HC70A Winter 2005

Professor Bob Goldberg

Lectures #6 & #7

Science & the Constitution

Regulating Science

&

Who owns our Genes

Themes / Concepts

1. Review of US Form of Government
2. Where in Constitution is Science Mentioned?
3. What Amendments/Sections of the Constitution Deal with Science
4. How is Science Regulated on a Federal & State Level - Directly & Indirectly?
5. Regulating Genetic Engineering, Cloning, Stem Cells?
6. What is Intellectual Property?
7. What are Patents, Trademarks, Copyrights, & Trade Secrets?

~~ Stop 2/15/05 (~100')

8. What criteria are needed to Obtain a Patent?
9. How Does the Patent Process Work?
10. What is the Relationship between Patents, Biotech, Universities, Licensing, & Royalties?
11. Who owns our Genes?
12. Can Life be Patented?
13. "Myths" About Patents!!!

~ Stop 2/22/05 (120')

READING

Chapter 12 - Textbook

REFERENCES

(1) Cloning & the Constitution - Ira H. Carmen
ISBN 0-299-10340-4 1985

(2) A practical Guide to the Constitution -
J. K. Lieberman ISBN 0-520-21280-0 1999

(3) Human Gene Patents - J.A. Goldstein & E. Gold
Academic Medicine 77, 1315-1328 (2002)

(4) United States Code Title 35 - Patents

(5) Molecular Biotechnology -

(6) Patents in the Knowledge-Based Economy -
National Research Council of NAS (2003)
ISBN 0-0309-08636-1

(7) Federal Register Vol 66, No. 4 January 5, 2001
USPTO utility Examination Guidelines

What is the organization of the US Government?

INTELLECTUAL PROPERTY

(1) PATENT – constitutional Right

PROTECTS INVENTIONS

RIGHT TO EXCLUDE OTHERS FROM USING, SELLING, IMPORTING INVENTION FOR DEFINED TIME PERIOD

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

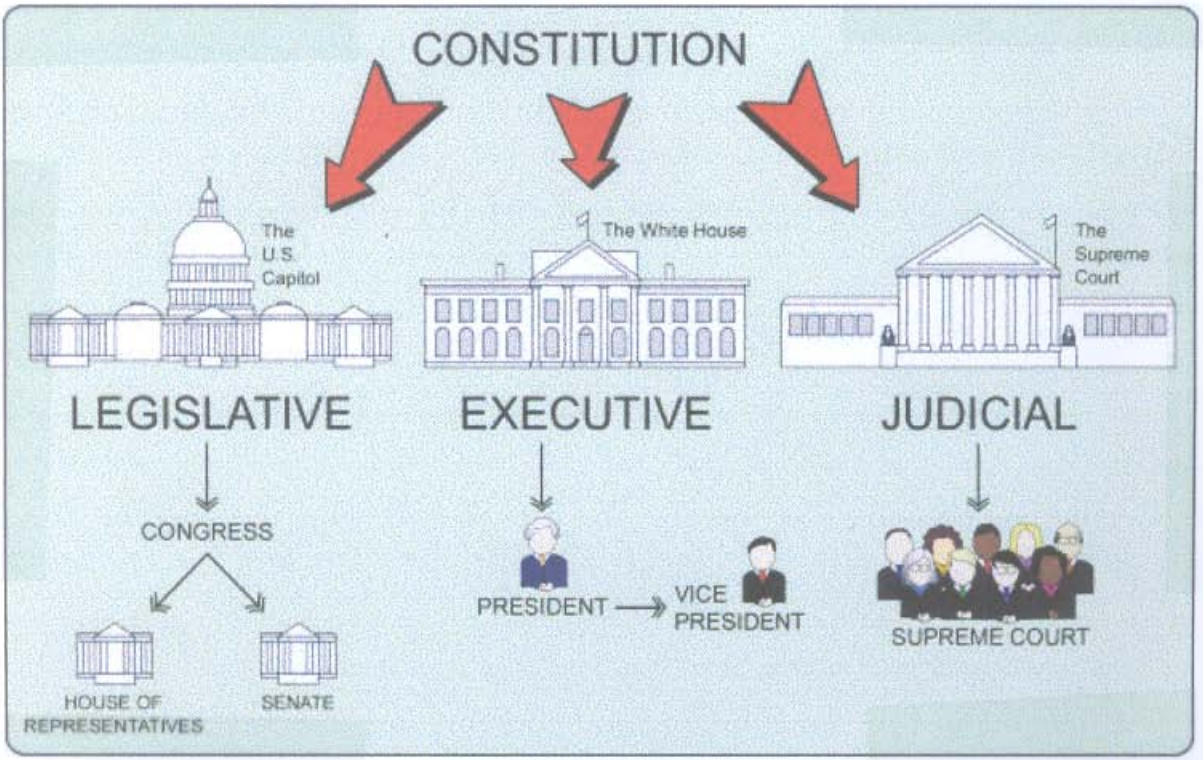
RIGHT TO EXCLUDE OTHERS FROM COPYING, REPRODUCING, PERFORMING

NO RIGHT TO Exclude use of Ideas

(4) TRADE SECRET – NOT Legislated per se

By definition – Protects anything by virtue of Secrecy!

Government of United States – A Separation of powers System



USA = Federal Republic balancing:

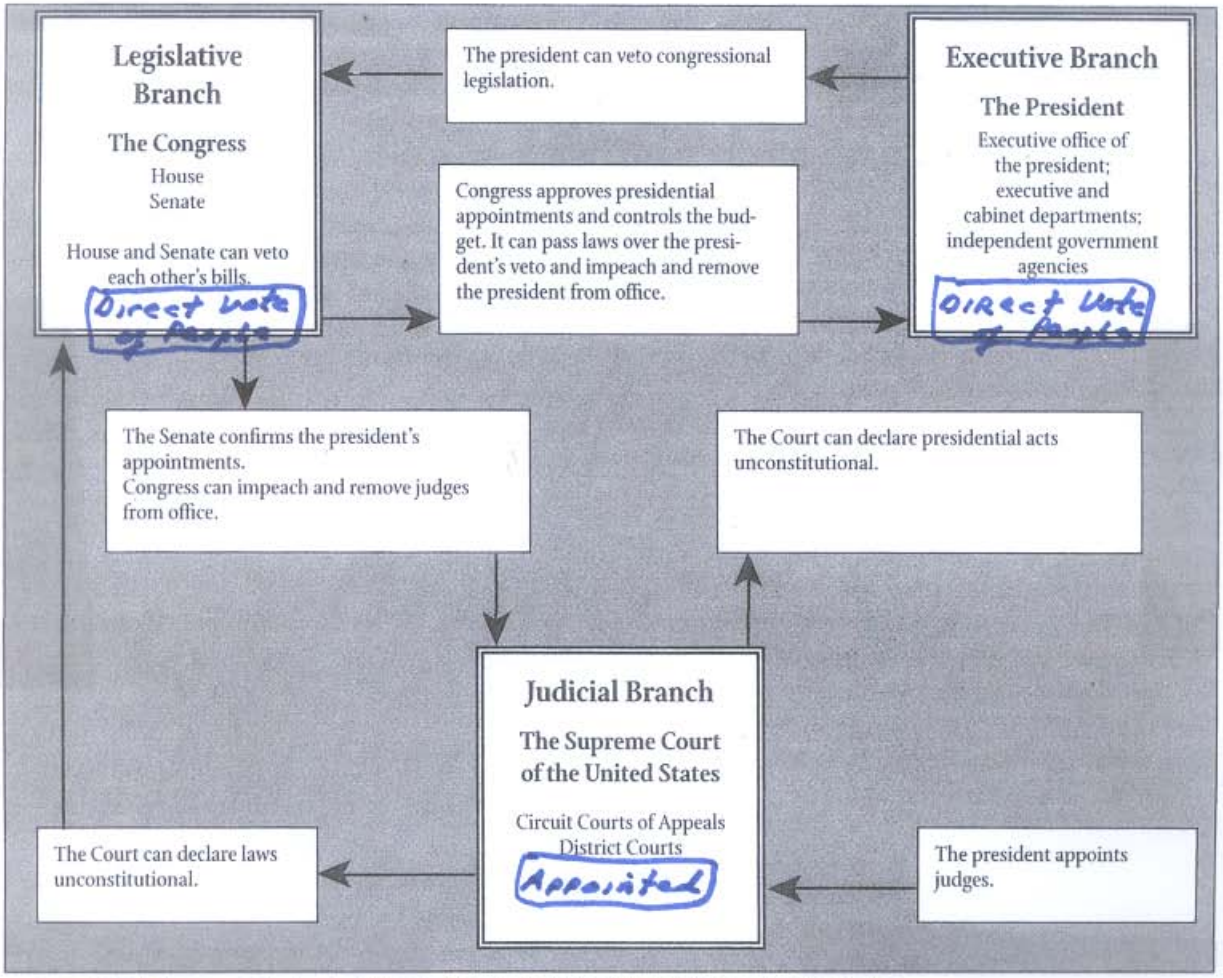
1. relations between national + state governments
2. relations between branches of national government (checks + balances)
3. relations between government + people (individual rights + Liberties)

1789

3

US System of Separation of Powers

FIGURE 1-2 The Separation of Powers/Checks and Balances



SOURCE: Janet A. Flammang et al., *American Politics in a Changing World* (Pacific Grove, Calif.: Brooks/Cole, 1990), 41.

Chief Justice John Marshall

Marbury vs. Madison (1803)

"Concept of Judicial Review"

Marbury v. Madison (1803)

"It is emphatically the province and duty of the judicial department to say what the law is. Those who apply the rule to particular cases, must of necessity expound and interpret that rule. If two laws conflict with each other, the courts must decide on the operation of each."

— Chief Justice John Marshall

JUDICIAL REVIEW NOT IN CONSTITUTION

So if a law be in opposition to the constitution; if both the law and the constitution apply to a particular case, so that the court must either decide that case conformably to the law, disregarding the constitution; or conformably to the constitution, disregarding the law; the court must determine which of these conflicting rules governs the case. This is of the very essence of judicial duty.

"Activist Judges?" → Voting Rights, Civil Rights, Reproductive Rights, Gender Equality, Affirmative Action, Age Discrimination - etc.

HOW CAN SCIENCE AND RESEARCH BE REGULATED in the US AT THE FEDERAL, STATE, & LOCAL LEVELS?

What Parts of CONSTITUTION AFFECT SCIENCE?

SECTION/AMENDMENT	WHAT IS APPLICATION?
Article I, Section 8.1	Promote the General Welfare
Article I, Section 8.8	PAtents
Article I, Section 8.18	Make all Laws to Execute
Amendment I	Freedom of Speech, Inquiry
Amendment III	
Amendment IV	Searches/Siegures - DNA Testing
Amendment V	Due Process - Privacy - Reproduction
Amendment X	Powers Reserved States - "Police" Powers
Amendment XIII	SLAVERY / Patenting HUMANS & "OWNing" CLONES
Amendment XIV	Due Process - State / Privacy / Reproduction / CLONING

What is in the Constution 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 the 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, or 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 III - 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 think

Other Parts of the Constitution Cont'd

(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

(6) Amendment X (Powers not delegated to the US)

The powers not delegated to the United States by the constitution, nor prohibited to the States, are reserved to the States, or to the people.

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?
environment, GMOs, etc.

(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) - Lemmed as "the authority to provide for the public health, safety, & 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't

Amendment XIII

Involuntary servitude – patenting humans

Amendment XIV

States / due process / liberty (privacy)
↳ procreative choice / cloning

CAN SCIENTIFIC INQUIRY & RESEARCH BE REGULATED?

"CLONING & THE CONSTITUTION"
I. CARNEN – 1976

(1) Freedom of Speech includes Right to Scientific Inquiry ∴ have right to think about nature, ponder theories, hypotheses, and how the world/universe works – Griswald 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 – TERRORISM?

∴ "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

(14)

Uncensored exchange of scientific results

Journal Editors and Authors Group*

The process of scientific publication, through which new findings are reviewed for quality and then presented to the rest of the scientific community and the public, is a vital element in our national life. New discoveries reported in research papers have helped improve the human condition in myriad ways: protecting public health, multiplying agricultural yields, fostering technological development and economic growth, and enhancing global stability and security.

But new science, as we know, may sometimes have costs as well as benefits. The prospect that weapons of mass destruction might find their way into the hands of terrorists did not suddenly appear on September 11, 2001. A policy focus on nuclear proliferation, no stranger to the physics community, has been with us for many years. But the events of September 11 brought a new understanding of the urgency of dealing with terrorism. And the subsequent harmful use of infectious agents brought a new set of issues to the life sciences. As a result, questions have been asked by the scientists themselves and by some political leaders about the possibility that new information published in research journals might give aid to those with malevolent ends.

