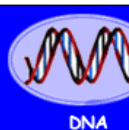


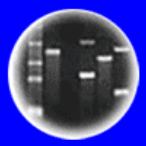

HC70A & SAS70A
Spring 2017
Genetic Engineering in Medicine, Agriculture, and Law

Professors Bob Goldberg & John Harada

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

DNA
Genetic Code of Life

Entire Genetic Code of a Bacteria



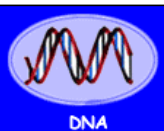
DNA Fingerprinting

Cloning: Ethical Issues and Future Consequences

Plants of Tomorrow

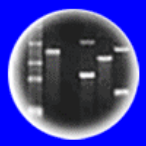
UCLA

UCDAVIS
UNIVERSITY OF CALIFORNIA



DNA
Genetic Code of Life

Entire Genetic Code of a Bacteria



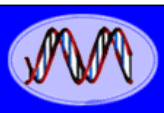
DNA Fingerprinting

Cloning: Ethical Issues and Future Consequences

Plants of Tomorrow

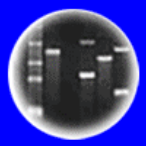
THEMES

1. The Constitution & Intellectual Property
2. A History of Patents
3. What is Intellectual Property?
4. What Are the Different Forms of Intellectual Property?
5. What Are Patents?
6. What Are Copyrights?
7. What Are Trademarks and Service Marks?
8. What Are Trade Secrets?
9. When Are Different Forms of Intellectual Property Used in Genetic Engineering?
10. American Invents Act-First to File vs. First to Invent-CRISPR War
11. What Can be Patented?
12. What Are the Criteria to Obtain a Patent?
13. Who Makes and Interprets Patent Laws?
14. Infringement - Do Patents Carry Over to Offspring? Monsanto Case
15. Infringement – Written Description - Eli Lilly Case
16. Is the US Patent System Morally Neutral?
17. Landmark Genetic Engineering Patent Cases
18. Can Genes Be Patented? Myriad Case
19. Can Genetic Tests Be Patented? Prometheus Case
20. Does the Patent System Stifle Innovation?
21. Reflections on Genetic Engineering
22. What's a GMO?



DNA
Genetic Code of Life

Entire Genetic Code of a Bacteria



DNA Fingerprinting

Cloning: Ethical Issues and Future Consequences

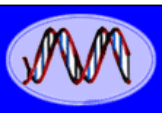
Plants of Tomorrow

TEXT READING

Chapter 12
Pages 314-317

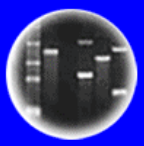
SELECTED PATENT REFERENCES

1. *United States Patent and Trademark Office (www.uspto.gov)*
2. *Patent, Copyright, & Trademark, By R. Stim, 14th Edition (2016)*
3. *Federal Register, USPTO Gene Utility Guidelines, Volume 66 (4), January 5, pages 1092-1099 (2001)*
4. *United States Patent and Trademark Office, Guidance For Subject Matter Eligibility Analysis For Claims Involving Laws of Nature and/or Natural Products (e.g., genes). (www.uspto.gov), March 4, (2014) (New Myriad Case Rules)*
5. *United States Patent and Trademark Office, Interim Guidance on Patent Subject Eligibility, Federal Register, Volume 79 (241), December 16, 2014*
6. *A Patent Perspective on US Human Stem Cell Research. Nature Biotech. 32, 633-637 (2014)*
7. **** Mayo vs. Prometheus, Supreme Court Decision, March 12 (2012)*
8. ****Association For Molecular Pathology vs. Myriad Genetics, Supreme Court Decision, June 13 (2013)*
9. ****Bowman vs. Monsanto, Supreme Court Decision, June 13 (2013)*
10. ****The History of Patenting Genetic Material, By Jacob E. Cherkow & Henry T. Greely , Annu. Rev. Genetics, 49, 161-182 (2015)*
11. *Diagnostics Need Not Apply, By Rebecca S. Eisenberg, J. Science & Technology Law, 21.2 (2015)*
12. *United States Patent and Trademark Office, July 2015 Update on Subject Eligibility, Federal Register, Volume 80 (146), July 30, 2015*
14. *USPTO Report to Congress on Confirmatory Genetic Diagnostic Test Activity, 2015*



DNA
Genetic Code of Life

Entire Genetic Code of a Bacteria



DNA Fingerprinting

Cloning: Ethical Issues and Future Consequences

Plants of Tomorrow

Patents Relevant to Genes, Genetic Engineering, & Biotechnology in the News

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

MONSANTO
BIOTECHNOLOGY
innovation – collaboration – speed

INTELLECTUAL PROPERTY

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

Monsanto Wins Case on Genetically Altered Soybeans

Gene Patents Draw High Court Review in Biotechnology Test

US Supreme Court upends diagnostics patents

PROMETHEUS®
Therapeutics & Diagnostics

Justices, 9-0, Bar Patenting Human Genes

MYRIAD

How Do Patent Legal Disputes Wind Up in The Supreme Court?

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

Article I - Section 8.18

The Congress shall have the Power:

[18] "To make all Laws which shall be necessary and proper for carrying into Execution the forgoing Powers, and all other Powers vested by this Constitution in the Government of the United States, or in any Department or Officer thereof.

Key Concept: Congress Established Patent and Trademark Office (USPTO) and Intellectual Property laws

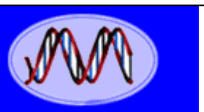
Patent Laws Are Set Forth in Title 35 of US Code - Sections 101, 102, 103, & 112.

How Are Patents Issued and Adjudicated?

US Patent & Trademark Office
Issues Patent

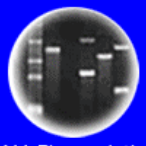
Decision Can Be Appealed to
the Federal Court of Appeals
Federal Circuit

Decision Can Be Appealed to
the Supreme Court



DNA
Genetic Code of Life

Entire Genetic Code
of a Bacteria



DNA Fingerprinting

Cloning: Ethical Issues
and Future Consequences

Plants of Tomorrow

Patent History
Origins & Importance

The United States Can Trace Its Patent Roots Back 600 Years

1. *First Patents Issued in Venice in Early 1400s to Glass Craftsmen – Concept Established*

2. *Current Patent System Originated in 1449 in Great Britain (568 Years Ago!!)*
   a. First Patent to John Utynam of Flanders by King Henry VI
   b. *Method For Cambridge Kings and Eton Colleges' Stained Glass Windows*
   c. Method Not Previously Known in England (Flanders is in Belgium)
   d. King Gave a 20-Year Monopoly to John Utynam in Exchange For Knowledge of His Stained Glass Method

3. *Inventor (John Utynam) Gave Knowledge & Know How to Society in Exchange For a 20-Year Monopoly to His Invention*
   a. He Taught Others in England How to Make Stained Glass
   b. In Exchange Other People Could Not Use His Method Without His Permission ***KEY CONCEPT-BENEFIT TO SOCIETY***

4. *United States Patent System Follows Tradition Established in Great Britain and Passed on the US Colonies*
   a. In US Constitution
   b. Patent Act of 1793 Written and Administered by Thomas Jefferson Laid the Foundation For a Patent System That Exists to this Day
      ii. What is Patentable Subject Matter ("Any New or Useful Art, Machine, Manufacture, or Composition of Matter")
      iii. What Invention Must be Written in Patent (e.g., Written Description)-***KEY CONCEPT-OTHERS CAN KNOW WHAT THE INVENTION IS AND BUILD UPON IT-SOCIETY CAN PROGRESS***

The First United States Patent Issued-*Notice Signature*

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

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 Pensylvania 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, 2d by dissolving and boiling them when so burnt in Water, 3rd 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, entituled "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.

