

HC 70A

WINTER 2003

Professor Bob Goldberg

Learning Unit #5

Science and the Constitution:

Who owns our Genes?

THEMES/CONCEPTS

- ✓ ① Science in the Constitution
- ✓ ② Regulating Science
- ✓ ③ What is Intellectual Property?
- ✓ ④ Patents, Trademarks, & Copyrights
- ✓ ⑤ What is a patent?
- ⑥ ^{Stop} What criteria used to award a patent?
- ⑦ How does the Patent Process work?
- ⑧ How do Patents drive Biotech Industry?
- ⑨ What about Patents & University?
- ⑩ Who owns our genes?
- ⑪ Is Life Patentable?
- ⑫ Objections to Patents

1- 2.5 hr Lecture
2/4/03

⊕

1- 1.75 hr Lecture
2/11/03

⊕

RR Film - Night Line
Kerry Hallis
0.5hr

Science is a very human form of knowledge. We are always at the brink of the known, we always feel forward for what is to be hoped. Every judgment in science stands on the edge of error, and is personal. Science is a tribute to what we can know although we are fallible. In the end the words were said by Oliver Cromwell: 'I beseech you, in the bowels of Christ, think it possible you may be mistaken'.

JACOB BRONOWSKI'
'The Ascent of MAN''
1973

①

Risks of Common Activities

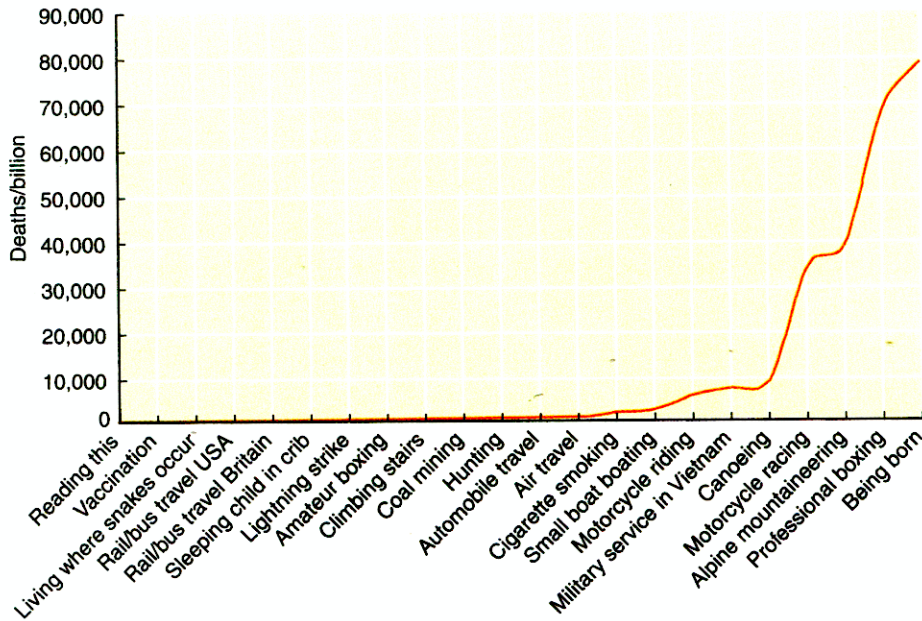


Figure 20.9 Real risks of common activities from actuary data. The risk is not the total number of deaths, but rather the total number divided by the number of people engaged in each activity. Sources: W. Stannard, *Insurance*, October 25, 1969; E. E. Pochin (1974), Occupational and other fatality rates, *Community Health* 6:2-13.

What are the benefits vs. the risks?

No Science/Technology is free of Risk

Automobiles, Roads, Aviation, Telecommunications, Medicine, Information Technology, Nuclear Energy, Genetic Engineering -

②

NEW KEY TECHNOLOGIES OF PAST 100 years

- ① Telecommunications
telegraph, telephone, fax, answering machines, mobile phones, pagers
- ② AUTOMOBILE & ROADS
- ③ Aviation - Space Technology
airplanes, rockets, satellites - tv phone, telecommunication, weather prediction, etc.
- ④ CHEMICALS
plastics, fertilizers, herbicides, pesticides, drugs, understanding of chemicals
- ⑤ FARMING & Food Production
tractor, genetics, irrigation, fertilizers, herbicides, pesticides (fungus, insects, bacteria), satellites, gene engineering, food processing, refrigeration → transport
- ⑥ Nuclear Energy
- ⑦ Information / Computers
computers, ATMs, email, electronic banking
- ⑧ Reproduction
IVF, contraception, Pre-natal Diagnosis, "twins"

⑨ Gene Technologies

Genetic Engineering, Genome Projects, DNA Testing,
Age of DNA, Forensics

Technology Has Become a Dominant Force
in Industrialized Society - Allows us
to live the way we do - All Technologies
Affect the way we think & live - Carry
risks & rewards -

NEED SCIENCE-BASED SOLUTIONS
TO MITIGATE RISKS
IF ANY

HOW CAN SCIENCE AND
RESEARCH/Experimentation
Be Regulated in the
USA ?

What is in the Constitution About Science?

DIRECTLY?

① Article I - Section 8.8

Among the Congressional delegated/Vested powers is: the authority "to PROMOTE THE PROGRESS OF SCIENCE AND USEFUL ARTS by securing for limited times to AUTHORS and INVENTORS the exclusive Right to their respective Writings and Discoveries."

② Article I - Section 8.18

"To Make ALL LAWS which shall be necessary and proper for carrying into Execution the foregoing Powers, and all other Powers vested by this Constitution of the United States, or in any Department or Officer thereof."

Key word: INVENTOR not science. Wanted to promote economic advancement + promote a NATIONAL economic policy grounded in private property rights

∴ Established Patent & Trade Office + Patent LAWS/codes 1836

INDIRECTLY?

① Preamble

"We the People of the United States, in order to form a more perfect Union, establish Justice, insure domestic TRANQUILITY, provide for the common defense, promote the General Welfare,
----- "

② Article I - Section 8.1

Among the Congressional Delegated/Vested powers is: "Power to lay and collect TAXES, Duties, Imports, and EXCISES, to pay the Debts, and provide for the common Defense and general Welfare

- ∴ Established: National Academy of Sciences (1863), Smithsonian Institute (1846), National Bureau of Standards (1901), Public Health Service (1912), NIH (1930), National Science Foundation (Office for Scientific Research and Development → A-bomb) (1946), USDA, EPA, FDA, CDC, NASA, etc., etc.

ALL vested under Constitutional grant to Congress to promote the general welfare - all involved in science activities - science + technology closely interconnected

What other Parts of the Constitution Affect Science & Scientific Research &/or Applications?

- ① Amendment I - Bill of Rights (Freedom of Speech + Expression)
"Congress shall make no Law respecting establishment of religion, prohibiting the free exercise thereof, or abridging the freedom of speech, or of the press, or the right of the people peaceably to assemble,
....."
- ② Amendment IV - Bill of Rights (Searches & Seizures)
"The right of the people to be secure in their persons, houses, papers, and effects, against unreasonable searches and seizures, shall not be violated, and no warrants issued, but upon probable cause, supported by oath or affirmation, and particularly describing the place to be searched, and the persons or things to be seized."
- ③ Amendment V - Bill of Rights (Life, Liberty, Property)
"No person shall be deprived of life, liberty, or property without due process of law....."
Griswold vs. Connecticut (1965)
Liberty = Privacy = right to things

Other Parts of the Constitution con't

④ Amendment XIII (Involuntary Servitude)

"Neither slavery nor involuntary servitude, except as punishment for a crime whereof the party shall have been duly convicted, shall exist with the United States...."

⑤ Amendment XIV (State Life, Liberty, Due Process)

Section 1: "nor shall any State deprive a person of life, liberty, or property without due process of law...."

liberty = right to privacy

HOW DO THESE ARTICLES AND AMENDMENTS APPLY TO SCIENCE?

① Article I - Section 8.8

Intellectual property → patents / patent law

② Article I - Section 8.1

promote the general welfare → fund / explore science
→ regulate health (federal police powers) → DNA testing?

③ Amendment X

police powers to states

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

Gibbons vs. Ogden (1824) - John Marshall

"that immense mass of legislation, which embraces everything within a territory or state ----"

"the totality of state legislative power = the police power" (1827) - defined as "the authority to provide for the public health, safety, and morals" → DNA testing?

④ Amendment IV

body parts - e.g., DNA samples / DNA testing

⑤ Amendment V

liberty (privacy) - procreative choice / cloning?

How do amendments relate to science? Con 14

⑥ Amendment VIII

Involuntary servitude - patenting humans

⑦ Amendment XIV

States / due process / liberty (privacy)

↳ procreative choice / cloning

CAN SCIENTIFIC INQUIRY & RESEARCH BE REGULATED?

- ① Freedom of Speech includes Right to Scientific Inquiry ∴ have right to think about nature, ponder theories, hypotheses, and how the world/universe works — *Griswold vs. Connecticut (1965) Privacy*
- ② Freedom of Speech/Press includes Right to Publish ∴ have right to publish scientific theories, results, hypothesis, "scientific speech" — BUT NOT ABSOLUTE (Freedom of Speech not absolute) — ∴ might be outweighed by PUBLIC INTEREST (e.g., publishing a paper on how to make bioweapons?) — must have redeeming social importance — no threat to community standards —
∴ "Have the right to do research & advance the state of man's knowledge"
- ③ Freedom to assemble peacefully ∴ groups can come together in a meeting, laboratory, etc. to do research! Exchange ideas, exchange views, seek truth, instruct, teach, learn about science — all protected by FIRST Amendment —

∴ HAVE AN ABSOLUTE RIGHT TO CARRY OUT SCIENTIFIC INQUIRY/RESEARCH

WHAT ABOUT EXPERIMENTATION? CAN IT BE REGULATED?

There is NO FUNDAMENTAL RIGHT of Scientific Inquiry TO UNDERTAKE EXPERIMENTS!!

- ① When move from Reflection, theory, thought to experimentation & testing hypothesis → move from world of speech (talking, publishing) to WORLD of ACTION!! Action = CONDUCT!
- ② CAN distinguish between research that is Hazardous & that which is not hazardous —
- ③ Experimentation triggers public welfare considerations.
- ④ freedom to pursue knowledge is distinguishable from right to choose the method for achieving that knowledge.

What is the Relationship Between Science & The Law?

