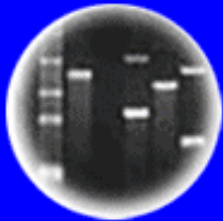


DNA
Genetic Code of Life



Entire Genetic Code
of a Bacteria



DNA Fingerprinting



Cloning: Ethical Issues
and Future Consequences



Plants of Tomorrow



HC70A, SAS70A, & PLSS059 Winter 2019 Genetic Engineering in Medicine, Agriculture, and Law

Professors Bob Goldberg, John Harada,
& Channapatna Prakash

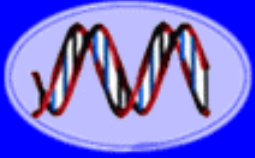
Lecture 10
Science & The Constitution: **Who Owns
Your Genes?**

UCLA

TUSKEGEE
UNIVERSITY

UC DAVIS
UNIVERSITY OF CALIFORNIA

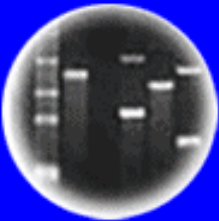
THEMES



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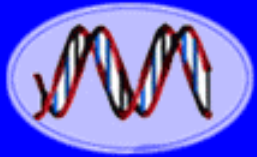


Cloning: Ethical Issues
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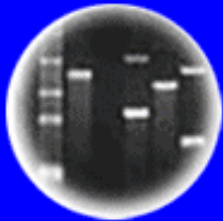
1. The Constitution & Regulating Science
2. A History of Patents
3. What is Intellectual Property?
4. What Are the Different Forms of Intellectual Property?
5. What Are Patents?
6. What Are Copyrights?
7. What Are Trademarks and Service Marks?
8. What Are Trade Secrets?
9. When Are Different Forms of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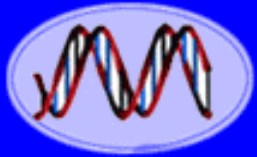
TEXT READING

Chapter 12

Pages 337-341

SELECTED PATENT REFERENCES

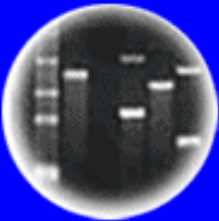
1. *United States Patent and Trademark Office (www.uspto.gov)*
1. *Patent, Copyright, & Trademark, By R. Stim, 14th Edition (2016)*
1. *Federal Register, USPTO Gene Utility Guidelines, Volume 66 (4), January 5, pages 1092-1099 (2001)*
2. *United States Patent and Trademark Office, Guidance For Subject 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)*
3. *United States Patent and Trademark Office, Interim Guidance on Patent Subject Eligibility. Federal Register, Volume 79 (241), December 16, 2014*
4. *A Patent Perspective on US Human Stem Cell Research. Nature Biotech. 32, 633-637 (2014)*
1. **** Mayo vs. Prometheus, Supreme Court Decision, March 12 (2012)*
1. **** Association For Molecular Pathology vs. Myriad Genetics, Supreme Court Decision, June 13 (2013)*
2. **** Bowman vs. Monsanto, Supreme Court Decision, June 13 (2013)*
3. **** The History of Patenting Genetic Material, By Jacob E. Cherkow & Henry T. Greely, Annu. Rev. Genetics, 49, 161-182 (2015)*
4. *Diagnostics Need Not Apply, By Rebecca S. Eisenberg, J. Science & Technology Law, 21.2 (2015)*
5. *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. *CRISPR's Epic Patent Fight Changed the Course of Biology. Wired, September 11, 2018*



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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?

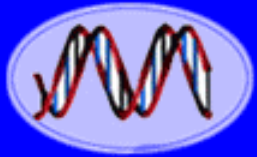


US Patent & Trademark Office (USPTO) Issues Patent

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 (CAFC)

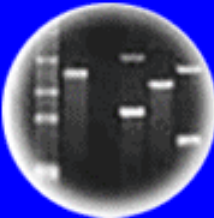
Decision Can Be Appealed to the Supreme Court (SCOTUS)



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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*

1. *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

2. *Inventor (John Utynam) Gave Knowledge & Know How to Society in Exchange For a 20-Year Monopoly to His Invention*

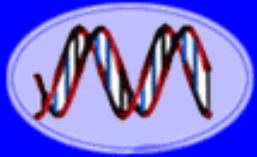
- a. He Taught Others in England How to Make Stained Glass
- b. In Exchange Other People Could Not Use His Method Without His Permission

KEY CONCEPT-BENEFIT TO SOCIETY

3. *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

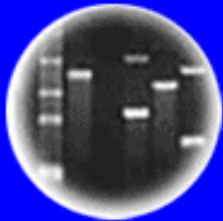




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What Are the Different Types of Intellectual Property?