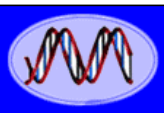
G. Washington

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.

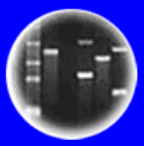
Edm: Randolph Attorney General for the United States.

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



DNA
Genetic Code of Life

Entire Genetic Code of a Bacteria



DNA Fingerprinting

Cloning: Ethical Issues and Future Consequences

Plants of Tomorrow

What Are the Different Types of Intellectual Property?

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

1. Patent
2. Copyright
3. Trademark or Service Mark
4. Trade Secret

What Are Patents?

1. A patent is the grant of a property right to the inventor, issued by the USPTO, that allows the patent owner to maintain a monopoly for a limited period of time on the use and development of the invention.

2. The right to EXCLUDE OTHERS from making, using, offering for sale, or selling, the invention in the United States or "importing" the invention into the United States
   (e.g., can't make in another country & important 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 2037.

"How to Make bobg" US patent No. 7,989,755, June 6, 2017

© What Are Copyrights?

The bobg HC70A Lectures©

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. Copyright created the moment the work assumes tangible form.

2. Protects the *form of expression* and not the subject matter of the writing. Must be original, have some form of creativity, and be fixed in tangible medium.

3. A copyright gives the owner of a creative work the right to EXCLUDE 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 from first publication, or 120 years from time of creation, whichever is shorter. Created today, then operative until 2137!*

5. *There are NO international copyrights. However, US copyrights are protected in other countries by treaties (e.g., Berne Convention)*

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 & Handouts)	Works With No Creativity (e.g., Phone Book, List of Names)
Video Games	Facts and Ideas in Databases
Computer Program (Software)	Software Elements and Algorithms
Factual Databases	

What Can and Cannot Be Copyrighted?

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	Facts and Ideas in Databases
Computer Program	Software Elements and Algorithms
Architectural and Design Works	

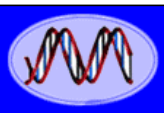
® What Are Trademarks & Service Marks? TM

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).

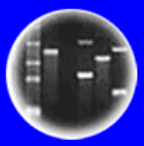
3. Trademark law-decisions of state and federal courts + US statutes-is applied to resolve disputes when competing businesses adopt similar product names or logos (Lanham Act).

4. Not in Constitution.



DNA
Genetic Code of Life

Entire Genetic Code of a Bacteria



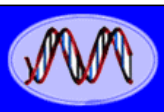
DNA Fingerprinting

Cloning: Ethical Issues and Future Consequences

Plants of Tomorrow

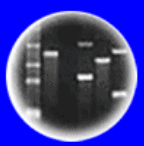
Should Trademarks Be Permitted on Team Names Such as the Washington Redskins and Cleveland Indians?

a. Yes
b. No



DNA
Genetic Code of Life

Entire Genetic Code of a Bacteria



DNA Fingerprinting

Cloning: Ethical Issues and Future Consequences

Plants of Tomorrow

Trade Mark vs. 1st Amendment?

Supreme Court rejects Redskins' trademark appeal case

The Supreme Court announced today (2106) that it would not take up an appeal by the Washington Redskins concerning the constitutionality of a federal law that directs the United States Patent and Trademark Office to refuse the registration of a trademark that disparages "persons, living or dead, institutions, beliefs, or national symbols."

What Are Trade Secrets?

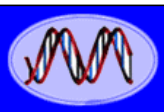
1. INFORMATION that companies keep secret to give them an advantage over their competitors.

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.

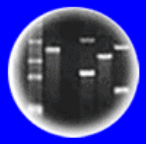
4. Trade Secret Law-decisions of state and federal courts + US statutes-plus-criminal anti-theft statutes.

5. Not in Constitution.



DNA
Genetic Code of Life

Entire Genetic Code of a Bacteria



DNA Fingerprinting

Cloning: Ethical Issues and Future Consequences

Plants of Tomorrow

How Are Trade Secrets Protected?

Non-Disclosure Agreements (NDAs) & Theft Laws

- Defend Trade Secrets Act of 2016
- Economic Espionage Act of 1996
- Uniform Trade Secrets Act of 1979
- California Trade Secrets Act of 1995

CHINESE-AMERICAN PLEADS GUILTY TO STEALING GENETICALLY-ENGINEERED SEEDS

A US jury just convicted two men for selling a secret Oreo-whitening technique to China

Justice Department Victory in Convictions for Theft of DuPont Titanium Dioxide Secrets Intended to Benefit Chinese-Owned Company

Patents vs. Trade Secrets?

Patents	Trade Secrets
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	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	Trade Secrets
1. Society Gains Knowledge 2. Patents Published 18 Months After Filing (Patent Pending Status) 3. Patent Expires After 20 Years	1. Prevent Competitors From Gaining Proprietary Information 2. Society Does Not Get Access to Trade Secret Knowledge 3. Limited Protection

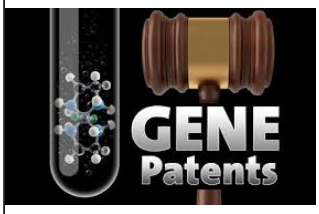
Patent vs. Trade Secret?