Journals that dealt especially with microbiology, infectious agents, public health, and plant and agricultural systems faced these issues earlier than some others, and have attempted to deal with them. The American Society for Microbiology (ASM), in particular, urged the National Academy of Sciences to take an active role in organizing a meeting of publishers, scientists, security experts, and government officials to explore the issues and discuss what steps might be taken to resolve them. In a one-day workshop at the Academy in Washington, DC, cohosted by the Center for Strategic and International Studies on January 9, 2003, an open forum was held for that purpose. A day later, a group of journal editors, augmented by scientist-authors, government officials, and others, held a separate meeting designed to explore possible approaches.

What follows reflects some outcomes of that preliminary discussion. Fundamental is a view, shared by nearly all, that there is information that, although we cannot now capture it with lists or definitions, presents enough risk of use by terrorists that it should not be published. How and by what processes it might be identified will continue to challenge us, because, as all present acknowledged, it is also true that open publication brings benefits not only to public health but also to efforts to combat terrorism.

The statements follow:

FIRST: The scientific information published in peer-reviewed research journals carries special status and confers unique responsibilities on editors and authors. We must protect the integrity of the scientific process by publishing manuscripts of high quality, in sufficient detail to permit reproducibility. Without independent verification, a requirement for scientific progress, we can neither advance biomedical research nor provide the knowledge base for building strong biodefense systems.

SECOND: We recognize that the prospect of bioterrorism has raised legitimate concerns about the potential abuse of published information, but also recognize that research in the very same fields will be critical to society in meeting the challenges of defense. We are committed to dealing responsibly and effectively with safety and security issues that may be raised by papers submitted for publication, and to increasing our capacity to identify such issues as they arise.

THIRD: Scientists and their journals should consider the appropriate level and design of processes to accomplish effective review of papers that raise such security issues. Journals in disciplines that have attracted numbers of such papers have already devised procedures that might be employed as models in considering process design. Some of us represent some of those journals; others among us are committed to the timely implementation of such processes, about which we will notify our readers and authors.

FOURTH: We recognize that on occasion an editor may conclude that the potential harm of publication outweighs the potential societal benefits. Under such circumstances, the paper should be modified or not be published. Scientific information is also communicated by other means: seminars, meetings, electronic posting, etc. Journals and scientific societies can play an important role in encouraging investigators to communicate results of research in ways that maximize public benefits and minimize risks of misuse.

*Group members: Ronald Atlas, President, ASM, and Editor, *CRC Critical Reviews in Microbiology*; Philip Campbell, Editor, *Nature*; Nicholas R. Cozzarelli, Editor, PNAS; Greg Curfman, Deputy Editor, *New England Journal of Medicine*; Lynn Enquist, Editor, *Journal of Virology*; Gerald Fink, Massachusetts Institute of Technology; Annette Flanagin, Managing Senior Editor, *Journal of the American Medical Association*, and President, Council of Science Editors; Jacqueline Fletcher, President, American Phytopathological Society; Elizabeth George, Program Manager, National Nuclear Security Administration, Department of Energy; Gordon Hammes, Editor, *Biochemistry*; David Heyman, Senior Fellow and Director of Science and Security Initiatives, Center for Strategic and International Studies; Thomas Inglesby, Editor, *Biosecurity and Bioterrorism*; Samuel Kaplan, Chair, ASM Publications Board; Donald Kennedy, Editor, *Science*; Judith Krug, Director, Office for Intellectual Freedom, American Library Association; Rachel E. Levinson, Assistant Director for Life Sciences, Office of Science and Technology Policy; Emilie Marcus, Editor, *Neuron*; Henry Metzger, National Institute of Arthritis and Musculoskeletal and Skin Diseases, National Institutes of Health; Stephen S. Morse, Columbia University; Alison O'Brien, Editor, *Infection and Immunity*; Andrew Onderdonk, Editor, *Journal of Clinical Microbiology*; George Poste, Chief Executive Officer, Health Technology Networks; Beatrice Renault, Editor, *Nature Medicine*; Robert Rich, Editor, *Journal of Immunology*; Ariella Rosengard, University of Pennsylvania; Steven Salzburg, The Institute for Genome Research; Mary Scanlan, Director, Publishing Operations, American Chemical Society; Thomas Shenk, President Elect, ASM, and Past Editor, *Journal of Virology*; Herbert Tabor, Editor, *Journal of Biological Chemistry*; Harold Varmus, Memorial Sloan–Kettering Cancer Center; Eckard Wimmer, State University of New York at Stony Brook; Keith Yamamoto, Editor, *Molecular Biology of the Cell*.

www.pnas.org/cgi/doi/10.1073/pnas.0630491100

PNAS policy on publication of sensitive material in the life sciences

On January 9, 2003, the National Academy of Sciences (NAS) and the Center for Strategic and International Studies (CSIS) cosponsored a public meeting with the broad agenda "to bring together scientists and policymakers to discuss whether current publication policies and practices in the life sciences could lead to the inadvertent disclosure of 'sensitive' information to those who might misuse it." Several journals, including PNAS, had already developed procedures in this regard.

Participants in the January meeting discussed three recent papers (1–3) that some felt might benefit bioterrorists and therefore should have been modified or not published at all. Two of the papers were "Chemical Synthesis of Poliovirus cDNA: Generation of Infectious Virus in the Absence of Natural Template" (2) and "Expression of Mouse Interleukin-4 by a Recombinant Ectromelia Virus Suppresses Cytolytic Lymphocyte Responses and Overcomes Genetic Resistance to Mousepox" (3). The third paper in question, "Variola Virus Immune Evasion Design: Expression of a Highly Efficient Inhibitor of Human Complement" (1), was published last fall in PNAS. At that time, PNAS had no formal screening mechanism for identifying potentially sensitive information in submitted manuscripts. A retrospective analysis of the handling of this paper showed, however, that despite the absence of formal protocols to do so, the review process had screened for potentially sensitive information. First, the author explicitly called attention to the sensitive nature of the work in her cover letter. Second, the NAS member who edited the paper and the two referees also gave thoughtful consideration to potential bioterrorism implications, but both reviewers felt that the benefits clearly outweighed the potential for misuse. Finally, PNAS published a commentary on the paper that dealt directly with the security concerns and also concluded that publication of the paper was desirable (4).

Thus, issues related to potentially sensitive information were handled naturally, effectively, and responsibly by all concerned. Although the peer review process worked well on its own, in this case, I felt that an articulated and uniform practice should be established. In November 2002, I asked the PNAS Editorial Board to watch for papers that involve diseases and agents from the Centers for Disease Control's category A list (www.bt.cdc.gov/agent/agentlist.asp) that might pose a risk. In addition, our editorial office staff was asked to flag such papers before sending them to the Board. Over the last 2 months, we have flagged 20 papers, less than 1% of all submitted manuscripts. In all cases, the Board recommended no changes in normal editorial practices, and PNAS did not ask any of these authors to modify their papers. Their publication was not delayed.

PNAS policy on the publication of sensitive information is a work in progress. What would trigger a request to an author to modify a paper? Certainly a cookbook recipe for a weapon would not be permitted. This is, however, not a very useful example, because it is highly unlikely that such a paper would pass peer review, solely on scientific grounds. Predetermining exactly what types of submission would not be published is nearly impossible. Consider, however, the hypothetical example of a manuscript on how to make *Bacillus anthracis* ciprofloxacin-resistant. Because we have known for decades how to make bacteria resistant to this drug, the science behind the paper would seem routine, and the potential for misuse might be argued to preclude publication. But, because the United States is now using ciprofloxacin prophylactically for possible cases of anthrax, it is imperative that we understand the properties of resistant strains of *B. anthracis* that are likely to arise spontaneously. Therefore, depending on the nature of the science presented, a paper studying antibiotic resistance in anthrax could be suitable for publication. Any work of value to terrorists will also be of value in countering terrorism.

The scientists involved in the publication of the three papers called into question agree that publication of these papers was justified. PNAS Board member John Coffin put it succinctly:

> While these papers might be of theoretical value to terrorists, they do not point the way toward the manufacture of instruments of terrorism in any specific way, and their publication is likely to be of much greater value in advancing our efforts toward protection against the relevant agents.

One goal of the NAS/CSIS meeting was to start a dialogue between the life sciences and national security communities that might eventually lead to the development of a common set of publication policies for journals in the life sciences. Accordingly, the following day, publishers, editors, and scientist-authors convened to determine what, if any, formal policy could be articulated. The following editorial is the result (5). This will also be published in *Science* and *Nature*.

We must all recognize that protecting our world against both intentional acts of bioterrorism and the scourge of infectious diseases will depend on the effective communication of the science that we need for our common defense. At the same time, PNAS will continue to monitor submitted papers for material that may be deemed inappropriate and that could, if published, compromise the public welfare. We also urge authors to continue to act responsibly and to consider carefully the potential dual use of their results.

Nicholas R. Cozzarelli, *Editor-in-Chief*

1. Rosengard, A. M., Liu, Y., Nie, Z. & Jimenez, R. (2002) *Proc. Natl. Acad. Sci. USA* **99**, 8808–8813.
2. Cello, J., Paul, A. V. & Wimmer, E. (2002) *Science* **297**, 1016–1018.
3. Jackson, R. J., Ramsay, A. J., Christensen, C. D., Beaton, S., Hall, D. F. & Ramshaw, I. A. (2001) *J. Virol.* **75**, 1205–1210.
4. Lachmann, P. J. (2002) *Proc. Natl. Acad. Sci. USA* **99**, 8461–8462.
5. Journal Editors and Authors Group (2003) *Proc. Natl. Acad. Sci. USA* **100**, 1464.

Yes - Have a Right to Think, Inquire, Form Groups to Argue Ideas, & Do Research - But.....

What about Experimentation - Actually carrying out Experiments in a Lab, outside, Home, etc. ??

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.

CAN BE REGULATED DIRECTLY BY LAW or INDIRECTLY BY FUNDING!

HOW CAN EXPERIMENTATION BE REGULATED? Directly!!

(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 – citizen's "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 Bioweapons

e.g., ebola, anthrax

REGULATION OF EXPERIMENTS Con't

(d) Case # 4 – GMOs / Plants & Animals

Could BAN Because harmful to environment, affect native species – OR CAN Regulate (e.g., "welfare" of animals). GLO Fish

(e) Case #5 – Home Experiments

Affect "general welfare"

CAN THINK – BUT CAN'T ALWAYS ACT!

REGULATION OF EXPERIMENTATION Con't

Fed $

State $

INDIRECTLY!

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 (~60).

CASE #2 – Possible BAN on all human cloning ??
CONSTITUTIONAL?

(b) 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 (Historical)

FACTS – follow Recombinant DNA Advisory Committee Recommendations (RACs) before getting $ –

What is the Relationship Between Science & the Law?

1975 Recombinant DNA Guidelines

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

"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?

REGULATION OF SCIENCE

DIRECT & INDIRECT

(1) Recombinant DNA

Experimentation could be regulated by federal, state, & local governments — POLICE POWERS / GENERAL WELFARE

In Reality Regulated — Indirectly by Funding Granting Agency Requirements / Gene Therapy - HUMAN Subjects

(2) GMOs & Clones (Animal)

Release into ENVIRONMENT, Altered Composition of Food, use as "pesticide", etc. — Directly by General Welfare + Indirectly by Funding

Glofish! Meat from cloned cattle!

(3) Human Clones

Experimentation + Generation Could be regulated (is!) Directly by General Welfare + Indirectly by funding (federal)

(4) In Vitro Fertilization

Medical Licensing, FDA - intervention - Directly by General Welfare

Last →

(5) Human Reproduction & Cloning - Little Case Law

a. Griswold vs. Connecticut - 1965 Right to Privacy (ban on contraception)

"If the Fourth & Fifth Amendments were described... as protection against all government intrusions "of the sanctity of a man's home & the privacies of life"

"We deal with a right to privacy older than the Bill of Rights.. " If a Law against totalitarian Limit of Family Size is at complete variance with our constitutional concepts, then Law outlawing voluntary birth control als at variance "

"If the right to privacy means ANYTHING, it is the right of an individual, married or single, to be free from an unwarranted government intrusion into matters affecting a person as to whether to have a child"

b. Roe vs. Wade - 1973

c. Lifchez vs. Hartigan - 1990 Illinois State Ban on embryo freezing, experimental prenatal procedures, embryo donation, PGD, in vitro fertilization unconstitutional - right to use procedures to bring about pregnancy -

the state has a legitimate concern. Research may be restricted, for example, to protect the subject's right to autonomy and welfare by requiring informed, free and competent consent.