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

1. Patent

2. Copyright

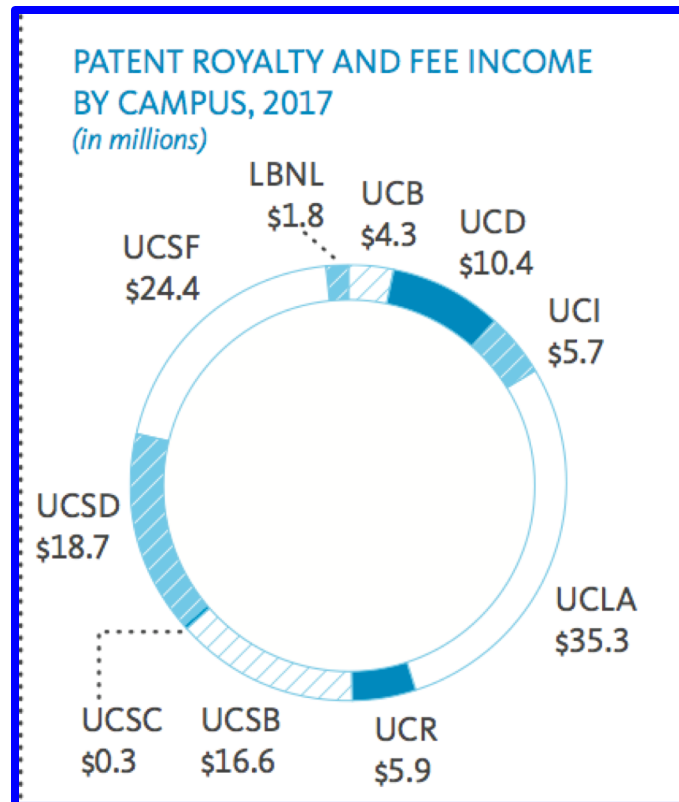
3. Trademark or Service Mark

4. Trade Secret

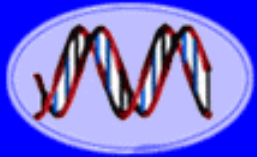
Applies to Private & Public Sectors!

University of California Royalties From Patent Licenses - 2017

\$126,000,000



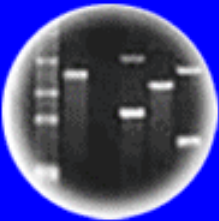
UCLA = \$35M → Inventors Get 33%



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What Are Patents?



1. A patent is the grant of a property right to the inventor, issued by the USPTO, that allows the patent owner to maintain a monopoly for a limited period of time on the use and development of the invention.
2. The right to EXCLUDE OTHERS from making, using, offering for sale, or selling, the invention in the United States or “importing” the invention into the United States (e.g., can’t make in another country & import back to United States)
3. What is granted is not the right to make, use, offer for sale, sell or import, but the right to EXCLUDE OTHERS from making, using, selling, or importing the invention.
Term=20 years from filing date. File today, then lasts until 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 2139!
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 | |

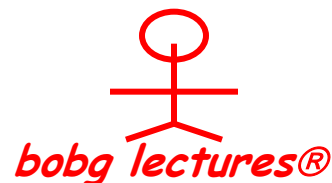
What Can and Cannot Be Copyrighted?

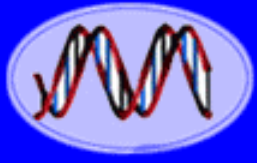
| What Can Be Copyrighted? | What Cannot Be Copyrighted? |
|--|--|
| Literary Works | Works Not In Tangible Form (e.g., spontaneous speech) |
| Scientific Publications (Including Figures, Tables, & Graphs) | Titles, Names, Phrases, Slogans, Lettering |
| Musical Works | Ideas, Procedures, Methods, Processes, Concepts, Principles, Devices |
| Dramatic Works | <u>Common Information With No Authorship</u> (e.g., Calendar, Ruler, Height & Weight chart) |
| Picture, Graphic, and Sculpture Works | Human Genome Sequence |
| Motion Pictures and Other Audiovisual Works | <u>Works With No Creativity</u> (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).**
1. **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."**
Declared unconstitutional by Supreme Court in 2017 on 1st Amendment Grounds

2. Not in Constitution.

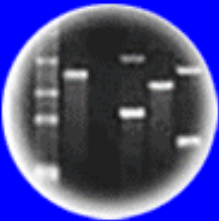




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DNA Fingerprinting



Cloning: Ethical Issues
and Future Consequences



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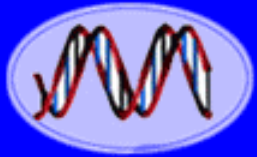
Trade Mark vs. 1st Amendment?

The Slants Win Supreme Court Battle
Over Band's Name In Trademark
Dispute **Matal vs. Tam - 8-0 (2017)**

June 19, 2017 · 10:29 AM ET



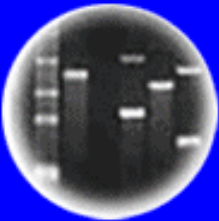
Writing for all eight participating justices, Justice Alito wrote that the disparagement clause "offends a bedrock First Amendment principle: ***"Speech may not be banned on the ground that it expresses ideas that offend."*** The Court also unanimously rejected the government's argument that trademarks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



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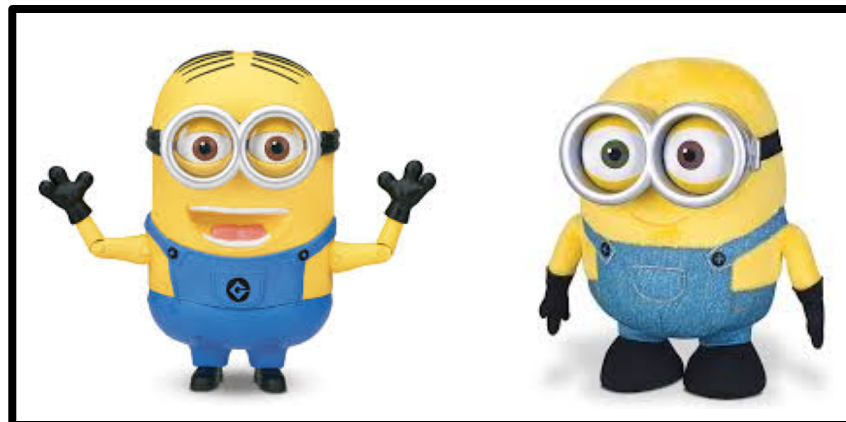
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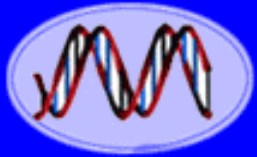
The Same Trademark Can Be Used in Different Businesses!

