





HC70A, SAS70A, & PLSS599
Winter 2022
Genetic Engineering in Medicine,
Agriculture, and Law

Professors Bob Goldberg, John Harada, & Channapatna Prakash

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





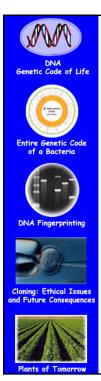


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# Entire Genetic Code of a Bacteria DNA Fingerprinting Cloning: Ethical Issues and Future Consequences

#### **THEMES**

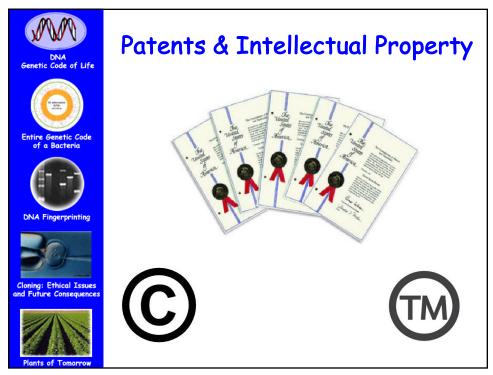
- 1. The Constitution & Regulating Science
- 2. A History of Patents
- 3. What is Intellectual Property?
- 4. What Are the Different Forms of Intellectual Property?
- 5. What Are Patents?
- 6. What Are Copyrights?
- 7. What Are Trademarks and Service Marks?
- 8. What Are Trade Secrets?
- 9. When Are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



# TEXT READING

Chapter 12 Pages 337-341

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# 1. Article I - Section 8.8

# The Congress shall have the Power:

[8] "To Promote the <u>Progress of Science</u> and the useful Arts, by securing for limited Times to Authors and <u>Inventors</u> the <u>exclusive Right</u> to their Writings and <u>Discoveries</u>"

<u>Keyword</u>: Inventors not Science.

Wanted to Promote Economic Development & Promote a <u>National</u>
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.

<u>Key Concept</u>: 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!!



- 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 Agoll)
  - First Patent to John Utynam of Flanders by King Henry VI
  - Method For Cambridge Kings and Eton Colleges' Stained Glass Windows
  - Method Not Previously Known in England (Flanders is in Belgium)
  - King Gave a 20-Year Monopoly to John Utynam in Exchange For Knowledge of His Stained Glass Method
- 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

  - In US Constitution

    Patent Act of 1793 Written and Administered by <u>Thomas Jefferson</u> Laid the
    Foundation For a Patent System That Exists to this Day
    - 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





# 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 - 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 & important back to United States)
- 3. What is granted is not the right to make, use, offer for sale, sell or import, but the right to <u>EXCLUDE OTHERS</u> from making, using, selling, or importing the invention. <u>Term</u>=20 years from <u>filing date</u>. File today, then lasts until 2042.

"How to Make boba" US Patent No. 8,989,755, March 1, 2022

## $\hat{\mathbf{C}}$

## What Are Copyrights?

The bobg HC70A Lectures©

- A form of protection provided to <u>authors</u> of "<u>original works of</u>

  <u>AUTHORSHIP</u> that are <u>TANGIBLY</u> 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 <u>FORM of expression</u> and <u>not the subject</u>

  <u>matter</u> of the writing. Must be original, <u>have some form of creativity</u>,
  and be fixed in tangible medium.
- 3. A copyright gives the owner of a creative work the right to <u>EXCLUDE</u> <u>OTHERS</u> 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 2142!
- 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?

What Can Be Copyrighted?	What Cannot Be Copyrighted?
Literary Works	Works Not In Tangible Form (e.g., spontaneous speech)
Scientific Publications (Including Figures, Tables, & Graphs)	Titles, Names, Phrases, Slogans, Lettering
Musical Works	Ideas, Procedures, Methods, Processes, Concepts, Principles, Devices
Dramatic Works	Common Information With No Authorship (e.g., Calendar, Ruler, Height & Weight chart)
Picture, Graphic, Sculpture, Architecture, and Design Works	Human Genome Sequence
Motion Pictures and Other Audiovisual Works (e.g., HC70A Taped Lectures & Handouts)	Works With No Creativity (e.g., Phone Book, List of Names)
Video Games	Facts and Ideas in Databases
Computer Program (Software)	Software Elements and Algorithms
Factual Databases	

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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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# (R) 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 reregistered every 10 years.
- 2. A service mark is the same as a trademark-except that <u>trademarks</u> <u>promote products</u> and <u>service marks promote services</u> (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 (<u>Lanham Act</u>, 1946).
- 4. <u>Lanham Act</u> provision <u>prohibits</u> the <u>registration</u> of <u>trademarks</u> that <u>may</u> "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 1<sup>st</sup> Amendment Grounds
- 5. Not in Constitution.

boba lectures®

Oca Cola



# Trade Mark vs. 1st Amendment?

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

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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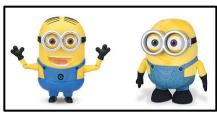


# The Same Trademark Can Be Used in Different Businesses!

# MinION Sequencing



#### Minion Cartoon Character





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#### What Are Trade Secrets?