1975 Recombinant DNA Guidelines

		BIOLOGICAL CONTAINMENT (FOR <i>E. COLI</i> HOST SYSTEMS ONLY)		
		EK1	EK2	EK3
PHYSICAL CONTAINMENT	P1	<p>DNA from nonpathogenic prokaryotes that naturally exchange genes with <i>E. coli</i></p> <p>Plasmid or bacteriophage DNA from host cells that naturally exchange genes with <i>E. coli</i>. (If plasmid or bacteriophage genome contains harmful genes or if DNA segment is less than 99 percent pure and characterized, higher levels of containment are required.)</p>		
	P2	<p>DNA from embryonic or germ-line cells of cold-blooded vertebrates</p> <p>DNA from other cold-blooded animals and lower eukaryotes (except insects maintained in the laboratory for fewer than 10 generations)</p> <p>DNA from plants (except plants containing known pathogens or producing known toxins)</p> <p>DNA from low-risk pathogenic prokaryotes that naturally exchange genes with <i>E. coli</i></p> <p>Organelle DNA from nonprimate eukaryotes. (For organelle DNA that is less than 99 percent pure higher levels of containment are required.)</p>	<p>DNA from nonembryonic cold-blooded vertebrates</p> <p>DNA from moderate-risk pathogenic prokaryotes that naturally exchange genes with <i>E. coli</i></p> <p>DNA from nonpathogenic prokaryotes that do not naturally exchange genes with <i>E. coli</i></p> <p>DNA from plant viruses</p> <p>Organelle DNA from primates. (For organelle DNA that is less than 99 percent pure higher levels of containment are required.)</p> <p>Plasmid or bacteriophage DNA from host cells that do not naturally exchange genes with <i>E. coli</i>. (If there is a risk that recombinant will increase pathogenicity or ecological potential of host, higher levels of containment are required.)</p>	
	P3	<p>DNA from nonpathogenic prokaryotes that do not naturally exchange genes with <i>E. coli</i></p> <p>DNA from plant viruses</p> <p>Plasmid or bacteriophage DNA from host cells that do not naturally exchange genes with <i>E. coli</i>. (If there is a risk that recombinant will increase pathogenicity or ecological potential of host, higher levels of containment are required.)</p>	<p>DNA from embryonic primate-tissue or germ-line cells</p> <p>DNA from other mammalian cells</p> <p>DNA from birds</p> <p>DNA from embryonic, nonembryonic or germ-line vertebrate cells (if vertebrate produces a toxin)</p> <p>DNA from moderate-risk pathogenic prokaryotes that do not naturally exchange genes with <i>E. coli</i></p> <p>DNA from animal viruses (if cloned DNA does not contain harmful genes)</p>	<p>DNA from nonembryonic primate tissue</p> <p>DNA from animal viruses (if cloned DNA contains harmful genes)</p>
	P4		<p>DNA from nonembryonic primate tissue</p> <p>DNA from animal viruses (if cloned DNA contains harmful genes)</p>	

"SHOTGUN" EXPERIMENTS USING *E. COLI* K-12 OR ITS DERIVATIVES AS THE HOST CELL AND PLASMIDS, BACTERIOPHAGES OR OTHER VIRUSES AS THE CLONING VECTORS

EXPERIMENTS IN WHICH PURE, CHARACTERIZED "FOREIGN" GENES CARRIED BY PLASMIDS, BACTERIOPHAGES OR OTHER VIRUSES ARE CLONED IN *E. COLI* K-12 OR ITS DERIVATIVES

Were these Guidelines legislated & could they have been legislated?

HOW CAN EXPERIMENTATION BE REGULATED?

① Police Powers of Federal + State Governments to Promote the General Welfare PUBLIC + PRIVATE

"If inherently hazardous to protect welfare of public or individual"

(a) CASE #1 - RECOMBINANT DNA - Cambridge, MA city council

Facts - Cambridge City Council in 1974 tried to ban all recombinant DNA Experiments from inside city
"Threats of diseases + monsters that could be brought about by recombinant DNA - gene splicing should be banned within city limits"

Outcome - After a heated debate - Cambridge Experimentation Review Board recommended going forward under NIH Guidelines - citizens "jury" the CERB - lay people came to sensible conclusion -
Obviously Fears never realized

(b) Possible Case #2 - Human Cloning

Could ban because not 100% confident that health/welfare child be like "normal" child - but might conflict with "right to privacy - procreative choice"

(c) CASE #3 - Registration of potential pathogens for Biowarrens

e.g., ebola, anthrax

HOW CAN EXPERIMENTATION BE REGULATED?

① Police Powers of Federal + State Governments to Promote the General Welfare (PUBLIC + PRIVATE)

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REGULATION OF EXPERIMENTATION CON'T

Fed #

(2) Funding - Research # PUBLIC

Regulate thru power of funding Research

(a) No Constitutional Right to obtain \$ for scientific inquiry/research -

Case #1 - Embryonic Stem Cells / Human

Facts - Was banned under Papa Bush & allowed under Clinton - Baby Bush only allows research on stem cell lines that exist (260).

Case #2 - possible BAN on all human cloning?? CONSTITUTIONAL?

(L) Must abide by conditions of funding Agencies to obtain \$ - Can't send in grants or get \$

Case #1 - Transgenic Plants / Testing

Facts - observe USDA/EPA guidelines for field tests

Case #2 - Human Subjects

Facts - Follow IRB (Institution Review Boards) guidelines & obtain informed consent of patients & confidentiality clauses

→ Case #3 - Recombinant DNA (His torical)

Facts - Follow Recombinant DNA Advisory Committee Recommendations (RACs) before getting \$ -

Who owns our Genes?

Article I. Section 8. P

.... Power to promote the Progress of Science and useful Arts, by securing for limited Times to Authors & Inventors the exclusive Right to their respective Writings & Discoveries. "

- ① Is a Gene Patentable? A "switch"? In your body?
- ② Is the technique of recombinant DNA patentable?
- ③ Are living organisms patentable?

WHAT IS INTELLECTUAL PROPERTY?

- ① Patents
- ② Copyrights
- ③ TRADEMARKS



UNITED STATES PATENT AND TRADEMARK OFFICE

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What Are Patents, Trademarks, Servicemarks, and Copyrights?

(Excerpted from *General Information Concerning Patents* print brochure)

Some people confuse patents, copyrights, and trademarks. Although there may be some similarities among these kinds of intellectual property protection, they are different and serve different purposes.

What Is a Patent?

A patent for an invention is the grant of a property right to the inventor, issued by the Patent and Trademark Office. The term of a new patent is 20 years from the date on which the application for the patent was filed in the United States or, in special cases, from the date an earlier related application was filed, subject to the payment of maintenance fees. US patent grants are effective only within the US, US territories, and US possessions.

The right conferred by the patent grant is, in the language of the statute and of the grant itself, "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. 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, offering for sale, selling or importing the invention.

What Is a Trademark or Servicemark?

A trademark is a word, name, symbol or device which is used in trade with goods to indicate the source of the goods and to distinguish them from the goods of others. A servicemark is the same as a trademark except that it identifies and distinguishes the source of a service rather than a product. The terms "trademark" and "mark" are commonly used to refer to both trademarks and servicemarks.

Trademark rights may be used to prevent others from using a confusingly similar mark, but not to prevent others from making the same goods or from selling the same goods or services under a clearly different mark. Trademarks which are used in interstate or foreign commerce may be registered with the Patent and Trademark Office. The registration procedure for trademarks and general information concerning trademarks is described in a separate pamphlet entitled "Basic Facts about Trademarks".

What Is a Copyright?

Copyright is a form of protection provided to the authors of "original works of authorship" including literary, dramatic, musical, artistic, and certain other intellectual works, both published and unpublished. The 1976 Copyright Act generally gives the owner of copyright the exclusive right to reproduce the copyrighted work, to prepare derivative works, to distribute copies or phonorecords of the copyrighted work, to perform the copyrighted work publicly, or to display the copyrighted work publicly.

The copyright protects the form of expression rather than the subject matter of the writing. For example, a description of a machine could be copyrighted, but this would only prevent others from copying the description; it would not prevent others from writing a description of their own or from making and using the machine. Copyrights are registered by the [Copyright Office of the Library of Congress](#).

What is A TRADEMARK?

- ① A word, NAME, symbol or device to indicate **source of goods** and to distinguish them from others
- ② Registered with USPTO
- ③ Lasts for 10 years ⊕ 10 year Extension
∴ **20 years MAXIMUM**
- ④ CAN prevent others from using SAME mark — but **NOT** from selling/TRADING SAME goods under a different mark.
- ⑤ Domain NAMES for web sites fall within USPTO x trademark system
- ⑥ CAN be transferred, sold, acquired like any property right

bobg[®]

WHAT IS A COPYRIGHT?

18

The baby Book²

- ① Form of Protection to **authors** of "original works of authorship," including literary, drama, Musical, artistic, and certain other intellectual works. Both published & unpublished works.
- ② Gives owner of copyright the exclusive right to do & authorize others to do the following:
 - (a) To reproduce the work in copies
 - (b) to prepare derivative works
 - (c) to distribute copies
 - (d) to perform work publicly or by means of digital transmission
 - (e) to display work publicly
- ③ copyright protection starts when work created in fixed form - Non-registered right (unlike patents & trademarks) - Through Library of Congress
- ④ What is not copyright protected?
 - (a) works that have not been fixed in tangible form (e.g., an improvisational speech).
 - (b) ideas, procedures, methods, processes, principles, discoveries, devices - as distinguished from a description
 - (c) works consisting entirely of information that is common property & contains no original authorship (e.g., a calendar).
- ⑤ Form of Expression / Not Subject Matter
- ⑥ Protected for author's life + 70 years - For works made by Hire - For 95 years from publication, or 120 years from creation (which starts

What is a Patent?

ONE FORM OF INTELLECTUAL PROPERTY

- ① Exclusive rights granted to an inventor for a limited time to "exclude others from making, using, offering for sale, or selling the invention, in the United States.
- ② Right is to exclude others from making, selling, using invention, but NOT right to make, use, sell, import.
- ③ Claims in invention set nature of protection.
- ④ Invention may be a composition of matter or Process/Utility (How to do something).
- ⑤ US Patents only valid in US
- ⑥ CAN be sold, traded, assigned to others like any property right.
- ⑦ Is NOT ownership - only a right granted for limited time. COMPACT BETWEEN INVENTOR + SOCIETY
- ⑧ LASTS for 20 years FROM TIME OF FILING - NOT when patent issued!

How to Make baby

United States Patent 8,763,432

2/4/03

What is a Patentable Invention?

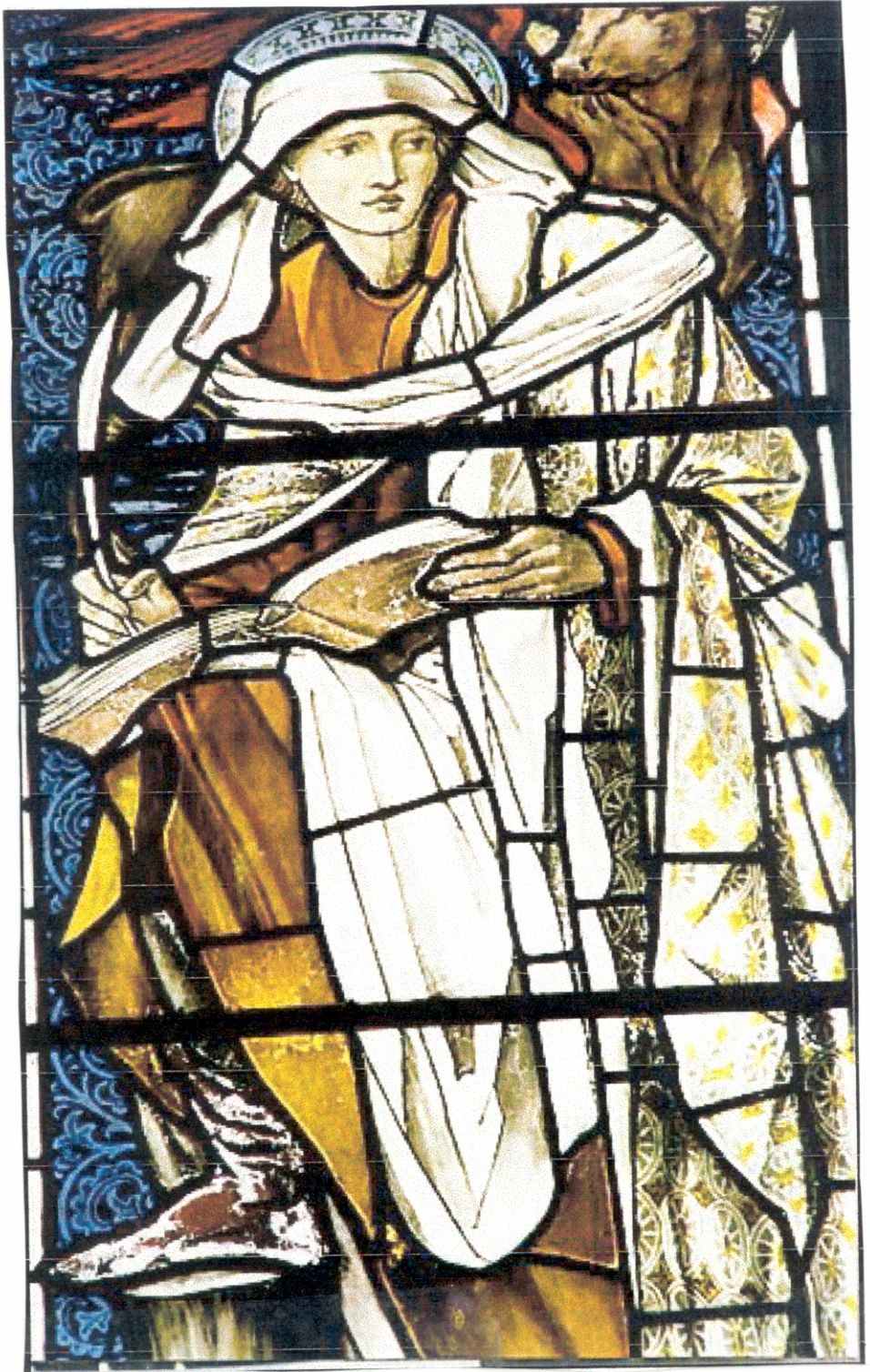
35 U.S.C. 101:

"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 this title."

