Who owns our Genes?

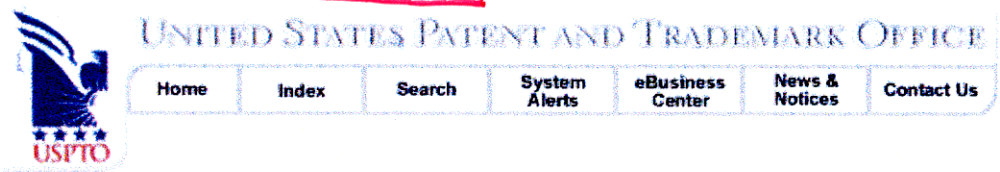
Article I. Section 8.8

.... 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?
   yes yes no
2. Is the technique of recombinant DNA patentable?
   yes
3. Are Living organisms patentable?
   yes

WHAT IS INTELLECTUAL PROPERTY?

1. Patents
2. Copyrights
3. Trademarks
4. Trade Secrets



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.

1 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.

2 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".

3 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.

4 Trade Secrets = Anything — PROBLEM FOR SOCIETY?

INTELLECTUAL PROPERTY

1. **PATENT** – constitutional Right
   - PROTECTS INVENTIONS
   - RIGHT TO EXCLUDE OTHERS FROM using, SELLING, IMPORTING
   - NO RIGHT TO make $
2. **TRADEMARK** – legislated Right
   - PROTECTS SYMBOL/NAME INDICATING SOURCE OF GOODS
   - RIGHT TO EXCLUDE OTHERS FROM USING similar Mark
   - NO Right to PREVENT SAME Business
3. **COPYRIGHT** – Constitutional Right
   - PROTECTS ORIGINAL WORKS OF AUTHORSHIP / FORM OF EXPRESSION
   - RIGHT TO EXCLUDE OTHERS FROM COPYING, REPRODUCING, PERFORMING
   - NO RIGHT TO Exclude use of Ideas
4. **TRADE SECRET** – NOT Legislated per se
   - By definition – Protects anything by virtue of Secrecy!

TRADE SECRETS

EXAMPLE: DNA sequences

1. Idea, Formula, Physical Device, Process, Information, Pattern, etc. that:

   PROVIDES owner with competitive edge in Marketplace

   TREATED in way TO PREVENT THEFT, ACQUISITION, or COMPETITORS FROM learning ABOUT it

2. Do it yourself protection:

   NOT legislated – LASTS as long as kept confidential!

   but CAN sign confidentiality agreements

   PROTECTED by theft, improper acquisition (bribery), etc

3. If secret discovered independently by lawful means – can't be prevented from using it

   E.G., NOT VIOLATION OF TRADE SECRET LAW TO Analyze or Reverse Engineer obtained PRODUCT TO determine its TRADE Secret

LOSS TO SOCIETY? IF Everything Protected By Trade secrets?

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

RIGHTS ARISE BY USE OR REGISTRATION with US PTO

3. Lasts for 10 years (+) 10 year Extension

∴ 20 years MAXIMUM (Registration) Lasts indefinitely if owner continues to use it – Right of Registration vs. Right of Use!

First to Use has right to register! REGISTRATION NOT REQUIRED!

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 & trademark system

6. CAN be transferred, sold, acquired like any property right

bobg®

WHAT IS A COPYRIGHT?

The bobz Book © ← no longer required (>1989)

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.

   Software
   Movies
   Novels
   Architecture
   Video Games

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

   ← RIGHTS prevent others!

3. copyright protection starts when work created in fixed form – Non-registered right (unlike patents + trademarks) – through Library of Congress

   Write it
   Paint it
   Put on internet
   ↳ copyrighted

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).

   PROTECTED with or WITHOUT REGISTRATION
   CAN BE SOLD

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 first)

   Library of Congress

REGISTRATION PROTECTS / AIDS IN FIGHTING INTRINGEMENT!

What is a Patent?

PROTECTS INVENTIONS

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. CLAIMS

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
2/10/04

US = First to Invent
Japan/Europe = First to File

Benefit to Society vs. Trade Secrets?

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)

"~~Any~~ thing under the sun made by man"

Key words

New & useful!!

