

List of Acronyms and Glossary of Terms

List of Acronyms

ADAMHA	— Alcohol, Drug Abuse, and Mental Health Administration
AID	— Agency for International Development
AIDS	— Acquired Immunodeficiency Syndrome
APHIS	— Animal and Plant Health Inspection Service
ARS	— Agricultural Research Service (USDA)
ATCC	— American Type Culture Collection
BPAI	— Board of Patent Appeals and Interferences
CCPA	— U.S. Court of Customs and Patent Appeals
CSRS	— Cooperative State Research Service (USDA)
DNA	— deoxyribonucleic acid
EPA	— Environmental Protection Agency
EPC	— European Patent Convention
EPO	— European Patent Office
FDA	— Food and Drug Administration
FDCA	— Federal Food, Drug and Cosmetic Act
FIFRA	— Federal Insecticide, Fungicide, and Rodenticide Act
FSIS	— Food Safety and Inspection Service (USDA)
IDA	— International Depository Authority
IMRU	— Institute of Microbiology at Rutgers University
ISA	— international searching authority
IVI	— In Vitro International, Inc.
MMTV	— mouse mammary tumor virus
NASA	— National Aeronautics and Space Administration
NEPA	— National Environmental Policy Act
NIH	— National Institutes of Health
NRRL	— Northern Regional Research Laboratory (Agricultural Research Service Culture Collection)
NSF	— National Science Foundation
OTA	— Office of Technology Assessment (U.S. Congress)
PCT	— Patent Cooperation Treaty
PL	— Public Law
PPA	— Plant Patent Act of 1930
PTO	— U.S. Patent and Trademark Office
PVPA	— Plant Variety Protection Act
PVPC	— Plant Variety Protection Certificate
PVPO	— Plant Variety Protection Office (USDA)
RNA	— ribonucleic acid
(PA)	— tissue plasminogen activator
TSCA	— Toxic Substances Control Act
UN	— United Nations

UPOV	International Union for the Protection of New Varieties of Plants
USDA	— United States Department of Agriculture
WIPO	— World Intellectual Property Organization

Glossary of Terms

Amino acid: Any of a group of 20 molecules that are linked together in various combinations to form proteins. Each different protein is made up of a specific sequence of these molecules with the unique sequence coded for by DNA.

Animal: A nonhuman living being with a capacity for spontaneous movement and a rapid motor response to stimulation. Animals can be divided into two groups, invertebrates (animals without backbones) and vertebrates (animals with backbones).

Animal deposit: The new patentable status of animals raises questions about their placement in depositories as part of the patent application process. To date no animal has been deposited in a depository, and the deposit of whole animals would not be practical, but it is conceivable that the maintenance of frozen embryos in depositories might be possible provided that the embryos can be successfully frozen and recovered. See *deposit* and *depositories*.

Animal patents: The patenting of nonhuman transgenic animal life forms. The United States is currently the only country that has issued a patent for an animal developed using biological techniques. The ability to patent animals introduces a new legal concept of animal ownership and raises a number of ethical, economic, and practical issues.

Asexual reproduction: As used in this report—reproduction of plants by purely vegetative means without the function and interaction of the two sexes. Examples of asexually reproduced plants are roses, peach trees, and lilies.

Bacterium (pi. bacteria): Any of a group of one-celled micro-organisms having round, rodlike, spiral, or filamentous bodies that are enclosed by a cell wall or membrane and lack fully differentiated nuclei.

Biotechnology: any technique that uses living organisms or substances from those organisms to make or modify a product, to improve plants or animals, or to develop micro-organisms for specific uses. These techniques include the use of novel technologies such as recombinant DNA, cell fusion, and other new bioprocesses. See *genetic engineering* and *recombinant DNA*.

Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure:

This Treaty, established in 1977, became effective in 1980. It requires that those contracting states, which allow or require the deposit of micro-organisms as part of their patent procedures, deposit these micro-organisms in a recognized International Depository Authority (IDA) that complies with Treaty requirements, and maintain them there for 30 years. Three IDAs are currently recognized in the United States. See *depositories* and *International Depository Authority*.

Carrier: See vector.

Cell: The smallest component of life. A membrane-bound protoplasmic body capable of carrying on all essential life processes. A single cell unit is a complex collection of molecules with many different activities all integrated to form a functioning, self-assembling, self-regulating, and self-reproducing biological unit.