Diamond vs. Chakrabarty (1980)

"Anything under the Sun made by man"

WHAT DOES STAINED GLASS
HAVE TO DO WITH PATENTS?



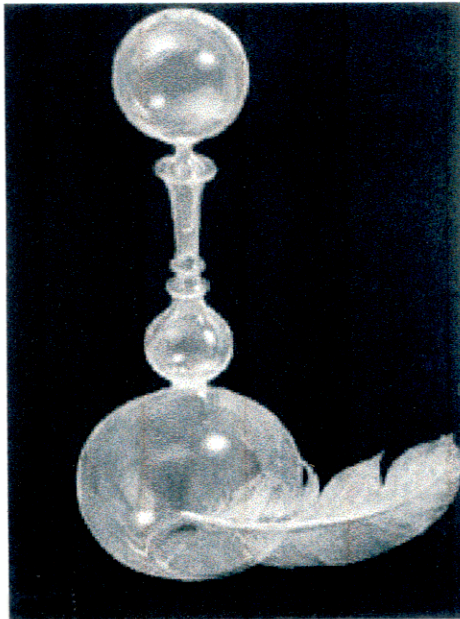
What ARE the Origins of Patents?

Patents Date Back to 15th Century in Great Britain - Crown began to make specific grants of privilege to manufacturers & traders

- ① Letter Patents marked by the King's Great Seal were first patents.
- ② Earliest Known Patent -
1449 to John of Uetynam by King Henry VI
20 year monopoly for a method of stained glass making required for Eton College windows - method not previously known in England
- ③ Great Britain has longest continuous patent tradition in world.
- ④ Tradition passed to American colonies & the United States ∴ can trace us patent roots back ~ 550 years! Rooted in market system, property rights, & trade

VENICE PATENT STATUTE
OF 1474

Venetian Glass Blowing Secrets Revealed



⁷⁰This is the Venice Patent Statute of 1474: "We have among us men of great genius, apt to invent and discover ingenious devices; and in view of the grandeur and virtue of our City, more such men come to us every day from divers parts. Now, if provision were made for the works and devices discovered by such persons, so that others who may see them could not build them and take the inventor's honor away, more men would then apply their genius, would discover, and would build devices of great utility and benefit to our Commonwealth. Therefore: Be it enacted that, by the authority of this Council every person who shall build any new and ingenious device in this City, not previously made in our Commonwealth, shall give notice of it to the office of our General Welfare Board when it has been reduced to perfection so that it can be used and operated. It being forbidden to every other person in any of our territories and towns to make any further device conforming with and similar to said one, with out the consent and license of the author, for the term of 10 years." Quoted in Mandich, Venetian Patents (1450-1550), 30 J.PAT.OFF. SOC'Y 166, 176-77 (1948).

Written description for others to see + build upon "progress"

Patent for 10 years

PATENTS in OTHER PARTS OF 15th Century world!!

What Are the Criteria for Granting a Patent?

Note: ① Patent Criteria Set Forth in Title 35 of US Code - Sections 101, 102, 103, & 112.

② Patents only valid within country issued - Each country has own criteria for awarding a patent - although principles are similar.

ENFORCED BY FEDERAL COURTS

- ① Must be Patent-Eligible Subject Matter
- ② Must Have Specific, Substantial, & Credible Utility
No Throw Aways TRANSPARENT & SKATEBOARD
SECRETED PROTEIN TAPSHARP
- ③ Must Be NOVEL (New!)
- ④ Must Be non-obvious
- ⑤ Must Have a written description of the invention
- ⑥ Must describe the Best Mode of practicing the invention

CONTRACT BETWEEN INVENTOR & SOCIETY -

INVENTOR PUBLISHES INVENTION & TELLS SOCIETY WHAT IT IS & HOW to use it. In return - Society Gives Inventor a Monopoly for 20 years to Exclude Others ②1 FROM Practicing Invention

What is Patent-Eligible Subject Matter?

22

① Laws of Nature, Naturally occurring Phenomena, & Abstract Ideas ARE NOT patent-eligible Subject Matter DIAMOND vs. Diehr (1981)

∴ Natural substances already exist in nature & cannot be patented - e.g., genes IN chromosomes IN cells!

② Chemical compositions, mixtures, machines, methods of use, methods of manufacture, genes, and living organisms ARE patent-eligible as long as they are claimed in a form that does not occur in nature & altered in some way by "HAND OF MAN." ∴ Natural substances are patent eligible if they meet these criteria!

∴ YOUR genes in YOUR BODY ARE NOT PATENT ELIGIBLE!

③ But - purifying or isolating materials from nature makes them novel because "isolated & purified" materials do not exist in nature - ∴ patent-eligible

→ (a) Parke-Davis & Co. vs. H.K. Mulford & Co. (1982)

Purified Protein - Adrenalin

→ (b) In re Bergy (1977)

Purified Microorganisms - biologically pure cultures to produce antibiotics

Patent - Eligible Can it

(c) In re Kratz (1979)

pure strawberry flavoring - 2-methyl-2-pentanoic acid

(d) DIAMOND vs. Chakrabarty (1980)

"oil-eating"

LANDMARK CASE -

"a human-made, non-natural microorganism is patentable - Anything under the sun that is made by MAN is patentable"

∴ genetically engineered cells are patent-eligible - oil-eating bacteria

(e) Harvard Mouse Patent - # 4,736,866 to Philip Leder & Timothy Stewart (1988)

LANDMARK PATENT - a mammalian genetically-engineered organism can be patented & was!!
ONCOGENE FOR testing carcinogens. Reliably one down with cancer.

NOT IN CANADA

(f) J.E.M. Ag Supply, Inc. vs. Pioneer-Hybrid (2001)

LANDMARK CASE - utility patent on producing hybrid seeds - ∴ sexually produced plant hybrids can be patented

SUBJECT MATTER IS PATENT-ELIGIBLE IF ALTERED BY HAND OF MAN - A product of human ingenuity -

DNA Sequences themselves not patent eligible -

(23)

just information

Higher & Lower organisms!

WHAT IS MEANT BY UTILITY?

35 U.S.C. 101

Federal Register
V. 66 #4
Friday, 1/5/01

"Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any useful improvement thereof, may obtain a patent therefor, subject to the conditions of this title"

FIRST

- ① The inventor discloses a PRACTICAL OR REAL WORLD BENEFIT available from the invention — NO Throw Away
↳ TRANSGENIC masses for food
↳ protein for slugs
- ② Development of a product to the extent that it is commercially salable in the market place is NOT required to establish usefulness.
- ③ Specific and Substantial Utility credible by person of ordinary skill in the art
- ④ Cases
 - (a) A purified DNA molecule, isolated from natural environment, with sequence 5'AGGT^{3'} (composition of matter), to produce a specific useful protein — DNA sequence itself NOT patentable.
 - (b) A purified DNA molecule, isolated from natural environment, with sequence 5'ATAGT^{3'} to be used as a marker for cystic fibrosis —

Different Patent Categories Involving Recombinant DNA

Table 23.1 Common types of patent categories, with examples from recombinant DNA technology

Categories	Examples
Product patents	
Substance	Cloned genes, recombinant proteins, monoclonal antibodies, plasmids, promoters, vectors, cDNA sequences, and monovalent vaccines
Compositions of matter	Multivalent vaccines, biofertilizers, bioinsecticides, pharmaceutical mixtures, microorganisms, and transgenic organisms
Devices	Pulsed-field gel electrophoresis apparatus, DNA sequencing apparatus, and microprojectile gene transfer machine <i>PCR machine</i>
Process patents	
Process of preparation	DNA isolation, synthesizing double-stranded DNA, vector-insert construction, polymerase chain reaction (PCR) applications, and purification of recombinant protein
Method of working	Nucleic acid hybridization assays, diagnostic procedures, detection systems using PCR, and mutant assays
Use	Applying biofertilizers and bioinsecticides, fermentation of genetically modified organisms, and nontherapeutic animal treatment systems

Cohen/Boyer Recombinant DNA Patent

A method for replicating a biologically functional DNA, which comprises: transforming under transforming conditions compatible unicellular organisms with biologically functional DNA to form transformants; said biologically functional DNA prepared in vitro by the method of: (a) cleaving a viral or circular plasmid DNA compatible with said unicellular organism to provide a first linear segment having an intact replicon and termini of a predetermined character; (b) combining said first linear segment with a second linear DNA segment, having at least one intact gene and foreign to said unicellular organism and having termini ligatable to said termini of said first linear segment, wherein at least one of said first and second linear DNA segments has a gene for a phenotypical trait, under joining conditions where the termini of said first and second segments join to provide a functional DNA capable of replication and transcription in said unicellular organism; growing said unicellular organisms under appropriate nutrient conditions; and isolating by means of said phenotypical trait imparted by said biologically functional DNA.

Method of Making Recombinant DNA Molecules

Figure 23.1 The first claim of U.S. patent 4,237,224, granted to S. Cohen and H. Boyer on 2 December 1980 and entitled "Process for producing biologically functional molecular chimeras."

What is Meant By Novel & Non-obvious?

35 U.S.C. 102 + 103

① An invention is novel if it is NEW - not "Anticipated" - or described previously by the prior art. PRIOR ART refers to all published works regarding invention - including literature, public lectures, and published patents -

∴ NEVER DISCUSS OR PUBLISH YOUR INVENTION BEFORE FILING A PATENT! Then it is the public domain & not new! And considered prior art - 1 Year in US to file after disclosure.

② An invention is NON-OBVIOUS if -

Graham vs. John Deere (1966) - Non obvious analysis by court

"A person of ordinary skill CANNOT BRIDGE the GAP between prior art & claimed invention"

∴ if molecular biologists think about using radioactive probes - cannot invent a new type of radioactive probe - using a different label -

Case #1

Case #2

BUT if invent a way to make a non-radioactive probe - not previously in literature (prior art) - this process/use could be non-obvious!

What is Meant by Written Description and Best Mode of Practice?

26

35 U.S.C. 112

"Patents are a compact between inventor & society - patents promote PROGRESS (Article I) by securing complete disclosure of invention to public in exchange for inventor's legal right to exclude other people from practicing invention for a limited time"

e.g. Recombinant DNA Patent

↳ biotech industry & basic knowledge

2.

① Must provide a written description of the invention so that people with adequate skill in art will know how the invention was made & how to reproduce the invention & what the invention is -
Case - Generic drugs row of patent

② Must provide a written description that describes the best way to use & practice invention -

Case

Regents of UC vs. Eli Lilly (1997)

Rat Insulin
CONA CASE

Claimed Lilly infringed on patents manufacturing insulin - based on rat cona. Court said description not sufficient for human insulin - can't use rat cona sequence to predict human sequence

no written description of art in humans!

