




DNA
Genetic Code of Life




Entire Genetic Code
of a Bacteria





DNA Fingerprinting



Cloning: Ethical Issues
and Future Consequences



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HC70A Spring 2021 Genetic Engineering in Medicine, Agriculture, and Law

Professor Bob Goldberg

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

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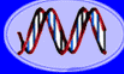


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THEMES

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 Wars
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

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AIDS virus used in gene therapy to fix 'bubble baby' disease

Patents by Inventor Donald B. Kohn

Donald B. Kohn has filed for patents to protect the following inventions. This listing includes patent applications that are pending as well as patents that have already been granted by the United States Patent and Trademark Office (USPTO).

METHODS FOR TREATING SICKLE CELL DISEASE
Publication number: 20210155927

Abstract: The present disclosure provides a method of modifying a globin gene in the genome of a hematopoietic stem/progenitor cell (HSPC), the method comprising: A) obtaining HSPCs from an individual having a globin gene comprising a sickle cell disease (SCD)-associated single nucleotide polymorphism (SNP) to generate an in vitro population of CD34+ HSPCs and B) contacting the in vitro population with a genome editing composition, as described in further detail below. Also provided is a method of treating sickle cell disease (SCD) in an individual including administering to an individual an in vitro mixed population derived from the method of modifying a globin gene, as well as kits for practicing the same.

Type: Application
Filed: April 10, 2019
Publication date: May 27, 2021
Inventors: Mark A. DeWitt, David I. Martin, Wendy Magis, Jacob E. Corn, Mark C. Walters, Donald B. Kohn, Zulema Romero Garcia

'Wicked' Problems, Orchard Therapeutics and Bubble Babies: A California Stem Cell Story



Column: California's stem cell program found a disease cure, but it's being blocked by a biotech firm

Stem cell agency says it's going all out on 'bubble baby' cure

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Patents & Intellectual Property

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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!!

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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.



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How Are Patents Issued and Adjudicated?



US Patent & Trademark Office (USPTO) Issues Patent

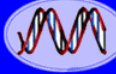
Decision Can Be Appealed to the US Patent Trial & Appeal Board (PTAB)

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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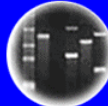
Patent History Origins & Importance




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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 (572 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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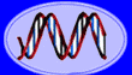
What Are the Different Types of Intellectual Property?

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

Applies to Private & Public Sectors!

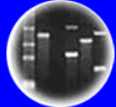
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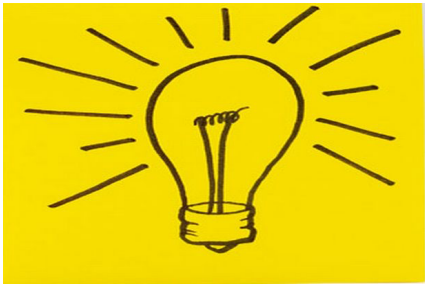
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University of California Royalties From Patent Licenses - 2020

>\$200,000,000



UCLA = \$92M → 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 2040.*

“How to Make bobg” US Patent No. 8,989,755, June 1, 2021

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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 2141!*
5. *There are NO international copyrights. However, US copyrights are protected in other countries by treaties (e.g., Berne Convention)*

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What Can and Cannot Be Copyrighted?

| <u>What Can Be Copyrighted?</u> | <u>What Cannot Be Copyrighted?</u> |
|---|--|
| 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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| Musical Works | Ideas, Procedures, Methods, Processes, Concepts, Principles, Devices |
| Dramatic Works | Common Information With No Authorship (e.g., Calendar, Ruler, Height & Weight chart) |
| Picture, Graphic, and Sculpture Works | Human Genome Sequence |
| Motion Pictures and Other Audiovisual Works | Works With No Creativity (e.g., Phone Book, List of Names) |
| Video Games | Facts and Ideas in Databases |
| Computer Program | Software Elements and Algorithms |
| Architectural and Design Works | |

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® What Are Trademarks & Service Marks? ™

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." Declared unconstitutional by Supreme Court in 2017 & 2019 on 1st Amendment Grounds
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 - 8-0 (2017)**

June 19, 2017 - 10:29 AM ET

Supreme Court Strikes Down Law Barring Vulgar Trademarks **Inacu vs. Brunetti - 9-0 (2019)**