MinION Sequencing



Minion Cartoon Character

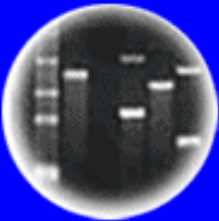




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Except For Famous or Strong Trademarks - Principle of Dilution

*If Mark is Well Known, Then another business Using The
Same Mark Will Cause Confusion and Dilute Its Strength*



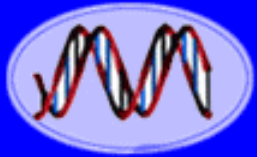
PORSCHE



What Are Trade Secrets?



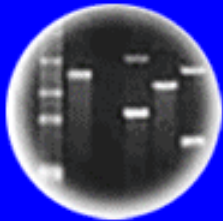
1. INFORMATION that companies keep secret to give them an advantage over their competitors.
 2. Any information that has commercial value, that has been maintained in confidence by a business, and that is not known to competitors
 3. For example, formula for Coca Cola, gene sequence database, genome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

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 | <ol style="list-style-type: none">1. Prevent Competitors From Gaining Proprietary Information2. Society Does Not Get Access to Trade Secret Knowledge3. Limited Protection |

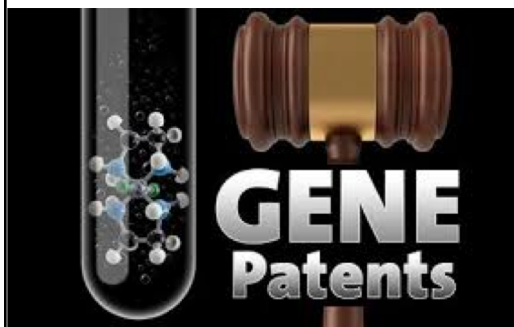
File Patent or Keep as Trade Secret?

SUPREME COURT OF THE UNITED STATES

Syllabus

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

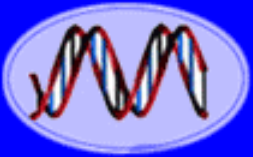
Justices, 9-0, Bar Patenting Human Genes



MYRIAD
GENE PATENT LITIGATION

Summary of Intellectual Property Characteristics

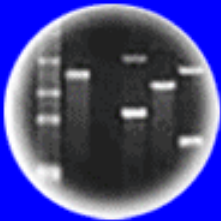
| | |
|---------------------|---|
| Patent | <ul style="list-style-type: none">• Constitutional Right• Protects Inventions• Right to Exclude Others From Using Invention• No Right to Make \$ |
| Copyright | <ul style="list-style-type: none">• Constitutional Right• Protects Original Works of Authorship & 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 (Lanham Act)• 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 |



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How Does the Patent System Work?

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

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

2018

CRISPR Patent Fight Now a Winner-Take-All Match

UC Appealed Patent Decision by USPTO Under Old System

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



Battle Was 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

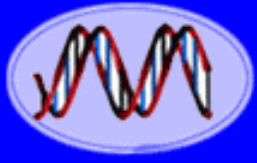
Process, Machine, Manufacture, or Composition of Matter

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

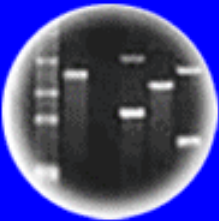
1. Utility Patents (Most Common)
 - a. Process or Method
 - i. Recombinant DNA or Stem Cell
 - b. Machine or Apparatus
 - i. PCR or Sequencing Machine
 - c. Article of Manufacture
 - i. Transgenic Organism
 - d. Composition of Matter
 - i. Engineered DNA Sequence
 - e. Improvements to Any of the Above
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



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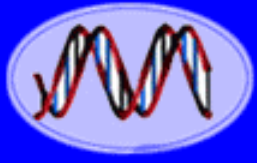
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You Have Isolated an Insulin cDNA, Inserted It Into a Plasmid, and Transformed *E. Coli* With the Insulin cDNA Plasmid.

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 |

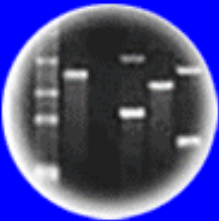




DNA
Genetic Code of Life



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 |



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
1. 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 Priority 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:

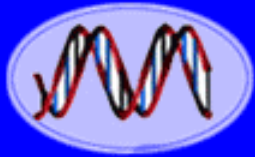
1. The Criteria For Awarding a Patent (to invalidate the patent) or
2. If Someone, or Some Entity, is Practicing an Invention in Violation of the Patent (to enforce the patent)