HOW DOES THE PATENT PROCESS WORK?

(27)

- ① Legislated by Congress (Article I) and enforced by Federal Courts & Guided by Federal Courts (e.g., living organisms can be patented).
- ② Patent is filed at USPTO in Washington &/or with other national patent offices (or EPO (European Patent Office))
FILING DATE CRITICAL - TIME PERIOD FOR PATENTS START AT TIME OF FILING!!
Country specific
PATT
- ③ PATENT APPLICATION PUBLISHED 18 MONTHS FROM FILING DATE - ∴ invention becomes prior art.
- ④ USPTO EXAMINES Patent Application: Goes over
over
Criteria
**patent eligible? utility? novel? Non-obvious?
written description? best mode of practice?**
- ⑤ Patent Examiners Review Application:
 - (a) at least Bachelor's Degree in Technical field - 46% have Ph.D's & 17% Master's Degrees (10/1/01)
 - (b) work for 4 years before given authority to make decision on patent after rigorous training & review -
- ⑥ Review Process (\bar{x} = 25 Months) CLOCK RUNS FROM FILING DATE
 - (a) Complies with format & legal rules
 - (b) Scope of protection / invention claimed by inventor
 - (c) What are claims / invention?
 - (d) Search Prior Art / literature & Patent literature
 - (e) Send Official Letter Allowing &/or Rejecting claims
Applicant can respond
 - (f) Final letter Allowing or Rejecting - Applicant can appeal or appeal to Courts (Diamond vs. Chakrabarty)
- ⑦ Challenged - very expensive litigation (\$1-3M)

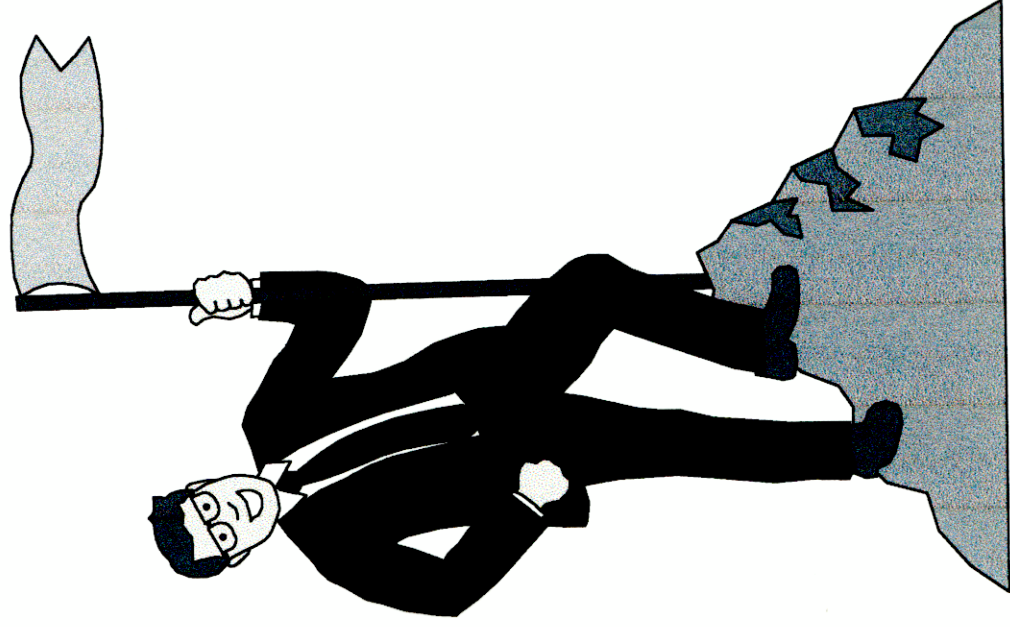
WHAT IS IMPORTANCE OF PATENT SYSTEM?

"Promote Progress of Science"

- ① Stimulate INVENTION & Entrepreneurship - Economic Progress - Incentives to invest
- ② Promotes Disclosures of Inventions (as opposed to trade secrets) & allows others to learn from them, develop improvements, acquire new knowledge (e.g., recombinant DNA, PCR)
- ③ Provides Incentives to Invest - in production & application of knowledge because benefits allocated to companies using patents - inventor's exclusive right to prevent others from making, using, selling invention without a license.
No patent - no financial incentive
- ④ Small companies depend heavily on IP - to attract \$ - establish alliances to share costs on research & development

COSTS OF BRINGING NOVEL MEDICINES TO MARKET considerable
Products can be easily copied
RECOUP COSTS FOR INVESTMENTS in RESEARCH & DEVELOPMENT that don't pay off
PATENT LIFE reduced by 10 years for clinical trials needed to approve $\frac{1}{3}$ - $\frac{1}{2}$ life time of patent
need to make a return on investment

The Strength of US Is Its Patent System. Ask any Patent Attorney.



The Italian Story

Ok here + After Patent System in place

Cancer v. Malaria

→ progress in drugs

→ where are the vaccines?

GENETIC ENGINEERING (+) PATENTS MADE A NEW INDUSTRY!

1976



Some Facts About Biotechnology

- More than 325 million people worldwide have been helped by the more than 130 biotechnology drugs and vaccines approved by the U.S. Food and Drug Administration (FDA). Of the biotech medicines on the market, 70 percent were approved in the last six years.
- There are more than 350 biotech drug products and vaccines currently in clinical trials targeting more than 200 diseases, including various cancers, Alzheimer's disease, heart disease, diabetes, multiple sclerosis, AIDS and arthritis.
- Biotechnology is responsible for hundreds of medical diagnostic tests that keep the blood supply safe from the AIDS virus and detect other conditions early enough to be successfully treated. Home pregnancy tests are also biotechnology diagnostic products.
- Consumers already are enjoying biotechnology foods such as papaya, soybeans and corn. Hundreds of biopesticides and other agricultural products also are being used to improve our food supply and to reduce our dependence on conventional chemical pesticides.
- Environmental biotechnology products make it possible to clean up hazardous waste more efficiently by harnessing pollution-eating microbes without the use of caustic chemicals.
- Industrial biotechnology applications have led to cleaner processes that produce less waste and use less energy and water in such industrial sectors as chemicals, pulp and paper, textiles, food, energy, and metals and minerals. For example, most laundry detergents produced in the United States contain biotechnology-based enzymes.
- DNA fingerprinting, a biotech process, has dramatically improved criminal investigation and forensic medicine, as well as afforded significant advances in anthropology and wildlife management.
- There are 1,457 biotechnology companies in the United States, of which 342 are publicly held.
- Market capitalization, the total value of publicly traded biotech companies at market prices, was \$224 billion as of early May 2002.
- The biotechnology industry has more than tripled in size since 1992, with revenues increasing from \$8 billion in 1992 to \$27.6 billion in 2001.
- The U.S. biotechnology industry currently employs 179,000 people; that's more than all the people employed by the toy and sporting goods industries.
- Biotechnology is one of the most research-intensive industries in the world. The U.S. biotech industry spent \$15.6 billion on research and development in 2001.
- The top five biotech companies spent an average of \$89,400 per employee on R&D in 2000.
- The biotech industry is regulated by the Food and Drug Administration (FDA), the Environmental Protection Agency (EPA) and the Department of Agriculture (USDA).

Industry Statistics: 1992-2001*

Year	2001	2000	1999	1998	1997	1996	1995	1994	1993	1992
Sales*	20.7	19.3	16.1	14.5	13	10.8	9.3	7.7	7.0	5.9
Revenues*	28.5	26.7	22.3	20.2	17.4	14.6	12.7	11.2	10	8.1
R&D Expense*	15.7	14.2	10.7	10.6	9.0	7.9	7.7	7.0	5.7	4.9
No. of Public Companies	342	339	300	316	317	294	260	265	235	225
No. of Companies	1,457	1,379	1,273	1,311	1,274	1,287	1,308	1,311	1,272	1,231
Employees	191,000	174,000	162,000	155,000	141,000	118,000	108,000	103,000	97,000	79,000

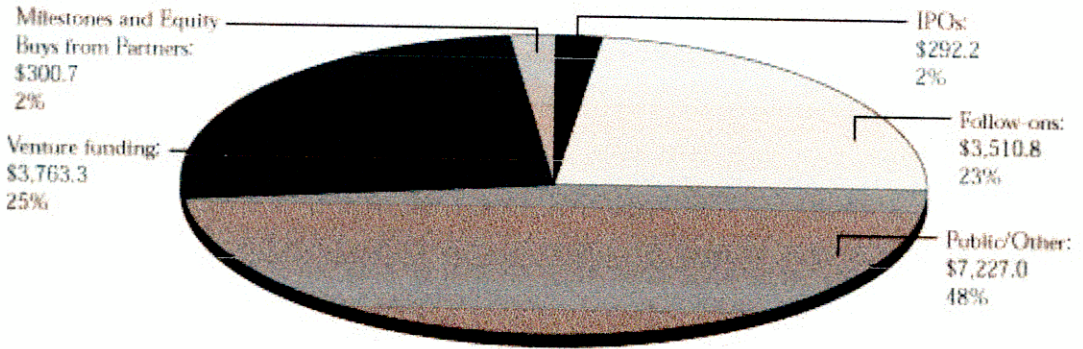
*Amounts are U.S. dollars in billions.
 Source: Ernst & Young LLP, annual biotechnology industry reports, 1993-2002.
 Financial data based primarily on fiscal-year financial statements of publicly traded companies.

- ① Market Capitalization = 224 Billion in May, 2002
- ② 130 Biotech Drugs in Use
- ③ 350 Biotech Drugs are in Trials
- ④ 16 Billion Spent on R&D in 2001
- ⑤ 179,000 employees over 1500 companies

BIOTECH IS A BIG BUSINESS

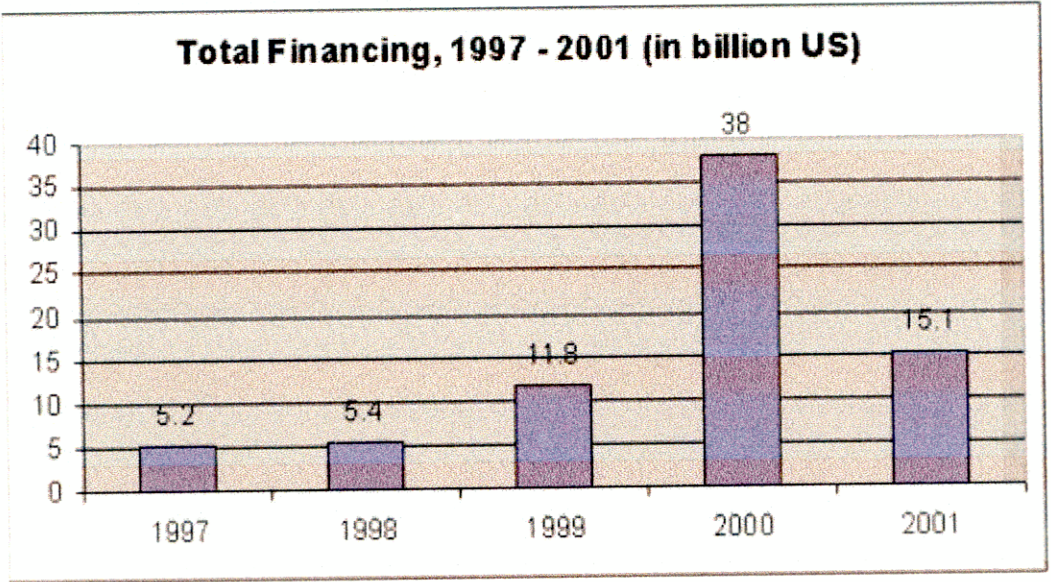
Biotech Industry Financing, 2001

Total: \$15,094 Million
(all figures in millions)



Source: BioWorld

Total Financing, 1997 - 2001 (in billion US)