What Can Be Patented

- ☺ Process or Method
- ☺ Machine or Apparatus
- ☺ Article of Manufacture
- ☺ Composition of Matter (SEQUENCE OF GENE OR PROTEIN OR BOTH!!)
  - ♠ Chemical Compounds
  - ♠ Physical Mixtures
- ☺ Improvements of Any of the Above

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What Can Be Patented

Diamond v. Chakrabarty, 447 U.S. 303, 206 U.S.P.Q. 193 (1980)

The U.S. Supreme Court established the rule that compositions of matter that are made by man, i.e. that are "not nature's handiwork, but [the inventor's] own", are patentable subject matter.

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 – 555 years ago!

1449 to John of Utynam 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 → IN CONSTITUTION

IF ANTI-MARKET → ANTI-PATENT

→ "anti-American??"

VENICE PATENT STATUTE OF 1474

Venetian Glass Blowing Secrets Revealed

SOCIETAL INTEREST

VS.

TRADE SECRETS!

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

[70]This 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).

PROGRESS PROMOTED

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.

COUNTRY Specific

ENFORCED BY FEDERAL COURTS

1. Must be Patent-Eligible Subject Matter
2. Must Have Specific, Substantial, & Credible Utility

   NO THROW AWAYS — TRANSgenic Mice as snake oil secreted protein for shampoo — THROW AWAYS — Snake oil Shampoo

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

Specification of Patent + Claims → Subject Matter which regarded as 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 from Practicing Invention

NOTE

What is Patent-Eligible Subject Matter?

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 Proteins — Adrenalin (DRUG!)

→ (b) In re Bergy (1977)
Purified Microorganisms — biologically pure culture to produce antibiotics

Patent-Eligible Can it

(c) In re Kratz (1979)

pure strawberry flavoring – 2-methyl-2pentanoic 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)

TRANSGENIC ANIMAL FACTOR VIII COW

NOT IN CANADA

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

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

TRANSGENIC PLANT (Bt CORN)

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 – just information

Higher + lower organisms!

(g) Cell Line – Moore vs. Regents UC

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 therefore, 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 mouse for food
→ protein for shampoo

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'AGCT3' (composition of matter), to produce a specific useful protein — DNA sequence itself NOT patentable.

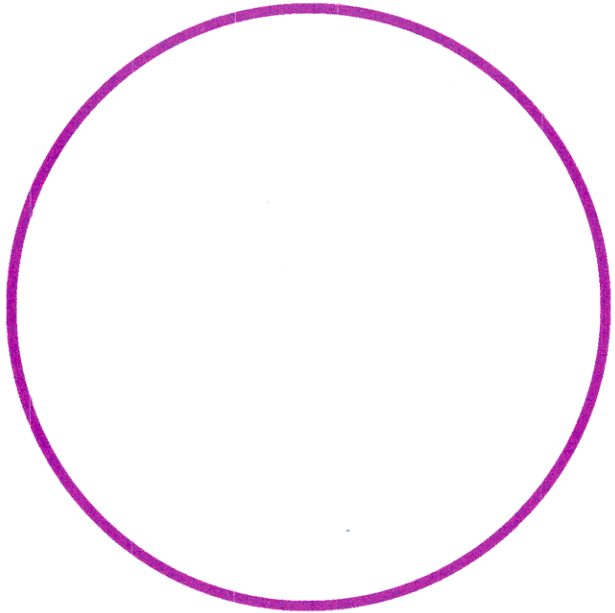
vague

vague!

VS.

(b) A purified DNA molecule, isolated from natural environment, with sequence 5'AAAGT3' to be used as a marker for cystic fibrosis —

Patent Claims



The "Claims" of a patent define the scope of the invention. In the U.S., peripheral claiming is used. That is, the claim language defines the "edge" of the property right.

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 PCR machine
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

Utility patent

DNA, Protein sequences

GENE CHIP, SEQUENCING MACHINE

PCR, Recombinant DNA
TRANSGENIC PLANTS
GENE CHIP PROCESS

Cohen/Boyer Recombinant DNA Patent

A method for replicating a biologically functional DNA, which compromises: 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 and 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.

CAN'T OBTAIN PATENT IF INVENTION IN PUBLIC DOMAIN – ∴ → PRIOR ART

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"

Case #1 ∴ if molecular biologists think about using radioactive probes – cannot invent a new type of radioactive probe – using a different label –

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!