SUPREME COURT OF THE UNITED STATES

Syllabus

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

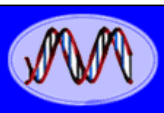
Justices, 9-0, Bar Patenting Human Genes



MYRIAD
GENE PATENT LITIGATION

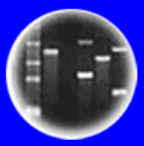
Summary of Intellectual Property Characteristics

Patent	· Constitutional Right · Protects Inventions · Right to Exclude Others From Using Invention · No Right to Make $
Copyright	· 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	· 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	· Legislated Right · Protects Anything By Virtue of Secrecy/Confidentiality/Privacy



DNA
Genetic Code of Life

Entire Genetic Code of a Bacteria



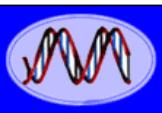
DNA Fingerprinting

Cloning: Ethical Issues and Future Consequences

Plants of Tomorrow

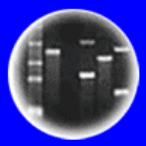
Examples of Intellectual Property Protections For Genetic Engineering

Creative Work	Patent	Copyright	Trademark	Trade Secret
Gene in Plasmid (*Only If Different From Natural Sequence)	√*			√
Gene Sequence (*Only If Different From Natural Sequence)	√*			√
Gene Database		√	√	√
DNA Software (*If Part of A Machine/Technical/Physical Result)	√*	√	√	√
Transgenic Organism	√			√
Biotech Co. Logo			√	
23 & Me Website (*As a Business)		√	√*	
DNA Test to Detect CF			√	√
Research Article		√		
Stem Cell Line (* In USA)	√*			√
PCR Technique	√			√
Genome Project Website		√		
CRISPER Technique	√			√



DNA
Genetic Code of Life

Entire Genetic Code of a Bacteria



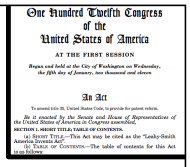
DNA Fingerprinting

Cloning: Ethical Issues and Future Consequences

Plants of Tomorrow

How Does the Patent System Work?

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

An Act

To amend title 35, United States Code, to provide for patent reform.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

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

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

American Invents Acts of 2011

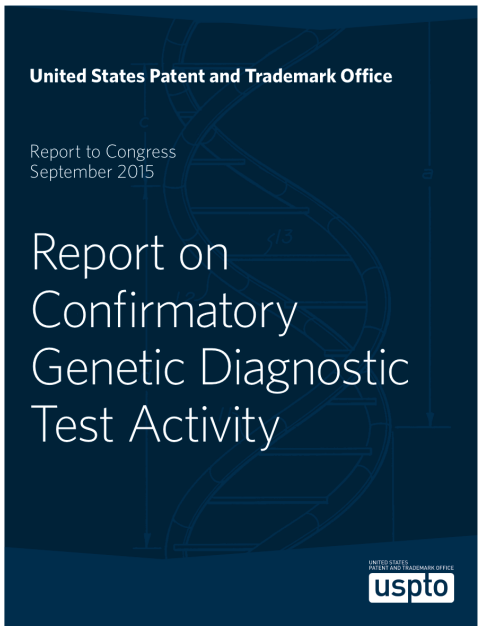
President Barack Obama signs the America Invents Act September 16, 2011, at Thomas Jefferson High School for Science and Technology in Alexandria, VA.

- Biggest Change in US Patent System in 60 Years
- To Make US Patents Consistent With Those of Other Countries
- First To File
- Patent Runs For 20 Years (14 Years For Design Patent)
- No Patents on Human Organisms
- Requires USPTO To Issue a Report on Second Opinion Gene Diagnostic Tests
- Started on March 16, 2013

THE AMERICA INVENTS ACT:

USPTO Guidance on Genetic Diagnostic Tests

THE AMERICA INVENTS ACT:



Although the evidence on each of these points was limited in its scope and mixed in its implications, recent Supreme Court decisions make it unlikely that exclusive provision of a diagnostic test, whether for an original diagnosis or to confirm the original result, will be possible based on patenting and licensing behavior. Patients seeking independent confirmation of diagnostic results will almost certainly be able to find it as long as the demand level for the test (or research interest in the particular gene or condition) supports a market for multiple test providers. For this reason, much of the USPTO's factual findings may now be superseded by intervening judicial decisions. In view of the altered legal landscape, the USPTO's recommendations to Congress are limited in scope.

PROMETHEUS® Therapeutics & Diagnostics

MAYO CLINIC

THE AMERICA INVENTS ACT:

Interference Under Old System

THE AMERICA INVENTS ACT:

United States Patent	8,697,359
Zhang	April 15, 2014

CRISPR-Cas systems and methods for altering expression of gene products

Broad Institute wins bitter battle over CRISPR patents
2017

CRISPR Patent Fight Now a Winner-Take-All Match

UC Appealing Patent Decision by USPTO

Lab notebooks could determine who was first to invent a revolutionary gene-editing technology.

Battle Being Fought Under the Old System of *First to Invent*

The US Patent System

1. Exclusive Rights Granted To an Inventor For a Limited Period of Time (20 years) to Exclude Others From Making, Using, Offering For Sale, Selling, or Importing the Invention

2. Country Specific
   a. Can't Block Someone From Making. Using, or Selling Invention In Another Country If Not Patented in That Country
   b. Can't Be Imported, However, Into The Patent Country
   c. Can File a PCT (Patent Cooperative Treaty) Application

3. Claims in Invention Set Nature of Protection-What is Claimed in the Invention? READ CLAIMS!!!

4. Can Be Sold, Traded, Assigned to Others Like Any Property Right

5. Patent Property Right is Owned For Only a Limited Period of Time-Time-Dependent Monopoly (20 Years)
   a. Invention Ultimately Belongs to Society

6. Lasts 20 years From Time of Filing

7. Governed By Constitution and Federal Laws

What is a Patentable Invention?

35 U.S.C. 101 (Note: United Sates 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

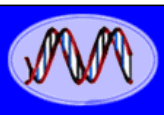
What Can Be Patented?

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

What Are the Different Types of Patents?

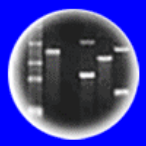
Specified in the Claims

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. Engineered 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



DNA
Genetic Code of Life

Entire Genetic Code of a Bacteria



DNA Fingerprinting

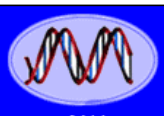
Cloning: Ethical Issues and Future Consequences

Plants of Tomorrow

You Have Isolated an Insulin cDNA, Inserted It Into a Plasmid, and Transformed *E. Coli* With the Insulin cDNA Plasmid.

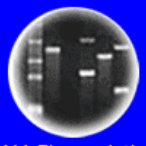
What Type of Patents Are You Able to Obtain?

Patent	Type
Insulin cDNA	Method
cDNA Sequence	Composition of Matter
Recombinant Insulin *E. coli*	Article of Manufacture
Use in Making Human Insulin	Method



DNA
Genetic Code of Life

Entire Genetic Code of a Bacteria



DNA Fingerprinting

Cloning: Ethical Issues and Future Consequences

Plants of Tomorrow

You Have Isolated an Insulin cDNA, Inserted It Into a Plasmid, and Transformed *E. Coli* With the Insulin cDNA Plasmid.

What Type of Patents Are You Able to Obtain?

Patent	Type
Insulin cDNA	Method
cDNA Sequence	Composition of Matter
Recombinant Insulin *E. coli*	Article of Manufacture
Use in Making Human Insulin	Method

What Are the Criteria For Granting a Patent?