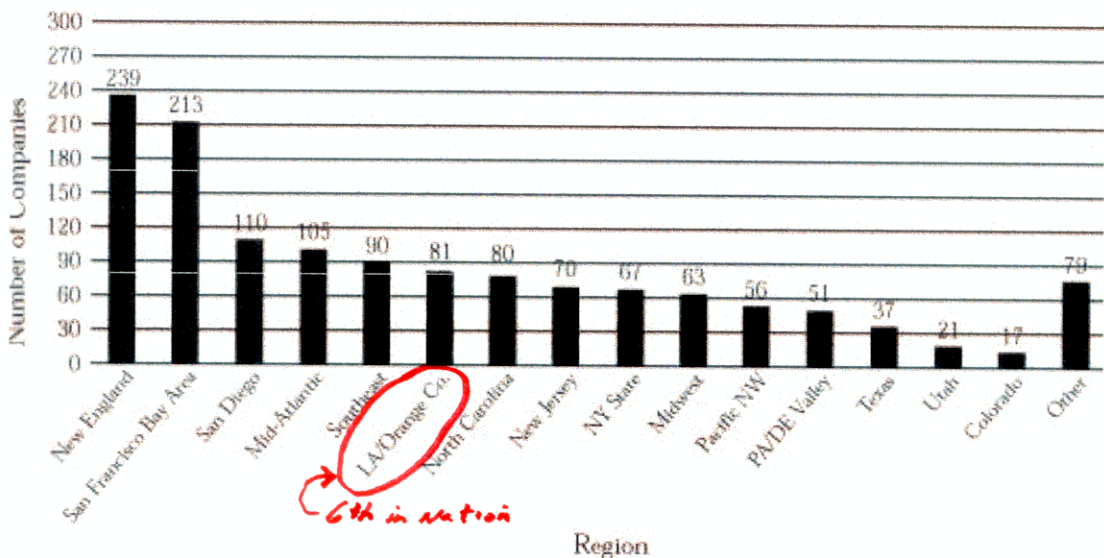


Would NOT have happened without
Patent Protection!!

BIOTECH COMPANIES BY REGION & MARKET CAPITALIZATION

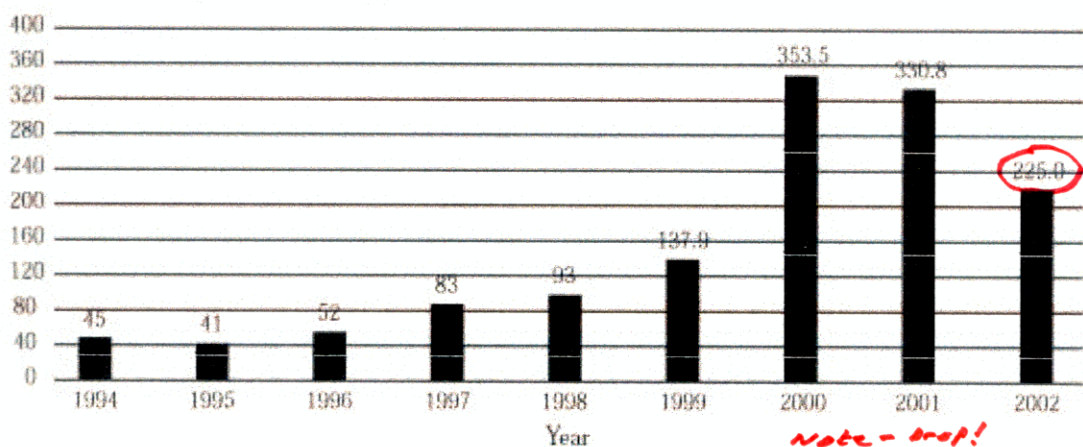
Started in 1976

Private and Public Biotech Companies by Region



Source: Ernst & Young LLP, *Biotechnology Industry Report: Focus on Fundamentals*, 2001

Market Capitalization, 1994-2002*

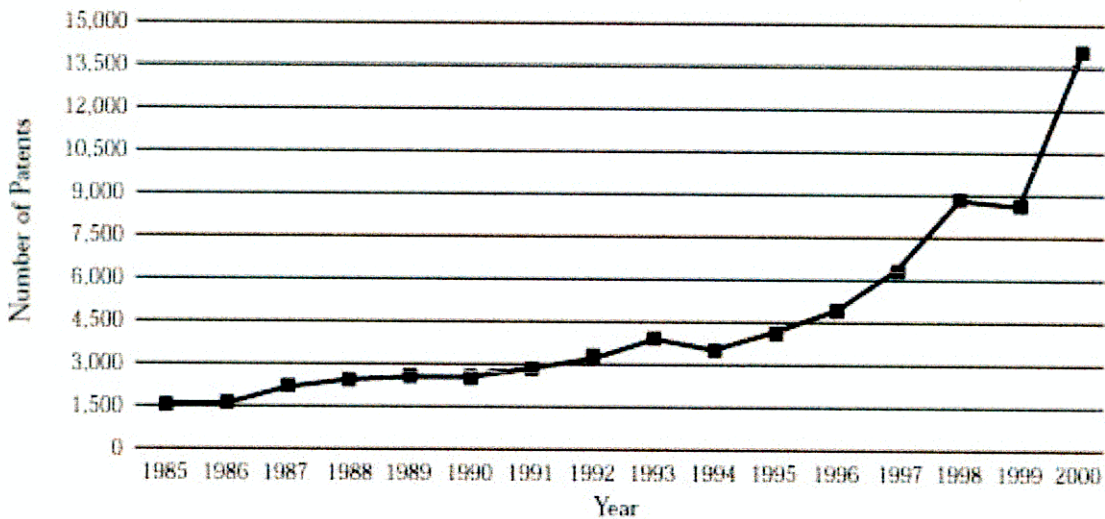


*Amounts are U.S. dollars in billions.

Source: Ernst & Young LLP and BioWorld

BIOTEC-RELATED PATENTS

Total Patents Granted per Year

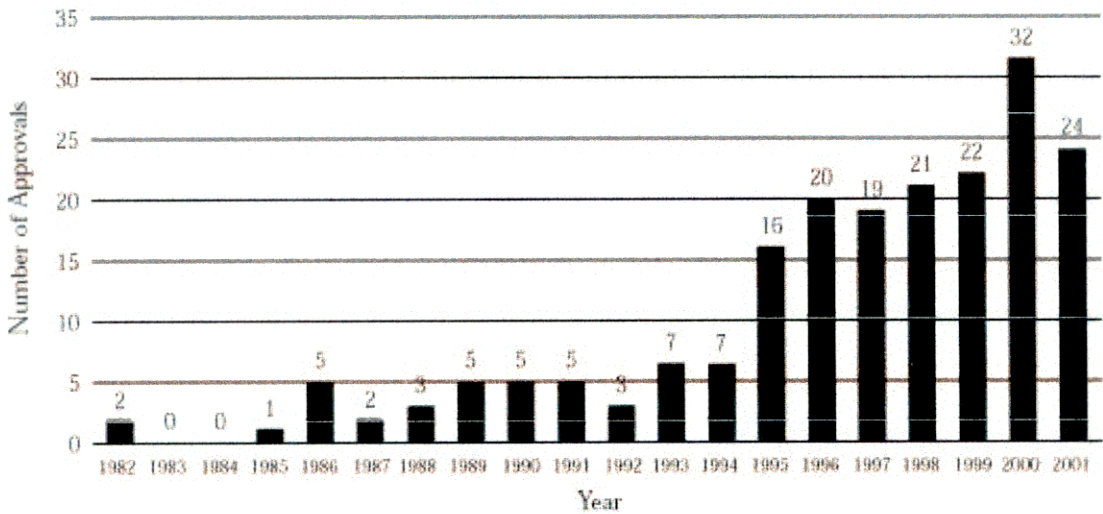


Source: U.S. Patent and Trademark Office

Increase parallels increase in
DNA Sequencing

DRUG + VACCINE APPROVALS PER YEAR

**New Biotech Drug and Vaccine/
New Indication Approvals by Year**



Source: BIO

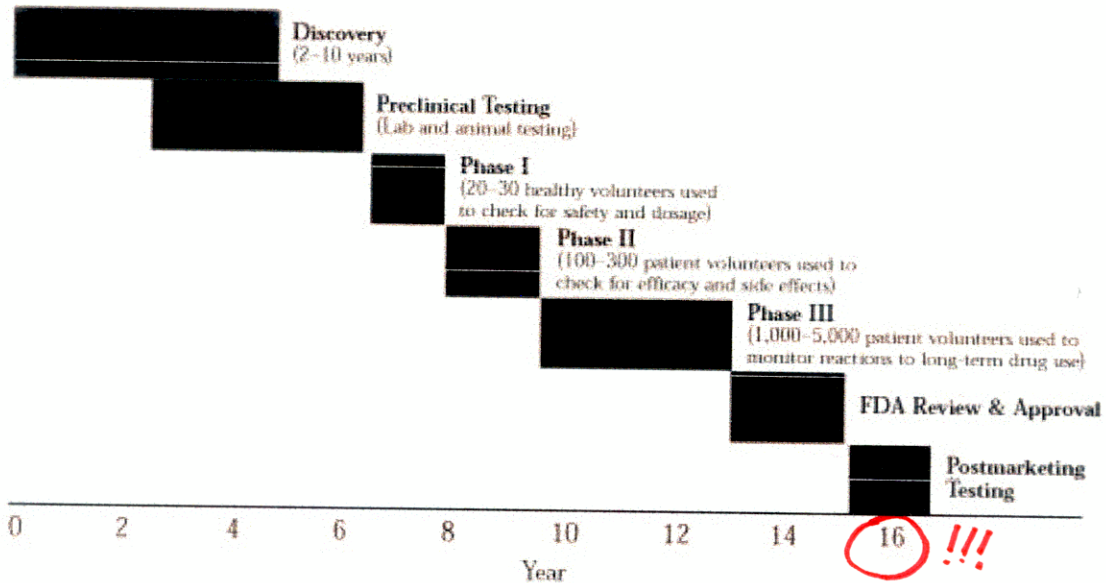
Biotech Industry Founded with
Genentech in 1976!

"Promote the Progress" (Article I)

DRUG DISCOVERY & APPROVAL PROCESS IS LONG & COSTLY

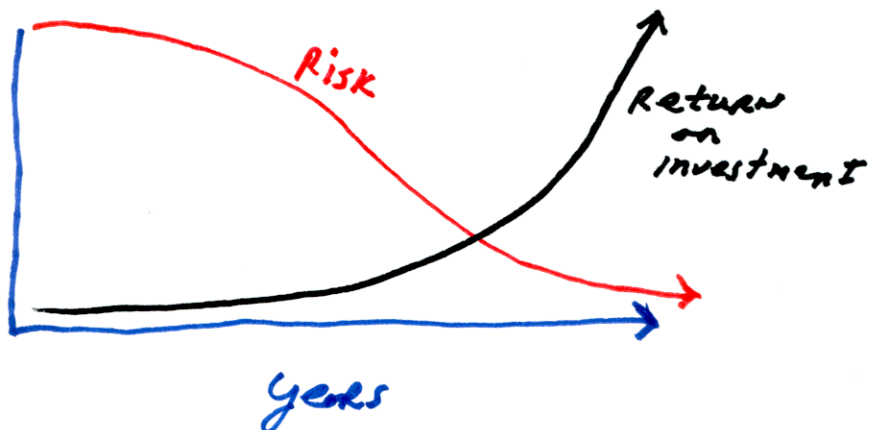
Patent Clock Starts Running at Filing Date
- Approval might be 10-15 years away

Biotech Drug Discovery Process



Source: Ernst & Young LLP, *Biotechnology Industry Report: Convergence*, 2000

∴ Need to recover R+D Costs in Remaining 5-10 years of Patent Protection





c e r e s



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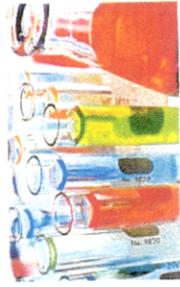


Developing breakthrough
plants and plant-based products
to benefit human health and agriculture.

