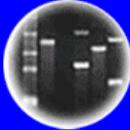


DNA
Genetic Code of Life



Entire Genetic Code
of a Bacteria



DNA Fingerprinting



Cloning: Ethical Issues
and Future Consequences



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HC70A, SAS70A, & PLSS059 Winter 2018 Genetic Engineering in Medicine, Agriculture, and Law

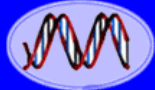
Professors Bob Goldberg, John Harada,
& Channapatna Prakash

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

UCLA

TUSKEGEE
UNIVERSITY

UC DAVIS
UNIVERSITY OF CALIFORNIA



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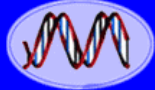
Cloning: Ethical Issues
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THEMES

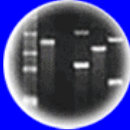
1. The Constitution & Regulating Science
2. A History of Patents
3. What is Intellectual Property?
4. What Are the Different Forms of Intellectual Property?
5. What Are Patents?
6. What Are Copyrights?
7. What Are Trademarks and Service Marks?
8. What Are Trade Secrets?
9. When Are Different Forms of 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?



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TEXT READING

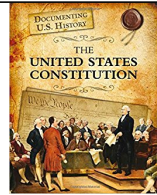
Chapter 12
Pages 314-317

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*
15. *Titanic Clash Over CRISPR Patents Turns Ugly, Nature, September 22, 2016*
16. *Court Rules on CRISPR. Nature, February 23, 2017*

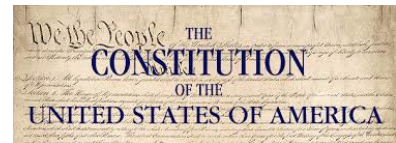


Continue Lecture 9 on Regulating Science



What Does the Constitution Say Directly About Science?

Is the Word "Science" in the Constitution?



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"

Keyword: Inventors not Science.

Wanted to Promote Economic Development & Promote a National Economics Policy Grounded in Property Rights.
That is, Entrepreneurship!

PATENTS!!

How Does the Constitution Deal Indirectly With Science?

Without Using the Word Science or Mentioning the Progress of Science and Discoveries?

Article I - Section 8.1

The Congress shall have the Power:

[1] “To lay and collect Taxes, Duties, Imposts, and Excises, to pay the Debts and provide for the common Defense and general Welfare of the United States; but all Duties, Imposts, and Excises shall be uniform throughout the United States”

Key Concept: Provide For the General Welfare-Which Can Apply to Almost Everything Dealing With Science, Health, Medicine, Agriculture, and Safety!

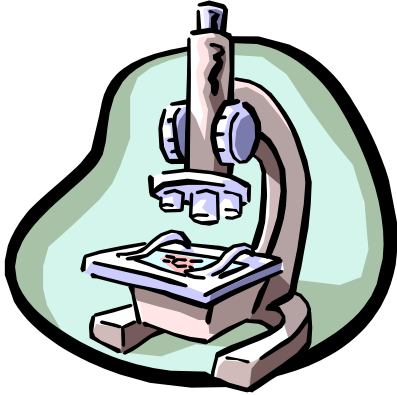

Article I - Section 8.18

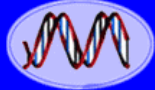
The Congress shall have the Power:

[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 Agencies Such as **NIH, NSF, USDA, & EPA** That Can Write Rules That Regulate Genetic Engineering

How Can Genetic Engineering Be Regulated Directly By The Federal Government?

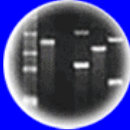




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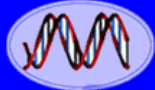


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Article I - Section 8.1

Promote the General Welfare: Federal Powers

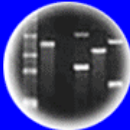
- Fund Science Research & Exploration (NIH, NSF, NASA)
- Regulate Health (e.g., disease outbreaks) (CDC)
- Regulate Medical Testing Devices/Services (DNA Testing)
- Regulate Drugs (FDA)
- Regulate Food Additives (FDA)
- Regulate Releases Into the Environment (GMOs)
- Regulate Lab Conditions
- Regulate Private DNA Testing/Sequencing Services (23&Me)
- Regulate Human Cloning and Stem Cell Funding
- Establish DNA Databases (CODIS)
- Establish Criminal Codes/Laws