* * *

Would A Ban On Cloning Infringe Upon The Right To Make Reproductive Decisions?

A variety of personal desires may motivate people to utilize cloning. The NBAC (National Bioethics Advisory Commission) report suggests it would be "understandable, or even, as some have argued desirable," to create a child from one adult if both members of the couple have a lethal recessive gene; from a dying infant if his father is dead and the mother wants an offspring from her late husband; or from a terminally ill child to create a bone marrow donor.

* * *

The right to make decisions about whether or not to bear children is constitutionally protected under the constitutional right to privacy and the constitutional right to liberty. The Supreme Court in 1992 reaffirmed the "recognized protection accorded to liberty relating to intimate relationships, the family, and decisions about whether or not to beget or bear a child." Early decisions protected a married couple's right to privacy to make procreative decisions, but later decisions focused on individuals' rights as well: "If the right of privacy means anything, it is the right of the individual, married or single, to be free from unwarranted governmental intrusion into matters so fundamentally affecting a person as the decision whether to bear or beget a child."

A federal district court has indicated that the right to make procreative decisions encompasses the right of an infertile couple to undergo medically-assisted reproduction, including in vitro fertilization and the use of a donated embryo. Lifchez v. Hartigan [735 F.Supp. 1361 (N.D. Ill. 1990)] held that a ban on research on fetuses was unconstitutional not only because it was impermissibly vague, but also because it impermissibly infringed upon a woman's fundamental right to privacy. Although the Illinois statute banning embryo and fetal research at issue in the case permitted in vitro fertilization, it did not allow embryo donation, embryo freezing, or experimental prenatal diagnostic procedures. The court stated: "It takes no great leap of logic to see that within the cluster of constitutionally protected choices that includes the right to have access to contraceptives, there must be included within that cluster the right to submit to a medical procedure that may bring about, rather than prevent, pregnancy."

* * *

However, cloning is too qualitatively different from normal reproduction and from the types of assisted reproduction protected by the *Lifchez* case to simply assume the same Constitutional protections apply.

(6) Human Cloning? Stem Cell Research?

If right to cloning constitutional – it could be regulated & surrounded by legislation – compelling state interest (e.g., protect health of clone – because a clone genotype already existed & ∴ affect how clone treated by self, family, social institutions – treated by

or it healthy to begin with!

As George Annas suggests, "[t]his change in kind in the fundamental way in which humans can 'reproduce' represents such a challenge to human dignity and the potential devaluation of human life (even comparing the 'original' to the 'copy' in terms of which is to be more valued) that even the search for an analogy has come up empty handed."

Cloning is not a process of genetic mix, but of genetic duplication. In even the most high-tech reproductive technologies available, a mix of genes occurs to create an individual with a genotype that has never before existed on earth. Even in the case of twins, their futures are unknown and the distinction between the offspring and their parents is acknowledged. In the case of cloning, however, the genotype in question has already existed. Even though it is clear that a clone will develop into a person with different traits because of different social, environmental, and generational influences, there is strong speculation that the fact that he or she has a genotype that already existed will affect how the resulting clone is treated by himself, his family, and social institutions.

Just as in the scientific inquiry context, even if a fundamental constitutional right to clone were recognized, any legislation that would infringe unduly upon this right would be permissible if it were narrowly tailored to further a compelling state interest.

STATES THAT REGULATE HUMAN CLONING USING THEIR "POLICE POWERS" TO PROMOTE the General Welfare

States with existing statutes regarding human cloning

State	Reproductive Cloning Forbidden?	Therapeutic Cloning Forbidden?
Arkansas	Yes	Yes
California	Yes	No (state funds allocated)
Iowa	Yes	Yes
Michigan	Yes	Yes
Missouri	No, but state funding forbidden	No
New Jersey	Yes	No
North Dakota	Yes	Yes
Rhode Island	Yes	No
South Dakota	Yes	Yes
Virginia	Yes	Law unclear

What if Reproductive Cloning Was 100% Successful?!!

Intellectual Property

Who Owns our Genes?

NO ONE, OF COURSE!!

Patents Affect How Science is Carried Out & How Basic Science is Translated into Business

Cohen-Boyer Recombinant DNA Patent

United States Patent *4,237,224*
Cohen , et al. **December 2, 1980**

Process for producing biologically functional molecular chimeras

Abstract

Method and compositions are provided for replication and expression of exogenous genes in microorganisms. Plasmids or virus DNA are cleaved to provide linear DNA having ligatable termini to which is inserted a gene having complementary termini, to provide a biologically functional replicon with a desired phenotypical property. The replicon is inserted into a microorganism cell by transformation. Isolation of the transformants provides cells for replication and expression of the DNA molecules present in the modified plasmid. The method provides a convenient and efficient way to introduce genetic capability into microorganisms for the production of nucleic acids and proteins, such as medically or commercially useful enzymes, which may have direct usefulness, or may find expression in the production of drugs, such as hormones, antibiotics, or the like, fixation of nitrogen, fermentation, utilization of specific feedstocks, or the like.

Inventors: **Cohen; Stanley N.** (Portola Valley, CA); **Boyer; Herbert W.** (Mill Valley, CA)
Assignee: **Board of Trustees of the Leland Stanford Jr. University** (Stanford, CA)
Appl. No.: **001021**
Filed: **January 4, 1979**

Current U.S. Class: **435/69.1**; 435/69.2; 435/69.3; 435/69.4; 435/69.5; 435/69.51; 435/69.52; 435/69.6; 435/91.1; 435/91.4; 435/91.41; 435/183; 435/207; 435/212; 435/231; 435/252.33; 435/320.1; 435/820; 435/849; 530/311; 530/397; 530/399; 530/808; 536/23.1
Intern'l Class: C12P 021/00
Field of Search: 195/1,28 N,28 R,112,78,79 435/68,172,231,183

Chakrabarty - "Life is patentable" patent

United States Patent [19]

Chakrabarty

[11] **4,259,444**

[45] **Mar. 31, 1981**

[54] **MICROORGANISMS HAVING MULTIPLE COMPATIBLE DEGRADATIVE ENERGY-GENERATING PLASMIDS AND PREPARATION THEREOF**

[75] Inventor: **Ananda M. Chakrabarty**, Latham, N.Y.

[73] Assignee: **General Electric Company**, Schenectady, N.Y.

[21] Appl. No.: **260,563**

[22] Filed: **Jun. 7, 1972**

[51] **Int. Cl.**[3] **C12N 15/00**

[52] **U.S. Cl.** **435/172**; 435/253; 435/264; 435/281; 435/820; 435/875; 435/877

[58] **Field of Search** ..... 195/28 R, 1, 3 H, 3 R, 195/96, 78, 79, 112; 435/172, 253, 264, 820, 281, 875, 877

[56] **References Cited**

PUBLICATIONS

Annual Review of Microbiology vol. 26 Annual Review Inc. 1972 pp. 362–368.

Journal of Bacteriology vol. 106 pp. 468–478 (1971).

Bacteriological Reviews vol. 33 pp. 210–263 (1969).

Primary Examiner—R. B. Penland

Attorney, Agent, or Firm—Leo I. MaLossi; James C. Davis, Jr.

[57] **ABSTRACT**

Unique microorganisms have been developed by the application of genetic engineering techniques. These microorganisms contain at least two stable (compatible) energy-generating plasmids, these plasmids specifying separate degradative pathways. The techniques for preparing such multi-plasmid strains from bacteria of the genus Pseudomonas are described. Living cultures of two strains of Pseudomonas (*P. aeruginosa* [NRRL B-5472] and *P. putida* [NRRL B-5473]) have been deposited with the United States Department of Agriculture, Agricultural Research Service, Northern Marketing and Nutrient Research Division, Peoria, Ill. The *P. aeruginosa* NRRL B-5472 was derived from *Pseudomonas aeruginosa* strain 1c by the genetic transfer thereto, and containment therein, of camphor, octane, salicylate and naphthalene degradative pathways in the form of plasmids. The *P. putida* NRRL B-5473 was derived from *Pseudomonas putida* strain PpG1 by genetic transfer thereto, and containment therein, of camphor, salicylate and naphthalene degradative pathways and drug resistance factor RP-1, all in the form of plasmids.

18 Claims, 2 Drawing Figures

Plant Genetic Engineering Patents

Bayer Cropscience, Max Planck Society, Monsanto Company Resolve Agrobacterium Patent Dispute

ST. LOUIS (February 4, 2005) - Bayer CropScience, based in Monheim, the Max Planck Society and their affiliate Garching Innovation GmbH, both based in Munich, and Monsanto Company announced today that they have reached an agreement that resolves long-standing patent interference or other proceedings in different countries involving the use of Agrobacterium-mediated transformation to create transgenic crops. Agrobacterium transformation technology allows scientists to transfer DNA to plant cells.

Under the agreement, Max Planck Society, Bayer CropScience, Garching Innovation, and Monsanto will cross license their respective Agrobacterium-mediated transformation technologies worldwide. Bayer CropScience, Max Planck's exclusive licensee, and Monsanto will provide each other, in selected areas of the world, non-exclusive licenses related to the development, use and sale of transgenic crops. Monsanto will also provide Max Planck Society with a license in the United States for research purposes.

Additional details of the agreement were not disclosed.

"This agreement secures freedom for the involved parties in the field of Agrobacterium-mediated transformation technology, thereby ensuring present and future market access for their respective technologies in the United States and Canada," said Dr. Bernward Garthoff, member of the Bayer CropScience Board of Management, responsible for R&D.

"This is a positive development for agricultural biotechnology as a whole," said Robert T. Fraley, Ph.D., Executive Vice President and Chief Technology Officer for Monsanto. "Through the agreement, the parties recognize the global contributions of the Max Planck and Monsanto scientists who invented this technology. This agreement enables their respective agricultural innovations to reach consumers and farmers without hindrance."

Bayer CropScience, a subsidiary of Bayer AG with annual sales of about EUR 5.8 billion (2003), is one of the world's leading innovative crop science companies in the areas of crop protection, non-agricultural pest control, seeds and plant biotechnology. The company offers an outstanding range of products and extensive service backup for modern, sustainable agriculture and for non-agricultural applications. Bayer CropScience has a global workforce of about 19,000 and is represented in more than 120 countries, ensuring proximity to dealers and consumers. Further information is available at www.bayercropscience.com.

Max Planck Society for the Advancement of Science, one of Germany's largest non-profit research organizations, comprises 78 individual institutes, each of which conducts research in areas of the natural sciences and the humanities. As the technology transfer agency for the Max Planck Society, Garching Innovation GmbH fosters and manages the commercialization of inventions and know-how discovered or created at Max Planck institutes. Further information is available at www.mpg.de.

Monsanto Company (NYSE: MON) is a leading provider of technology-based solutions and agricultural products that improve farm productivity. For more information on Monsanto, see: www.monsanto.com.

Polymerase Chain Reaction or PCR Patent

United States Patent [19]

Mullis

[11] **Patent Number: 4,683,202**

[45] **Date of Patent: * Jul. 28, 1987**

[54] **PROCESS FOR AMPLIFYING NUCLEIC ACID SEQUENCES**

[75] Inventor: **Kary B. Mullis**, Kensington, Calif.

[73] Assignee: **Cetus Corporation**, Emeryville, Calif.

[*] Notice: The portion of the term of this patent subsequent to Jul. 28, 2004 has been disclaimed.

[21] Appl. No.: **791,308**

[22] Filed: **Oct. 25, 1985**

Related U.S. Application Data

[63] Continuation-in-part of Ser. No. 716,975, Mar. 28, 1985, abandoned.

[51] **Int. Cl.**[4] **C12P 19/34;** C12N 15/00; C12N 1/00; C07H 21/04; C07H 21/02

[52] **U.S. Cl.** **435/91;** 435/177.3; 435/317; 536/27; 536/28; 536/29; 935/17; 935/18; 935/16

[58] **Field of Search** 435/91, 172.3, 317; 536/27, 28, 29; 935/17, 18

[56] **References Cited**

PUBLICATIONS

Gaubatz et al, "Strategies for Constructing Complementary DNA for Cloning", J. Theor. Biol. 95: 679 (1982).

Caton and Robertson, *Nucleic Acids Research*, vol. 7, pp. 1445–1456 (1979).

Rossi et al., *J. Biol. Chem.*, 257, 9226–9229 (1982).