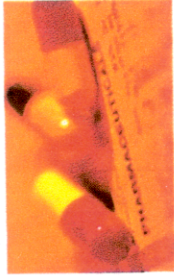


c e r e s

Genomics Driven Product Development



Chemicals



Pharmaceuticals



Herbicide TDVS



Food and Feed



Fiber

Massively Parallel Prototype Development

Prototype 1
2
3
4

Prototype 1
2
3
4

Prototype 1
2
3
4

Prototype 1
2
3
4

Prototype 1
2
3
4



Breakthrough Genes

Data Mining

Knowledge Base and IP

Genomics Engine



Dangers of Monopolies



The Ghost of Teddy Roosevelt

Sherman Antitrust Act

“Trustbusters”

Temper Patent Power

Plus "Market Pull" — new breakthrough technology

364

polaroid vs. digital photography

What About Patents & Universities?

Bayh-Dole Act (1980)

Enables small businesses, universities, and other non-profit Federal contractors & grantees to obtain exclusive rights to their inventions —

Meaning - inventions made from federal grant & can be patented & licensed —

↳ Huge role in stimulating biotech industry & entrepreneurs —



UNIVERSITY OF CALIFORNIA (UC) OFFICE OF TECHNOLOGY TRANSFER (OTT)

oversees UC systemwide efforts to encourage the use of University research results for the public benefit. OTT focuses on patenting and licensing inventions and in working with industry in support of the University's education, research, and public service mission. UC faculty members and researchers will find information of interest within the FACULTY RESOURCES view of the OTT Home Page. The INDUSTRY RESOURCES view will be especially helpful to commercial firms looking for partnerships, licensing or other technology-related opportunities. The RESOURCES FOR ADMINISTRATORS section was developed for those who work at UC in technology transfer and research administration. Useful information for this group is also found on the Research Administration Office Home Page (RAO).

Or, if you know just what you're looking for, use one of the links below:

POPULAR PAGES: [Annual Reports](#) | [Available Technologies](#) | [Operational Tools](#) | [Company Information](#) | [UC Tech Transfer Policy/Special Reports](#) | [Guidance for Industry](#) | [Disclosing an Invention](#) | [Inventor Inquiries](#) | [OTT Guidance Memos](#) | [Strawberry Licensing](#)

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[Ask OTT](#)



[2001 Annual Report](#)



[President's Retreat: Five Years of Progress](#)

UC Researchers / Faculty lead the Nation in Inventions at Universities

Consider the facts

University of California (UC) leads the nation's universities in the number of inventions reported by researchers. In FY01, inventors from nine UC campuses reported more than 950 inventions — close to three new inventions a day. (See p. 14)

The UC Technology Transfer Program is first among U.S. universities, both in terms of the number of patents granted and in the number of successfully commercialized inventions.

UC has an active portfolio of approximately 5,000 inventions. Of that total, more than 850 technologies generated fees and royalty income this year. (See p. 20)

The Hepatitis-B Vaccine is UC's leading commercialized technology, bringing in close to \$24 million in FY01. UC's smallest patent income for a technology this year was 64 cents. (See p. 21)

There typically is a two-year lag between the filing of a patent application and the issuance of a U.S. patent. The University holds more than 2,600 U.S. patents as a result of research at nine UC campuses and three national laboratories UC manages for the Department of Energy. (See pp. 17 and 31)

Even though the patents from two top-earning technologies, Gene Splicing and Human Growth Hormone, expired within the past few years, total FY01 licensing revenues exceeded \$80 million. The top 25 commercialized UC inventions earned royalties exceeding \$55.8 million in FY01. (See pp. 20-21)

Under University policy, researchers are allocated a share of royalties generated through the licensing of their inventions. In FY01, a total of 932 inventors received \$33.1 million from UC inventions. (See p. 24)

Agricultural products are an essential part of the Technology Transfer Program. This year, in addition to strawberries that have dominated the world market, consumers will have access to a "designer" walnut, whose red skin presents an attractive new option to the gourmet chef. Four new mandarin oranges also will soon enter the marketplace. (See p. 8)

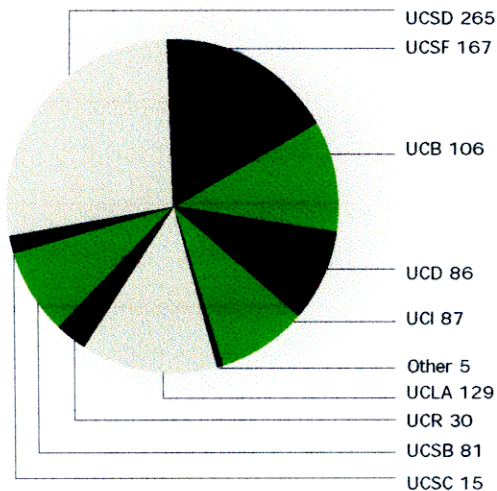
Technology transfer takes time. For example, new inventions in health sciences frequently require as much as 10 years for development, as such discoveries need to go through clinical trials and gain approval from the Food and Drug Administration. Two inventions in the health sciences patented in the early 1990s are just now entering the marketplace. Early signs indicate that the wait pays off in cutting-edge medical advances. (See p. 6)

Private industry is a strong supporter of research at the University of California. In FY01, UC entered into over 2,600 agreements with industry providing more than \$216 million for the University research enterprise.

\$216 in Research Support from Private Industry

UC INVENTIONS & ROYALTY REVENUE

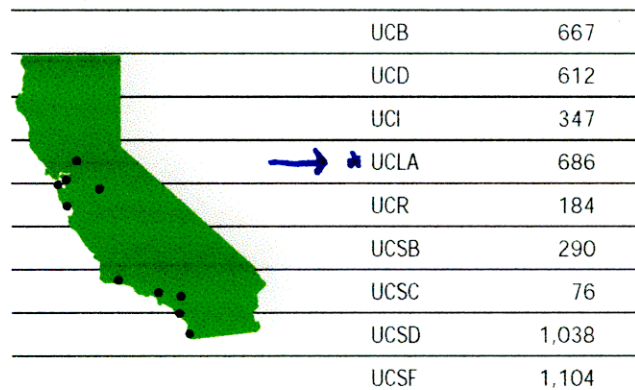
EXHIBIT 2
INVENTION DISCLOSURES BY CAMPUS*
Year Ended June 30, 2001



* Inventions having inventors from more than one campus are counted multiple times, once for each campus with an inventor; thus the total number of inventions in this chart exceeds the 957 total inventions reported in the text. The category "Other" includes inventions with a DOE Laboratory or UCOP inventor.

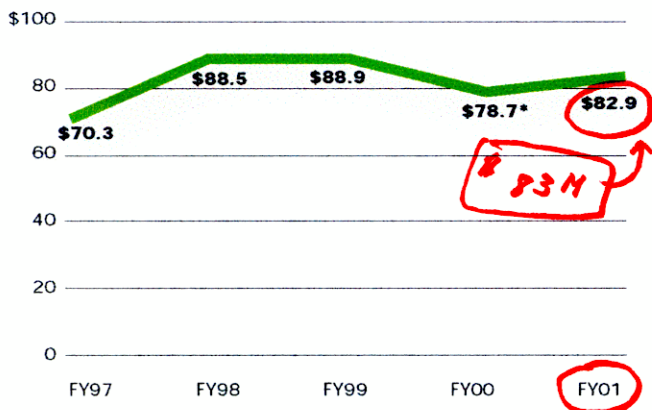
As of June 30, 2001, the systemwide invention portfolio was comprised of 4,982 active inventions. The size of each campus invention portfolio is indicated in the exhibit below.

EXHIBIT 3
CAMPUS INVENTION PORTFOLIOS*
Year Ended June 30, 2001



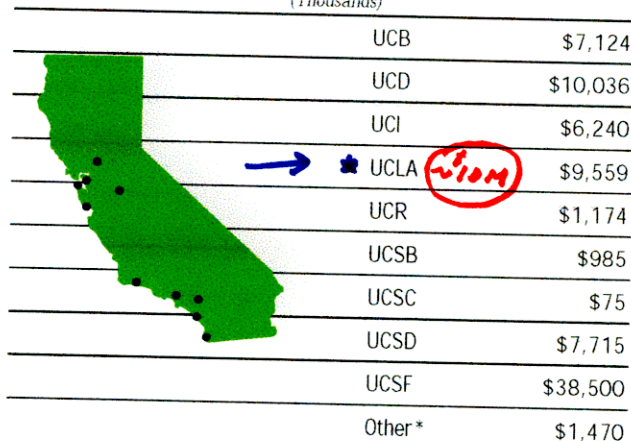
* Inventions associated with inventors from more than one campus are reported multiple times in this exhibit.

EXHIBIT 13
TOTAL LICENSING AND REVENUE*
(Millions)



* In FY00, the University received a \$200 million payment as settlement for a long-standing infringement suit involving the University's Human Growth Hormone patent. Because of the unique nature and magnitude of this settlement, monies attributable to the settlement are excluded from the year-by-year trend analyses in this and similar figures in the remainder of this report.

EXHIBIT 14
TOTAL LICENSING REVENUES BY CAMPUS
Year Ended June 30, 2001
(Thousands)



* Revenues primarily from a portfolio of 74 OTT-managed DOE Laboratory inventions, most disclosed prior to the establishment of the Laboratory-based licensing offices.

OFFICE OF THE PRESIDENT

CHANCELLORS
LABORATORY DIRECTORS

September 4, 1997

Dear Colleagues:

The enclosed University of California Patent Policy will be effective October 1, 1997. This policy supersedes the November 18, 1985 policy, and rescinds the April 16, 1990 revision to that policy (a one-page Summary of Changes is provided). Inventions reported on or after October 1, 1997 will be subject to the new policy. Inventions reported before the effective date will be governed by the November 18, 1985 policy. Also enclosed is a "Patent Acknowledgment" to be signed by all new employees as of October 1st. This form replaces the "Patent Agreement."

The purpose of the new policy is to simplify and restructure the formula for distributing royalty income from inventions, and to establish a new campus and Laboratory research allocation. This policy is the result of extensive review and discussion within the University community. Additional information regarding implementation of the new policy will be published in the near future by the Office of Technology Transfer.

The enclosed policy applies to all employees and others specified within the policy, except individuals in the following collective bargaining units: Research Support Professional, Technical, and Police. Until collective bargaining agreements have been ratified by both parties in these units, affected employees will remain subject to the requirements of the April 16, 1990 Patent Policy.

Sincerely,

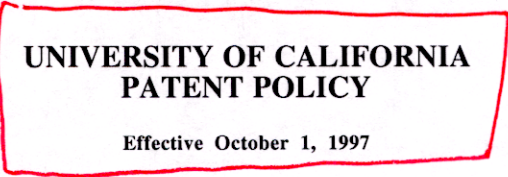
Richard C. Atkinson
President

Enclosures

cc:

Members, President's Cabinet
Academic Council Chair Weiss
Members, Technology Transfer
Advisory Committee
Academic Vice Chancellors

Administrative Vice Chancellors
Research Vice Chancellors
Executive Director Feuerborn
Special Assistant Gardner
Principal Officers of the Regents



PREAMBLE
STATEMENT OF POLICY
PATENT RESPONSIBILITIES AND ADMINISTRATION

I. PREAMBLE

It is the intent of the President of the University of California, in administering intellectual property rights for the public benefit, to encourage and assist members of the faculty, staff, and others associated with the University in the use of the patent system with respect to their discoveries and inventions in a manner that is equitable to all parties involved.