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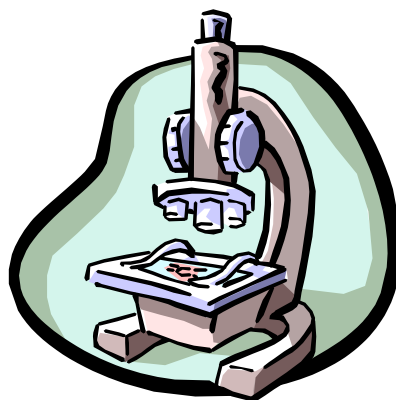


Cloning: Ethical Issues
and Future Consequences



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How Can Genetic Engineering Be Regulated Directly By The State Governments & Municipalities?



Amendment X

Powers Not Delegated to the United States:

“The powers not delegated to the United States by the Constitution, nor prohibited by it to the States, are reserved to the States respectively, or to the people.”

Key Concept: State Promotion of General Welfare=Police Powers

Amendment X

Police Powers to States & Localities

State Funding and Regulation of:

- Science Research & Exploration
- Health (e.g., disease outbreaks)
- Medical Testing Devices/Services (DNA Testing)
- Drugs (as long as not interstate commerce)
- Food Additives
- Releases Into the Environment (GMOs)
- DNA Data Bases, etc.



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Can GloFish Can Be Sold In California?

- **Cal. Depart. of Fish and Game Code § 15007 (2007) Regulation** Makes it illegal to spawn, cultivate, or incubate any transgenic fish in the state controlled waters of the Pacific Ocean.
- **Cal. Depart. of Fish and Game Code Ruling (2015)** The Dept. of Fish and Game will propose the addition of an exception to Section 1.92 that would allow the sale of transgenic tropical aquarium fish that the Dept. has determined pose no foreseeable risk or harm to native fish or wildlife.

Genetic Engineering & The Law!



State GMO Laws? - Article VI - Preemption Clause

"The Constitution, and the laws of the United States which shall be made in pursuance thereof; and all treaties made, or which shall be made, under authority of the United States, shall be the supreme law of the land; and the judges in every State shall be bound thereby"

State Laws That Conflict With Federal Law Are "Without Effect" A Federal Law That Conflicts With State Law Will "Preempt" State Law. A State Court Cannot Issue Rulings That Contradict Decisions of a Federal Court. Altria Group vs. Good, 2008; Maryland vs. Louisiana, 1981; Abelman vs. Booth, 1859

Public Law 114-216
114th Congress

An Act
To reauthorize and amend the National Sea Grant College Program Act, and for other purposes.

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

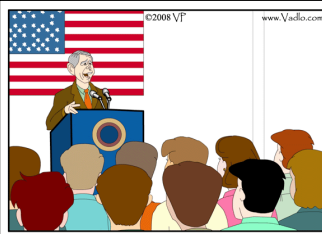
SECTION 1. NATIONAL BIOENGINEERED FOOD DISCLOSURE STANDARD.

The Agricultural Marketing Act of 1946 (7 U.S.C. 1621 et seq.) is amended by adding at the end the following:

"Subtitle E—National Bioengineered Food Disclosure Standard



Vermont GMO Labeling Law Is Invalid!!



I have ordered science grants to be distributed by National Lottery Commission.



How Can Genetic Engineering and Science Be Regulated Indirectly?

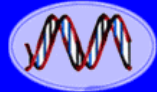


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- 
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Regulate Science Through Power of Funding and Research \$\$\$



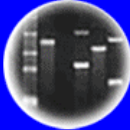
1. **No Constitutional Right to Obtain Funding For Research at Federal, State, and Local Levels**
 - a. **Federal Embryonic Stem Cell Research Restricted**
 - b. **Must Apply For Grants Which Are Merit-Based and Peer-Reviewed**
2. **Must Abide By Conditions of Funding Agencies to Obtain Research \$**
 - a. **Recombinant DNA Guidelines**
 - b. **Human Institutional Review Boards (IRBs)**
 - c. **Release of GMOs Into the Environment (EPA)**
 - d. **Destruction of Human Embryos**



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The Only Federal Laws Dealing With **FUNDING** Genetic Engineering Procedures



PUBLIC LAW 114-113—DEC. 18, 2015

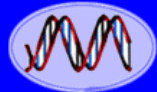
2017 Congressional Budget (Expires 9/30/17)