Primary Examiner—James Martinell

Attorney, Agent, or Firm—Janet E. Hasak; Albert P. Halluin

[57] **ABSTRACT**

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

21 Claims, 12 Drawing Figures

Patents & Copyrights ARE Federally-Protected Constitutional Rights! Adjudicated in Federal Courts — only mention of "Science" in constitution!

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."

Is a Gene Patentable? A "Switch"? In Your Body?
Is the technique of recombinant DNA patentable?
Are living organisms patentable?

US Patent System is "Morally Neutral"

(1) Bypasses public debate on social issues related to technology innovation

(2) Patent will issue even if device not in public interest (e.g., pollution)

(3) European Patents Different - "inventions are considered unpatentable where their commercial exploitation would be contrary to public policy or morality"

(4) In US Congress makes laws as to what can be patented or not - No patents on any invention or discovery useful solely in utilization of nuclear weapons (42 USC 2181)

WHAT IS INTELLECTUAL PROPERTY?

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

These are Property Rights - can be sold, traded, or licensed

Country Specific!

UNITED STATES PATENT AND TRADEMARK OFFICE

Home | Index | Search | System Alerts | eBusiness Center | News & Notices | Contact Us

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.

TRADE Secret - Anything! Societal problem?

What is A TRadeMark?

(1) A word, NAME, SYMBOL or device to indicate source of goods and to distinguish them from others. or a Service Mark to distinguish a source of service.

(2) Registered with USPTO to protect NAMES of products + services!

(3) LASTS for 10 years (+) 10 year Extensions indefinitely!

If stop using for three continuous years - it's abandoned

(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®

MUST Be distinctive - MC Donald's
Coca Cola
Kinko's (service)
Blockbuster (service)
AMAZON.com

WHAT IS A COPYRIGHT?

The boby Book ©

(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 first)

What CAN be copyrighted?

1. Literary works
2. Musical works, including words
3. Dramatic works, including music
4. Choreographic works
5. Pictorial, Graphic, & Sculptural works
6. Motion pictures & other audiovisual works
7. Sound recordings
8. Architectural works
10. Video Games

Computer programs are "literary works"

What CANNOT be copyrighted?

1. Works not fixed in tangible form
2. Titles, names, phrases, slogans, Lettering
3. Ideas, procedures, methods, systems, processes, concepts, principles, discoveries, devices (but illustrations of these can be copyrighted) Patents
4. COMMON information with no authorship (eg, a calendar, height & weight charts, ruler) —

write it, Paint it, Record it, Put on internet → Copyrighted

Registrations helps in fighting infringement!

Scientific publications can be copyrighted!

The Plant Cell, Vol. 13, 2409–2425, November 2001, www.plantcell.org © 2001 American Society of Plant Biologists

Regional Localization of Suspensor mRNAs during Early Embryo Development

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And Figures, Tables in publication need permission to Reproduce — Even authors!

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.
   ↳ set/describe structure of invention
4. Invention may be a composition of matter or Process/Utility (How to do something) or Machine
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 is issued!

1995 GATT Agreement
previously 17 years from issue
17 years Minimum In-Force
2000 GATT

How to Make baby
United States Patent 8,763,432
2/4/03

Patentable Inventions are specified under United States Code 35

Sections 101, 102, & 103, (& 112) are most important

What is a Patentable Invention?

"35 U.S.C. 101:

Whoever invents or discovers any 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"

Key words - New & useful

What Can Be Patented

- ☺ Process or Method (Recombinant DNA, PCR)
- ☺ Machine or Apparatus (PCR Machine)
- ☺ Article of Manufacture (Genetically Engineered Bacteria or Mouse!)
- ☺ Composition of Matter (SEQUENCE OF GENE OR PROTEIN OR BOTH!!)
  - ♠ Chemical Compounds
  - ♠ Physical Mixtures
- ☺ Improvements of Any of the Above (different patent)

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 is a TRADE SECRET?

(1) "Unprotected" FORM OF Intellectual Property

(2) Information of <u>any sort</u> that is valuable to owner, not generally known, & has been kept <u>secret</u> by the owner.

(3) What can be "protected" as trade secrets? Customer lists, designs, Manufacturing processes, FORMULAS, DNA sequences or Information not generally known

(4) Protected in several states by Trade Secret Laws

(5) Trade secret owner has right to keep others from Misappropriating (stealing) & using trade secret. e.g., employees leaving & going to another company (Confidentiality & non-compete clauses)

(6) Discovery of Trade secret thru independent research or reverse engineering of product is <u>NOT</u> a Trade Secret

(7) EXAMPLES: Coca Cola Formula

DO NOT HAVE SAME PROTECTION AS COPYRIGHTS & PATENTS – BUT These are DISCLOSED Publically!!

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?

PATENTS VS. TRADE SECRETS?

With Patents - Society Gains Knowledge Because Patents Published (18 Months after Filing date)

↳ Patent Pending Status

With TRade Marks - Prevent Competitors FROM gaining Proprietary Knowledge - even Patents Published

AND Patents Expire After 20 years!

∴ Coca Cola FORMULA a trade secret!

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 – ~600 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 systems, property rights, + trade → In constitution

If anti-patent → anti-Market

VENICE PATENT STATUTE OF 1474

Venetian Glass Blowing Secrets Revealed

SOCIETAL INTEREST

VS.

TRADE SECRETS!

"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).

written description for others to see + build upon = progress

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.

ENFORCED BY FEDERAL COURTS

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

NO THROW AWAYS — TRANSgenic Mice & Soluble secreted protein stops tumor

3. Must Be NOVEL (new!)
4. Must Be NON-Obvious

Specification of Patent + CLAIMS = SUBJECT MATTER of Invention

5. Must Have a Written Description of the invention (V)
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 (IP) FROM Practicing Invention

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, Gases, 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

→ (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-cyclohexanoic 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 Corn

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

NOT IN CANADA

(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 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 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

Concept vs. Reduce to Practice

(4) Cases

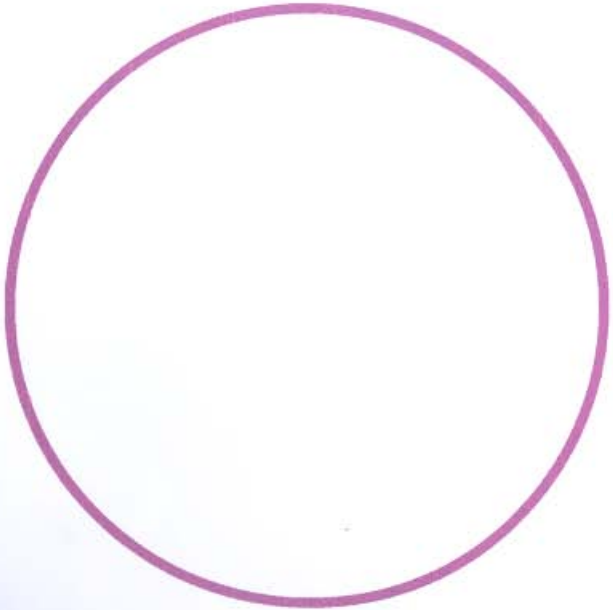
(a) A purified DNA molecule, isolated from natural environment with sequence 5' AGCT 3' (composition of matter), to produce a specific useful protein — DNA sequence itself NOT patentable.

vague

vs.

(b) A purified DNA molecule, isolated from natural environment, with sequence 5' AAAGT 3' 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. (by prior invention) 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"

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

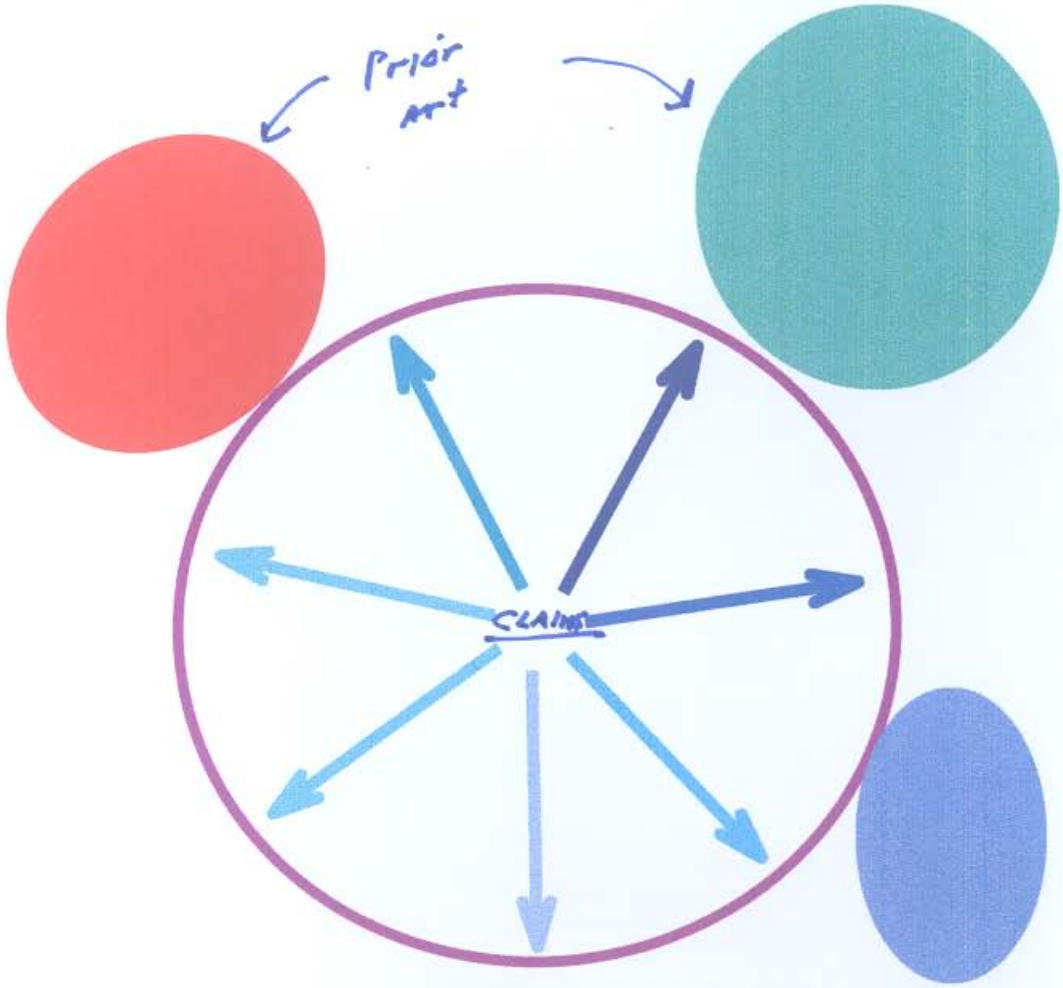
Case #1

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

Case #2

PRIOR ART LIMITS THE SCOPE OF PATENT CLAIMS

The requirement for novelty of 35 USC §102 means that a patent claim cannot include what is already in the prior art.



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

SPECIFICATION (CLAIMS)

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"

Article I Section 8.8

ENORMOUS Benefit TO SOCIETY

RECOMBINANT DNA
PCR
APPLE/MICROSOFT

e.g. Recombinant DNA patent → biotech industry + basic knowledge

(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 —

→ what you give to society

case — generic drugs now off patent

(2) Must provide a written description that describes the best way to use + practice invention —

case — Regents of UC vs. Eli Lilly (1997)

UC

Rat insulin cDNA case

claimed Lilly infringed on patents manufacturing insulin — based on rat cDNA. Court said description not sufficient for human insulin — can't use rat cDNA sequence to predict human sequence

no written description of use in humans!