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

Nature Biotechnology
January 1998

| Second Letter | | | |
|---------------|---------|----------|----------|
| U | C | A | G |
| UUU Phe | UUC Leu | UAU Tyr | UUG Cys |
| UUC Phe | UUC Leu | UAC Tyr | UUG Cys |
| UUA Leu | UUA Leu | UAA Stop | UAG Stop |
| UUG Leu | UUG Leu | UAG Stop | UAG Stop |
| CUU Leu | CUU Leu | CAU His | CGU Arg |
| CUC Leu | CUC Leu | CAC His | CGU Arg |
| CUA Leu | CUA Leu | CAG His | CGU Arg |
| CUG Leu | CUG Leu | CAG His | CGU Arg |
| AUU Ile | AUU Ile | AUA Ile | AUG Met |
| AUC Ile | AUC Ile | AUA Ile | AUG Met |
| AUA Ile | AUA Ile | AUA Ile | AUG Met |
| AUG Met | AUG Met | AUA Ile | AUG Met |
| GUU Val | GUU Val | GAU Asp | GGU Gly |
| GUC Val | GUC Val | GAU Asp | GGU Gly |
| GUA Val | GUA Val | GAA Glu | GGA Gly |
| GUG Val | GUG Val | GAA Glu | GGA Gly |

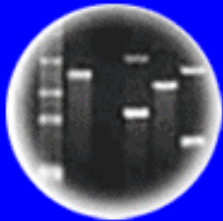
What are the Properties of the Genetic Code?



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Plants of Tomorrow

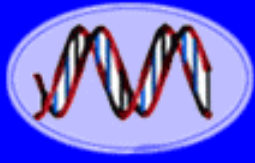
Regents of the University of California v. Eli Lilly and Co *Infringement-Written Description Challenge (1998)*

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.

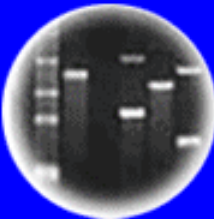
The Court of Appeals Federal District Invalidated One of UC Patents Claiming Human Insulin cDNA on the Basis of the Rat cDNA - Because of Inadequacy of Written Description and Because UC Did Not Have a Human Insulin cDNA!!



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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."

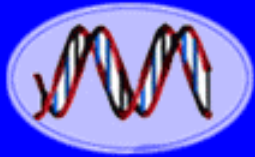
How Are Patents Challenged in the Courts?

Interference

1. Under Old System in the US Issued Patents Could Be Challenged On First to Invent.
2. But Still Needed To Use a Criterion For Awarding a Patent (to Invalidate the Patent).
3. Generally This Was "Non-Obviousness" and/or Knowledge in the "Prior Art"

Pivotal CRISPR patent battle won by Broad Institute

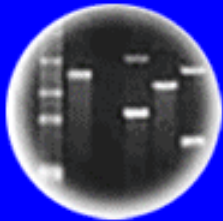
UC Patent Claims Components of the CRISPR System and Use in Test Tube and Bacteria. Broad/MIT Patent (2014) Claims Use in Human and Mammalian Cells. Court of Appeals Federal District Decided That This Was Not Obvious and Turned Down UC Berkeley's Interference on Broad CRISPR Patent



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Plants of Tomorrow

CRISPR Patent Wars (2014-2018)

\$\$\$\$\$\$\$\$\$\$\$\$\$\$\$\$?

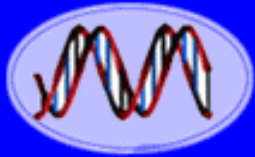
VS.

Cohen-Boyer Patent (1980)

Generated \$240M over 17
Year Life of Patent

*Non-Exclusive Licensing for \$10,000
Plus a Percentage of Down-Stream
Product Net Sales*

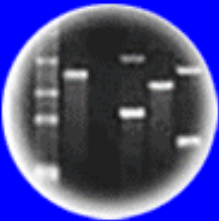
Think About What Would Have Happened
If UC and Stanford Gave an **Exclusive License** To One
Entity For Recombinant DNA!!!!!!!



DNA
Genetic Code of Life



Entire Genetic Code
of a Bacteria



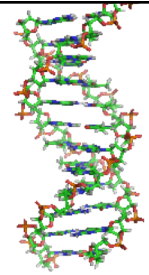
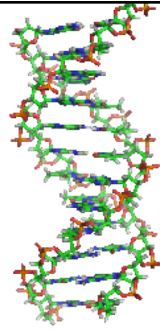
DNA Fingerprinting



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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

[19]

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

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

Related U.S. Application Data

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

[56] References Cited
PUBLICATIONS

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

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

[57] ABSTRACT

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

United States Patent
Chakrabarty

[19]

[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 FpG1 by genetic transfer thereto, and containment therein, of camphor, salicylate and naphthalene degradative pathways and drug resistance factor RP-1, all in the form of plasmids.

18 Claims, 2 Drawing Figures



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)**

MYRIAD

GENE PATENT LITIGATION

In 2013 Everything Changed!!

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



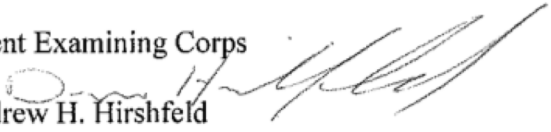
UNITED STATES PATENT AND TRADEMARK OFFICE

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

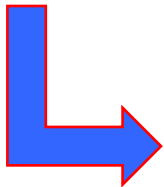
SUPREME COURT OF THE UNITED STATES

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

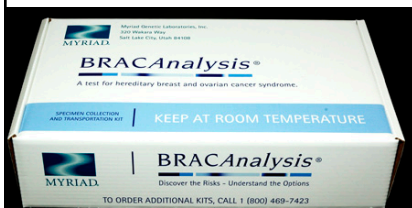
Abstract

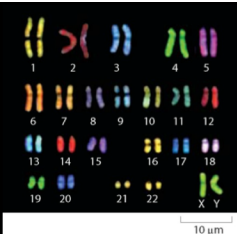
The present invention relates generally to the field of human genetics. Specifically, the present invention relates to methods and materials used to isolate and detect a human breast and ovarian cancer predisposing gene (*BRCA1*), some mutant alleles of which cause susceptibility to cancer, in particular 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

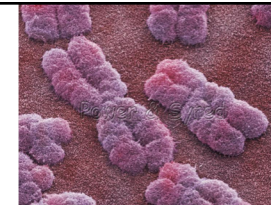
What is claimed is:

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* 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.