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

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

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

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

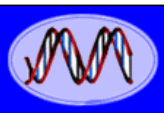
What Are the Criteria For Granting a Patent?

1. Must Be Patent-Eligible Material
2. Must Have Specific, Substantial, and Credible Utility
3. Must Be Novel and New
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.

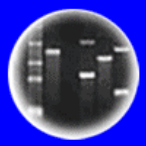
- A Patent Is Only Valid in Country Where Issued. Each Country Has Its Own Set of Criteria

- 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



DNA
Genetic Code of Life

Entire Genetic Code of a Bacteria



DNA Fingerprinting

Cloning: Ethical Issues and Future Consequences

Plants of Tomorrow

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

a. Yes
b. No

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
   g. CRISPR Procedure

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 *(UNCERTAIN NOW DUE TO MYRIAD CASE)*
   a. Purified Proteins (e.g., adrenaline-epinephrine-Parke-Davis vs. Mulford & Co., 1912-Judge Learned Hand)
   b. Purified Natural Substances (e.g., aspirin-salicylic acid, strawberry flavoring-In Re Katz-1979)
   c. Purified Microorganisms (e.g., pure culture of antibiotic-producing bacteria-In Re Bergy-1977)
   d. NOT DNA Sequences Identical to What is in Chromosomes (Myriad, 2013)

5. Non-Obvious Improvements on Any of the Above (Different Patent)

What Is Not Patent-Eligible Subject Matter?

A Critical Criterion For Genes & Gene Tests

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 & diagnostic tests)

∴ Your Genes Are Not Patent Eligible Subject Matter - In or Out of YOUR BODY!

∴ Nor Are Gene Diagnostic Tests!

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

Utility (Claims)	1. Must Have a Practical or Real World Benefit 2. Specific and Substantial Utility Credible By Person of Ordinary Skill in The Art 3. Commercial Development is NOT Required to Establish Usefulness
Novel	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	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)	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 Invention 4. Written Description and Best Mode of Practice are Part of the Patent Specification Which Includes the Claims (What the Invention is)

Specific Examples

Subject Matter	1. A Cloned Gene – Not Patentable - Exists in Nature (Myriad Case) 2. A DNA Diagnostic Test – Uncertain - May Simply be Measuring What is in Nature (Mayo vs. Prometheus Case)
Utility	1. A Purified DNA Molecule With Sequence 5'ACGT3' (composition of matter) - Not Patentable-No Utility 2. A Purified DNA Molecule With Sequence 5'ACGT3' To Be Used As a Diagnostic Marker For Cystic Fibrosis -Not Patentable-Nature
Novel & New	1. A Method of Producing Recombinant DNA Molecules - Patentable 2. Never Before in Prior Art and not Anticipated By Prior Art
Non-Obvious	1. A New Type of Radioactive probe to Detect DNA - Not Patentable-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 - Patentable Because Not Obvious and Not In Prior Art
Written Description & Best Mode of Practice	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 (1997) 4. Federal 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 Violated Written Description Provision 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

How Does The Patent Process Work?

1. Patent Application Filed At USPTO in Washington and/or in Other Countries (e.g. European Patent Office – *Unitary EU Patent*). Can also File a PCT (Patent Cooperation Treaty) Application to Get Filing Date In Other Countries and Opinion on Patentability. Goes to US in 30 Months.
   a. Filing Date Critical
   b. Time Period For Patent Starts When Patent Application Filed (20 Years)
   c. Invention Priority-First To File

2. Patent Application Published After 18 Months and Becomes Prior Art – But Have a One-Year "Grace Period" To Publish Your Own Patent Research Prior to Filing Patent

3. Patent Examiners At USPTO Examine Patent Application
   a. Patent Examiners-At Least a Bachelor's Degree in Technical Field-46% Have PhD. Degrees-Must Work at Least Four years Before given Authority To Review Patent Applications
   b. Review: Patent Eligible? Prior Art? Novel and New? Utility? Non-Obvious? Written Description? Best Mode of Practice? Claims?

4. Review Process (Average of 25 Months)
   a. Send Official Letter Accepting or Rejecting Claims-Some or All
   b. Applicant Can Respond
   c. Final Letter Granting or Rejecting Patent Application
   d. Applicant Can Appeal to Federal Courts (e.g., *Diamond vs. Chakrabarty Case*)

5. Challenge (Very Expensive)
   a. Infringement-Someone Illegally Practicing Invention (e.g., UC vs. Lily)
   b. Interference-I Invented First (e.g., CRISPR War)

The United States Patent System Is "Morally Neutral"

1. Bypasses Public Debate on Social Issues Related To Technology Innovation - *laissez faire* attitude – does not make judgments about what is "good" for society. Courts allow the market to decide which inventions are morally acceptable

2. Patent Can Be Issued Even If Device Is Not In Public Interest (e.g., Car That Pollutes)

3. Congress Makes Laws on What Is Patentable and What Is Not-If You Don't Like It, Write Your Representatives
   a. Specific Criteria For Issuing a Patent Governed By Laws of Congress
   b. Patent Laws Are Administered By the USPTO
   c. Interpreted By the Federal Courts
   d. Example
      i. No patents on any invention or discovery useful solely in utilization of nuclear weapons
      ii. 42 USC 2181

4. European Union (EU) Patents Differ (1998)-"Inventions Are Considered Unpatentable If Their Commercial Exploitation Would Be Contrary to Public "Order" (Policy) or "Morality."

How Are Patents Challenged in the Courts?
Infringement

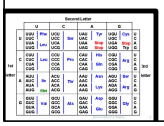
Existing Patents Can Be Challenged Only On:

1. The Criteria For Awarding a Patent (to invalidate the patent) or

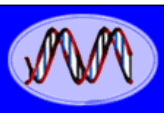
2. If Someone, or Some Entity, is Practicing an Invention in Violation of the Patent (to enforce the patent)

The Written-Description Requirement in *UC v. Lilly*: A Rat Is a Rat Is a Rat...

Nature Biotechnology
January 1998

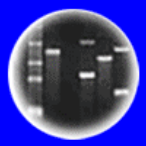


What are the Properties of the Genetic Code?



DNA
Genetic Code of Life

Entire Genetic Code of a Bacteria



DNA Fingerprinting

Cloning: Ethical Issues and Future Consequences

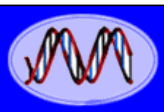
Plants of Tomorrow

Regents of the University of California v. Eli Lilly and Co

UC sued Eli Lilly and Co. for infringing two of UC's patents allegedly covering Lilly's human insulin product. One of these patents, U.S. Patent No. 4,652,525 ("the '525 patent"), claimed the "cDNA" sequence for human insulin.

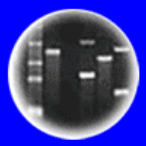
The specification [the part of the patent describing the invention] shall contain a *written description* of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same . . . .