Cell culture: The propagation of cells removed from multicellular organisms in a laboratory environment that has strict sterility, temperature, and nutrient requirements. The term is also used to refer to any particular individual sample.

Cell fusion: The joining of the membrane of two cells, thus creating a single hybrid cell that contains the nuclear matter from the parent cells.

Chakrabarty decision: A landmark 1980 Supreme Court decision holding that a live, human-made, micro-organism, that had been genetically engineered in a laboratory by Ananda Chakrabarty, was patentable as a “manufacture” or “composition of matter”.

Chromosome: A thread-like structure contained in the nucleus of a cell that carries the genes that convey hereditary characteristics.

Claim: The part of the patent that points out and distinctly claims the subject matter that the applicant regards as the invention. Claims represent the metes and bounds of the property to be protected. See *specification*.

Consequential reasoning: A form of ethical reasoning that analyzes the consequences of a particular action (e.g., the encouragement and development of new inventions). Consequentialist reasoning has been used to outline the pros and cons of patenting animals.

Copyright: Copyright protection applies to eight categories of works: literary; musical; dramatic; pantomime and choreographic; pictorial, graphic and sculptural; motion pictures and audio-visual work; sound recording; and computer programs. Copyright protects the expression of an idea, not the idea itself.

Cultivar: An international term denoting certain cultivated plants that are clearly distinguishable from others by one or more characteristics and which when reproduced retain those characteristics. In the United

States “variety” is considered to be synonymous with cultivar (derived from cultivated variety). See *plant variety*.

Deoxyribonucleic acid (DNA): The molecule in chromosomes that is the repository of genetic information in all organisms (with the exception of a small number of viruses in which the hereditary material is ribonucleic acid—RNA). The information coded by DNA determines the structure and function of an organism.

Deposit: Placement of micro-organisms, vectors, cells, plant tissues, seeds, and other biological materials that are newly isolated, novel, manmade, or not generally available to the public on a long-term basis, in recognized patent depositories as part of the patent application process. See *animal deposit* and *depositories*.

Depositories: A facility that accepts, maintains, classifies, and distributes cultures of micro-organisms, viruses, cells, and other genetic and biological material. Since 1983, a few depositories have begun to accept seeds and plant tissue cultures, but to date no depository has accepted any animal. Depositories can be public, private, for profit, or nonprofit. Three depositories in the United States are currently recognized as International Depository Authorities (IDAs) for patent purposes. See *Budapest Treaty* and *International Depository Authority*.

Enzyme: Any of a group of catalytic proteins that are produced by living cells and that mediate and provide chemical processes without themselves being destroyed or altered.

Eukaryote: A cell or organisms with a membrane-bound, structurally discrete nucleus and other well-developed subcellular compartments. Eukaryotes include all organisms except viruses, bacteria, and blue-green algae.

First generation hybrid: The first generation resulting from a cross mating of two distinctly different parental types.

Gene: The fundamental physical and functional unit of heredity, the portion of a DNA molecule that is made up of an ordered sequence of nucleotide base pairs that produce a specific product or have an assigned function.

Genetic engineering: Technologies (including recombinant DNA methods) used by scientists to isolate genes from an organism, manipulate them in the laboratory, and insert them stably in another organism. See *recombinant DNA* and *biotechnology*.

Genotype: The genetic constitution of an organism as distinguished from its physical appearance (phenotype).

Germplasm: The total genetic variability, represented by germ cells or seeds, available to a particular population of organisms.

Harvard mouse: A transgenically engineered mouse developed at Harvard and patented in April 1988, the first animal ever to be patented, The Harvard mouse was engineered to be unusually susceptible to cancer and was developed for use in the testing of carcinogens and cancer therapies.

Hybrid: An offspring of a cross between two genetically unlike and individual plants or animals.

Hybridoma: A new cell resulting from the fusion of a particular type of immortal tumor cell line, a myeloma, with an antibody-producing B lymphocyte. Cultures of such cells are capable of continuous growth and specific (i.e., monoclonal) antibody production.

Hydrolysis: A chemical process of decomposition involving the splitting of a chemical bond and the addition of the elements of water.