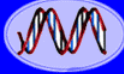







Writing for all eight participating justices, Justice Alito wrote that the disparagement clause "offends a bedrock First Amendment principle: *"Speech may not be banned on the ground that it expresses ideas that offend."* The Court also unanimously rejected the government's argument that trademarks are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


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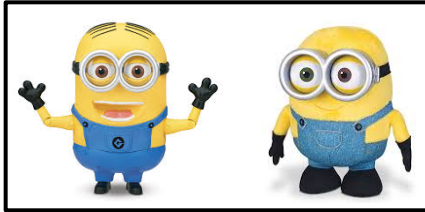
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The Same Trademark Can Be Used in Different Businesses!

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*









Microsoft



TESLA



PORSCHE



amazon

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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

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Patents vs. Trade Secrets?

| Patents | Trade Secrets |
|---|--|
| <ol style="list-style-type: none"> 1. Society Gains Knowledge 2. Patents Published 18 Months After Filing (Patent Pending Status) 3. Patent Expires After 20 Years-Society Can Use 4. Patent Law Protection | <ol style="list-style-type: none"> 1. Prevent Competitors From Gaining Proprietary Information 2. Society Does Not Get Access to Trade Secret Knowledge 3. Limited Protection |

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Patents vs. Trade Secrets?

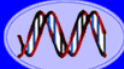
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Summary of Intellectual Property Characteristics

| | |
|---------------------|--|
| 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 |

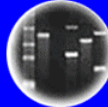
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How Does the Patent System Work?

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American Invents Acts of 2011 Went Into Effect March 16, 2013



- Biggest Change in US Patent System in 60 Years
- To Make US Patents Consistent With Those of Other Countries
 - First To File (Used to Be First to Invent)
 - Patent Runs For 20 Years
 - No Patents on Human Organisms

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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. **Patent Application Published** 18 Months from Filing Date
3. **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
4. **Claims in Invention Set Nature of Protection-What is Claimed in the Invention?** READ CLAIMS!!!
5. Can Be Sold, Traded, Assigned to Others Like Any **Property Right**
6. Patent Property Right is Owned For Only a **Limited Period of Time-Time-Dependent Monopoly (20 Years)**
 - a. Invention Ultimately Belongs to Society
7. Lasts **20 years** From Time of **Filing**

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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

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What About Genetic Engineering?

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**

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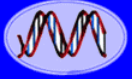
What Are the Different Types of Patents? Specified in the Claims

1. **Utility Patents (Most Common)**
 - a. **Process or Method**
 - i. Recombinant DNA, Stem Cell, CRISPR Procedure
 - b. **Machine or Apparatus**
 - i. PCR or Sequencing Machine
 - c. **Article of Manufacture**
 - i. Transgenic Organism (e.g., GloFish)
 - 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**

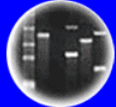
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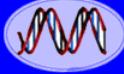
You Have Isolated an Insulin cDNA, Inserted It Into a Plasmid, and Transformed *E. Coli* With the Insulin cDNA Plasmid.

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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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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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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• **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)**

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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!

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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 Subject Material? 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) - OLD SYSTEM

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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.”**

39

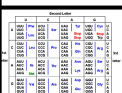
How Are Patents Challenged in the Courts? **Infringement** (Under Both Old and New Systems)

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...

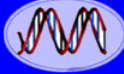
Nature Biotechnology
January 1998




| Gene | Sequence | Protein |
|------|----------|---------|
| ... | ... | ... |

What are the Properties of the Genetic Code?


40




DNA
Genetic Code of Life




Entire Genetic Code
of a Bacteria



DNA Fingerprinting



Cloning: Ethical Issues
and Future Consequences



Plants of Tomorrow

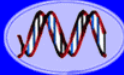
Regents of the University of California v. Eli Lilly and Co
Infringement-Written Description Challenge (1998)

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"), a rat insulin cDNA patent **claimed the "cDNA" sequence for human insulin.**


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

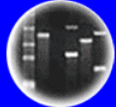
41




DNA
Genetic Code of Life




Entire Genetic Code
of a Bacteria



DNA Fingerprinting



Cloning: Ethical Issues
and Future Consequences



Plants of Tomorrow

Monsanto Wins Case on Genetically Altered Soybeans *Bowman vs. Monsanto - 2013*

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.