- FDA Cannot Spend Any Money to Review Applications For Clinical Trials That Involve Human Embryos With Heritable Genetic Modifications

Dickey-Wiker Amendment-1995

Federal Funds Cannot Be Used To:

- Create Human Embryos For Research Purposes
- Fund Research in Which a Human Embryo Will Be Destroyed, Discarded, or **Knowingly Subjected to Risk** or Injury of Death



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DNA Fingerprinting



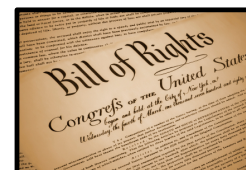
Cloning: Ethical Issues and Future Consequences



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Finally.....Can Scientific **Inquiry** Be Regulated?





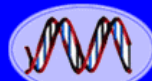
Amendment I



Freedom of Speech and Expression:

“Congress shall make no Law respecting an establishment of religion, prohibiting the free exercise thereof; or abridging freedom of speech, or of the press, of the right of the people peacefully to assemble, and to petition the Government for a redress of grievances.”

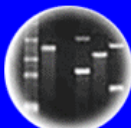
Key Concepts: Freedom to Think About Science, Publish, and Discuss Science in Meetings and Laboratories



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THERE IS NO FUNDAMENTAL RIGHT OF SCIENTIFIC INQUIRY TO CARRY OUT EXPERIMENTS!

1. When Moving From Reflection, Theory, Hypothesis, and Thought to TESTING AND EXPERIMENTATION - Move From World of Speech (talking, publishing) to WORLD OF ACTION AND CONDUCT.
2. Can Distinguish Between Research That is Hazardous or Potentially Hazardous and That Which is Not Hazardous (e.g., testing bombs in your house; recombinant DNA).
3. Experimentation Triggers Public Welfare Considerations
4. Freedom to Pursue Knowledge is Distinguishable From Right to Choose Method For Achieving That Knowledge (e.g., experimentation methods and approaches).

Can Think But Can't Always Act!

Experimentation Can Be Regulated Directly By Law and/or Indirectly By Funding!

Patents & Intellectual Property

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”

Keyword: Inventors not Science.
 Wanted to Promote Economic Development & Promote a National Economics Policy Grounded in Property Rights.
 That is, Entrepreneurship!

PATENTS!!

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?



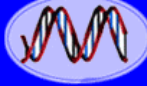
US Patent & Trademark Office (USPTO) Issues Patent

Decision Can Be Appealed to the US Patent Trial & Appeal Board (PTAB)


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

Decision Can Be Appealed to the Supreme Court

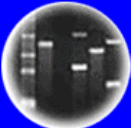
Patent History Origins & Importance




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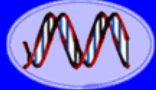


The United States Can Trace Its Patent Roots Back 600 Years

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**

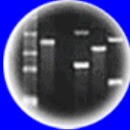





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What Are the Different Types of Intellectual Property?

**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 2038.

"How to Make bobg" US Patent No. 8,989,755, March 13, 2018



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 2138!
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	

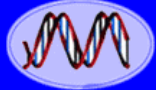
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Dramatic Works	Common Information With No Authorship (e.g., Calendar, Ruler, Height & Weight chart)
Picture, Graphic, and Sculpture Works	Human Genome Sequence
Motion Pictures and Other Audiovisual Works	Works With No Creativity (e.g., Phone Book, 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, 1946).
4. **Lanham Act provision prohibits the registration of trademarks that may "disparage persons, institutions, beliefs, or national symbols, or bring them into contempt or disrepute any "persons, living or dead."**
5. **Not in Constitution.**

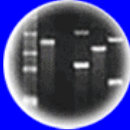




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Trade Mark vs. 1st Amendment?

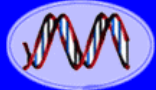
The Slants Win Supreme Court Battle
Over Band's Name In Trademark
Dispute *Matal vs. Tam*

June 19, 2017 · 10:29 AM ET

UCLA School of Law's Supreme Court clinic win
landmark trademark case



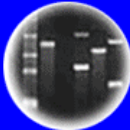
Writing for all eight participating justices, Justice Alito wrote that the disparagement clause "offends a bedrock First Amendment principle: **Speech may not be banned on the ground that it expresses ideas that offend.**" The Court also unanimously rejected the government's argument that trademarks are government, and not private, speech.