- 1. <u>INFORMATION that companies keep secret</u> 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.



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

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	Status) Patent Expires After 20 Years	2.	Society Does Not Get Access to Trade Secret Knowledge
		3.	Limited Protection

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# Summary of Intellectual Property Characteristics

Patent	· Constitutional Right				
	· Protects Inventions				
	· Right to Exclude Others From Using Invention				
	· No Right to Make \$				
Copyright	· Constitutional Right				
., 3	· Protects Original Works of Authorship & Expression				
	· Right to Exclude Others From Copying + Using + Performing				
	· No Right to Exclude Others From Using Ideas in Work				
Trademark	· Legislated Right (Lanham Act)				
	· Protects Symbol or Name Indicating Source of Goods/Services				
	· Right to Exclude Others From Using Same Mark				
Trade Secret	· Legislated Right				
	· Protects Anything By Virtue of Secrecy/Confidentiality/Privacy				





# How Does the Patent System Work?

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#### THE AMERICA Invents Act:

#### THE AMERICA Invents Act:

## 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 (Used to Be 17 Years)
    - No Patents on Human Organisms

#### The US Patent System

- 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 Patent
- 3. Pending Status Once Filed Until Granted (No Legal Protection)
- 4. 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

  - Can File a PCT (Patent Cooperative Treaty) Application
- 5. Claims in Invention Set Nature of Protection-What is Claimed in the Invention? READ CLAIMS!!!
- 6. Can Be Sold, Traded, Assigned to Others Like Any Property Right
- 7. Patent Property Right is Owned For Only a <u>Limited Period of Time</u>-Time-Dependent Monopoly (20 Years)
  a. Invention Ultimately Belongs to Society
- 8. Lasts 20 years From Time of Filing
- 9. Governed By Constitution and Federal Laws

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# What is a Patentable Invention?

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

"Whoever Invents or Discovers Any New and Useful Process, Machine, Manufacture, or Composition of Matter, or Any New and Useful Improvement Thereof, May Obtain a Patent Subject to the Conditions of the Title" Key Words: New & Useful

Process, Machine, Manufacture, or Composition of Matter

# What 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 (<u>Engineered</u> 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 (Hybrid Corn Variety)



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	Туре
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? Application MUST Address Each Criterion!

- 1. Must Be <u>Patent-Eligible</u> 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
- Must <u>Describe</u> the <u>Best Mode of Making</u> and Using, or Practicing, the <u>Invention</u> (<u>Enablement</u>)
- <u>These Criteria</u> <u>Are Set Forth in Title 35 of US Code</u> 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.
- <u>A Patent Is Only Valid in Country Where Issued</u>. Each Country Has Its Own Set of Criteria
- <u>A Contract Between Inventor and Society</u>. 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 <u>Subject Matter?</u>

- 1. Machine or Apparatus
  a. PCR Machine
  b. Sequencing Machine
  - **b**.

  - GeneChip Gel Electrophoresis Apparatus 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) c. d.

  - DNA Sequencing Sequence of Software Algorithms That Tell a Machine How to Run
  - CRISPR Procedure
- Article of Manufacture
  - A Genetically Engineered Organism (e.g., GloFish, Insect Resistant Plant)
- 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)

  - Purified Microorganisms (e.g., pure culture of antibiotic-producing bacteria-In
  - Re Bergy-1977) NOT DNA Sequences Identical to What is in Chromosomes (Myriad, 2013)
- Non-Obvious Improvements on Any of the Above (Different Patent)

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#### What Is Not Patent-Eligible <u>Subject Matter?</u> A Critical Criterion For Genes & Gene Tests

- 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
- 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?

- 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. Get Patent Pending Status Until Granted.
  - Filing Date Critical
  - Time Period For Patent Starts When Patent Application Filed (20 Years)
  - **Invention Priority-First To File**
- Patent Application Published After 18 Months and Becomes Prior Art But Have a "Grace Period" To <u>Publish</u> Your Own Patent Research Prior to Filing Patent
- 3. Patent Examiners At USPTO Examine Patent Application
  - 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
  - Review: Patent Eligible Subject Material? Prior Art? Novel and New? Utility? Non-Obvious? Written Description? Best Mode of Practice? Claims?
- Review Process (Average of 25 Months)
  - Send Official Letter Accepting or Rejecting Claims-Some or All
  - Applicant Can Respond

  - Final Letter Granting or Rejecting Patent Application
    Applicant Can Appeal to Federal Courts (e.g., Diamond vs. Chakrabarty Case)
- 5 Challenge (Very Expensive)
  - Infringement-Someone Illegally Practicing Invention (e.g., UC vs. Lily)
    Interference-I Invented First (e.g., CRISPR War) OLD SYSTEM

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## The United States Patent System Is "Morally Neutral"

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

# Existing Patents Can Be Challenged Only On:

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

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

Nature Biotechnology January 1998

What are the Properties of the Genetic Code?