In its decision, the Federal Circuit first addressed UC's claim to *human* proinsulin cDNA. The Court explained that although the '525 patent provided a hypothetical method of obtaining such human cDNA-which may or may not have worked-it does *not* provide a written description of the cDNA itself. The Court stated that the term "cDNA" appearing in the patent does not satisfy the written-description requirement, and that the specification did not provide any information regarding the relevant structure or physical characteristics of the cDNA encoding human proinsulin or the actual nucleotide sequence. As stated by the Court, "describing a method of preparing a cDNA or even describing the protein that the cDNA encodes . . . does not necessarily describe the cDNA itself." Accordingly, the Court held that the specification did not provide a written description supporting UC's claims for human proinsulin cDNA.



DNA
Genetic Code of Life

Entire Genetic Code of a Bacteria



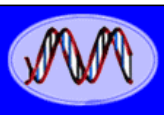
DNA Fingerprinting

Cloning: Ethical Issues and Future Consequences

Plants of Tomorrow

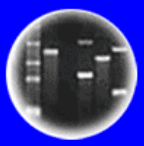
Should Farmers Be Able To Collect Patent-Protected Seeds in Their Fields, and Plant the Next Year Without Paying a Royalty?

a. Yes
b. No



DNA
Genetic Code of Life

Entire Genetic Code of a Bacteria



DNA Fingerprinting

Cloning: Ethical Issues and Future Consequences

Plants of Tomorrow

Monsanto Wins Case on Genetically Altered Soybeans

Bowman vs. Monsanto - 2013

Supreme Court in a 9 to 0 decision decided against Bowman and concurred with Monsanto that Bowman had infringed on its patent for herbicide-tolerant soybeans. *Infringement Use in Violation of Patent*

The Supreme Court denied Bowman's claim that principle of patent exhaustion enabled him to use soybean seeds that he sold and re-purchased from a grain elevator, grow them into soybean plants, select for herbicide-tolerant plants, collect their seeds, and use the seeds in the following growing season.

The exhaustion doctrine, also referred to as the first sale doctrine, is a U.S. common law patent doctrine that limits the extent to which patent holders can control an individual article of a patented product after a so-called authorized sale. Under the doctrine, once an authorized sale of a patented article occurs, the patent holder's exclusive rights to control the use and sale of that article are said to be "exhausted," and the purchaser is free to use or resell that article without further restraint from patent law. *However, under the repair and reconstruction doctrine, the patent owner retains the right to exclude purchasers of the articles from making the patented invention anew (i.e., making another article), unless it is specifically authorized by the patentee to do so.*

Lexmark Loses Supreme Court Case. Users Can Sell Refurbished Ink Cartridges Impression Products vs. Lexmark – 8 to 0 decision - 2017
Upheld principle of patent exhaustion!

"Take a shop that restores and sells used cars. The business works because the shop can rest assured that, so long as those bringing in the cars own them, the shop is free to repair and resell those vehicles. That smooth flow of commerce would sputter if companies that make the thousands of parts that go into a vehicle could keep their patent rights after the first sale."

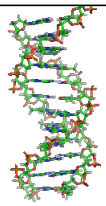
DNA
Genetic Code of Life

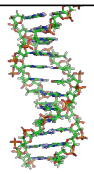
Entire Genetic Code of a Bacteria

DNA Fingerprinting

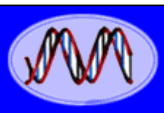
Cloning: Ethical Issues and Future Consequences

Plants of Tomorrow



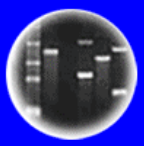


Can Genetically Engineered Genes and Organisms Be Patented?



DNA
Genetic Code of Life

Entire Genetic Code of a Bacteria



DNA Fingerprinting

Cloning: Ethical Issues and Future Consequences

Plants of Tomorrow

Should Patents Be Allowed on Genetically Engineered Organisms?

a. Yes
b. No

20. Should patents be allowed on genetically engineered organisms (e.g., oil-eating bacteria)?
    a. Yes
    b. No

A=20
B=12

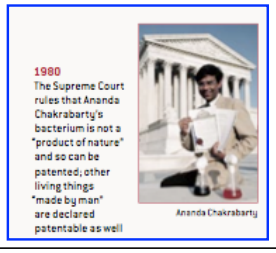
In The US Life Is Patentable

Useful Article of Manufacture

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

6/17/1980

Diamond vs. Chakrabarty
Oil Eating Bacteria



Harvard Mouse

Landmark Genetic Engineering Patents

United States Patent
Cohen, et al.

Recombinant DNA (Method)

4,237,224
December 2, 1980

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 (Method)

United States Patent [19]
Mullis

[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.⁴ C12P 19/34; C12N 15/00; C12N 1/00; C07H 21/04; C07H 21/02

[52] U.S. Cl. 435/91; 435/172.3; 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).
Catzo 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 (Article of Manufacture)

United States Patent [19]
Chakrabarty

[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.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 PpG1 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.

(Method)

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**; *(Boyds, 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.

(Method)

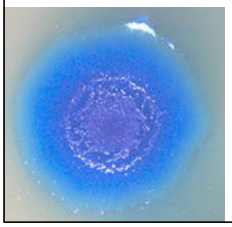
20110045592
A1
February 24, 2011

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**; *(Boyds, MD)* ; **Venter; J. Craig**; *(La Jolla, CA)*



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

(Method)

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.

United States Patent [19]
Chakrabarty

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

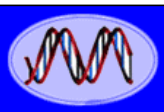
Purified Genes (e.g., Human Genes) And Their Sequences Were Patent-Eligible Subject Matter in the United States *Prior to 2013*

1. Genes (and Cells, Living Organisms, and Natural Substances) ARE Patent-Eligible As Long As They Are Claimed in a Form That Does Not Occur in Nature and Altered In Some Way By the "Hands of Man"

2. Purifying or Isolating Genes Makes Them Novel Because "Isolated and Purified" Materials Do Not Exist in Nature

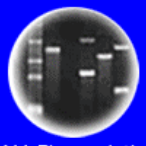
3. ∴ Genes Are Patent-Eligible If They Meet ALL of These Criteria: Invention Must Be: Novel, Useful, Non-Obvious, Have a Clear Written Description, and Document the Best Mode of Practice

    a. A "Switch" To Turn On Genes In Goat Mammary Glands (e.g., chimeric gene)
    b. A Gene Sequence to Produce Insulin in Bacteria Cells
    c. A Vector To Propagate Genes In Yeast Cells
    d. Diagnostic Test (Probe for Specific Disease-Breast Cancer)



DNA
Genetic Code of Life

Entire Genetic Code of a Bacteria



DNA Fingerprinting

Cloning: Ethical Issues and Future Consequences

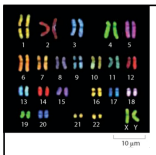
Plants of Tomorrow

Should Patents Be Allowed on Human Gene Sequences?