(3) Include claims

Eli Lilly vs. Regents UC

(1) UC has Patent on Rat Insulin cDNA clone + sequence

(2) Eli Lilly licensed Patent on Human Insulin cDNA to make human insulin in bacteria

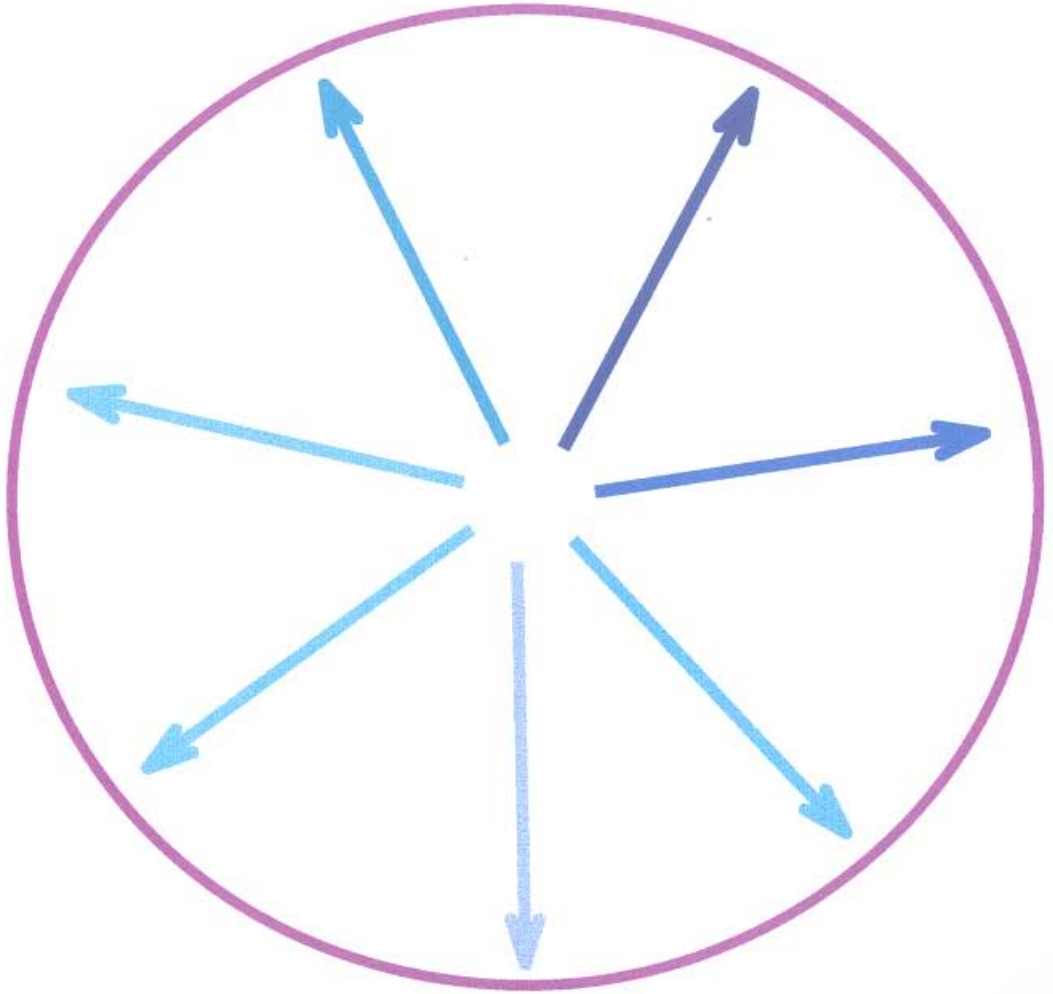
(3) UC sued Eli Lilly for patent Infringement + Lost

(4) Court said UC rat insulin written description could not instruct others how to manufacture/practice invention insulin

(5) Not obvious how to translate <u>rat</u> insulin cDNA sequence in <u>human</u> protein sequence — CODE degenerate!

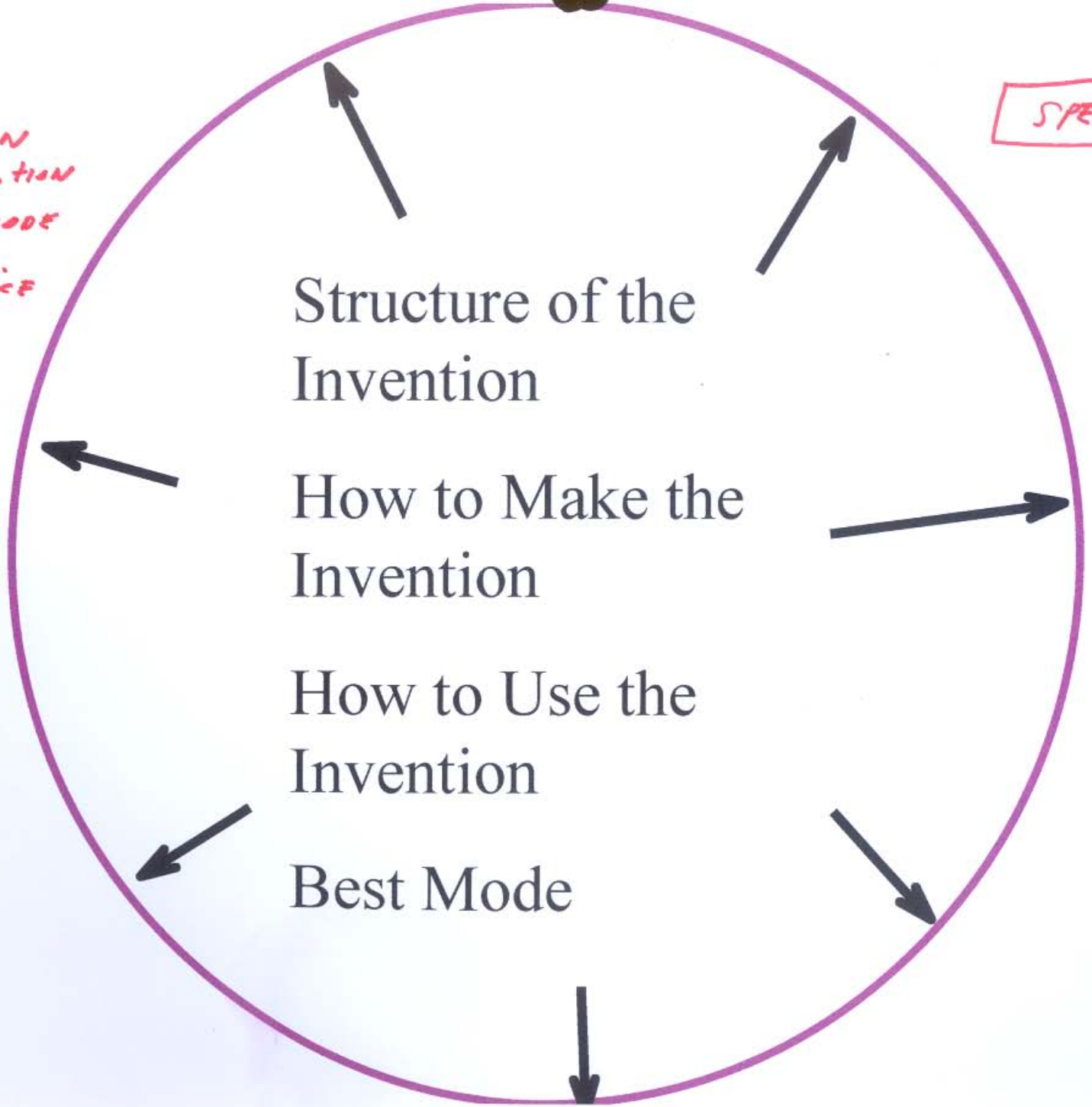
∴ violated written description

35 U.S.C. § 112, first paragraph tells what description must be provided to support the scope of a claim...



① WRITTEN DISCRIPTION
② BEST MODE OF PRACTICE
③ CLAIMS

SPECIFICATION



HOW DOES THE PATENT PROCESS WORK?

(1) Legislated by Congress (Article I) and enforced by Federal Courts + Guided by Federal Courts (e.g., living organisms can be patented). in 35 USC — USPTO under Commerce Dept. — Director appointed by President with 2/3 vote Senate — Section 8.1

Fed Courts + Congress

(2) Patent is filed at USPTO in Washington +/or with other national patent offices +/or EPO (European patent office) — FILING DATE CRITICAL — TIME PERIODS FOR PATENTS START AT TIME OF FILING!! — US VS. JAPAN — Clock Inventor Priority — Country specific GATT

FILING DATE + INVENTION DATE (US)

(3) PATENT APPLICATION PUBLISHED 18 months FROM Filing Date — ∴ invention becomes prior art.

<1995 + after 1995

(4) USPTO EXAMINES Patent Application: — Goes over Criteria

patent eligible? utility? Novel? Non-Obvious? written description? best mode of practice?

20 years from Filing 1995 minimum of 17 years in-force 2000

(5) Patent Examiners Review Application:

(a) at least Bachelor's Degree in Technical field — 46% have PhD'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)

INTERFERENCE VS. INFRINGEMENT

TO OBTAIN A PATENT
THE EXAMINERS Address!

1. Patent Eligible Material?
2. Substantial, Credible, & Specific Utility (Claims)
3. New/Novel - not in Prior Art
4. not obvious
5. Written description
6. Best Mode of Practice

Claims

7. filing date / Invention date (US)

IMPORTANCE OF:

(1) Filing Date

a. Starts Clock (WORLD)

b. Europe & JAPAN – Priority for invention – FIRST TO File (Race)

(2) Invention Date

a. US – FIRST to INVENT!

b. Priority for Invention (competing inventions)

MUST have written record in Bound Books in Ink!

interference

Interference

vs.

Infringement

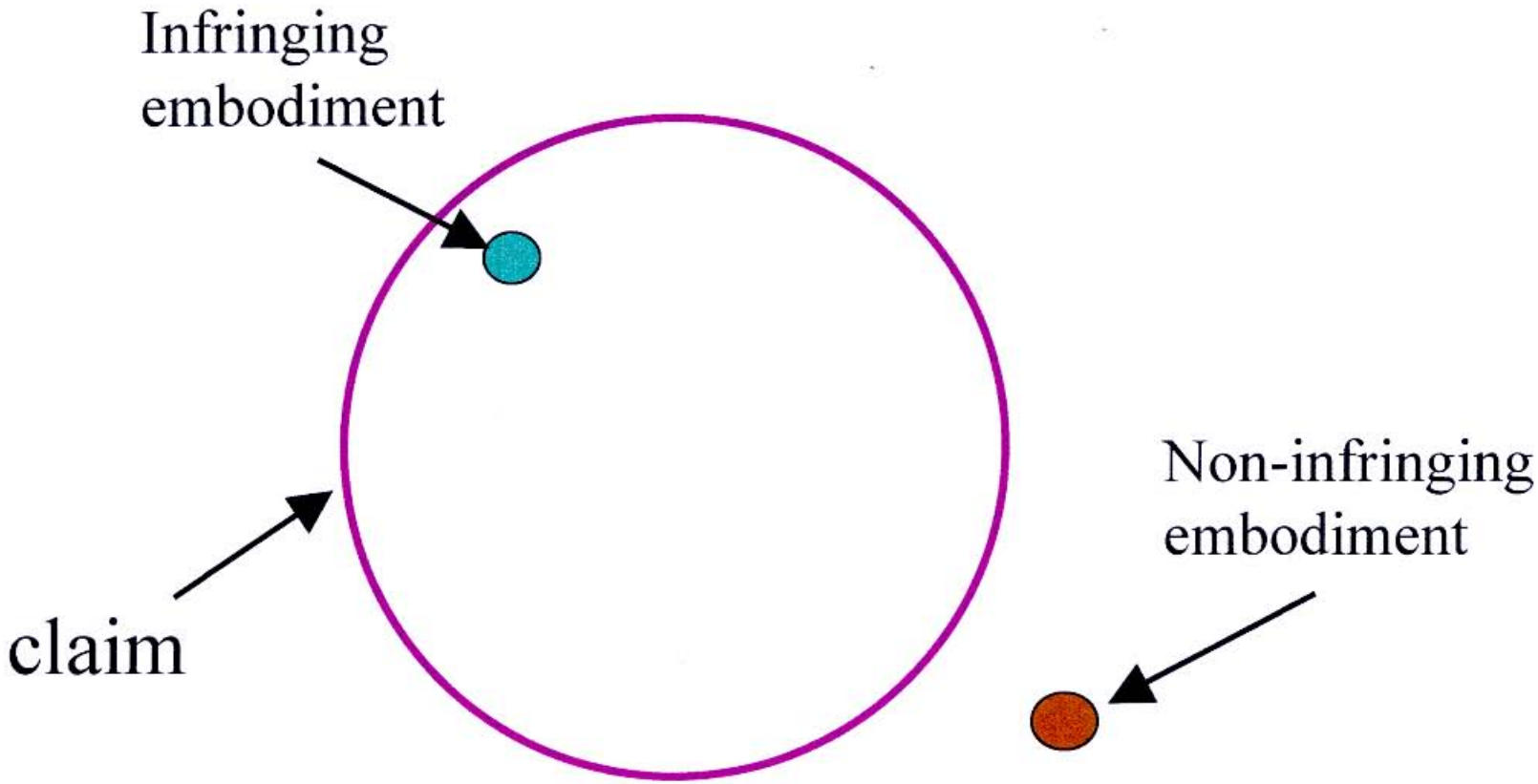
Documenting Inventions

- U.S. is the only "first to invent" country
- Everyone else is "first to file"
- An "interference" is a proceeding to determine who is first to invent
  - Evidence of invention date is usually from inventor's notebook

Infringement

"Infringement" of a patent occurs when a competitor makes, uses, sells, offers to sell or imports an embodiment of the invention without the permission of the patent owner.