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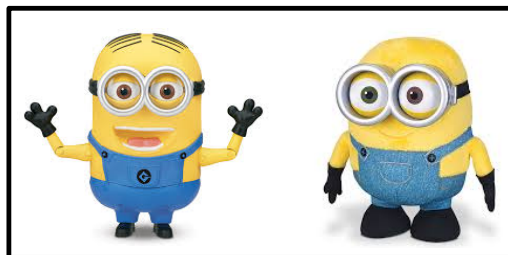
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The Same Trademark Can Be Used in Different Businesses!

MinION Sequencing



Minion Cartoon Character



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.



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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
<ol style="list-style-type: none">1. Society Gains Knowledge2. Patents Published 18 Months After Filing (Patent Pending Status)3. Patent Expires After 20 Years-Society Can Use4. Patent Law Protection	<ol style="list-style-type: none">1. Prevent Competitors From Gaining Proprietary Information2. Society Does Not Get Access to Trade Secret Knowledge3. Limited Protection

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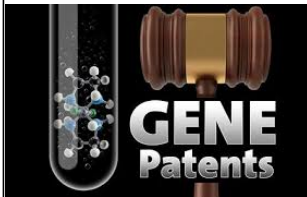
Patent vs. Trade Secret?

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	<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
Trade Secret	<ul style="list-style-type: none">• Legislated Right• Protects Anything By Virtue of Secrecy/Confidentiality/Privacy

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 16th day of September, one thousand and eleven.
 An Act
 To amend title 35, United States Code, to provide for patent reform.
 Enacted by the Senate and House of Representatives of the United States of America in Congress assembled.
 September 16, 2011.
 Public Law 112-241
 125 Stat. 2790

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**

United States Patent <i>Zhang</i>	8,697,359 April 15, 2014
<i>CRISPR</i> -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 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, 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



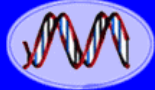
Plants of Tomorrow

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 <i>E. coli</i>	Article of Manufacture
Use in Making Human Insulin	Method

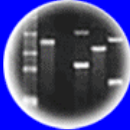




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Plants of Tomorrow

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

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Insulin cDNA	Method
cDNA Sequence	Composition of Matter
Recombinant Insulin <i>E. coli</i>	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

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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

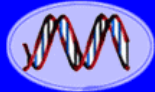
1. **Laws of Nature-Including Algorithms and Mathematical Formulas [Including Software-Unless Leads to Physical Result/Transformation (Currently Before Supreme Court)]**
2. **Abstract Ideas**
3. **Naturally Occurring Phenomena**
4. **Naturally Occurring Substances That Exist in Nature-Including Cells,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

How Does The Patent Process Work?

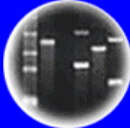
1. **Patent Application Filed At USPTO in Washington and/or in Other Countries (e.g. European Patent Office - Unitary EU Patent). Can also File a PCT (Patent Cooperation Treaty) Application to Get Filing Date In Other Countries and Opinion on Patentability. Goes to US in 30 Months.**
 - a. **Filing Date 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)**



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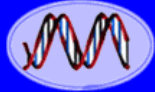
Plants of Tomorrow

Regents of the University of California v. Eli Lilly and Co Written Description Challenge

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

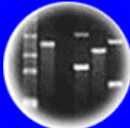
In its decision, the Federal Circuit first addressed UC's claim to *human* proinsulin cDNA. The Court explained that although the '525 patent provided a hypothetical method of obtaining such human cDNA—which may or may not have worked—it does *not* provide a written description of the cDNA itself. The 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.



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Plants of Tomorrow

Monsanto Wins Case on Genetically Altered Soybeans

Bowman vs. Monsanto - 2013

Infringement Challenge - Use in Violation of Patent

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.

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.

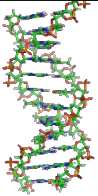
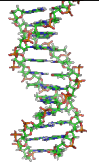
Lexmark Loses Supreme Court Case. Users Can Sell Refurbished Ink Cartridges

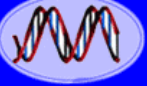
Impression Products vs. Lexmark - 8 to 0 decision - 2017

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."

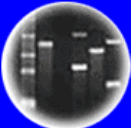






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Plants of Tomorrow

Can Genetically Engineered Genes and Organisms Be Patented?