In a unanimous opinion written by Justice Elena Kagan, the Supreme Court ruled that **Bowman's conduct infringed Monsanto's patents** and that the doctrine of patent exhaustion does not permit a farmer to reproduce patented seeds by planting and harvesting saved crop seeds without the patent holder's permission. The Court held that, when a farmer plants a harvested and saved seed, thereby growing another soybean crop, that action constitutes an unauthorized "making" of the patented product.

The doctrine of patent exhaustion holds that once a patent owner has sold a patented product for the first time, they no longer have control over it: the buyer can use, sell, license, or destroy it as they wish.

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How Are Patents Challenged in the Courts?




Interference (Only Old System)

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 These Were "Non-Obviousness" (Knowledge in the "Prior Art") &/or "First to Invent"

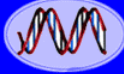
Pivotal CRISPR patent battle won by Broad Institute

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


43

| THE AMERICA INVENTS ACT: | Interference Under Old System 2014-2021 | THE AMERICA INVENTS ACT: |
|--|---|---|
| United States Patent <i>Zhang</i> Eukaryotic Gene Editing | 8,697,359 April 15, 2014 | |
| <i>CRISPR</i> -Cas systems and methods for altering expression of gene products | | |
| United States Patent Application Kind Code <i>Doudna; Jennifer A.; et al.</i> Test-Tube & Bacteria - CRISPR-CAS9 Components | 20180298406 A1 October 18, 2018 | |
| METHODS AND COMPOSITIONS FOR RNA-DIRECTED TARGET DNA MODIFICATION AND FOR RNA-DIRECTED MODULATION OF TRANSCRIPTION | | |
| <div style="border: 1px solid black; padding: 10px; margin: 0 auto; width: 80%;"> <p>CRISPR Patent Fight Now a Winner-Take-All Match</p> <p>UC Appealed Patent Decision by USPTO Under Old System</p> <p>Lab notebooks could determine who was first to invent a revolutionary gene-editing technology.</p> </div> | | |
| <div style="border: 1px solid black; padding: 5px; margin: 0 auto; width: 90%;"> <p>Broad Institute wins bitter battle over CRISPR patents</p> </div> | | |
|  |  |  |


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DNA
Genetic Code of Life




Entire Genetic Code
of a Bacteria



DNA Fingerprinting



Cloning: Ethical Issues
and Future Consequences



Plants of Tomorrow

CRISPR Patent Wars (2014-2021)

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

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!!!!!!!

45

In US Living Organisms and Genetic
Engineering **Are** Patentable


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

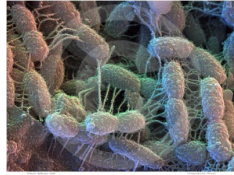
1988

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

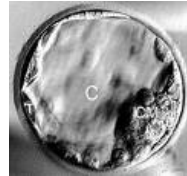


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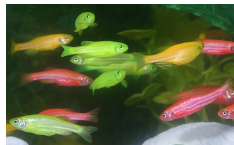
Transgenic Living Organisms **CAN** Be Patented and Are Patent-Eligible Subject Material!



Article of
Manufacture



But Must
Meet All of
the
Criteria
For
Obtaining a
Patent



47

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**

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

PCR (Method)

United States Patent
Mullis

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

United States Patent
Chakrabarty

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

[54] **PROCESS FOR AMPLIFYING NUCLEIC ACID SEQUENCES**
[73] Inventor: **Kary B. Mullis**, Kensington, Calif.
[72] Assignee: **Cetus Corporation**, Emeryville, Calif.
[*] Notice: The portion of the term of this patent subsequent to Jul. 28, 2004 has been disclaimed.

[31] Appl. No.: **791,308**
[22] Filed: **Oct. 28, 1985**

Related U.S. Application Data
[63] Continuation-in-part of Ser. No. 716,875, Mar. 28, 1983, abandoned.
[51] Int. Cl.³ **C2P 19/36; C12N 15/00; C12N 1/00; C07H 21/04; C07H 21/02**
[52] U.S. Cl. **438/91; 435/177.3; 435/311; 536/27; 536/28; 536/29; 935/77; 935/18; 935/16**
[53] Field of Search **435/91; 435/311; 536/27; 28; 29; 935/17; 18**
[56] References Cited
PUBLICATIONS

mentary DNA for cloning". *J. Theor. Biol.* 95: 679 (1982).
Cetus and Robertson, *Nucleic Acids Research*, vol. 7, pp. 1445-1450 (1979).
Rove et al., *J. Biol. Chem.*, 257: 9226-9229 (1982).