The University recognizes the need for and desirability of encouraging the broad utilization of the results of University research, not only by scholars but also in practical application for the general public benefit, and acknowledges the importance of the patent system in bringing innovative research findings to practical application.

Within the University, innovative research findings often give rise to patentable inventions as fortuitous by-products, even though the research was conducted for the primary purpose of gaining new knowledge.

The following University of California Patent Policy is adopted to encourage the practical application of University research for the broad public benefit; to appraise and determine relative rights and equities of all parties concerned; to facilitate patent applications, licensing, and the equitable distribution of royalties, if any; to assist in obtaining funds for research; to provide for the use of invention-related income for the further support of research and education; and to provide a uniform procedure in patent matters when the University has a right or equity.

II. STATEMENT OF POLICY

Inventors assign patent rights to UC

A. An agreement to assign inventions and patents to the University, except those resulting from permissible consulting activities without use of University facilities, shall be mandatory for all employees, for persons not employed by the University but who use University research facilities, and for those who receive gift, grant, or contract funds through the University. Such an agreement may be in the form of an acknowledgment of obligation to assign. Exemptions from such agreements to assign may be authorized in those circumstances when the mission of the University is better served by such action, provided that overriding obligations to other parties are met and such exemptions are not inconsistent with other University policies.

B. Those individuals who have so agreed to assign inventions and patents shall promptly report and fully disclose the conception and/or reduction to practice of potentially patentable inventions to the Office of Technology Transfer or authorized licensing office. They shall execute such declarations, assignments, or other documents as may be necessary in the course of invention evaluation, patent prosecution, or protection of patent or analogous property rights, to assure that title in such inventions shall be held by the University or by such other parties designated by the University as may be appropriate under the circumstances. Such circumstances would include, but not be limited to, those situations when there are overriding patent obligations of the University arising from gifts, grants, contracts, or other agreements with outside organizations. In the absence of overriding obligations to outside sponsors of research, the University may release patent rights to the inventor in those circumstances when:

- (1) the University elects not to file a patent application and the inventor is prepared to do so, or
- (2) the equity of the situation clearly indicates such release should be given, provided in either case that no further research or development to develop that invention will be conducted involving University support or facilities, and provided further that a shop right is granted to the University.

C. Subject to restrictions arising from overriding obligations of the University pursuant to gifts, grants, contracts, or other agreements with outside organizations, the University agrees, following said assignment of inventions and patent rights, to pay annually to the named inventor(s), or to the inventor(s)' heirs, successors, or assigns, 35% of the net royalties and fees per invention received by the University. An additional 15% of net royalties and fees per invention shall be allocated for research-related

40

purposes on the inventor's campus or Laboratory. Net royalties are defined as gross royalties and fees, less the costs of patenting, protecting, and preserving patent and related property rights, maintaining patents, the licensing of patent and related property rights, and such other costs, taxes, or reimbursements as may be necessary or required by law. Inventor shares paid to University employees pursuant to this paragraph represent an employee benefit.

When there are two or more inventors, each inventor shall share equally in the inventor's share of royalties, unless all inventors previously have agreed in writing to a different distribution of such share.

Distribution of the inventor's share of royalties shall be made annually in November from the amount received during the previous fiscal year ending June 30th, except as provided for in Section II.D. below. In the event of any litigation, actual or imminent, or any other action to protect patent rights, the University may withhold distribution and impound royalties until resolution of the matter.

D. The DOE Laboratories may establish separate royalty distribution formulas, subject to approval by the President. Distribution of the inventor's share of DOE Laboratory royalties shall be made annually in February from the amount received during the previous fiscal year ending September 30th. All other elements of this policy shall continue to apply.

E. Equity received by the University in licensing transactions, whether in the form of stock or any other instrument conveying ownership interest in a corporation, shall be distributed in accordance with the Policy on Accepting Equity When Licensing University Technology.

F. In the disposition of any net income accruing to the University from patents, first consideration shall be given to the support of research.

III. PATENT RESPONSIBILITIES AND ADMINISTRATION

A. Pursuant to Regents' Standing Order 100.4(mm), the President has responsibility for all matters relating to patents in which the University of California is in any way concerned. This policy is an exercise of that responsibility, and the President may make changes to any part of this policy from time to time, including the percentage of net royalties paid to inventors.

B. The President is advised on such matters by the Technology Transfer Advisory Committee (TTAC), which is chaired by the Senior Vice President--Business and Finance. The membership of TTAC includes the Provost and Senior Vice President--Academic Affairs, the Director of the Office of Technology Transfer, and representatives from the campuses, DOE Laboratories, Academic Senate, the Division of Agriculture and Natural Resources and the Office of the General Counsel. TTAC is responsible for:

1. reviewing and proposing University policy on intellectual property matters including patents, copyrights, trademarks, and tangible research products;
2. reviewing the administration of intellectual property operations to ensure consistent application of policy and effective progress toward program objectives; and
3. advising the President on related matters as requested.

C. The Senior Vice President--Business and Finance is responsible for implementation of this Policy, including the following:

1. Evaluating inventions and discoveries for patentability, as well as scientific merit and practical application, and requesting the filing and prosecution of patent applications.
2. Evaluating the patent or analogous property rights or equities held by the University in an invention, and negotiating agreements with cooperating organizations, if any, with respect to such rights or equities.
3. Negotiating licenses and license option agreements with other parties concerning patent and or analogous property rights held by the University.
4. Directing and arranging for the collection and appropriate distribution of royalties and fees.
5. Assisting University officers in negotiating agreements with cooperating organizations concerning prospective rights to patentable inventions or discoveries made as a result of research carried out under gifts, grants, contracts, or other agreements to be funded in whole or in part by such cooperating organizations, and negotiating with Federal agencies regarding the disposition of patent rights.
6. Approving exemptions from the agreement to assign inventions and patents to the University as required by Section II.A. above.
7. Approving exceptions to University policy on intellectual property matters including patents, copyrights, trademarks, and tangible research products.

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[Go Back](#)

Who Owns YOUR Genes?

The Original Question

(42)

- ① Genes in YOUR body exist in NATURE and are NOT PATENT ELIGIBLE OR PATENTABLE.
- ∴ NO ONE OWNS the intellectual property associated with your genes in your body - there is none!
- ② YOU "own" the genes in your body. You do not have to give a sample of your genes to anyone except (a) voluntarily or (b) by a Search Warrant (14th Amendment - right of people to be secure in their persons)
- ③ PURIFIED genes ARE PATENT ELIGIBLE because they do not exist in purified form in nature and have been altered by "the hand of MAN" But must satisfy all criteria for patenting - particularly "actual, substantial, credible - utility"
- ④ Patents on PURIFIED GENES do not cover genes in YOUR BODY - you do not infringe on Patent Use!!
- ⑤ Who owns YOUR genes if voluntarily give them? They belong to doctor or hospital - Moore vs. Regents of UC (1990) - for policy reasons ^{CA} promoting medical research, person (you) do not retain ownership of cells/tissues (DNA) taken with informed consent - INVENTIVE STEP OUTSIDE BODY!

WHAT FORM OF GENES APPEARS IN PATENT APPLICATIONS?

In what form do genes or DNA sequences appear in patent claims?

Patent claims may assert rights over DNA in various ways, for example, they may claim one or more of the following:

- the DNA sequence, whether comprising a complete or partial gene
- promoters
- enhancers
- individual exons
- expressed sequences as expressed sequence tags (ESTs) or cDNAs
- whole transcribed genes as cDNAs
- individual mutations known to cause disease
- variation between people not associated with disease (polymorphisms)
- cloning vectors, formed from bacterial DNA, which are used to replicate DNA sequences
- expression vectors, also formed from bacterial DNA, which are used to express proteins in replicated DNA sequences
- isolated host cells transformed with expression vectors, which are cells that have been created to express particular proteins
- amino acid sequences (proteins)
- the use of such proteins as medicines
- antibodies, which are used as markers
- nucleic acid probes, which are fragments of DNA that are used to locate particular parts of DNA sequences
- methods of identifying the existence of a DNA sequence or a mutation or deletion in an individual
- testing kits for detecting genetic mutations
- whole genomes

RULE: Purified / Isolated Form

"HAND OF MAN"

NOVEL

USEFUL

NON-OBVIOUS

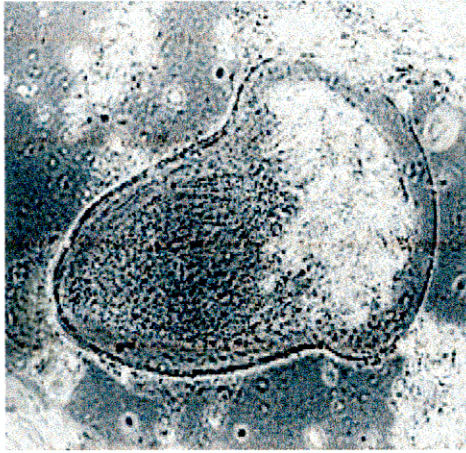
Described

Best Mode of Practice

Specific, substantial,
& credible!

invention!

Can Life Be Patented?



Bacteria



Plant

CAN LIVING ORGANISMS BE PATENTED?

BOTH LOWER & HIGHER ORGANISMS!

- ① Purified Microbial Cultures do not exist in nature & are patentable - Patent-Eligible

In re Bergy (1977) - *Streptomyces velosus* producing antibiotics

Louis Pasteur patent # 141,072 (1873) - Purified yeast free of organic germs or disease

Articles of manufacture

- ② HUMAN-MADE non-natural Microorganism

Diamond vs. Chakrabarty (1980) - Genetically altered bacteria to consume oil -

Supreme Court - "Anything under the sun that is made by man" is patentable

- ③ Harvard Mouse

Leder & Stewart patent # 4,736,866 (1988)

"Applies to a transgenic non-human mammal whose germ cells contain recombinant activated oncogene, or an ancestor of said mammal"

Hand of Man - But in 12/2002 Canadian Supreme Court said Mouse itself cannot be patented - gene sequence & process getting it into germ cells can.

- ④ TRANSgenic PLANTS / Hybrid PLANTS

Pioneer-Hybrid

Patenting Mice - Leder/Stewart - Harvard Oncogene Mouse Patent

MILESTONE

Transgenic Non-Human Mammals

INVENTORS: P. LEDER and T. A. STEWART

Assignee: President and Fellows of Harvard College, Cambridge, Mass.

U.S. Patent 4,736,866

Date of Patent: 12 April 1988



In 1980, the U.S. Supreme Court defined a patentable invention as one that included "anything under the sun that is made by man." In 1988, a transgenic mouse was the first genetically engineered animal to be patented. In this case, the transgene consisted of a cancer-causing gene (oncogene) driven by a promoter in the long terminal repeat of the mouse mammary tumor virus (MMTV LTR). The oncogene was the *myc* gene from the chicken myelocytomatosis OK10 virus. The invention entailed cloning an MMTV LTR-*myc* fusion gene into a plasmid, injecting linearized plasmid DNA into the male pronuclei of fertilized one-celled mouse eggs, identifying offspring that expressed the *myc* gene, and establishing transgenic mouse lines. In some of these lines the *myc* gene was expressed in several different tissues, and in other lines it was limited to one or a few tissues. The in-

tegration of the MMTV LTR-*myc* gene construct, according to Leder and Stewart, "increases the probability of the development of neoplasms (particularly malignant tumors) in the animal." These transgenic organisms can be used to test whether a compound either causes or prevents cancer and as a source of cell lines from cells of various tissues such as the heart that are difficult to culture. Since 1989, Du Pont has been selling one of these lines of transgenic mice under the trade name OncoMice. More generically, others prefer to call this mouse line the "Harvard Oncomouse" or, for short, just "oncomouse."