Who Owns Your Genes?



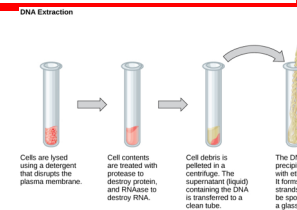
1. **Genes in Your Body Exist in Nature and Are NOT Patent-Eligible Subject Material or Patentable**
2. **∴ NO ONE OWNS the Intellectual Property Associated With Your Genes In Your Body-There is None!**
3. **YOU “Own” the Genes In Your Body**

What About Purified Genes?

*Central Question - Are Genes Patent-Eligible Material?
No - Because of the Myriad Decision*



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

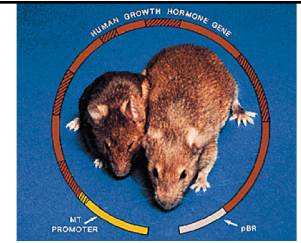
The invention provides polynucleotides for expression of genes in suspensor cells in plants and methods for using such polynucleotides.

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

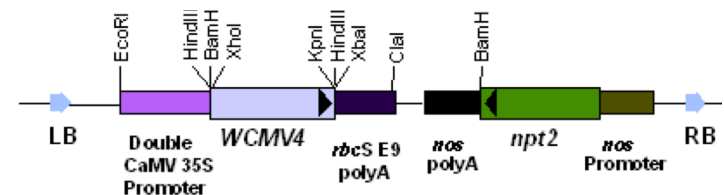


What Is Patent-Eligible Subject Matter After Myriad?

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 Differences From Nature

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



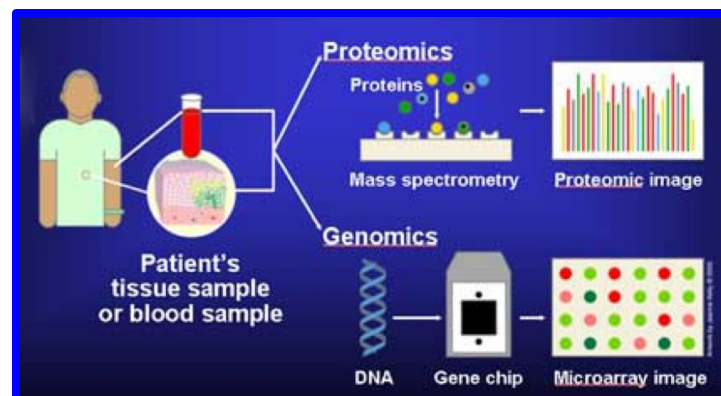
What About Genetic Diagnostic Tests?

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.

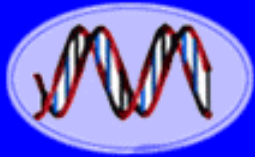
The Court has long held that this provision contains an important implicit exception. “[L]aws of nature, natural phenomena, and abstract ideas” are not patentable. *Dia-*

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

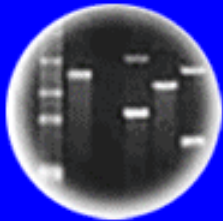
Decision cites landmark Supreme Court ruling in *Myriad Genetics case* *Sequenom vs. Ariosa Diagnostics* - 2014



DNA
Genetic Code of Life



Entire Genetic Code
of a Bacteria



DNA Fingerprinting



Cloning: Ethical Issues
and Future Consequences



Plants of Tomorrow

United States Patent and Trademark Office

Report to Congress
September 2015

Report on Confirmatory Genetic Diagnostic Test Activity

However, especially with respect to most gene-based diagnostics that rely on a correlation between the presence or absence of a particular genetic marker or mutation, almost always there are numerous well-known and effective ways to detect the marker which could not be encompassed by a patent claim. Once the key correlation is published, a third party could exploit any of the well-known methods to use the correlation in a diagnostic test in competition with the patent holder. Unless and until the legal environment shifts again, it is difficult to conceive of a gene-based diagnostic correlation that could be exclusively protected by a patented means of determining the correlation owned by single provider.

