Part IV
Biotechnology and Intellectual Property Rights in the U.S.

4.1. Historical development in the U.S.:

Over the last quarter of a century, the U.S. Congress and the courts have greatly strengthened the protection of intellectual property rights for biological inventions, including plants.[22] The original Patent Act of 1790 provided no protection for plants or animals, no matter how much intellectual effort had gone into producing a particular variety or breed. Plants and animals were considered to be "products of nature" and thus cannot be patented.

In 1930 Congress passed the Plant Patent Act, which allowed the granting of "plant patents" for asexually reproduced plants—those that are reproduced by means other than seeds, such as by tissue culture or propagation of cuttings.[23] The

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[22]The following timeline shows the chain of basic research that led to the development of seeds bioengineered to resist insects, viruses, and herbicides.
1901: Ishiwata Shigetane discovers that the cause of a disease outbreak in silkworms is a new species of bacteria, later called Bacillus thuringiensis, or Bt.
1905: Sir Roland Biffen shows that the ability of wheat to resist infection with a fungus is genetically inherited.
1907: Erwin Smith and C. O. Townsend discover that the cause of crown galls is a bacterium called Agrobacterium tumefaciens.
1930s: Plant breeders notice that plants infected with a mild strain of a virus are protected from infection with a more destructive strain.
1938: The first commercial insecticide that contains Bt hits the market.
1947: Armin Braun shows that A. tumefaciens introduces a factor into plant cells that permanently transforms them into tumor cells.
1950s: Studies show that proteins produced by Bt bacteria kill insects.
1972: Ernest Jaworski reports that glyphosphate herbicides work by inhibiting a critical biochemical pathway in plants.
1974: Jeff Schell and Marc Van Montagu discover that a circular strand of DNA (a plasmid) carried by A. tumefaciens transforms plant cells into tumor cells.
1977: Eugene Nester, Milton Gordon, and Mary-Dell Chilton show that genes on the A. tumefaciens plasmid are transferred into infected plant cells.
1981: Helen Whiteley and Ernest Schnepf, at the University of Washington, clone a Bt toxin gene.
1983: Jeff Schell and Marc Van Montagu, Mary-Dell Chilton and colleagues, and scientists at Monsanto introduce genes into plants by using A. tumefaciens plasmid vectors.
1986: Roger Beachy shows that plants bioengineered to produce a viral coat protein are protected from infection with the virus.
1990: Field trials show that Bt cotton strains resist bollworm and budworm.
1994: Genetically engineered virus-resistant squash seeds hit the market.
1996: Bt cotton hits the market.
1996: Herbicide-resistant strains of soybeans, cotton, canola, and corn reach the market.
[*1999 WORLD BOOK.* Multimedia Encyclopedia].

[23]Asexually reproduced plants, which are genetically identical to their donor plants, include many types of fruit and nut trees and also ornamental plants.

act did not include protection for sexually reproduced plants because at the time it was thought that plants grown from seed could not be guaranteed to be identical to their parents. The act also excluded tuber crops.

Forty years later Congress provided a different sort of protection to sexually reproduced plants other than hybrids with the Plant Variety Protection Act of 1970. By this time it was clear that plants grown from seed could remain true to type from generation to generation, so the act allowed the U.S. Department of Agriculture to safeguard new varieties that were stable, distinct, and uniform by issuing Plant Variety Protection Certificates. The protection offered by these certificates, however, was relatively weak. Only exact copies were covered, so a breeder could introduce minor cosmetic changes in a particular variety and get a separate certificate. Furthermore, the owner of a protected variety could not prevent other breeders from using the plant in their own breeding programs. Nor could the owner of a variety keep farmers from saving seeds for their own use or to sell to others.

This protection was upgraded in the form of Plant Variety Protection Act Amendments in 1994.[24] Now the protection certificates guard against "essentially derived varieties," which are varieties that differ from the protected plant by only minor changes, although Congress was rather vague on what differentiates "minor" from "not minor" changes. Farmers must now get a license to sell seeds of protected varieties, although they may still keep the seeds for their own replanting. The 1994 amendments also extended protection to tuber crops and first-generation hybrids.