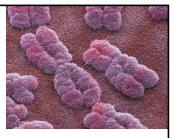
a. Yes
b. No

19. Should patents be allowed on human gene sequences?
    a. Yes
    b. No

A=5
B=27



Who Owns Your Genes?



1. Genes in Your Body Exist in Nature and Are NOT Patent-Eligible Subject Material or Patentable

2. ∴ NO ONE OWNS the Intellectual Property Associated With Your Genes In Your Body-There is None!

3. YOU "Own" the Genes In Your Body

However…What About Purified Genes?

Central Question – Are Genes Patent-Eligible Material?

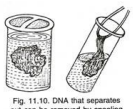
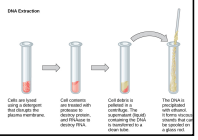


Fig. 11.10. DNA that separates out can be removed by spooling (spool = reel).



MYRIAD
GENE PATENT LITIGATION

After 2013……

SUPREME COURT OF THE UNITED STATES

Syllabus

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

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

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

Justices, 9-0, Bar Patenting Human Genes

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

MEMORANDUM

DATE: March 4, 2014

TO: Patent Examining Corps

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

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

SUPREME COURT OF THE UNITED STATES

Syllabus

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

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

The KEY SENTENCE

This Case Has Changed the Gene Patent Landscape

MYRIAD

United States Patent **5,693,473**
Shattuck-Eidens , et al. **December 2, 1997**

Linked breast and ovarian cancer susceptibility gene

Abstract

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

What is claimed is:

1. An isolated DNA comprising an altered ***BRCA1*** DNA having at least one of the alterations set forth in Tables 12A, 14, 18 or 19 with the proviso that the alteration is not a deletion of four nucleotides corresponding to base numbers 4184-4187 in SEQ. ID. NO:1.

2. An isolated DNA comprising an altered ***BRCA1*** DNA having one of the alterations set forth in Tables 12A or 14 with the provision that the alteration is not a deletion of four nucleotides corresponding to base numbers 4184-4187 in SEQ. ID. NO:1.

3. An isolated DNA comprising an altered ***BRCA1*** DNA having one of the alterations set forth in Tables 18 or 19.

4. A nucleic acid probe specifically hybridizable to a human altered ***BRCA1*** DNA and not to wild-type ***BRCA1*** DNA, said altered ***BRCA1*** DNA having one of the alterations set forth in Tables, 12A, 14, 18 or 19.

United States Patent **5,709,999**
Shattuck-Eidens , et al. **January 20, 1998**

Linked breast and ovarian cancer susceptibility gene

Abstract

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

These Patents Are No Longer Valid

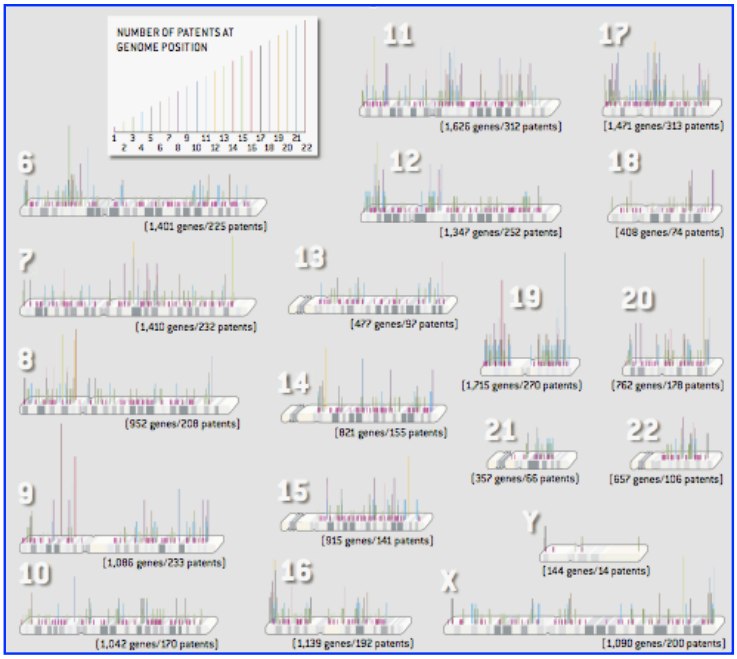
What is claimed is:

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.

Under The Myriad Rule – None of These Genes Are Patent-Eligible Subject Matter



Scientific American, February 2006

20% of Human Genes Have Been Patented (2006)

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

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

6,855,866
February 15, 2005

Polynucleotides useful for modulating transcription

Abstract

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

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

What Is No Longer Patent-Eligible Subject Matter?

- Genes
- Switches
- Oris
- PCR Primers

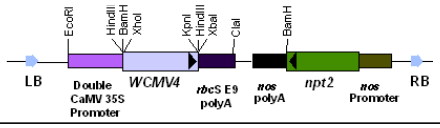
Any Nucleic Acid That Is Identical in Sequence To What is Found in Chromosomes

What Is Patent-Eligible Subject Matter After Myriad?

Any Nucleic Acid That Is <u>Substantially Different</u>
From What is Found in Chromosomes

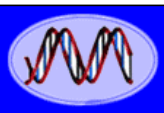
- cDNAs
- Chimeric Genes (e.g., Mouse Switch + GFP)
- Synthetic Genes or Chromosomes With Engineered Difference From Nature

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



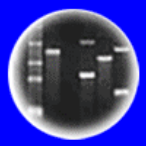
Should You Be Able To Patent Edited Human Genes & Have Intellectual Property Rights?

a. Yes
b. No



DNA
Genetic Code of Life

Entire Genetic Code of a Bacteria



DNA Fingerprinting

Cloning: Ethical Issues and Future Consequences

Plants of Tomorrow

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

a. Yes
b. No

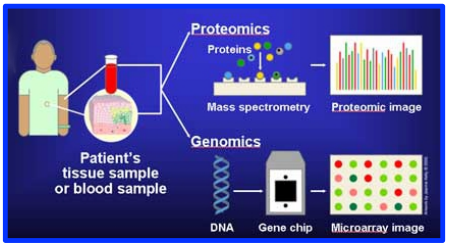
What About Genetic Diagnostic Tests?

MAYO CLINIC
—VS.—
PROMETHEUS

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

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

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



SUPREME COURT OF THE UNITED STATES

No. 10–1150

MAYO COLLABORATIVE SERVICES, DBA MAYO MEDICAL LABORATORIES, ET AL., PETITIONERS *v.* PROMETHEUS LABORATORIES, INC.

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

[March 20, 2012]

JUSTICE BREYER delivered the opinion of the Court.

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

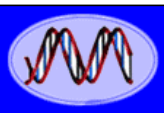
> "Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title." 35 U. S. C. §101.