Immobilized enzymes: Enzymes that are bonded to a carrier or trapped within a carrier, making them more stable when exposed to changes in reaction conditions.

Inoculum: Material introduced into a living organism.

Intellectual property: That area of the law involving patents, copyrights, trademarks, trade secrets, and plant variety protection.

International Depository Authority (IDA): Depositories recognized for patent purposes under the Budapest Treaty. Such depositories must be located in a member country and must comply with requirements essential for them to carry out their tasks in compliance with the Treaty. As of January 1988, a total of 19 institutions had acquired IDA status; 3 are in the United States. See *deposit*.

Invention: An original device, contraption, or process developed after study and experiment. Genetically engineered animals, plants, and micro-organisms have been recognized as patentable forms of biological invention in the United States, but this is not always the case in other countries, especially where animals are concerned.

March-in-rights: The right of a Federal agency to intercede and require the granting of a license if an invention is not practiced.

Microinjection: A technique used for the insertion of genes from one cell into another cell, in which highly purified copies of a specific gene of interest are injected into a cell. Copies of one specific gene of interest can be injected into a fertilized animal egg. The egg is then surgically implanted in a female animal's reproductive tract.

Micro-organisms: Minute, microscopic, or submicroscopic living organisms (e.g., bacteria, mycoplasma, and viruses.)

Monoclonal antibodies: Identical antibodies that recognize a single specific antigen and are produced by a clone of specialized cells.

National treatment: A key principle of the Paris Union Convention, which provides that, with regard to the protection of industrial property, nationals of any country of the Union are to enjoy in any of the other countries of the Union the advantages that their respective laws concerning industrial property grant to their own nationals. See *Paris Union Convention*.

Neoplasm: A new growth of tissue serving no physiological function (e.g. a tumor).

Novelty: One of the criteria used in the evaluation of patent applications. The invention or discovery being evaluated must be new and must not have previously existed through the work of others in order to be accepted on the grounds of novelty.

Obviousness: Obviousness is one of the criteria used in the evaluation of patent applications, Obviousness addresses the degree of difference between the invention being evaluated and that which is already known and available. See *prior art*.

Oncogenesis: The induction or formation of tumors.

Paris Union Convention: A universal treaty that establishes certain basic rights for residents and nationals of its member countries to protect industrial property rights (patents, utility models, industrial designs, trademarks, service marks, trade names, indications of source and unfair competition) under the laws of other member countries. The Convention is administered by the World Intellectual Property Organization (WIPO). See *national treatment*.

Patent: A patent is a grant issued by the U.S. Government through the U.S. Patent and Trademark Office (PTO) that gives the patent owner the right to exclude all others from making, using, or selling a patented invention within the United States and its territories and possessions for the term of the patent (17 years). A patent does not grant the inventor any affirmative right to use an invention. Laws of nature, physical phenomena, and abstract ideas cannot be patented. Patents have come to be viewed by many as vital for the protection of commercial and intellectual interests in the uses and products of various biotechnology techniques. The implications of patenting living organisms are the subject of some debate.

Patent infringement: Patent encroachment in a way that violates the personal property rights of the patent holder.

Plant breeding: The development of plants with certain desirable characteristics, such as disease resistance and improved harvestability and cold tolerance.

Plant patents: Authorized by the Plant Patent Act of 1930, plant patents protect asexually reproduced plant varieties, including cultivated sports, mutants, hybrids, and newly found seedlings. They cannot be obtained

for tubers or wild varieties found in nature that are not asexually reproduced.

Plant variety: Cultivated plants that are clearly distinguishable from others by one or more characteristics, and that when reproduced retain those distinguishing characteristics. See *cultivar*.

Plant variety protection: Patent-like protection for certain sexually produced plants. Plant variety protection is governed by Federal statute (the Plant Variety Protection Act), which is administered by the U.S. Department of Agriculture.

Plant variety protection certificate (PVPC): A certificate authorized by the Plant Variety Protection Act that provides a form of protection for new, distinct, uniform, and stable varieties of sexually reproducing uncultivated plants, and first-generation hybrids.

Plasmid: An extrachromosomal, circular piece of DNA found in the cytoplasm and capable of replicating and segregating independently of the host chromosome. See *vector*.