In The US Life Is Patentable

Useful Article of Manufacture

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

Diamond vs. Chakrabarty Oil Eating Bacteria

6/17/1980

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



Ananda Chakrabarty

Harvard Mouse



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

Landmark Genetic Engineering Patents

United States Patent
Cohen, et al.

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)

**Genetically Engineered Bacteria
(Article of Manufacture)**

United States Patent
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 terms of this patent subordinated to Jul. 28, 2004 has been disclaimed.
[21] Appl. No.: 791,300
[22] Filed: Oct. 25, 1985

Related U.S. Application Data
[63] Continuation-in-part of Ser. No. 716,975, Mar. 26, 1985, abandoned.
[51] Int. Cl. C12P 19/34; C12N 15/00; C12N 1/00; C07H 21/04; C07H 21/02
[52] U.S. Cl. 435/91; 435/173; 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).
Rosi et al. *J. Biol. Chem.* 257, 9226-9229 (1982).

Primary Examiner—James Martiniell
Attorney, Agent, or Firm—Janet E. Haski; Albert P. Hallinan

[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

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

[54] MICROORGANISMS HAVING MULTIPLE COMPATIBLE DEGRADATIVE ENERGY-GENERATING PLASMIDS AND PREPARATION THEREOF
[75] Inventor: **Ananda N. 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. C12N 15/00
[52] U.S. Cl. 435/172; 435/253; 435/264; 435/281; 435/320; 435/375; 435/377
[58] Field of Search 195/28 R, 1, 3 H, 3 R, 195/96, 78, 79, 112; 435/172, 233, 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. 210-243 (1969).
Primary Examiner—R. B. Fenland

Attorney, Agent, or Firm—Leo I. Malouf, James C. Davis, Jr.

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 thereof, 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 thereof, 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



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)**

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

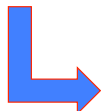
SUPREME COURT OF THE UNITED STATES

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
Shattuck-Eidens, et al. 5,693,473
December 2, 1997

Linked breast and ovarian cancer susceptibility gene

Abstract

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



What is claimed is:

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

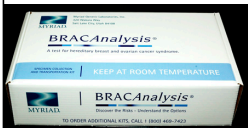
United States Patent
Shattuck-Eidens, et al. 5,709,999
January 20, 1998

Linked breast and ovarian cancer susceptibility gene

Abstract

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

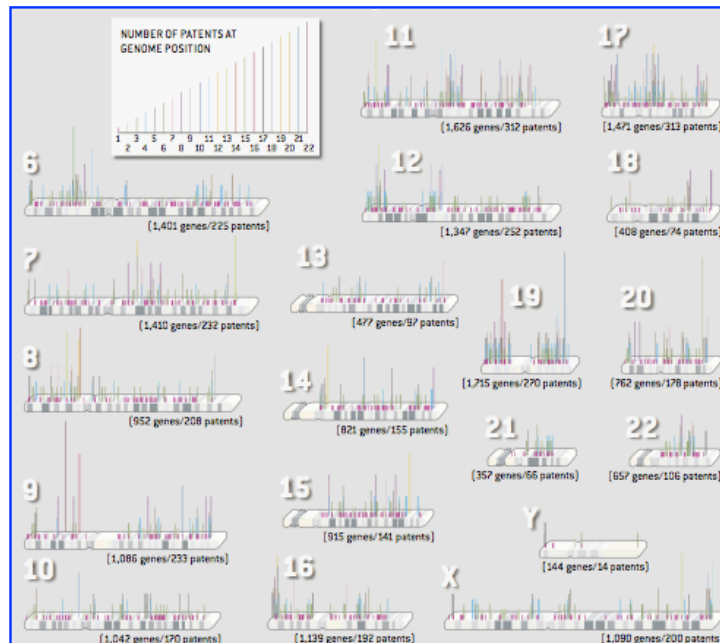
These
Patents
Are No
Longer
Valid

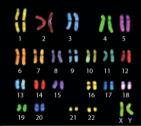


What is claimed is:

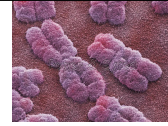
1. A method for detecting a germline alteration in a *BRCA1* gene, said alteration selected from the group consisting of the alterations set forth in Tables 12A, 14, 18 or 19 in a human which comprises analyzing a sequence of a *BRCA1* gene or *BRCA1* RNA from a human sample or analyzing a sequence of *BRCA1* DNA 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





Who Owns Your Genes?