Primary Examiner—James Martindell
Attorney, Agent, or Firm—James E. Haski, Albert P. Haski

[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 are 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.

[54] **MICROORGANISMS HAVING MULTIPLE COMPATIBLE DEGRADATIVE ENERGY-GENERATING PLASMIDS AND PREPARATION THEREOF**
[73] Inventor: **Ananda M. Chakrabarty**, Latham, N.Y.
[72] 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; 435/282; 435/973; 435/977**
[53] Field of Search **195/28 R; 1; 3 H; 3 H; 195/98; 78; 79; 112; 435/172; 253; 264; 820; 281; 873; 877**
[56] **References Cited**
PUBLICATIONS
Annual Review of Microbiology vol. 26 Annual Review Inc. 1972 pp. 362-368.
Journal of Bacteriology vol. 106 pp. 466-478 (1971).
Microbiological Reviews vol. 33 pp. 210-263 (1969).

Primary Examiner—R. B. Frenkel

Attorney, Agent, or Firm—Leo I. Maloni, 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-5471]) have been deposited with the United States Department of Agriculture and Nutrient Research Division, Northern Marketing and Nutrient Research Division, Prosser, Ill. The *P. aeruginosa* NRRL B-5471 was derived from *Pseudomonas aeruginosa* strain 1c by the genetic transfer thereof, and contained therein, of camphor, octane, salicylate and naphthalene degradative pathways in the form of plasmids. The *P. putida* NRRL B-5471 was derived from *Pseudomonas putida* strain PG21 by genetic transfer thereof, and contained therein, of camphor, salicylate and naphthalene degradative pathways and drug resistance factor (R.F.), all in the form of plasmids.

18 Claims, 2 Drawing Figures

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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)

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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

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SUPREME COURT OF THE UNITED STATES

Syllabus

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

The KEY SENTENCE



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.

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This Case Has Changed the Gene Patent Landscape



United States Patent
Shattuck-Eidens, et al. 5,683,471
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



Trade Secret Database

- 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 in 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.

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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



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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**

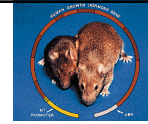
Filed: **November 28, 2000**

What Is No Longer Patent-Eligible Subject Matter?

- **Genes**
- **Switches**
- **Oris**
- **PCR Primers**
- **ASOs (Unless Modified Nucleotides)**
- **CRISPR & Cas9 (Unless Engineered)**

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

54

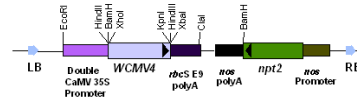


What Is Patent-Eligible Subject Matter After Myriad?

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
- Engineered CRISPR Cas9 and Guide DNAs

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



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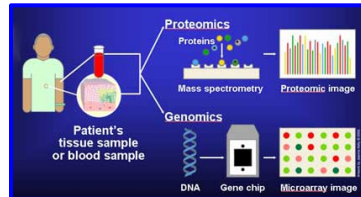
What About Genetic Diagnostic Tests?

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 30, 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. *Die-*

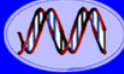
Still, as the Court has also made clear, to transform an inpatentable law of nature into a patent-eligible *application* of such a law, one must do more than simply state the law of nature while adding the words "apply it." See, e.g., *Benson, supra*, at 71–72.

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

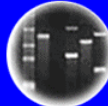
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DNA
Genetic Code of Life




Entire Genetic Code
of a Bacteria



DNA Fingerprinting



Cloning: Ethical Issues
and Future Consequences



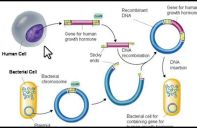
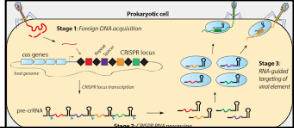
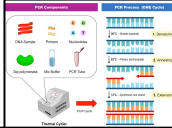
Plants of Tomorrow

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

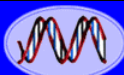
To the Contrary.....Patent Laws REQUIRE Disclosure of the Invention (Written Description & Best Mode of Practice) And ARE PUBLISHED 18 Months After Filing Application. *Alternative Would be Trade Secrets!*

∴ 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!!!