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

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

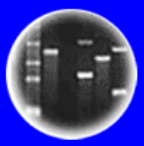
In *Mayo*, the Court addressed the patent-eligibility of method claims reciting "natural phenomena" or "law of nature" and concluded that (1) a newly discovered law of nature is itself unpatentable and (2) the application of that newly discovered law is also normally unpatentable if the application merely relies upon elements already well understood, routine, and conventional in the art. The Court explained that to transform an unpatentable law of nature into a patent-eligible application of the law, it must contain other elements or a combination of elements—an "inventive concept"—sufficient to ensure that the claim amounts to significantly more than the natural law itself, i.e., it must limit its reach to a particular inventive application of the law.

COURT RULING INVALIDATES PATENT ON NONINVASIVE TEST FOR DOWN SYNDROME
Decision cites landmark Supreme Court ruling in Myriad Genetics case **Sequenom vs. Ariosa Diagnostics - 2014**



DNA
Genetic Code of Life

Entire Genetic Code of a Bacteria



DNA Fingerprinting

Cloning: Ethical Issues and Future Consequences

Plants of Tomorrow

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

a. Yes
b. No

Moore v. Regents of the University of California - 1990

What About Genetically Engineered Organisms and Cell Lines?

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

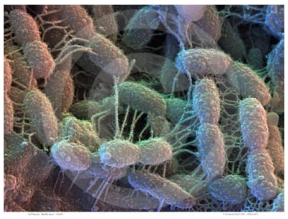
1980
The Supreme Court rules that Ananda Chakrabarty's bacterium is not a "product of nature" and so can be patented; other living things "made by man" are declared patentable as well

Ananda Chakrabarty

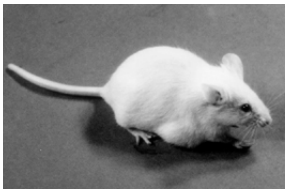
1988
Harvard University gets a patent for the OncoMouse, a rodent with a gene inserted that predisposes it to cancer

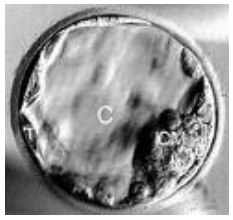
Diamond vs. Chakrabarty 6/17/1980

Transgenic Living Organisms CAN Be Patented and Are Patent-Eligible Subject Material!



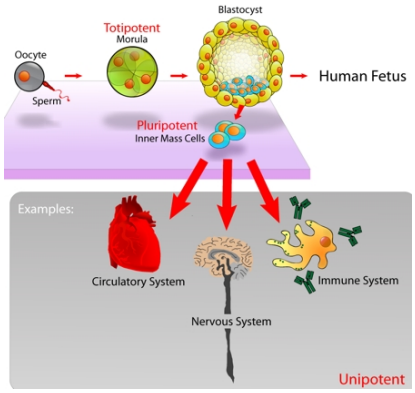
Article of Manufacture





But Must Meet All of the Criteria For Obtaining a Patent

What About 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

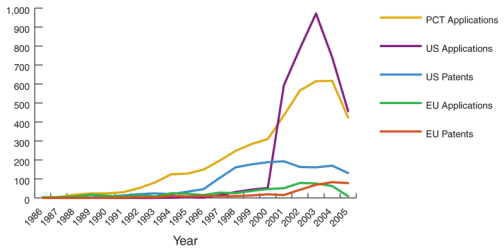
A purified preparation of primate embryonic ***stem cells*** is disclosed. This preparation is characterized by the following cell surface markers: SSEA-1 (-); SSEA-4 (+); TRA-1-60 (+); TRA-1-81 (+); and alkaline phosphatase (+). In a particularly advantageous embodiment, the cells of the preparation 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)

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

Stem Cell Patent Applications



MYRIAD GENE PATENT LITIGATION

PROMETHEUS® Therapeutics & Diagnostics

iPS Lines??

But in Europe They Are Unpatentable Because They Are Contrary To "Public Policy or Morality"

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

Europe rejects patent governing use of embryonic stem cells

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

Europe rejects Wisconsin's key stem-cell patent

Europe revokes controversial gene patent

› 18:25 19 May 2004 by Andy Coghlan

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

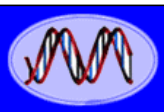
Concern	Response
Naturally Occurring Genes Should Not Be Patentable	Your Genes Cannot Be Patented – Only if Modified or Substantially Different From What is in Nature (Myriad Case, 2013)
Patents Should Not Be For Discoveries of Nature-Only Marketable Inventions	Laws of Nature Cannot Be Patented. Patents Do Not Guarantee That The Invention Is Marketable
Patents Delay Research Progress	All Patents Are Published. Therefore, New Innovations Stimulate Scientific Progress. Little Impact on Basic University Research
Life Forms (Including Higher Life Forms) Should Not Be Patented	Life Forms Cannot Be Patented Unless Manufactured by the "Hands of Man." A Transgenic Organism Does Not Exist in Nature. Chakrabarty Case (1980)
Research Tools (Enabling Methods) Should Not Be Patented	Methods Are Patentable Subject Matter According to US Patent Law and Stimulate Scientific Progress (e.g., Gene Splicing, PCR)
Prevent Inventions From Being Used In Third World	Not If Patent Not Issued in Third World. Knowledge In Patent Has Been Published. If Patented in Third World, Can Generally Obtain a Royalty-Free License to Use Technology
Someone Will Own Your Genes	Not In Your Body

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

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

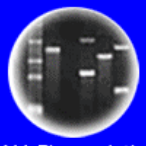
Concern	Response
Naturally Occurring Genes Should Not Be Patentable	Your Genes Cannot Be Patented – Only if Modified or Substantially Different From What is in Nature (Myriad Case, 2013)
Patents Should Not Be For Discoveries of Nature-Only Marketable Inventions	Laws of Nature Cannot Be Patented. Patents 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 (1981)
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 or in Isolated Form

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



DNA
Genetic Code of Life

Entire Genetic Code of a Bacteria



DNA Fingerprinting

Cloning: Ethical Issues and Future Consequences

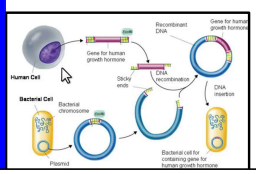
Plants of Tomorrow

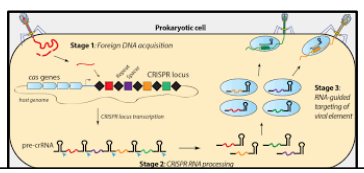
A Common Misperception…….Patents Inhibit the Free Exchange of Information

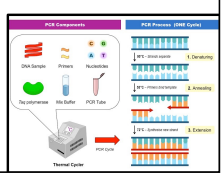
To the Contrary……Patent Laws REQUIRE Disclosure of the Invention (Written Description & Best Mode of Practice) And ARE PUBLISHED 18 Months After Filing Application. *Alternative Would be Trade Secrets!*

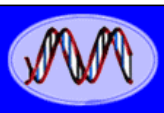
∴ Knowledge and Information in Patent Becomes Public Information and Can Stimulate New Innovation and Progress.