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



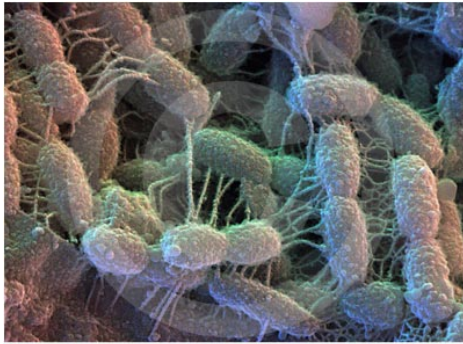
Ananda Chakrabarty



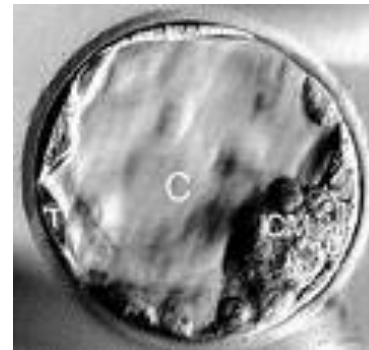
1988

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

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

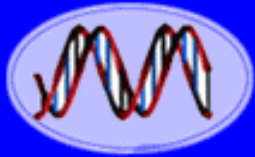


Article of
Manufacture



But Must
Meet All
of the
Criteria
For
Obtaining
a Patent

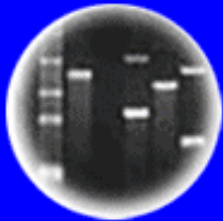




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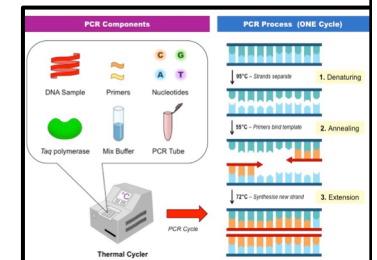
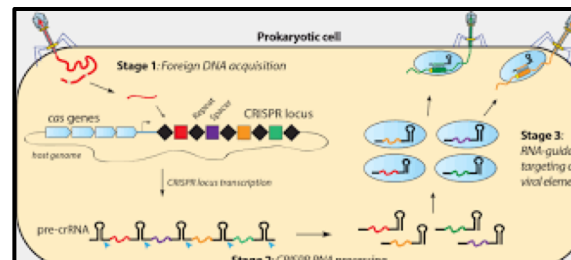
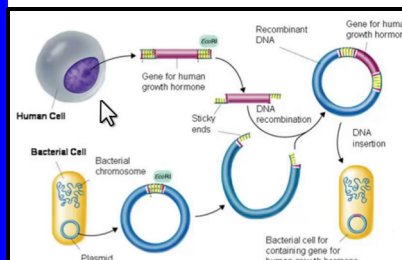
Plants of Tomorrow

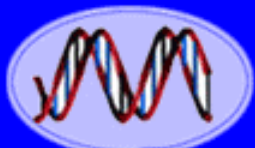
A Common Misperception.....Patents Inhibit the Free Exchange of Information

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!!!

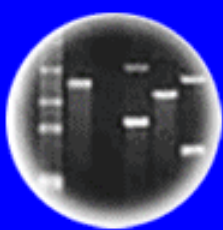




DNA
Genetic Code of Life



Entire Genetic Code of a Bacteria



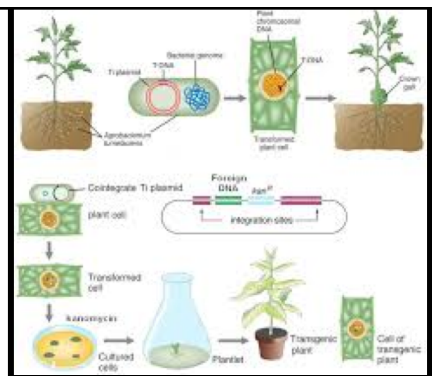
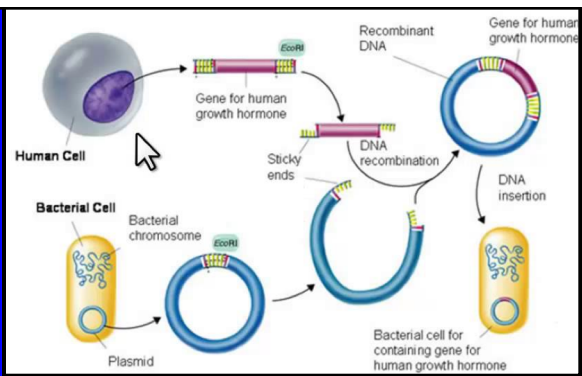
DNA Fingerprinting



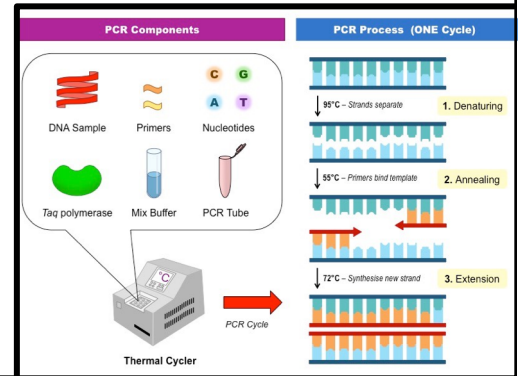
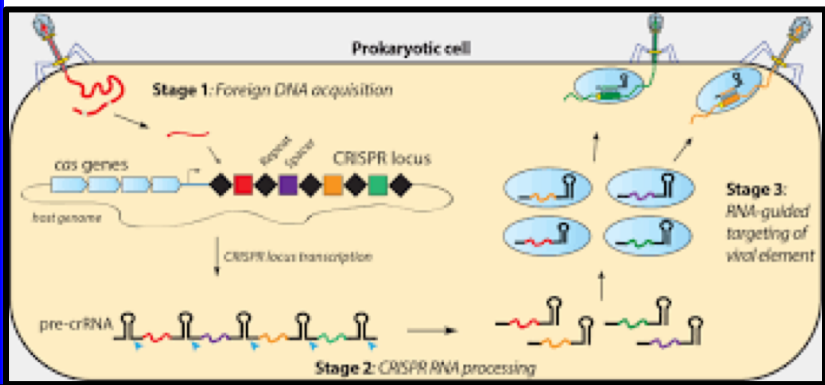
Cloning: Ethical Issues and Future Consequences