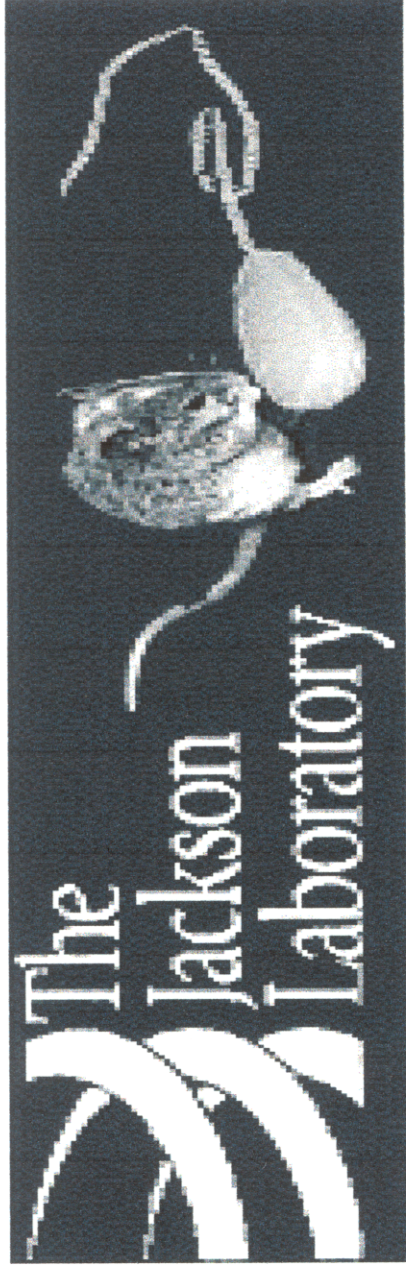
The granting of U.S. patent 4,736,866 was contentious, with much of the concern directed at the ethical implications of such patents. Those who oppose the patenting of transgenic animals argue that this type of patent violates the sanctity of life,

threatens the integrity of species, and fosters inhumane treatment of animals. Notwithstanding these allegations, since 1988, a large number of patents have been granted in the United States for various transgenic organisms. For example, there are now, to name a few, patents for transgenic animals that act as models for benign prostatic disease, inflammatory disease, altered fat tissue metabolism, and thrombocytopenia. To date, neither the U.S. courts nor the U.S. government has suggested that, in principle, any of these patents is inappropriate. The patenting of transgenic organisms is no longer an issue in the United States. By contrast, in Europe and elsewhere, it remains a serious question that has not been completely resolved, although the Harvard Oncomouse has been patented by the European Patent Office. In their decision, the examiners concluded that the benefit to humankind of this transgenic system outweighed other factors that would have made it unacceptable for patenting. However, public interest groups and political parties are continuing to challenge this judgment.

Precedent: *Diamond vs. Chakrabarty (1980)*

Should Life Be Patented?

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CANADA SAYS "NO" to Patenting Mice & Higher Life Forms

LEGAL AFFAIRS

Canada Rules That Transgenic Animals are Nonpatentable

Transgenic Organisms Cannot Be Declared "Inventions"

David J. Heller, L.L.B.

In a decision released on December 5 (2002 SCC 76), the Supreme Court of Canada ruled that plants and animals are not patentable in Canada. The Canadian Patent Office had already granted Harvard University a patent for the "process" that created the university's Oncomouse®. The question before the court was whether the mouse itself qualified.

Both the majority ruling and the dissent professed to confine their reasons to determining what Parliament did or did not intend 133 years ago when it defined "invention" in the Patent Act. The 5-4 majority decided that higher life forms cannot be patented in Canada unless Parliament explicitly says so, because "the patenting of higher life forms is a highly contentious and complex matter that raises serious practical, ethical, and environmental concerns".

Life Forms versus Inventions

The Canadian Patent Act defines "invention" as "any new and useful art, process, machine, manufacture, or composition of matter, or any new and useful improvement in any art, process, machine, manufacture, or composition of matter." If an invention fits into this definition and meets the other criteria for patentability, the Commissioner of Patents must grant a patent.

The majority decision by Justice Michel Bastarache ruled that the mouse is not a "manufacture," which is "commonly understood" to be nonliving. They concluded that "composition of matter" can apply to lesser life forms such as yeast, but not to higher life forms, "because the phrase must be considered in the context of the other words on the list. Just as 'machine' and 'manufacture' do not imply a living creature, the words 'composition of matter' are best read as not including higher life forms."

The majority conceded that a fertilized egg injected with a cancer-causing gene "may be a mixture of various ingredients," but said the mouse "does not consist of ingredients or substances that have been combined or mixed together by a

person." Rather, "animal life forms have numerous unique qualities that transcend the particular matter of which they are composed."

Justice William I.C. Binnie disagreed, saying that the profound cellular changes in the mouse render it "a composition of matter." Writing in dissent, he expressed admiration for the discovery and argued that it was precisely the sort of invention the Patent Act was meant to protect. If the majority acknowledges that the egg itself is an invention, why can't the mouse that grows from the egg be patented?

The Patent Act doesn't exclude the mouse, Justice Binnie contended. Many inventions, including pharmaceutical drugs, also depend on natural processes for their effect and "have numerous unique qualities that transcend the particular matter of which they are composed."

The dissent opinion continued, "The proper question is not whether Parliament intended to include 'oncomice' or 'higher life forms' or biotechnology generally in patent legislation," but whether it intended to protect inventions, such as oncomice, when the legislation was established.

Most other industrialized countries, including the U.S., Japan, New Zealand, and most of Europe, have allowed the patenting of higher life forms. They recognize the public interest in encouraging biotechnological research that may lead to the relief of illnesses such as cancer. They recognize the importance of an international patent regime that protects the fruits of such work, and thereby encourages private investment. The Supreme Court decision has put Canada out of step with its major competitors.

Possible Repercussions

The decision may also cast doubt on the ability of transgenic-seed manufacturers to protect their genetically modified plants in Canada. At present, these companies have obtained patents on the genes and seeds containing the genes. In *Schmeiser v. Monsanto* (2002 Federal Court of Appeal 309), this was seen as sufficient to give rise to infringement by a farmer growing plants that contained the genes.

However, we now have a Supreme Court ruling that denies patents on plants and other higher life forms. Would it not be open to argue that growing a higher life form con-

See Genes and Patents on page 59

Lower vs. Higher?

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Genes and Patents

Continued from page 6

taining a patented cell by conventional means (e.g., sexual reproduction) by definition cannot infringe patent? To hold otherwise would permit a patentee to do by the back door what he is explicitly forbidden to do by the front door, i.e., preventing reproduction of a higher life form.

The Harvard Mouse case is not only important from the standpoint of the patenting of animals and plants, but potentially has much broader implications on the issue of patentable subject matter in general. Patent claims to higher life forms have been denied on the basis that they were not contemplated by Parliament when the definition of invention was drafted.

As asked by the dissenting opinion, where in the 1869 definition of invention would we find Parliament contemplating the patenting of "moon rockets, antibiotics, telephones, e-mail, or hand-held computers," which now seems to be a prerequisite for patentability? It appears that Canadian infringement defense lawyers have a new tool in their briefcases.

The End for Patenting Transgenic Animals in Canada?

Given that the court's majority would not recognize the *Patent Act's* wording as open-ended, it is up to the Canadian

Parliament to clarify the point and decide whether to amend the law to permit patents on nonhuman higher life forms.

On December 9, 2002, Industry Minister Allan Rock told the House of Commons that the government plans to consult with Canadians and with the Canadian Biotechnology Advisory Committee (CBAC) before deciding what to do. The CBAC is a body of external experts charged with advising the Canadian government on the ethical, social, regulatory, economic, scientific, environmental, and health aspects of biotechnology.

In December 2001, the CBAC issued a Report to the Government of Canada recommending that higher life forms, including plants, seeds, and nonhuman animals, be recognized as patentable subject matter (subject to certain limits) under the existing *Patent Act*.

In the meantime, companies in Canada are still free to patent individual genes, other useful DNA sequences, cell lines, transgenic fertilized eggs (and presumably seeds), and the processes by which transgenic plants and animals are produced. **GEN**

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What Concerns HAVE BEEN RAISED ABOUT Patenting Genes & ORGANISMS?

See Federal Register 2001

- ① Genes are core of what it is to be human - no one should be able to own/control genes
- ② Naturally occurring genetic sequences should not be patentable
- ③ Patents should not be for discoveries of nature - only marketable inventions
- ④ Delay progress of research
- ⑤ Someone else will own our genes
- ⑥ Life forms should not be patented
- ⑦ Higher life forms should not be patented
- ⑧ Hinder Genetic Testing / Diagnosis Treatment - Tests based on genes - diagnostic tests
- ⑨ Research tools should not be patented - hinder progress.
- ⑩ Must show substantial utility - not just a DNA sequence - computational methods of finding
- ⑪ Gene Replacement Therapy - use patented genes -
- ⑫ Prevent patented inventions from being used in Third World Developing Countries
- ⑬ Patents on a person's body parts / cell lines / etc.

Royalty-free licenses to the Third world



ISAAA
INTERNATIONAL SERVICE
FOR THE ACQUISITION
OF AGRI-BIOTECH
APPLICATIONS

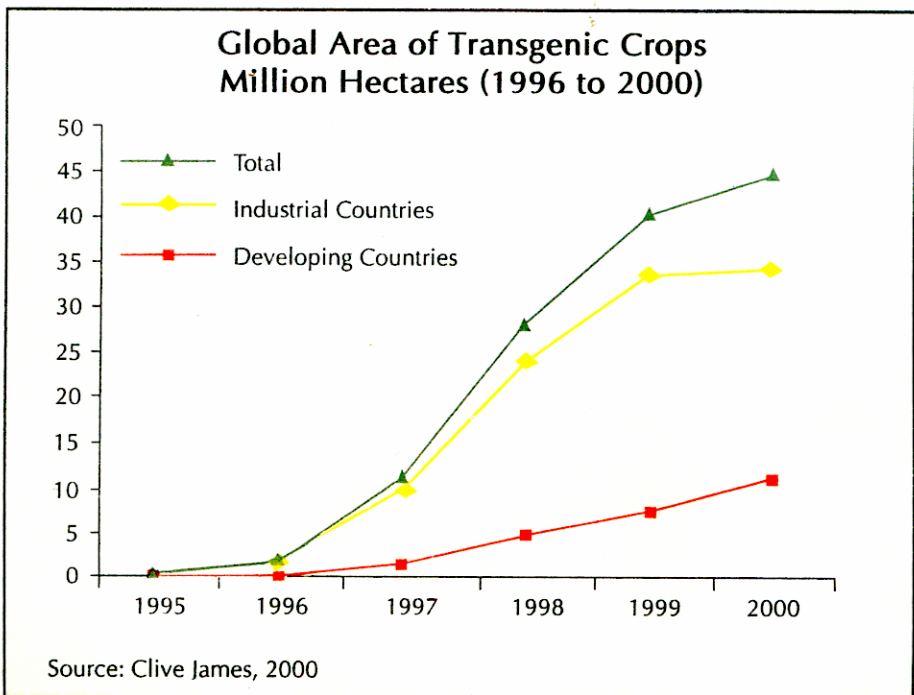
ISAAA Briefs

Global Review of Commercialized Transgenic Crops: 2000

by

Clive James

Chair, ISAAA Board of Directors



Moore vs. Regents UC (1990 - California)

One possible compromise -

a person could get 1-5% of total profits
for contributing cells, unique gene (rare variant), etc.
that plays a role in a discovery leading to an
invention that translates into a profitable product.

George Annas

Health Law Dept.

Boston U. School of Public Health

TRIAL (July, 2001)

PATENTS GRANTED ACCORDING
TO CRITERIA SET
by Congress

Use 35 101, 102, 103, 112

- ① Patent Eligible
- ② Useful
- ③ Novel
- ④ Non-obvious
- ⑤ Written Description
- ⑥ Best Mode of Practice

if utility is specific, substantial, & credible
patent must be issued by law -

To change requires change by Congress