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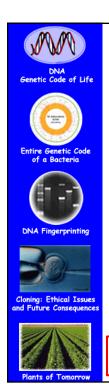


Regents of the University of California v. Eli Lilly and Co <u>Infringement-Written Description Challenge (1998)</u>

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!



## 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 <u>principle of patent exhaustion</u> enabled him to use soybean seeds that he sold and repurchased 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.

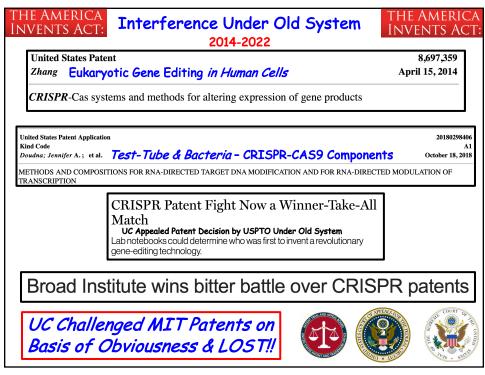
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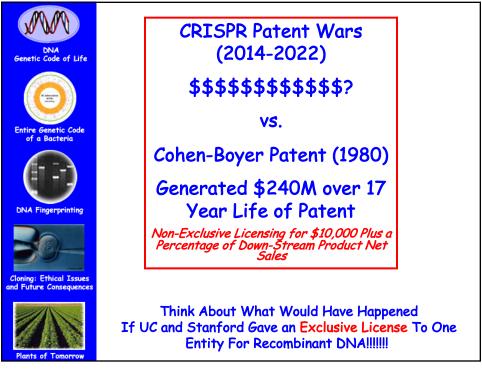
# How Are Patents Challenged in the Courts? Interference (Only Old System)

- 1. Under Old System in the US Issued Patents Could Be Challenged On First to Invent.
- 2. But Still Needed To Use a <u>Criterion For Awarding a Patent</u> (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 <u>Not Obvious</u> and Turned Down UC Berkeley's Interference on Broad <u>CRISPR Patent</u>





# 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



Harvard Mouse



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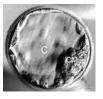
# Transgenic Living Organisms CAN Be Patented and Are Patent-Eligible Subject Material!







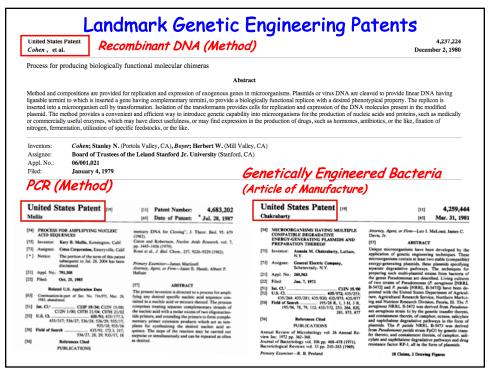






Article of Manufacture

But Must
Meet All of
the
Criteria
For
Obtaining a
Patent







#### In 2013 Everything Changed!!

#### SUPREME COURT OF THE UNITED STATES

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

Genes Not Patent-Eligible Subject Material



UNITED STATES PATENT AND TRADEMARK OFFICE

#### MEMORANDUM

DATE: March 4, 2014

TO: Patent Examining Corps FROM: Andrew H. Hirshfeld

Deputy Commissioner For Patent Examination Policy

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

Natural Products

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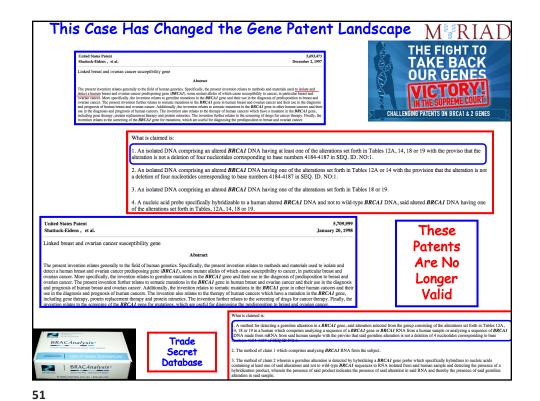
#### SUPREME COURT OF THE UNITED STATES

