Chapter 2
Introduction and Overview

"On the outskirts of Washington, DC, sits the U.S. Patent and Trademark Office. On long shelves and in wood cases, it houses the more than 4.75 million U.S. patents issued since 1790. In recent years this venerable office has seen a new kind of patent: genetically modified living matter, ranging from microorganisms to mammals."

Elizabeth Corcoran
Scientific American, **September 1988**

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INTRODUCTION

This report examines some of the legal, economic, ethical, religious, and practical considerations raised by the patenting of micro-organisms, cells, plants, and animals. This introductory chapter provides a context for the report's more technical material by reviewing the historical background of intellectual property protection for living organisms.

Intellectual property protection, which **for purposes of this report is defined as that area of the law involving patents, copyrights, trademarks, trade secrets, and plant variety protection, is not new.** The concept of patents, for example, has its roots in English law, where it was defined as the grant by the sovereign to a subject under some authority, title, franchise, or property. English common law is the root of much of American law. In the United States, the concept of intellectual property rights can be found in the U.S. Constitution (Article 1, Section 8), which gives Congress the power "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." In 1790, Congress enacted this Nation's first patent law (giving inventors a limited, exclusive right for their inventions) and copyright law (giving authors protection for the expression of their ideas).

Biotechnology, on the other hand, is relatively new. In the past 15 years, dramatic new developments in the ability to select and manipulate genetic material have created heightened interest in the commercial uses of living organisms. Biotechnology, broadly defined, includes any technique that uses living organisms (or parts of organisms) to make or modify products, to improve plants or animals, or to develop micro-organisms for specific uses. Although people have used organisms since the dawn of civilization to improve agriculture, animal husbandry, baking, and brewing, it is the novel uses of such biological techniques (e.g., recombinant DNA techniques, cell fusion techniques, monoclinal antibody technology, new bioprocesses for commercial production) that have caught the imagination of many people.

Patents have come to be viewed by many as vital to protecting commercial interests and intellectual property rights in biotechnology. In 1987 alone, the U.S. Patent and Trademark Office (PTO) issued 1,476 biotechnology patents, up from 1,232 in 1986 (table 2-1). About 6,900 biotechnology patent applications were pending as of January 1988 (7). The wide-reaching potential applications of biotechnology lie close to many of the world's major problems—malnutrition, disease, energy availability and cost, and pollution. Biotechnology can change the way we live due to its potential to produce new, safer, and more cost-effective products (15). In order to develop these new products, research and discovery resulting in the creation of new inventions must occur.

One novel result of the development of biotechnology is the creation and patenting of inventions that are themselves alive. Where once a credo of invention was to build a better mousetrap, U.S. law now permits the patenting of a new and useful mouse (see box 2-A).

The patenting of new life forms raises arguments in favor of and against the issuance of such patents. Most recently, public debate has centered on the patenting of animals (8,9). Such debate is to be expected when an old and relatively well-settled body of law must be applied to unforeseen technologies. Some proponents of patenting new life forms cite benefits of fostering innovation and technology transfer, rewarding creativity, and providing full

Table 2-l—Patents Issued in Biotechnology

Year	Number of patents issued
1983 ..., ., ., ...	1,018
1984	1,114
1985	1,076
1986	1,232
1987	1,476

SOURCE: 'U.S. Patent and Trademark Office Issues 1,476 Biotechnology Patents in 1997,' *Genetic Engineering News* 8(3):25, March 1966.

Box 2-A—A *Political History of Patenting Life*

1873 **Louis Pasteur** awarded patent 141,072 with a claim for a yeast.

1930 **Plant Patent Act** permits patenting of certain asexually reproducing plants, thus allowing the first patents on life forms.

1970 **Plant Variety Protection Act** provides patent-like protection for sexually reproducing plants.

1973 The first **recombinant DNA organisms are** generated.

1975 ***The*** **Asilomar Conference** urges adoption of guidelines for recombinant DNA research, setting a precedent of scrutiny and caution in recombinant DNA research.

1980 The **Patents and Trademarks Amendments** (Public Law 98-620) grant title to nonprofit **and** small businesses whose research was federally funded.

1980 **Genentech's initial public offering** raises public awareness of the commercial possibilities of genetic engineering.

1980 Stanford University and the University of California San Francisco are awarded the **Cohen-Boyer patent** on the basic technique of gene splicing.

1985 ***Ex Parte Hibbard*** establishes that plants are patentable subject matter under general utility patent provisions.

1987 In ***Ex Parte Allen, the*** Patent Appeals Board determines that multicellular animals are patentable subject matter.

1987 The **U.S. Senate adopts a moratorium on animal patents as part** of a supplemental appropriations bill. The moratorium is dropped in House-Senate conference.