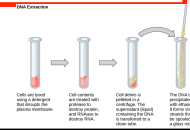


1. **Genes in Your Body Exist in Nature and Are NOT Patent-Eligible Subject Material or Patentable**
2. **∴ NO ONE OWNS the Intellectual Property Associated With Your Genes In Your Body-There is None!**
3. **YOU "Own" the Genes In Your Body**

What About Purified Genes?
Central Question - Are Genes Patent-Eligible Material?
No - Because of the Myriad Decsion



Fig. 11-10. DNA that separates out can be removed by spooling (spool = reel).



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

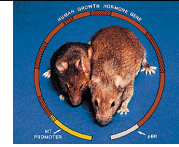
The invention provides polynucleotides for expression of genes in suspensor cells in plants and methods for using such polynucleotides.

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

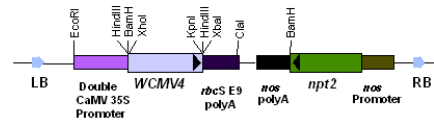


What Is Patent-Eligible Subject Matter After Myriad?

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

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

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



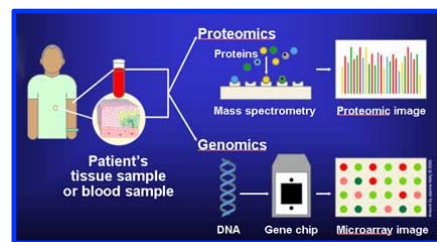
What About Genetic Diagnostic Tests?

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. *Di-*

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

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



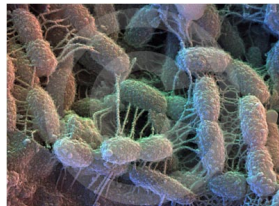
Ananda Chakrabarty



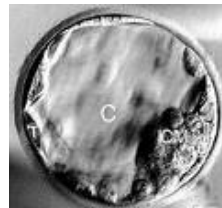
1980
Harvard University gets a patent for the OncoMouse, a rodent with a gene inserted that predisposes it to cancer

Diamond vs. Chakrabarty 6/17/1980

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

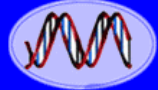


Article of
Manufacture



But Must
Meet All
of the
Criteria
For
Obtaining
a Patent

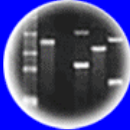




DNA Genetic Code of Life



Entire Genetic Code of a Bacteria



DNA Fingerprinting



Cloning: Ethical Issues and Future Consequences



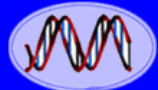
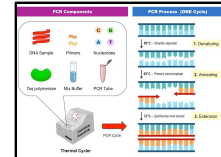
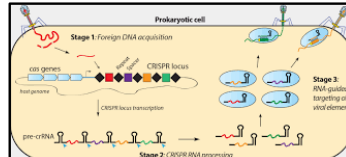
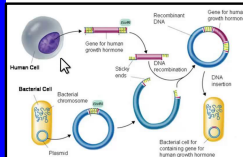
Plants of Tomorrow

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.

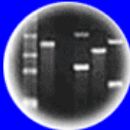
For Example: Recombinant DNA, Genetic Engineering, PCR, DNA Sequencing. CRISPER, etc!!!



DNA Genetic Code of Life



Entire Genetic Code of a Bacteria



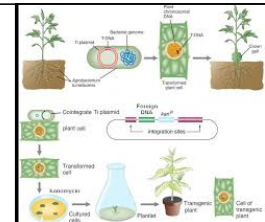
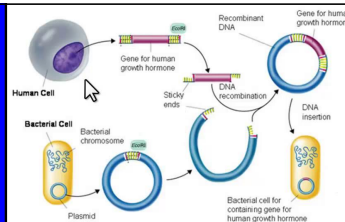
DNA Fingerprinting



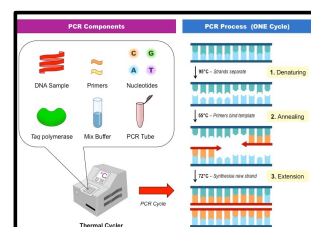
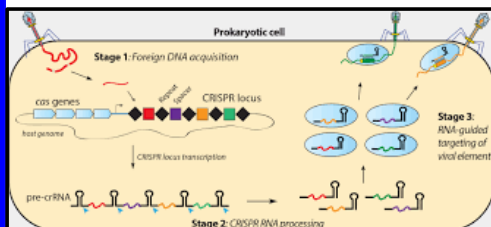
Cloning: Ethical Issues and Future Consequences