Infringement



Infringement

The typical remedies for infringement are:

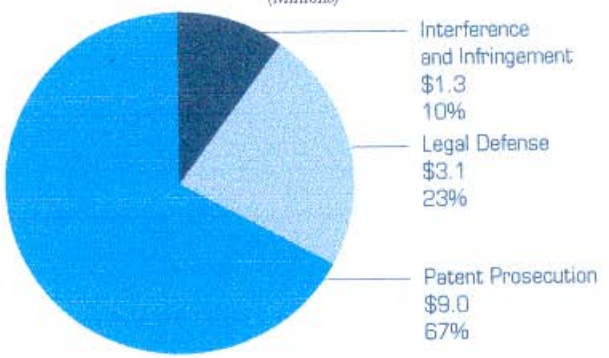
-] Damages ($$$)
-] Injunction (stop use by infringer)

Defending Patents is Expensive

EXHIBIT 18

NET LEGAL EXPENSES

Year Ended June 30, 2002
(Millions)



FY02 Net Legal Expenses = $13.4 Million

But have Big Payoffs – UC received $200M for settlement of Human Growth Hormone Patent Infringement Suit – FROM Genentech – Inventors (HGH cDNA in Mid 70's = $95M)

*Howard Goodman
John Shine
Peter Seeburg

Invisible Frontiers – S.S. Hall

WHAT IS IMPORTANCE OF PATENT SYSTEM?

"Promote Progress of Science"

(1) Stimulate INVENTION & Entrepreneurship — PROGRESS
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) — PROGRESS OF SCIENCE
vs. TRADE SECRETS

(3) Provides Incentives to Invest — in production & application of knowledge because benefits allocated to companies using patents — inventors exclusive right to prevent others from making, using, selling invention without a license.
No patent — no financial incentive
PROTECTION

(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 1/3-1/2 life time of patent need to make a return on investment

IF CLINICAL TRIAL 10 years, then patent life reduced by 1/2!!

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

The Italian Story

Before a better Patent System in place

Cancer v. Malaria

progress in drugs

where are the vaccines?

GENETIC ENGINEERING + PATENTS MADE A NEW INDUSTRY!

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BIO BIOTECHNOLOGY INDUSTRY ORGANIZATION

Home

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.

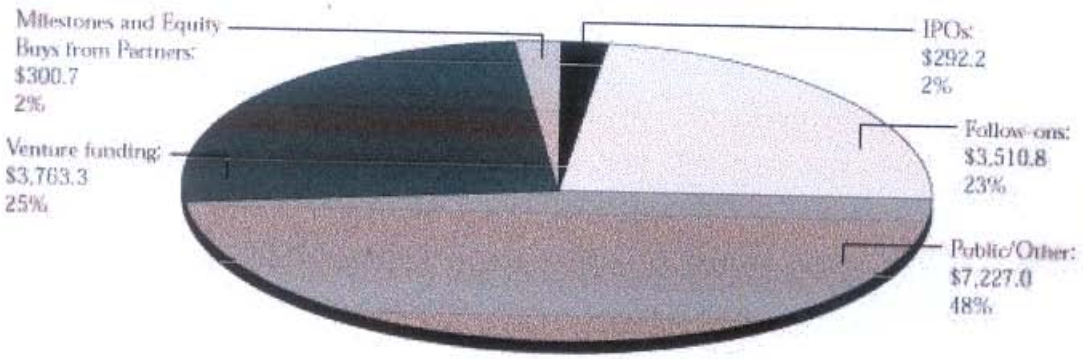
1. market capitalization = 224 BILLion in May, 2002
2. 130 Biotec Drugs in use
3. 350 Biotec Drugs Are in trials
4. 16 BILLion Spent on R+D in 2001
5. 179,000 employees over 1500 companies

75

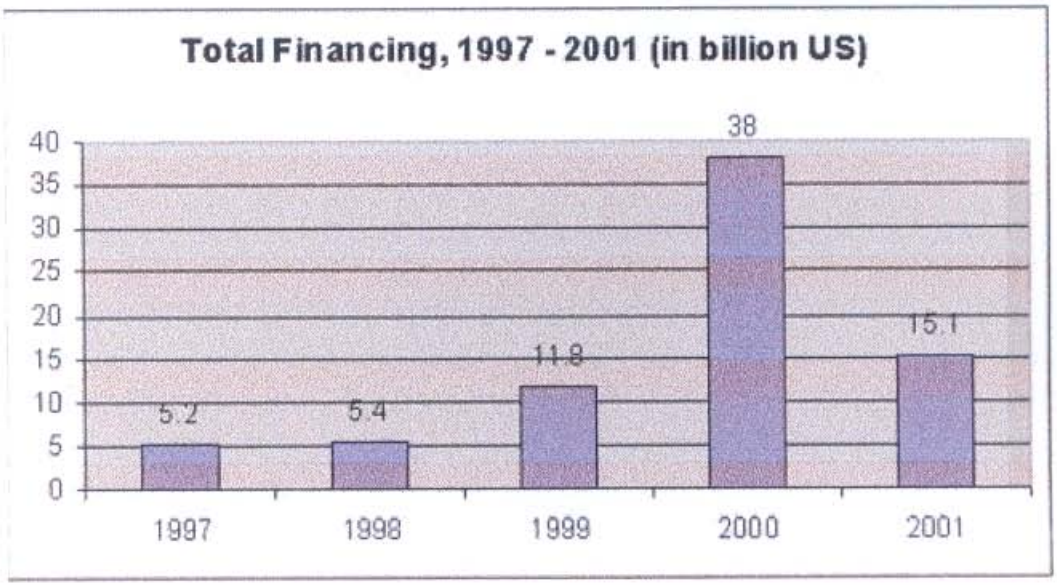
BIOTEC is A BIG BUSINESS

Biotech Industry Financing, 2001

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



Source: BioWorld



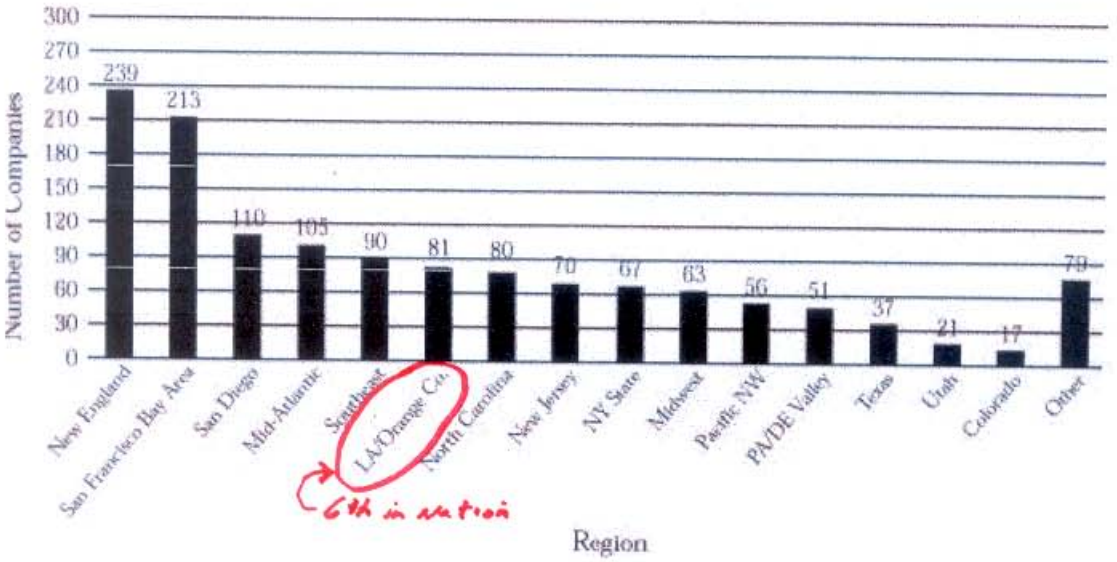
Would NOT have happened without patent protection!!

BIOTEC COMPANIES BY Region & Market Capitalization

Started in 1976

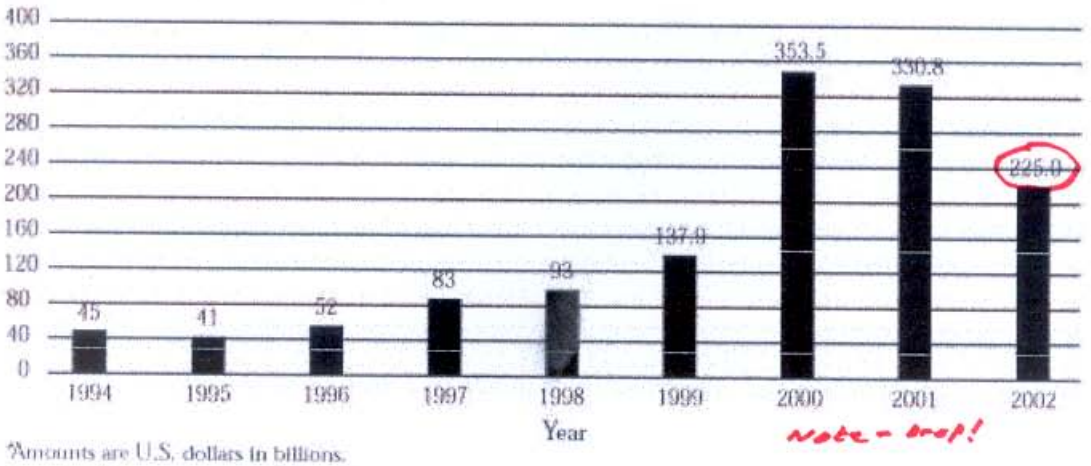
Private and Public Biotech Companies by Region

ECONOMIC Driver!



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

Market Capitalization, 1994–2002*

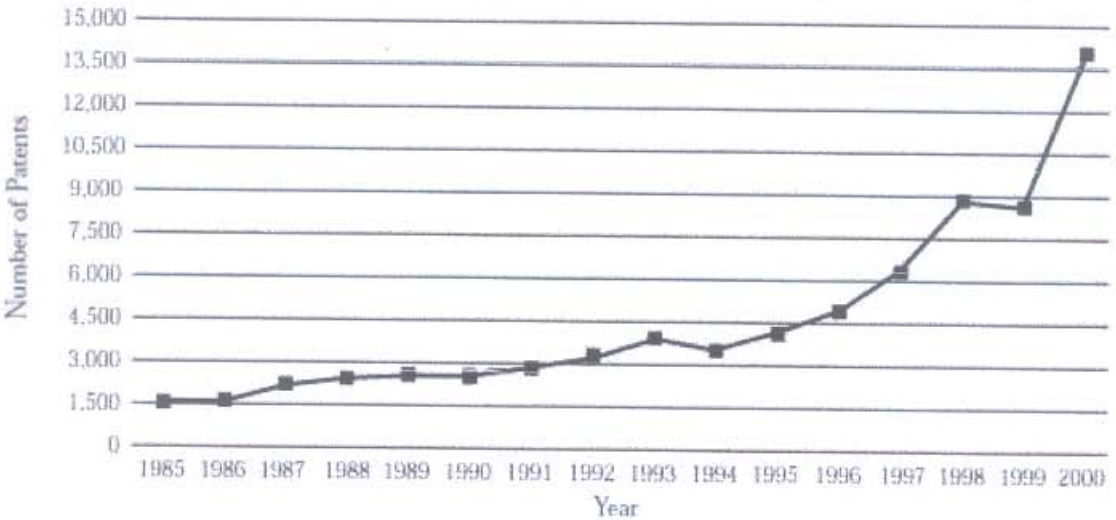


*Amounts are U.S. dollars in billions.