Polyploid: Having a chromosome number that is greater than two of the monoploid number. Polyploid oysters were among the first nonnaturally occurring, nonhuman, multicellular, living organisms to be declared patentable subject matter.

Prior art: That which is already known or available, part of the criteria of obviousness used in evaluating patent applications. See *obviousness*.

Recombinant DNA: A broad range of techniques involving the controlled manipulation of the genetic material of organisms. These techniques and their products have enormous potential in the development of new and improved products and processes in a wide variety of industrial sectors. The term is often used synonymously with genetic engineering. It is also used to describe a DNA molecule constructed by genetic engineering techniques composed of DNA from different individuals or species. See *biotechnology* and *genetic engineering*.

Restriction enzymes: Certain bacterial enzymes that recognize specific short sequences of DNA and cut the DNA where these sites occur. Restriction enzymes can be used to isolate a gene that has been identified in the hereditary material of an organism.

Right of Priority: A right granted by the Paris Union Convention of 1970, which enables any resident or national of a country to first file a patent application in any member country and thereafter to file a patent application for the same invention in any other member country within 12 months of the original filing, thus ensuring that the subsequently filed applications enjoy the right of priority established by the first filing date.

Seed: A mature ovule, consisting of an embryonic plant together with a store of food, all surrounded by a protective coat. A seed usually develops following the fertilization of an egg cell by a male generative cell from a pollen grain.

Sexual reproduction: Reproduction that occurs as a result of the interaction between the two sexes. In plants, sexual reproduction occurs when a female egg cell is fertilized by a male generative cell from a pollen grain. Examples of sexually reproduced plants are corn, wheat, and sorghum.

Somatic cell: One of the cells of the body that make up the tissues, organs, and parts of the individual, other than the germ cells.

Specification: For purposes of this assessment, a specification is the written part of a patent application that describes an invention and the manner and process of making it and using it clearly and concisely. The specification also includes one or more claims. See *claim*.

Sport: A plant or a part of a plant that abruptly shows a noticeable difference in appearance. Examples are a deeper red in a red apple, or an unusual color or shape in a flower. If these changes are the result of a true mutation they may be maintained by vegetative means once they have occurred.

Species: Reproductive communities and populations that are distinguished by their collective manifestation of ranges of variation with respect to many different characteristics and qualities.

Species barrier: The idea that there is a natural barrier between species that preserves their integrity or identity. This idea has no known foundation in biology. The parameters that limit the ranges and variations of species are fluid and variable, and species exist as reproductive communities rather than as separate creatures.

Species integrity: The idea that a species has integrity as a biological unit. This would have to be based on the identity of the genetic material carried by the species. However, it is not clear how a species might be defined genetically, and this issue is the subject of debate among those seeking to understand the nature of species.

Taxonomy: The discipline of naming and describing species of plants and animals and their orderly classification according to their presumed natural characteristics and relationships.

Tissue culture: The propagation of tissue removed from organisms in a laboratory environment that has strict sterility, temperature, and nutrient requirements.

Tissue plasminogen activator (tPA): A genetically engineered protein drug that helps to dissolve blood clots in patients who have suffered heart attacks.

Trademark: A distinctive mark, motto, device, or emblem that a manufacturer stamps, prints, or otherwise affixes to his goods so that they can be identified in the market and their source or origin vouched for. Trademarks are governed by Federal and State law.

Trade secret: Information used in a trade or business that is kept secret by its owner to provide a competitive business advantage (e.g. a plan, process, tool, mechanism, chemical compound, customer list, or formula). Protection of trade secrets is governed by State law.

Transgenic animals: Animals whose hereditary DNA has been augmented by the addition of DNA from a source other than parental germplasm usually from another animal or a human, in a laboratory, using

recombinant DNA techniques. At the moment, most of the research in this field is done on mice, but major research efforts in transgenic animal modification are also focusing on cattle, swine, sheep, poultry, and fish.

Utility patents: Usefulness or utility is one of the criteria used to evaluate patent applications, Utility patents are patents issued to inventors of any new and useful process, machine, manufacture, or composition or any new and useful improvement thereof.

Vector: A carrier or transmission agent. In the context of recombinant DNA technology, a vector is the DNA molecule used to introduce foreign DNA into host cells. Recombinant DNA vectors include plasmids, bacteriophages, and other forms of DNA.