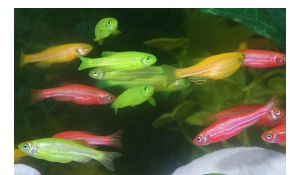
Richard E. Green¹, Johannes Krause¹, Susan E. Ptak¹, Adrian W. Briggs¹, Michael T. Ronan², Jan F. Simons², Lei Du², Michael Egholm², Jonathan M. Rothberg², Maja Paunovic³ & Svante Pääbo¹

25 overlapping DNA fragments
A1-4, A5-8, etc. (17-35 kb)

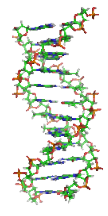


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Map of chromosome X

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

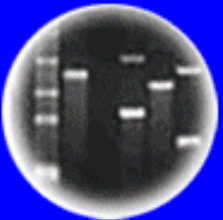




DNA
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Entire Genetic Code
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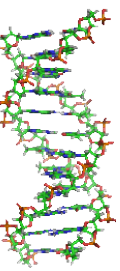
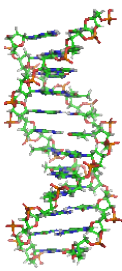
DNA Fingerprinting



Cloning: Ethical Issues
and Future Consequences



Plants of Tomorrow



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

HC70A & SAS70A
Winter 2012
The End!!

OR

Is It the Beginning?