1987 House Resolution 3119, **a bill to amend Title** 35 **of the United States Code to prohibit the patenting of genetically altered or modified animals** is introduced in the U.S. House of Representatives, but dies as the 100th Congress adjourns.

1988 Senate bill 2111, to amend Title 35 of the United States Code to prohibit the patenting of genetically altered or modified animals, is introduced in the U.S. Senate, but dies as the 100th Congress adjourns.

1988 **First animal patent (4,736,866)** is issued to Harvard University for a genetically engineered mouse.

1988 House Resolution 4970, the **Transgenic Animal Patent Reform Act** is passed by the U.S. House of **Representatives,** but dies as the 100th Congress adjourns.

SOURCE: Office of Technology Assessment, 1989.

disclosure of inventions to further advance the state of scientific research and technological developments. Some opponents of patenting believe that owning and manipulating living organisms is unethical, while others fear the economic consequences of patenting on various sectors of the economy (e.g., the effect of patented animals on livestock farmers).

The **debate over whether to permit the patenting of organisms frequently goes beyond simple questions of the appropriateness of patents per se, focusing instead on the consequences of the commercial use of patented organisms or the underlying merits of biotechnology itself.** Discussion regarding the patenting of a genetically engineered organism, for example, can turn to the environmental application of the organism (e.g., the field test of a micro-organism that is patented), the welfare of the organism (if it is an animal), scientific questions (e.g., whether the method of creating the organism represents a radical departure from traditional scientific or breeding methods), ethical issues (e.g., the morality of creating novel organisms or transferring genetic information between species), and economic considerations (e.g., whether the Federal Government should finance biotechnology-related research). **One inherent difficulty in examining the patenting** of **living organisms is *determining* which arguments raised are novel and directly related to patent issues, as opposed to those questions that would exist independent of patent considerations.**

WHAT IS A PATENT?

A U.S. patent is a form of property granted by the Federal Government to an inventor giving the inventor the right to exclude others from making, using, or selling the invention for a stated period of time (35 U.S.C. 154). Patents may be issued for a new and useful process, machine, manufacture, or composition of matter (35 U.S.C. 101 or so-called utility patents) or for asexually reproduced plants (35 U.S.C. 161-164).

The rationale behind the patent law is simple: to foster innovation, inventors must be guaranteed some degree of exclusivity on their inventions in order to be assured a reasonable profit and to justify the risks of development. In return for a patent, the inventor discloses how the invention works so that the knowledge is available to the public and others may build upon that knowledge.

HISTORY OF PATENTING LIVING ORGANISMS

Louis Pasteur was awarded a patent in 1873 (U.S. 141 ,072) which had as one of its claims a yeast, free from organic germs of disease, as an article of manufacture. This patent was the first of several "living matter" patents to be issued in the United States. Other early patents were issued on bacterial and viral vaccines. As a general rule, these patents claimed an organism in an inert carrier or in an inert culture medium (3).

Although no formal policy was issued barring the patenting of living organisms, the enactment by Congress of the Plant Patent Act of 1930 (35 U.S.C. 161-164) (which specifically permitted patent protection for asexually reproduced plants) was seen by many as standing for the proposition that in the absence of explicit congressional action, living matter itself was not patentable.

Patenting of Micro-Organisms and Cells

In 1980, the Supreme Court in the case of *Chakrabarty v. Diamond (4)* ruled in a 5-4 decision that a "manmade" micro-organism could be patented, in this case a bacterium engineered to breakdown four of the main components of crude oil. The decision rested in part on the premise that the patent statute as passed by Congress made no distinction between living and nonliving subject matter. Prior to the Court decision in *Chakrabarty, PTO* had considered micro-organisms products of nature, and thus not themselves patentable. The decision was hailed by some as assuring this country's technological future and was denounced by others as creating Aldous Huxley's "Brave New World." It left unclear whether patents would be permitted on higher life forms, The Court expressly refused to consider the potential hazards of the technology, saying

> [w]hatever their validity, the contentions now pressed on us should be addressed to the political branches of the Government, the Congress, and the Executive, and not to the courts.

Ananda M. Chakrabarty, then a research microbiologist with the General Electric Co., developed the oil-eating microbe using four naturally occurring plasmids—small circles of DNA that are not part of a cell's chromosomes—to confer the ability to degrade four different components of crude oil on a single strain of bacteria. Since the microbe itself would be the product sold, anyone would be able to secure and reproduce the organism for their own benefit, unless it was patented; therefore, Chakrabarty could not rely on trade secrecy to protect his invention, Initially, PTO granted Chakrabarty a patent on the process by which the microbe was developed and on the combination of the carrier (straw) and the bacterium. The Patent Office would not, however, grant a patent for the organism itself, contending that living things other than plants, which are specifically covered by the Plant Patent Act of 1930 and the Plant Variety Protection Act of 1970 (see chs. 3 and 5), could not be patented. However, the U.S. Court of Customs and Patent Appeals reversed this decision, and this reversal was ultimately upheld by the Supreme Court.