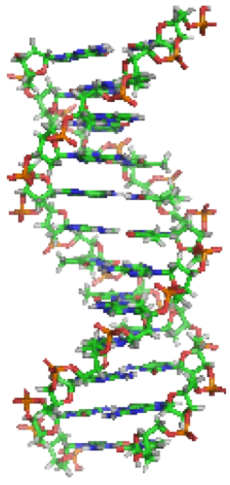
Plants of Tomorrow



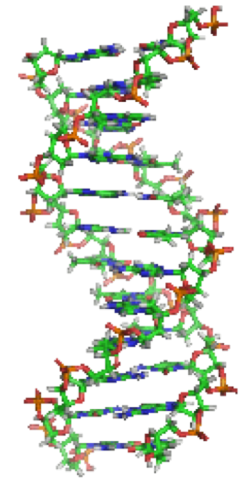
A Summary of Patents, Copyrights & Trademarks as They Apply to Genes & Genetic Engineering



| 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 | √ | | | √ |

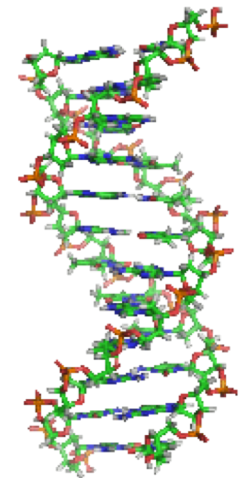
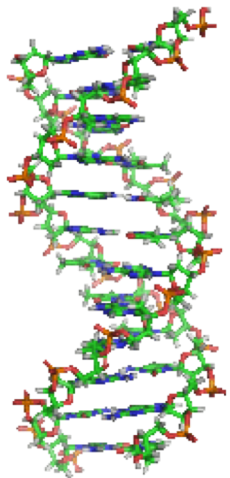


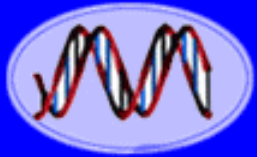
Recall...Way Back in January...



The Age of DNA!

Genetic Engineering Is
Manipulating DNA!

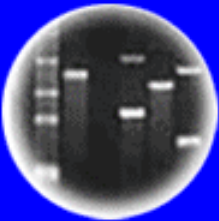




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DNA Fingerprinting



Cloning: Ethical Issues
and Future Consequences



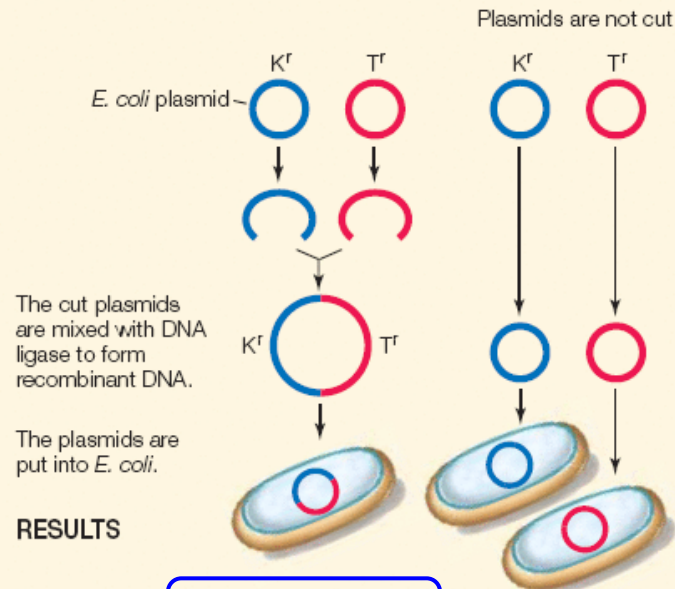
Plants of Tomorrow

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

EXPERIMENT

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

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



RESULTS

Some *E. coli* resistant to both antibiotics.

No *E. coli* doubly resistant.

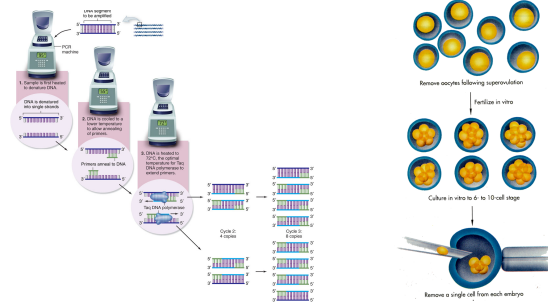
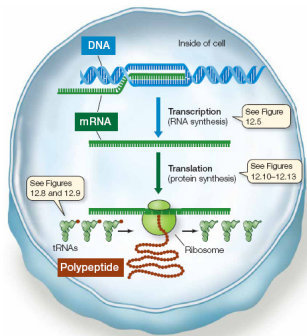
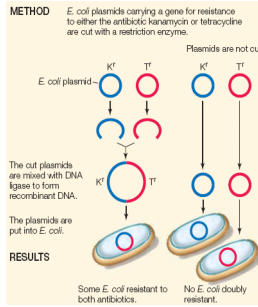
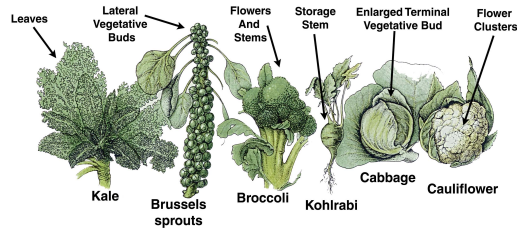
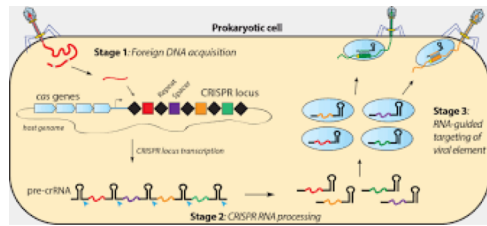
CONCLUSION: Two DNA fragments with different genes can be joined to make a recombinant DNA molecule, and the resulting DNA is functional.