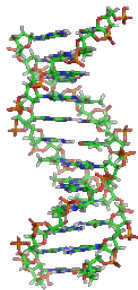
Plants of Tomorrow



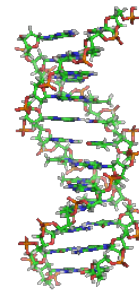
A Summary of Patents, Copyrights & Trademarks as They Apply to Genes & Genetic Engineering



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	√			√

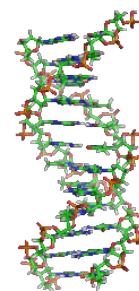
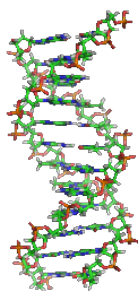


Recall.... Way Back in January...



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



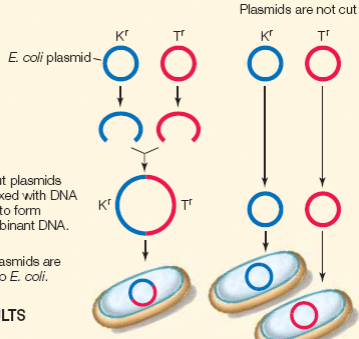
Genetic Engineering Technology Can Combine DNA (Genes) From Different Sources Leading to New Gene Combinations!!

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.

Plasmids are not cut



The cut plasmids are mixed with DNA ligase to form recombinant DNA.

The plasmids are put into *E. coli*.

RESULTS

Some *E. coli* resistant to both antibiotics. No *E. coli* doubly resistant.

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

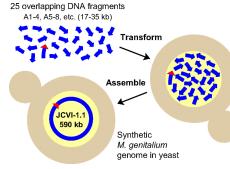
Where it all Began
One Summer in
1973!

What's a GMO?


Analysis of one million base pairs of Neanderthal DNA

Richard E. Green¹, Johannes Krause¹, Susan E. Ptak¹, Adrian W. Briggs¹, Michael T. Ronan², Jan F. Simons², Lei Du², Michael Egholm², Jonathan M. Rothberg², Maja Paunovic² & Svante Pääbo¹

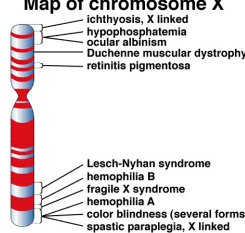
25 overlapping DNA fragments (A1-4, A5-8, etc. (17-35 kb))



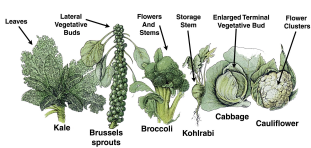
Synthetic *M. genitalium* genome in yeast



Map of chromosome X

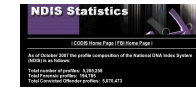


- ichthyosis, X linked
- hypophosphatemia
- ocular albinism
- Duchenne muscular dystrophy
- retinitis pigmentosa
- Lesch-Nyhan syndrome
- hemophilia B
- fragile X syndrome
- hemophilia A
- color blindness (several forms)
- spastic paraplegia, X linked




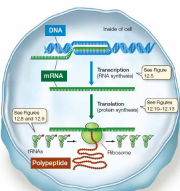
Kale, Broccoli sprouts, Broccoli, Kohlrabi, Cabbage, Cauliflower

NDIS Statistics



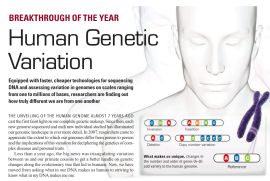
DNA Tribes Genetic Ancestry Analysis



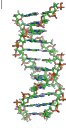


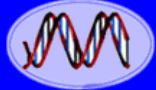
BREAKTHROUGH OF THE YEAR

Human Genetic Variation



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

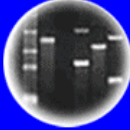




DNA
Genetic Code of Life



Entire Genetic Code
of a Bacteria



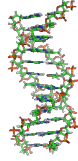
DNA Fingerprinting



Cloning: Ethical Issues
and Future Consequences



Plants of Tomorrow



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

HC70A, SAS70A, & PLS550
WINTER 2018

The End!!

OR

Is It the Beginning?