Sources: Ernst & Young LLP and BioWorld

BIOTEC-RELATED PATENTS

Total Patents Granted per Year

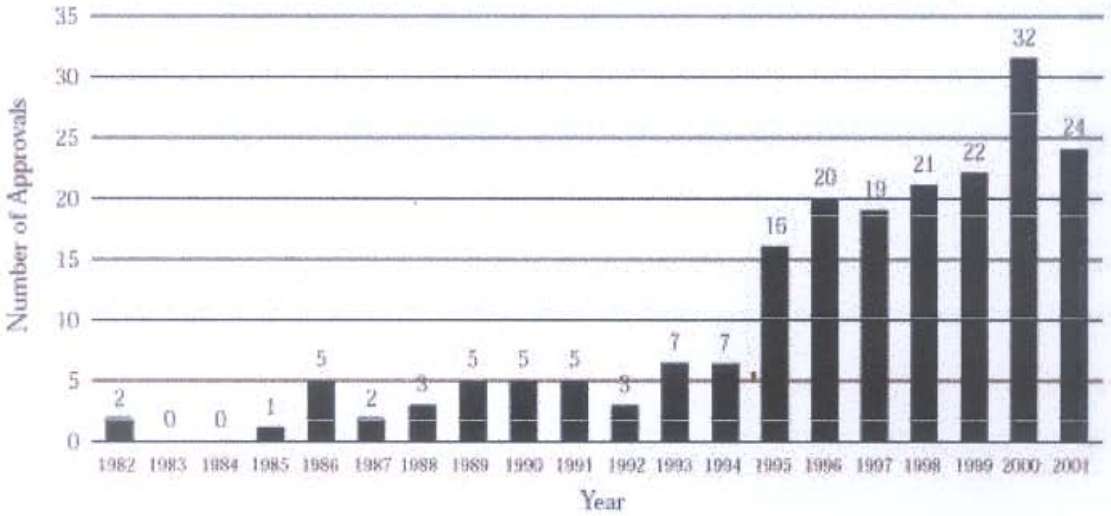


Source: U.S. Patent and Trademark Office

Increase parallels increase in DNA Sequencing

DRUG + VACCINE APPROVALS PER YEAR

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



Source: BIO

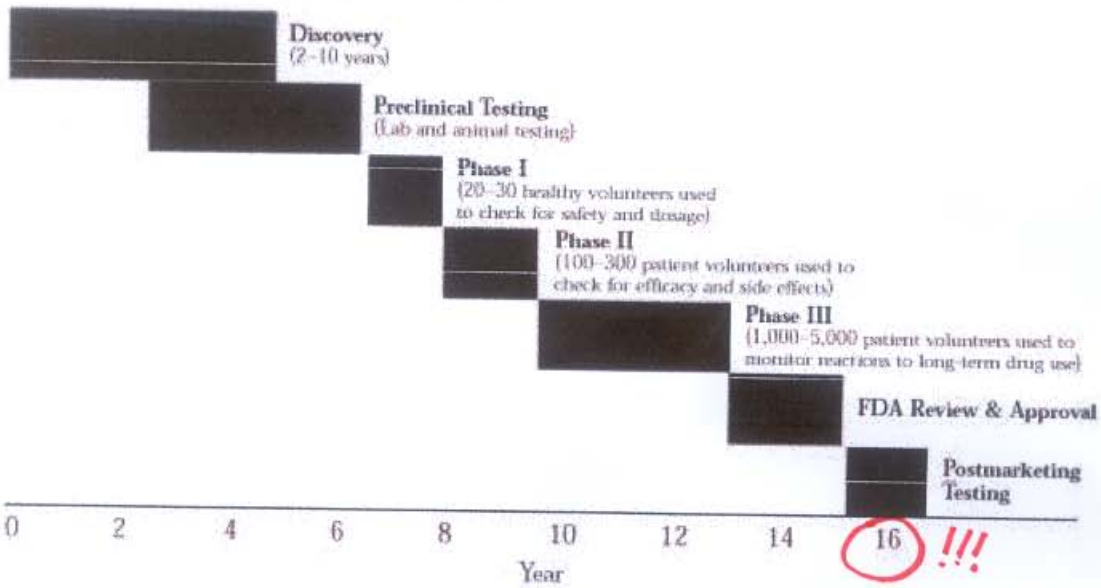
Biotec Industry founded with Genentech in 1976!

"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

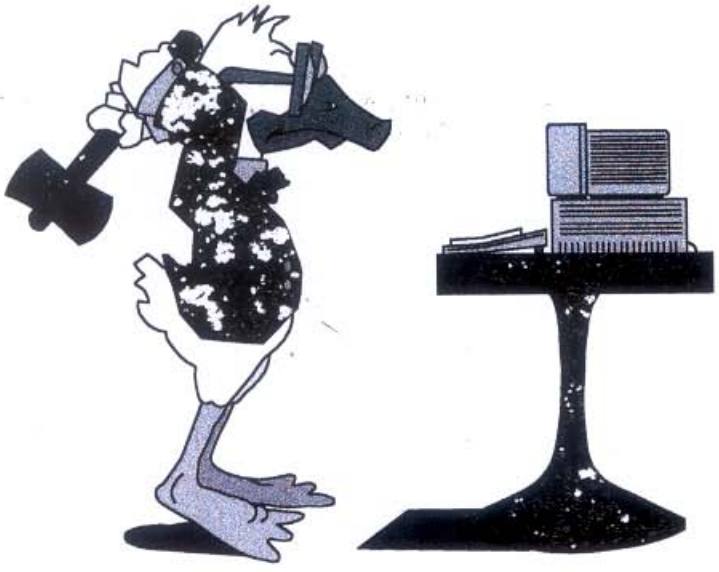
16 years

only 5 yrs patent in 4 years to get $ back!

∴ need to recover R+D costs in remaining 5-10 years of patent protection

DO PATENTS FACILITATE MONOPOLIES?

Dangers of Monopolies



The Ghost of Teddy Roosevelt

Sherman Antitrust Act

"Trustbusters"
Temper Patent Power

Plus "Market Pull" — new breakthrough technologies
polaroid vs. digital photography

NO!

81

Unless Anti-Market!

What About Patents & Univers, this?

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 biotec industry & entrepreneurs —

OTT
OFFICE OF TECHNOLOGY TRANSFER
Office of the President

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**

Directions to OTT
UC Contacts
Site Map

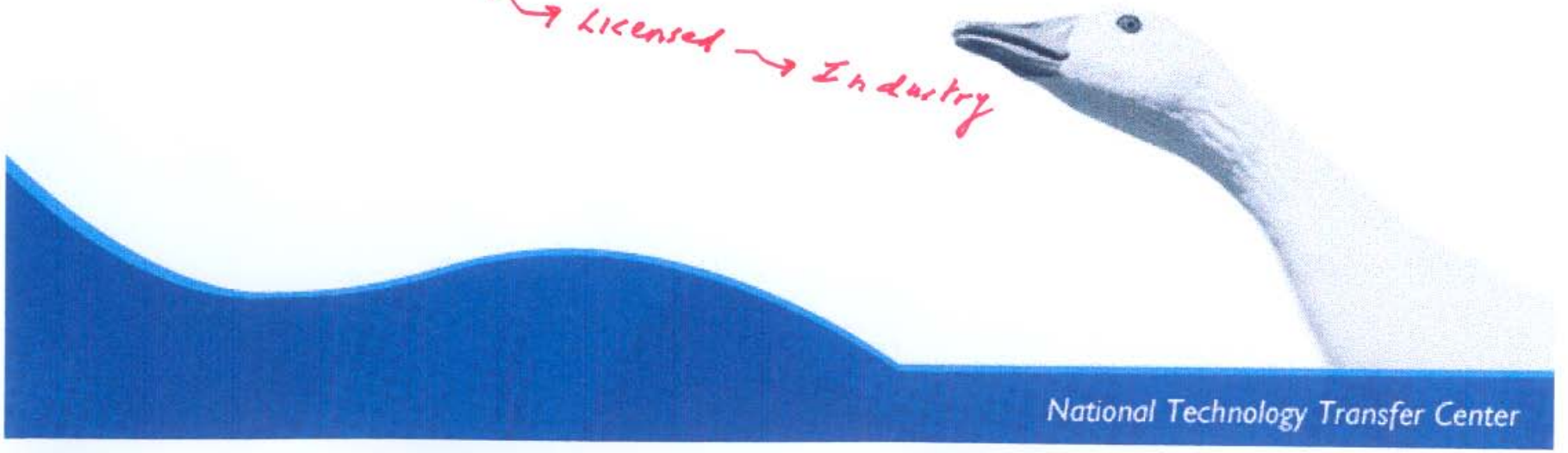
Ask OTT | **2001 Annual Report** | **President's Retreat: Five Years of Progress**

Innovation's Golden Goose

Possibly the most inspired piece of legislation to be enacted in America over the past half-century was the Bayh-Dole act of 1980. Together with amendments in 1984 and augmentation in 1986, this unlocked all inventions and discoveries that had been made in laboratories throughout the United States with the help of taxpayer's money. More than anything, this single policy measure helped to reverse America's precipitous slide into industrial irrelevance.

— The Economist Technology Quarterly, December 14, 2002

Basic Research → Licensed → Industry



National Technology Transfer Center

This report presents a preliminary list of the U.S. universities receiving the most patents for invention (i.e., utility patents) during the 2003 calendar year. All campuses are included.

Rank in 2003*	Number of Patents in 2003*	Organization*	(Rank in 2002)	(Number of Patents in 2002)
1	439	University of California	(1)	(431)
2	139	California Institute of Technology	(3)	(110)
3	127	Massachusetts Institute of Technology	(2)	(135)
4	96	University of Texas	(5)	(93)
5	85	Stanford University	(4)	(104)
6	84	University of Wisconsin	(6**)	(81)
7	70	Johns Hopkins University	(6**)	(81)
8	63	University of Michigan	(12)	(47)
9	61	Columbia University	(13)	(45)
10	59	Cornell University	(21**)	(35)
	59	University of Florida	(15)	(42)

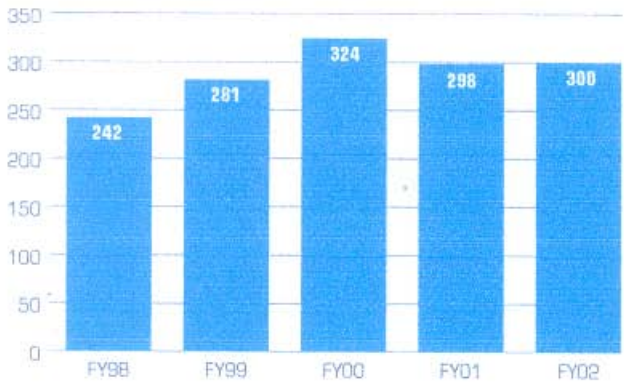
*The listed patent counts are preliminary. The final listing of patent counts for U.S. universities in 2003 should be available in late December of 2004.
** Indicates a tie in the ranking among two or more U.S. universities.

Is there a question about what the USPTO can or cannot do that you cannot find an answer for? Send questions about USPTO programs and services to the **USPTO Contact Center (UCC).** *You can suggest USPTO webpages or material you would like featured on this section by E-mail to the* **webmaster@uspto.gov.** *While we cannot promise to accommodate all requests, your suggestions will be considered and may lead to other improvements on the website.*

UC Patents

EXHIBIT 6

US PATENTS ISSUED TO UC



At the end of FY02, there were 2,502 US and 2,051 foreign patents in the systemwide portfolio (Exhibit 7). The number of US patents in each campus portfolio is presented in Exhibit 8.

EXHIBIT 8

CAMPUS US PATENT PORTFOLIOS*

Year Ended June 30, 2002

UCB	417
UCD	304
UCI	143
UCLA	348
UCR	71
UCSB	159
UCSC	18
UCSD	392
UCSF	645

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

EXHIBIT 7

TOTAL UC PATENT PORTFOLIO

2500 Patents

85

Top Earning UC Patents / Licensing Income

EXHIBIT 15

UC TOP-EARNING INVENTIONS*

Year Ended June 30, 2002
(Thousands)

Invention (Campus, Year Disclosed)		
Hepatitis-B Vaccine (SF, 1979 and 1981)	$	21,474
Treatment-Intracranial Aneurysms (LA, 1989)	$	6,803
Radiographic Media (SD, 1979)	$	5,456
Liposome Sizing Method (SF, 1977)	$	3,686
Interstitial Cystitis Therapy (SD, 1980)	$	2,986
Subtotal (Top Five Inventions)	**$**	**40,405**
Dynamic Skin Cooling Device (IR, 1993)	$	2,982
Camarosa Strawberry (DA, 1992)	$	2,360
Yeast Expression Vector (SF, 1982)	$	1,936
Laser/Water Atomic Microscope (SB, 1989)	$	1,839
Cochlear Implants (SF, 1979)	$	1,476
Liposome Storage Method (DA, 1984)	$	1,432
Fluorescent Conjugate Probes (BK, 1981)	$	1,198
Feline AIDS Virus Diagnostic (DA, 1986)	$	930
Feline Leukemia Virus Diagnostic (DA, 1980)	$	770
Fluorescence Gel Scanner (BK, 1990)	$	664
Chromosome Painting (LLL, 1985)	$	604
Aids for Learning Disabled (SF, 1994)	$	582
Nicotine Patch (LA, 1984)	$	534
Fluorescent Dyes-Calcium (BK, 1984)	$	513
Energy Transfer Primers (BK, 1994)	$	468
Firefly Luciferase (SD, 1984)	$	455
Diamante Strawberry (DA, 1997)	$	368
Intracellular DNA/RNA Targeting (SF, 1991)	$	359
Magnetic Resonance Imaging (SF, 1976)	$	357
Gene Reporter Matrix (BK, 1995)	$	316
Total Income (Top 25 Inventions)	**$**	**60,548**
Total Income (All Inventions)	**$**	**88,148**
% of Total from Top 5 Inventions		**45.7%**
% of Total from Top 25 Inventions		**68.5%**

*This list is limited to revenue-generating inventions that have been commercialized. UC inventions that have not yet reached the marketplace but generated FY02 income equivalent to others on the list (e.g. through issue fees and minimum royalties) include Optical Network Switch, $8.8 million (DA, 1997), and Human FV Phage Antibody Library, $1.1 million (BK/SF, 1996).