Where it all Began
One Summer in
1973!

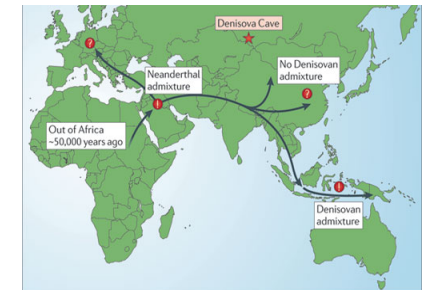
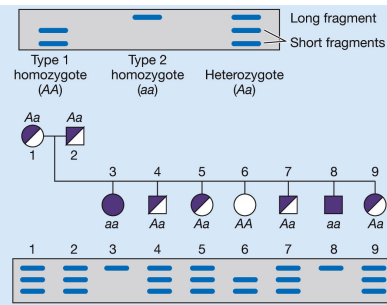
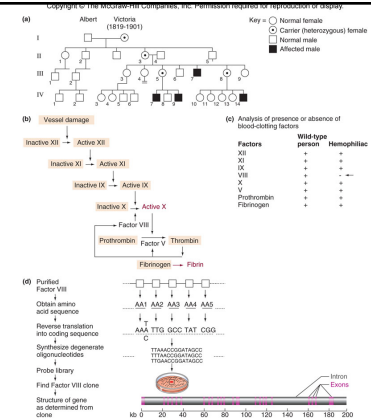
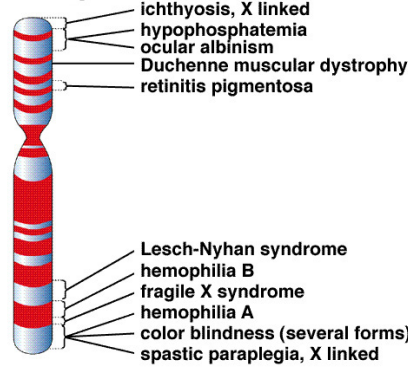
What's a GMO?

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 Paunovic³ & Svante Pääbo¹



Map of chromosome X



NDIS Statistics

ICODIS Home Page | FBI Home Page

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

Total number of profiles: 5,265,258
Total Forensic profiles: 194,785
Total Convicted Offender profiles: 5,070,473

DNA Tribes Genetic Ancestry Analysis

What's Your Tribe?

Discover your connections to over 695 world populations in 4 easy steps.

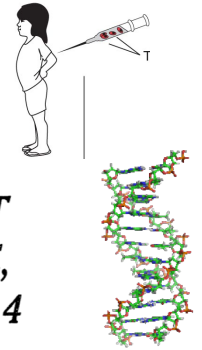
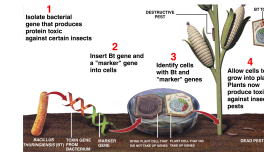
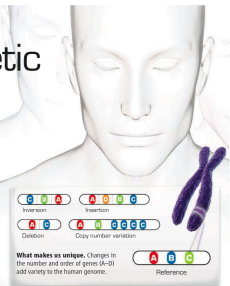
BREAKTHROUGH OF THE YEAR

Human Genetic Variation

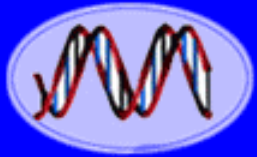
Equipped with faster, cheaper technologies for sequencing DNA and assessing variation in genomes on scales ranging from one to millions of bases, researchers are finding out how truly different we are from one another.

THE UNVEILING OF THE HUMAN GENOME ALMOST 7 YEARS AGO could be the first light on our complete genetic makeup. Although each new genome sequenced in ever more detail, in 2007, researchers came to appreciate the extent to which our genomes differ from person to person and the implications of this variation for deciphering the genetics of complex diseases and personal traits.

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



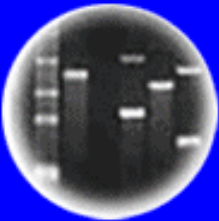
SCIENCE MAY PATENT NEW FORMS OF LIFE, JUSTICES RULE, 5 TO 4



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Genetic Code of Life



Entire Genetic Code
of a Bacteria



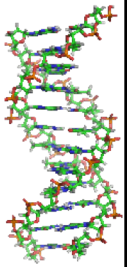
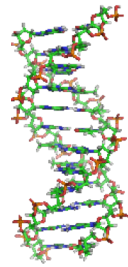
DNA Fingerprinting



Cloning: Ethical Issues
and Future Consequences



Plants of Tomorrow



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

HC70A, SAS70A, & PLS550
WINTER 2019

The End!!

OR

Is It the Beginning?