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[24]Types of intellectual property rights for new plant varieties and biological inventions: **Utility Patents:** Utility patents are administered by the Patent and Trademark Office (PTO) of the US Department of Commerce and grant ownership of new inputs and products for 20 years. Biological inventions were not patentable until 1980. In 1985, the PTO's Board of Appeals and Interferences approved the use of Utility Patents for plants, and in 1987, for animals. Although Utility Patents offer owners the strongest form of protection for new plant varieties, they are more difficult to acquire compared with other options for obtaining plant breeders' rights.
Plant Patents: The Plant Patent Act amended the Patent Act of 1970 and provided plant breeders protection for 17 years for asexually reproduced plant varieties. Specifically these include fruits, nuts, and ornamentals, but exclude tuber crops. As with Utility Patents, PTO administers Plant Patents.
Plant Variety Protection Certificates (PVPC's): The Plant Variety Protection Act of 1970 created PVPC's, which established plant breeders' rights for new plant varieties produced from seed, particularly field crops. PVPC's are awarded for new plant varieties determined to be distinct uniform, and stable. A 1980 amendment extended coverage to vegetables. Amendments in 1994 restricted farmer rights to resell protected seed, provided protection for tuber crops, and extended property rights protection from 17 to 20 years. A provision was also added to protect plant breeders from cosmetic infringements or superficial changes in the appearance of protected plant varieties that do not increase yield or value. A 1995 Supreme Court decision, *Asgrow v. Winterboer*, further restricted farmer rights to resell protected seed. The U.S. Department of Agriculture administers PVPC's. [An Economic Research Service Report. *Agricultural Resources and Environmental Indicators, 1996-97.* USDA/ ERS. Agricultural Handbook Number 712. p. 245-48].

Table 1: USDA technology transfer activities, 1987-93.

Year	Patents awarded	Patent license royalties	ACTIVE CRADA's[25]	Value of CRADA's
	(Number)	($1,000)	(Number)	($ million)
1987	34	-	85	1.6
1988	28	97	48	8.7
1989	47	418	86	15.6
1990	42	567	104	18.9
1991	57	834	139	25.6
1992	56	1,044	160	30.0
1993	57	1,483	185	34.0
1994	32	1,426	212	61.3

Source: USDA, ERS, 1996.[26]

Despite this string of laws expanding protection, the most significant change in intellectual property rights for biological inventions did not come from the Congress. It came instead from the U.S. Supreme Court and the U.S. Patent Office. In the landmark 1980 case of Diamond v. Chakrabarty, the court ruled that a genetically engineered microorganism could be patented under the 1970 Patent Act. Such an organism meets the criteria of a "manufacture" or "composition of matter," the court held. Following this ruling the U.S. Patent and Trademark Office extended this reasoning to plants and animals in a series of rulings during the 1980's. Thereby, utility patents (the type created by the 1970 Act) could be awarded for new types of plants, including seeds, plant parts, tissue cultures, and plant genes and also for new breeds of non–human animals.[27] As a result, the number of plant patents, plant variety protection certificates, and utility patents issued over the last 25 years have increased at a sharp rate. The plant variety protection act stimulated the development of new field crop varieties. New soybean, corn, and vegetable varieties accounted for 56% of the total plant variety protection certificates (Figure 10).[28]

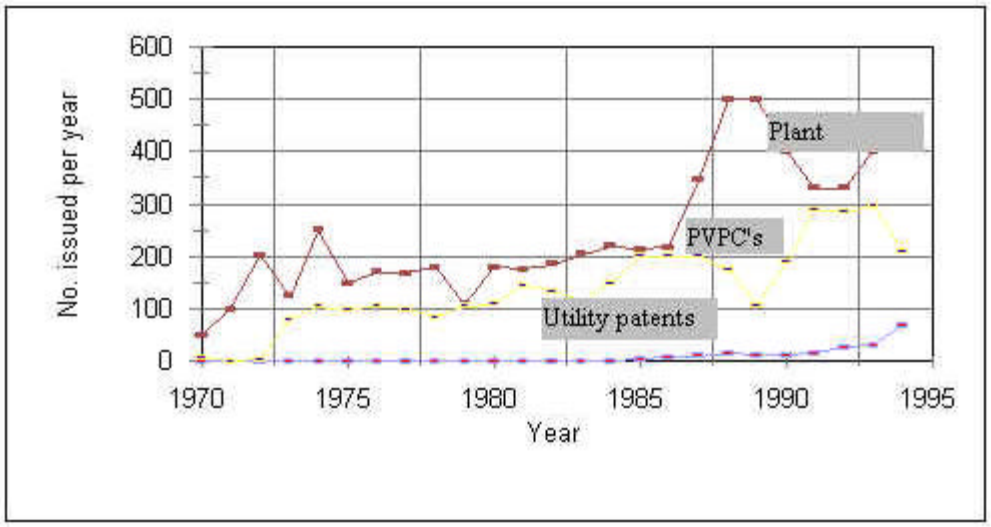
[25] Cooperative research and development agreements (CRADA's) are public – private agreements usually between the federal government and private industry. This mechanism allows USDA and the state agricultural experiment stations to transfer technologies, research results, and scientific resources (not money) to industry through joint research ventures. The cooperating firm can provide any of these resources, and can also transfer money to the federal agency as part of a research agreement. Cooperating firms have the first right to any patented inventions resulting from the agreement.