Previous - Recombinant DNA human growth hormone

86

86

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)

Expired

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

ONLY 16% of UC BUDGET PROVIDED FOR BY STATE FUNDS in 2002-03

∴ Need all Sources of Revenue!

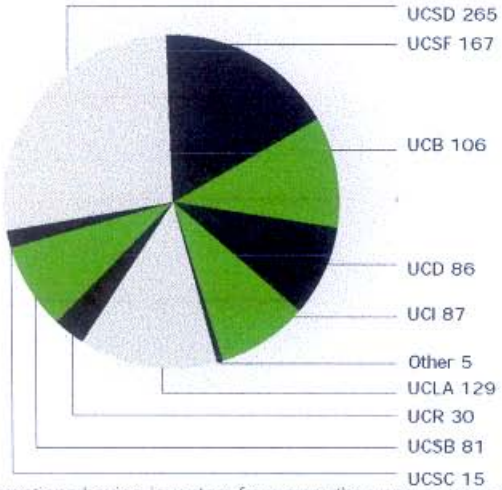
87

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

UCB	667
UCD	612
UCI	347
UCLA	686
UCR	184
UCSB	290
UCSC	76
UCSD	1,038
UCSF	1,104

*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)

UCB	$7,124
UCD	$10,036
UCI	$6,240
UCLA	$9,559
UCR	$1,174
UCSB	$985
UCSC	$75
UCSD	$7,715
UCSF	$38,500
Other*	$1,470

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

UC Royalty Income 2002

EXHIBIT 29

FY02 CAMPUS FINANCIAL ACTIVITY

Year Ended June 30, 2002
(Thousands)

	UCB	UCD	UCI	UCLA	UCR	UCSB	UCSC	UCSD	UCSF
Income from Royalties and Fees	$5,810	$16,401	$4,257	$10,118	$1,089	$2,347	$38	$12,690	$34,344
Less: Payments to Joint Holders	(56)	0	0	13	0	0	0	(632)	(5,371)
Adjusted Gross Income (A)	5,754	16,401	4,257	10,105	1,089	2,347	38	12,058	28,973
Legal and Other Direct Expenses	3,130	2,485	1,496	3,043	678	1,318	381	6,825	5,679
Less: Reimbursements	(2,197)	(647)	(632)	(1,475)	(191)	(479)	(122)	(3,001)	(3,008)
Net Legal Expenses (B)	933	1,838	864	1,568	487	839	260	3,824	2,671
Mandatory Distributions									
Inventor Shares	1,794	3,312	2,136	3,388	471	282	9	2,075	11,936
Research Allocation	77	12	5	48	15	17	1	138	93
General Fund Share[1]	757	2,813	314	1,287	33	307	-58	1,519	3,592
Total Distributions (C)	2,628	6,137	2,455	4,723	519	606	-48	3,732	15,621
Operating Expenses (D)[2]	308	1,457	358	1,060	402	661	232	862	1,796
Net Income/Loss (A-B-C-D)[3]	$1,885	$6,969	$580	$2,754	($319)	$241	($405)	$3,640	$8,885

to dept.

$1.3M to General Fund to support UCLA Activities

UCLA

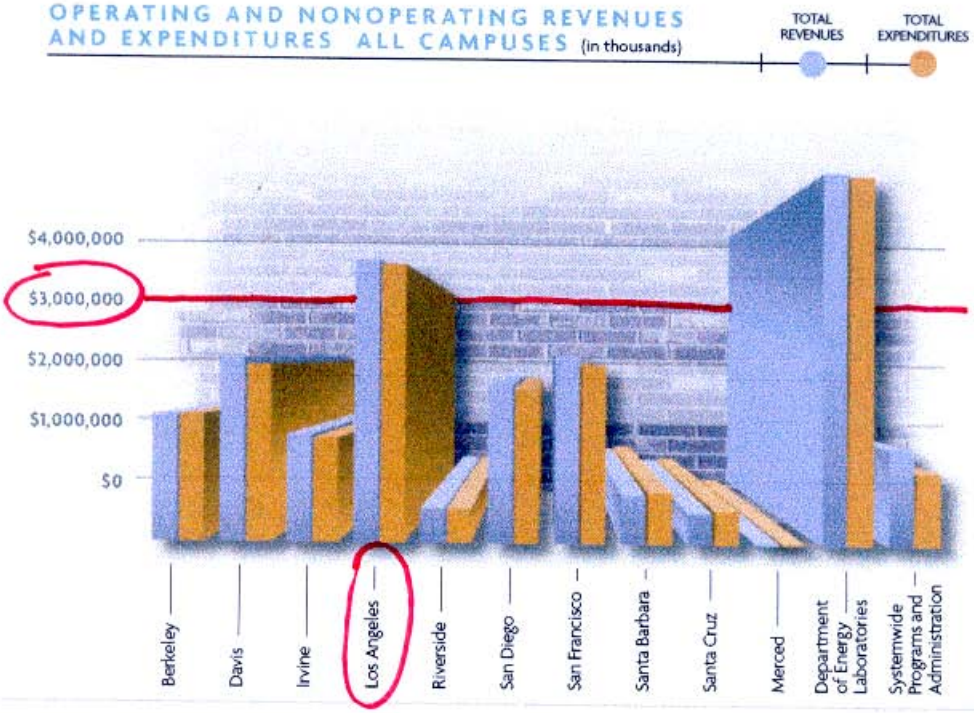
CAMPUS AND FINANCIAL HIGHLIGHTS

(dollars in thousands)

	For Fiscal Years Ended June 30	
	2003	2002
Enrollment - Fall Quarter		
Undergraduates	24,899	25,325
Graduates, and Interns and Residents	12,700	12,166
Staff Information		
Full-Time Equivalent		
(includes approximately 5,000 casuals and students)	27,353	26,763
Campus Land Area	419 acres	419 acres
OPERATING AND NONOPERATING REVENUE AND EXPENDITURES:		
Operating Revenue	$ 2,405,248	$ 2,213,593
Nonoperating Revenue	764,529	790,271
	$ 3,169,777	$ 3,003,864
Operating Expense	$ 3,081,629	$ 2,905,388
Nonoperating Expense	36,479	17,000
	$ 3,118,108	$ 2,922,388

University of California Expenditures
2002-2003

OPERATING AND NONOPERATING REVENUES AND EXPENDITURES ALL CAMPUSES (in thousands)

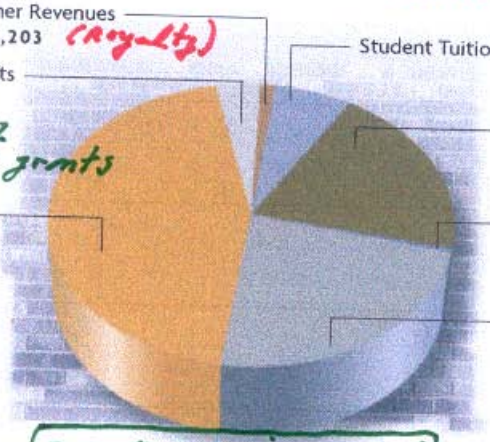


UCLA has the largest Budget of all UC campuses
~$3.2B/year

UCLA Revenue + Expenses

REVENUES SUPPORTING CORE ACTIVITIES

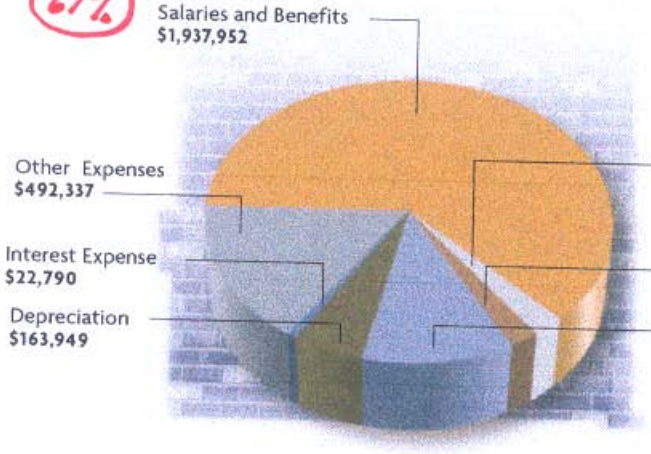
(in thousands)



The following chart displays the portion of operating and nonoperating expenses related to core activities of the campus, as of June 30, 2003:

EXPENSES ASSOCIATED WITH CORE ACTIVITIES

(in thousands)



2002-2003

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

University of California
OTT
OFFICE OF TECHNOLOGY TRANSFER
Office of the President

UNIVERSITY OF CALIFORNIA PATENT POLICY

Effective October 1, 1997

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

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

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.

Return to Main Page

Go Back

Who Owns Your Genes?

The Original Question

Who owns YOUR Genes? The original Question

(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 (IV 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" (novel, non-obvious utility)
But must satisfy all criteria for patenting – particularly "actually 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 CA) – for policy reasons promoting medical research, person (you) do not retain ownership of cells/tissues (DNA) taken with informed consent – INVENTIVE STEP OUTSIDE BOX!

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 TRANSGENIC PLANTS/ANIMALS
- 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 — Specific, substantial, + credible!

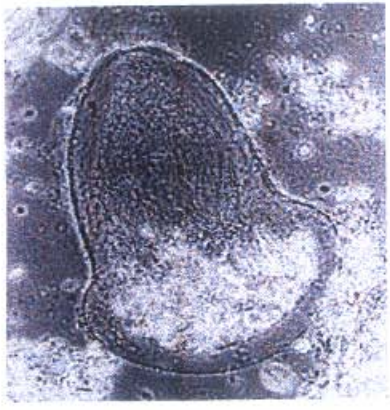
NON-OBVIOUS

Described

Best Mode of Practice

] invention!

Can Life Be Patented?



Bacteria

Plant

Should life be patentable?

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 integration 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.

TRANSGENIC ANIMALS/PLANTS

Precedent: Diamond vs. Chakrabarty (1980)

Should Life Be Patented?

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." STRANGE!

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

TRANSGENIC BYJANUS!

Lower vs. Higher?

COMPOSITION OF MATTER CAN apply to Lower Life forms (TRANSGENIC Bacteria, Yeast, Plant) but not Higher Life Form!

102

Harvard Mouse Con't

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**

David J. Heller, L.L.B., is at Ridout and Maybee (Toronto). Phone: (416) 865-3505. E-mail: dheller@ridoutmaybee.com. Website: www.ridoutmaybee.com.

(03)

What Concerns HAVE Been Raised About Patenting Genes & Organisms?

See Federal Register 2001 ← Handout

But Patents guided by Constitution + US Statutes

Change only by Congress!

(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

CURBED ONLY BY Statute/LAW BY Congress

(8) Hinder Genetic Testing / Diagnosis Treatment — Tests based on genes — diagnostic tests

*(9) Research Tools should not be patented — hinder progress. Enabling Patents (e.g., Recombinant DNA)

(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. Moore vs UC

could argue other way

PATENTS GRANTED ACCORDING TO CRITERIA SET by Congress

USC 35 101, 102, 103, 112

1. Patent Elijible
2. useful
3. novel
4. Non-Obvious
5. (I) 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

A Common Misperception...

Patents inhibit free exchange of information. + Innovation!

e.g., PCR, Recombinant DNA, transgenic Plants

TO THE CONTRARY…

The patent laws require **DISCLOSURE** of the structure of the invention, how to make and use it and the best mode of the invention. (35 U.S.C. § 112, first paragraph.)

Patent applications are typically **PUBLISHED** 18 months after filing and in any event upon issue.

An applicant is free to **DISCLOSE** the invention any time after the application is filed without jeopardizing patentability.

PROMOTE PROGRESS!