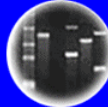
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DNA
Genetic Code of Life




Entire Genetic Code
of a Bacteria



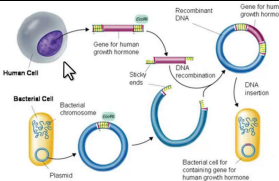
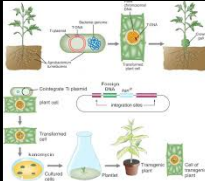
DNA Fingerprinting



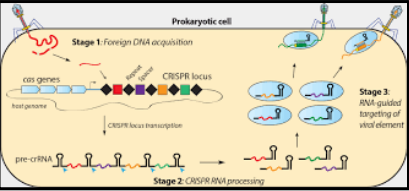
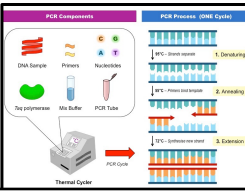
Cloning: Ethical Issues
and Future Consequences



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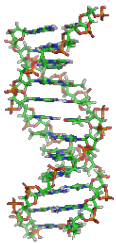
A Summary of Patents, Copyrights & Trademarks as They Apply to Genes & Genetic Engineering

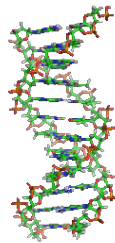
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| Creative Work | Patent | Copyright | Trademark | Trade Secret |
|--|--------|-----------|-----------|--------------|
| Gene in Plasmid (*Only If Different From Natural Sequence) | √* | | | √ |
| Gene Sequence (*Only If Different From Natural Sequence) | √* | | | √ |
| 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 | √ | | | √ |

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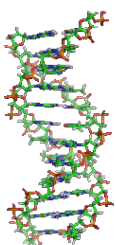
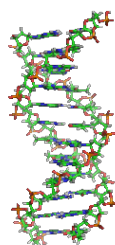


Recall....Way Back in March...

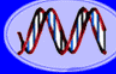


The Age of DNA!


Genetic Engineering Is
Manipulating DNA!

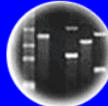
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Cloning: Ethical Issues and Future Consequences



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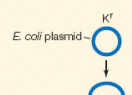
Genetic Engineering Technology Can Combine DNA (Genes) From Different Sources Leading to New Gene Combinations!!

EXPERIMENT

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

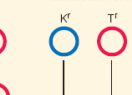
METHOD *E. coli* plasmids carrying a gene for resistance to either the antibiotic kanamycin or tetracycline are cut with a restriction enzyme.

Plasmids are not cut



E. coli plasmid -

K^r T^r



K^r T^r

The out 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.

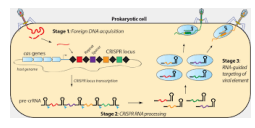

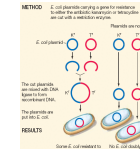
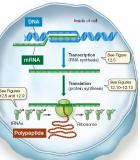

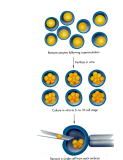
Where it all Began
One Summer in
1973!

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What's a GMO?

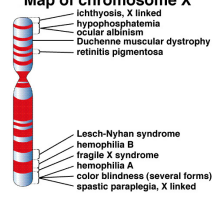
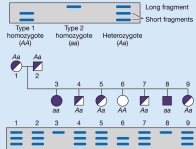



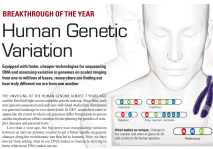
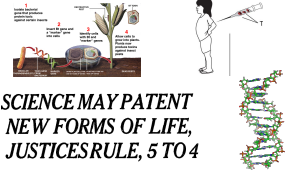
Analysis of one million base pairs of Neanderthal DNA

Richard E. Green¹, Johannes Krause¹, Susan E. Pääk¹, Adrian W. Briggs¹, Michael T. Ronan², Jan F. Simons², Lei Du¹, Michael Egholm¹, Jonathan M. Roiberg¹, Maja Paunovic¹, & Svante Pääbo¹

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

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

HC70A Spring 2021

The End!!

OR
Is It the Beginning?