Patenting of Plants

Although Congress had in 1930 expressly acted to create patent protection for asexually reproduced plants, the *Chakrabarty* decision opened up the issue of whether general patent law could be used to provide protection for any new and useful plant.

In 1985, the Board of Patent Appeals and Interferences (a review body within PTO) ruled that plants,

seeds, and plant tissue cultures were proper subject matter for utility patents (6). This constituted the first time that utility patents were granted for multicellular organisms.

Patenting of Animals

In April 1987, the Board of Patent Appeals and Interferences ruled that polyploid oysters were patentable subject matter (5). Subsequently, PTO announced that it would henceforth consider "non-naturally occurring nonhuman multicellular living organisms, including animals, to be patentable subject matter" under general patent law. This statement initiated broad debate and the introduction of legislation concerning the patenting of animals.

The first animal patent was issued in April 1988 to Harvard University, for genetically engineered mammals, such as mice (U.S. 4,736,866). Exclusive license to practice the patent went to E.I. du Pont de Nemours & Co., which was the major sponsor of the research. The patented mouse was genetically engineered to be very susceptible to cancer, thus facilitating the testing of carcinogens and of cancer therapies. Specifically, the patent covers a transgenic nonhuman eukaryotic animal (preferably a rodent such as a mouse) whose germ cells and somatic cells contain an activated oncogene sequence introduced into the animal . . . which increases the probability of the development of neoplasms (particularly malignant tumors) in the animal.

The first animal patent prompted newspaper editorials both pro and con. One editorial stated,

> . . . companies must have a way to protect their investments in research and innovation . . . It would be a travesty for Congress to halt this process(1).

But another countered,

> When it acts on animal patent applications, the Patent Office is in effect making public policy decisions with no public input. In a field with as far-reaching implications as genetic engineering, that should not be allowed to happen (2).

PTO had 21 other patents on genetically engineered animals pending at the time the mouse patent was granted. Three bills on the subject of animal patenting were introduced in the 100th Congress. One bill, H.R. 4970, passed the House of Representatives (9).

ORGANIZATION OF THE REPORT

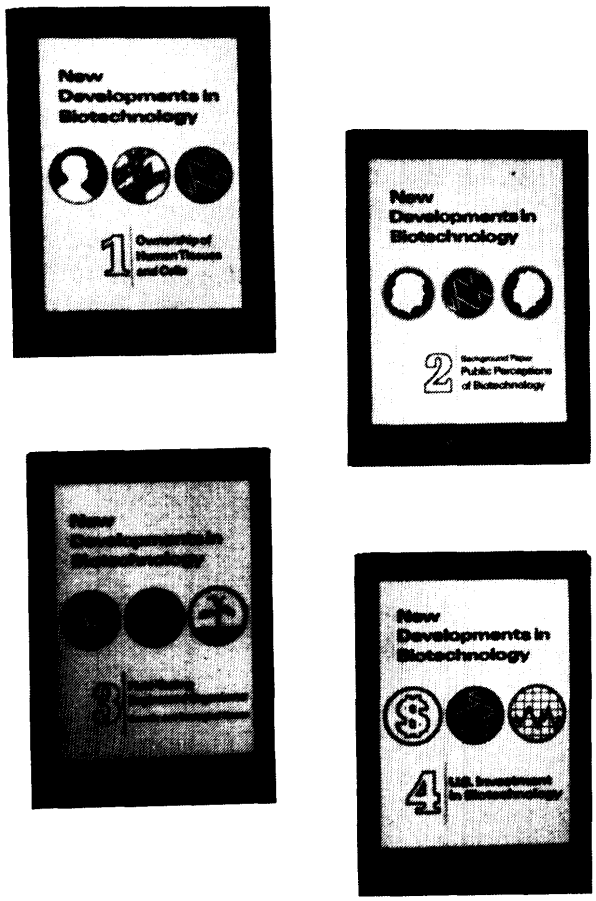
This special report is the fifth publication in OTA's assessment New Developments *in Biotechnology.*[1] The purpose of this special report is to review U.S. patent law as it relates to the patenting of micro-organisms and cells, plants, and animals. **The primary focus of this report is on subject matter patentability—what can and cannot be patented, as enacted by Congress under the patent statute and interpreted by the courts.** This report does not focus on issues related to process patent protection or issues related to the harmonization of international patent law.

Chapter 3 presents an overview of intellectual property law. Chapter 4 reviews issues related to the patenting of micro-organisms and cells. Chapter 5 examines intellectual property protection relating to plant life: plant patents, plant variety protection certificates, trade secrets, and utility patents. Chapters 6, 7, and 8 examine the scientific, regulatory, economic, and ethical issues related to the patenting of animals. Chapter 9 addresses deposit considerations. Chapter 10 reviews international subject matter protection for micro-organisms, cells, plants, and animals.