Syllabus

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

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







## Who Owns Your Genes?



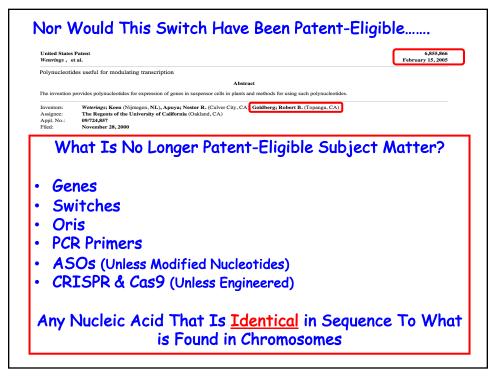
- Genes in Your Body Exist in Nature and Are NOT Patent-Eligible Subject Material or Patentable
- 2. .: NO ONE OWNS the Intellectual Property
  Associated With Your Genes In Your Body-There is
  None!
- 3. YOU "Own" the Genes In Your Body

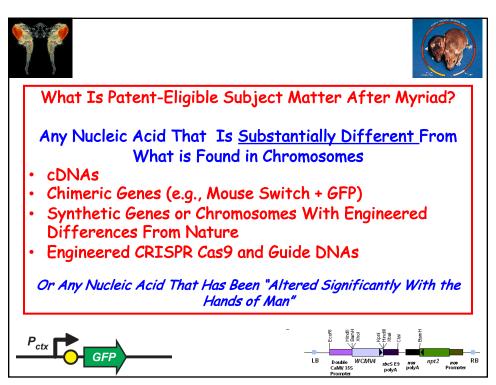
What About Purified Genes?

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









#### What About Genetic Diagnostic Tests?

# MAYO CLINIC **PROMETHEUS**

#### SUPREME COURT OF THE UNITED STATES

No. 10-1150

MAYO COLLABORATIVE SERVICES, DBA MAYO MEDICAL LABORATORIES, ET AL., PETITION-ERS v. PROMETHEUS LABORATORIES, INC. ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

JUSTICE BREVER delivered the oninion of the Court

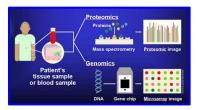
JUSTICE BREYER delivered the opinion of the Court.

Section 101 of the Patent Act defines patentable subject atter. 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 thereofer, 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 paper about his also made clear, to transform an impatentable law of nature into a patent-eligible application of such a law, one must do more than simply state the worf nature while adding the words "apply it." See, e.g., lenson, supra, at 71–72.



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 patents. 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

COURT RULING INVALIDATES PATENT ON NONINVASIVE TEST FOR DOWN SYNDROME

Court ruling in Muriad Genetics case Sequenom vs. Ariosa Diagnostics - 2014

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

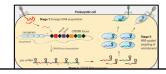
To the Contrary.......Patent Laws REQUIRE Disclosure of the Invention (Written Description & Best Mode of Practice) And ARE PUBLISHED 18 Months After Filing Application. Alternative Would be Trade Secrets!

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

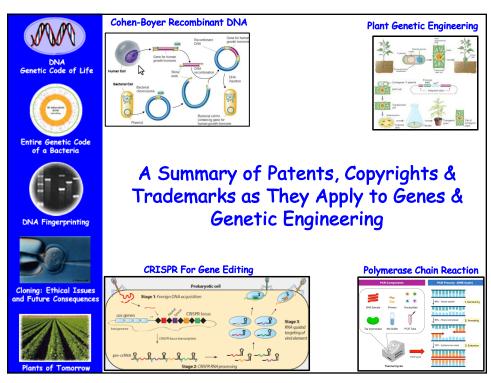
For Example: Recombinant DNA, Genetic Engineering, PCR, DNA Sequencing. CRISPER, etc!!!











Creative Work	Patent	Copyright	Trademark	Trade Secret
Gene in Plasmid (*Only If Different From Natural Sequence)	√*			√
Gene Sequence (*Only If Different From Natural Sequence)	√*			4
Gene Database		1	1	√
DNA Software (*If Part of A Machine/Technical/Physical Result)	√*	√	4	1
Transgenic Organism	√			√
Biotech Co. Logo			1	
23 & Me Website (*As a Business)		1	<b>√</b> *	
DNA Test to Detect CF			4	√
Research Article		√		
Stem Cell Line (* In USA)	√*			1
PCR Technique	√			<b>√</b>
Genome Project Website		√		
CRISPER Technique	<b>√</b>			<b>V</b>



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



# The Age of DNA!

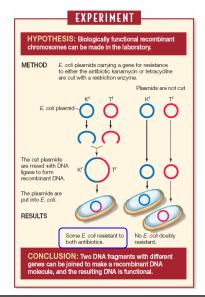
Genetic Engineering Is Manipulating DNA!



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



Where it all Began One Summer in 1973!