For Example: Recombinant DNA, Genetic Engineering, PCR, DNA Sequencing. CRISPER, etc!!!



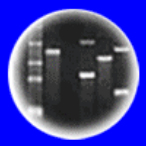






DNA
Genetic Code of Life

Entire Genetic Code of a Bacteria



DNA Fingerprinting

Cloning: Ethical Issues and Future Consequences

Plants of Tomorrow

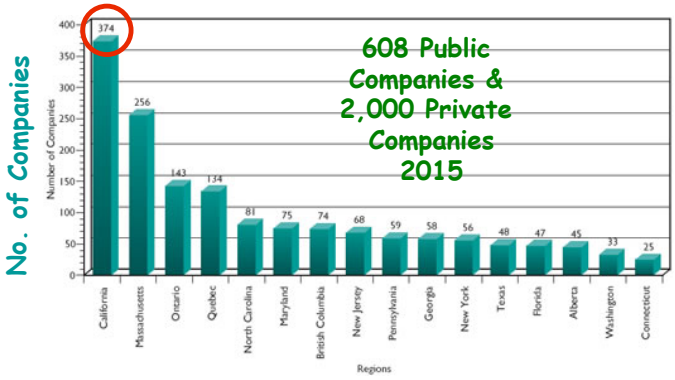
Patents Affect How Science is Carried Out and How Basic Science is Translated Into Business

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

$324B
Net Revenue in 2014

$404B
Market Cap as of April 27,2015

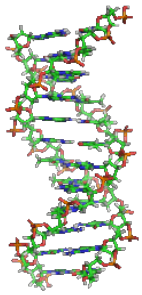
184,000 Employees



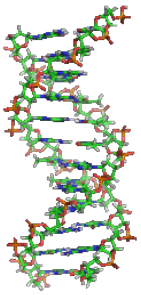
Note:

There Was No Biotech Industry Before 1980

Without Chakrabarty There Would Be Bo Biotech Industry!!

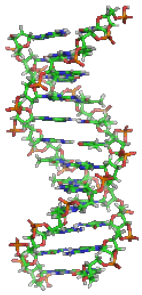


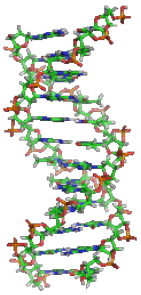
Recall….Way Back in January…

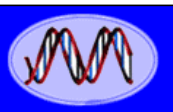


The Age of DNA!

Genetic Engineering Is Manipulating DNA!

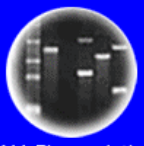






DNA
Genetic Code of Life

Entire Genetic Code of a Bacteria

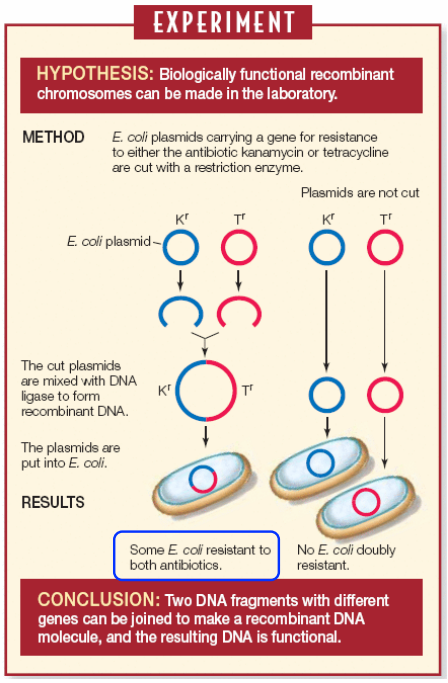


DNA Fingerprinting

Cloning: Ethical Issues and Future Consequences

Plants of Tomorrow

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

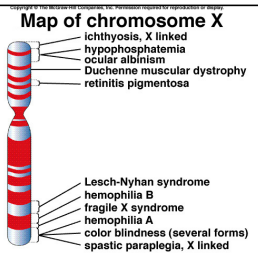


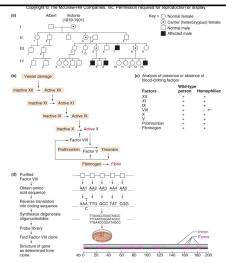
Where it all Began One Summer in 1973!

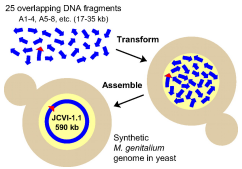
What's a GMO?

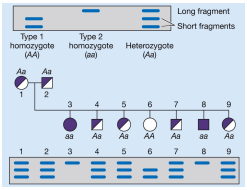
Analysis of one million base pairs of Neanderthal DNA

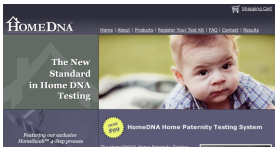
Richard E. Green[1], Johannes Krause[1], Susan E. Ptak[1], Adrian W. Briggs[1], Michael T. Ronan[2], Jan F. Simons[2], Lei Du[2], Michael Egholm[2], Jonathan M. Rothberg[2], Maja Paunovic[3]‡ & Svante Pääbo[1]

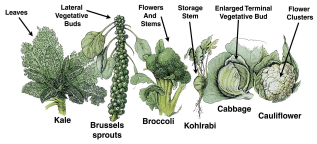


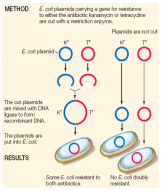


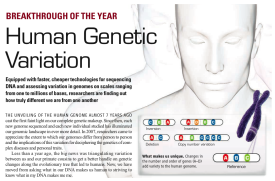


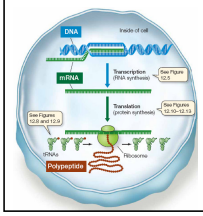


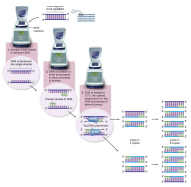


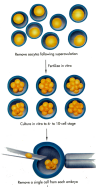


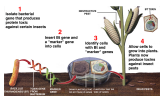




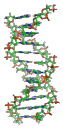


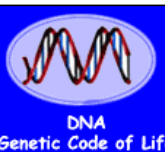


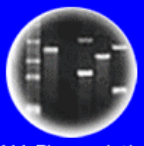


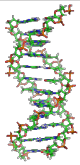


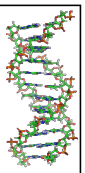
SCIENCE MAY PATENT NEW FORMS OF LIFE, JUSTICES RULE, 5 TO 4











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

HC70A & SAS70A SPRING 2017 The End!!

OR Is It the Beginning?