This report does not address in detail the following issues, which are the subjects of related OTA reports:

- intellectual property issues associated with mapping and sequencing the human genome (12);
- patents and intellectual property rights considerations related to commercial investment and industrial competitiveness (15);
- property rights related to the ownership of human tissues and cells (14);

[1] Earlier reports in the assessment of New Developments in Biotechnology are: *Ownership of Human Tissues and Cells—Special Report*, OTA-BA-337 (Washington. DC: U.S. Government Printing Office, March 1987); *Background Paper: Public Perceptions of Biotechnology*, OTA-BP-BA-45 (Springfield, VA: National Technical Information Service, May 1987); *Field-Testing Engineered Organisms: Genetic and Ecological Issues--special Report*, OTA-BA-350 (Lancaster, PA: Technomic Publishing Co., Inc., May 1987); New *Developments in Biotechnology: U.S. Investment—Special Report*, OTA-BA-360 (Springfield, VA: National Technical Information Service, July 1988).



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Four reports published under OTA's assessment of New Developments in Biotechnology.

- international patent law considerations other than subject matter patentability (11);
- genetic and ecological consequences of environmental release of micro-organisms, plants, and animals (13);
- technologies to maintain biological diversity (16); and
- use of animals in research, testing, and education (10).

SUMMARY

Patents on certain life forms have been permitted since the Plant Patent Act of 1930. The range of life forms susceptible to patenting has broadened, most significantly with the decision in *Diamond v. Chakrabarty* that a micro-organism could be patented; in Ex *parte Hibberd* that plants, seeds, and plant tissue cultures are patentable subject matter under the general patent laws; and in Ex *parte Allen* that a multicellular animal was patentable subject matter.

The patenting of living organisms, particularly animals, raises a number of ethical, economic, emotional, and practical issues, which are addressed in this report. The premise that life forms are patentable, and particularly that higher animals are patentable, has engendered considerable political controversy.

CHAPTER 2 REFERENCES

1. *Chicago Tribune,* "On Patented Mouse, Let Reason Rule," Apr. 17, 1988.
2. *Christian Science Monitor,* "Don't Jump into Designer Genes," The Christian Science Monitor, Apr. 25, 1988.
3. Cooper, I. P., *Biotechnology and the Law,* §2.02 *(New* York, NY: Clark Boardman, 1985).
4. *Diamond* v. *Chakrabarty, 447* U.S. 303 (1980).
5. *Ex parte Allen, 2* USPQ 2d 1425 (PTO Bd. Pat. App. & Int. 1987).
6. *Ex parte Hibberd, 227* USPQ 473 (PTO Bd. Pat. App. & Int. 1985).
7. Klausner, A., "Patent Office Reorganizes Biotech Coverage," *Biotechnology* 6(4):368, April 1988.
8. U.S. Congress, Committee on the Judiciary, Subcommittee on Courts, Civil Liberties, and the Administration of Justice, *Hearings on Patents and the Constitution: Transgenic Animals,* Serial No. 23 (Washington, DC: U.S. Government Printing Office, 1988).
9. U.S. Congress, House Committee on the Judiciary, Report 100-888, *Transgenic Animal Patent Reform Act,* to accompany H.R. 4970 (Washington, DC: U.S. Government Printing Office, 1988).
10. U.S. Congress, Office of Technology Assessment, *Alternatives to Animal Use in Research, Testing, and Education* (Springfield, VA: National Technical Information Service, February 1986).

11. U.S. Congress, Office of Technology Assessment, *Commercial Biotechnology: An International Analysis* (Elmsford, NY: Pergamon Press, Inc., January 1984),
12. U.S. Congress, Office of Technology Assessment, *Mapping Our Genes-The Genome Projects: How* Big? *How Fast?* OTA-BA-373 (Washington, DC: U.S. Government Printing Office, April 1988).
13. U.S. Congress, Office of Technology Assessment, New *Developments in Biotechnology-Field- Testing Engineered Organisms: Genetic and Ecological Issues,* OTA-BA-350 (Lancaster, PA: Technomic Publishing Co., Inc., May 1988),
14. U.S. Congress, Office of Technology Assessment, New *Developments in Biotechnology: Ownership of Human Tissues and Cells—Special Report,* OTA-BA-337 (Springfield, VA: National Technical Information Service, March 1987).
15. U.S. Congress, Office of Technology Assessment, *New Developments in Biotechnology: U.S. Investment—Special Report, OTA-BA-360* (Springfield, VA: National Technical Information Service, July 1988).
16. U.S. Congress, Office of Technology Assessment, *Technologies to Maintain Biological Diversity,* OTA-F-330 (Washington, DC: U.S. Government Printing Office, March 1987).