[26] As reported in: Agricultural Handbook Number 712. *Agricultural Resources and Environmental Indicators, 1996-97. p.250.*

[27] Sagoff, Mark. *Animals as Inventions: Biotechnology and Intellectual Property Rights.* Institute for Philosophy and Public Policy vol. 16, no. 1 (Winter 1996). [Available at: http://epn.org/ippp/sagoff1.html].

Although it is more difficult and expensive to receive a utility patent than a plant patent or a plant variety protection certificate, the utility patent provides much stronger and broader protection. The standard is obviousness, and the test for obviousness is whether the claimed subject matter would have been obvious to a person of ordinary skill in the art at the time the invention was made. This is a legal determination.

Figure 9. Intellectual property rights issued for new plant varieties, 1970-94.



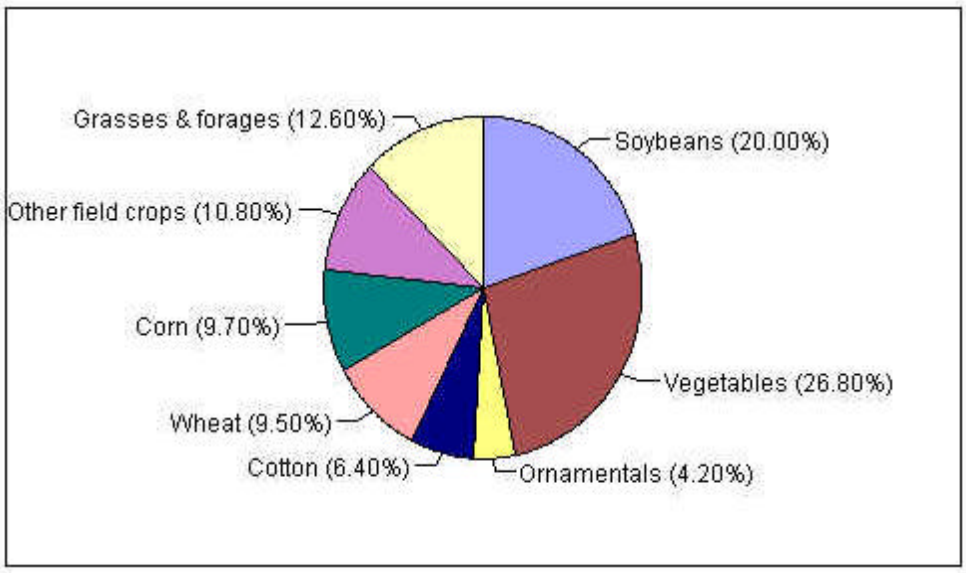
Source: USDA, ERS, 1996.[29]

A biotech patent, as any other patent, must demonstrate utility as well as novelty. Being useful in scientific research does not count. The utility test may be passed by a new therapeutic based on animal trial. The test of obviousness is more subjective. A patent examiner must decide whether the subject matter of the invention would have been obvious at the time the invention was made to a

[28] As reported in: Agricultural Handbook Number 712. *Agricultural Resources and Environmental Indicators, 1996-97.* p.247.
[29]Id. p. 247.

hypothetical person having ordinary skill in the art. The judgment of obviousness rests on evidence from the prior art that a particular avenue of investigation would have been "obvious to try" and would hold a reasonable expectation of success. Using a genetically engineered cell to produce a protein has been ruled obvious. [30]

Figure 10. Plant variety protection certificates issued in 1971-94.



Source: USDA, ERS, 1996[31]

Reasonable expectation of success goes to motivation or rationale as to why one of ordinary skill in the art would have found the claimed invention obvious. If the invention as claimed is not obvious, an innovation can be patented. In April 1987 the Patent Office announced that it "now considers nonnaturally occurring non-human multicellular living organisms, including animals, to be patentable subject matter." [32]

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[30]The University of British Columbia. What Can You Patent In Biotechnology? [Available at: http://www.library.ubc.ca/patscan/patbio.html].

[31]As reported in: Agricultural Handbook Number 712. *Agricultural Resources and Environmental Indicators, 1996-97.* p.248.

[32]Sagoff, Mark. *Animals as Inventions: Biotechnology and Intellectual Property Rights.* Institute for Philosophy and Public Policy vol. 16, no. 1 (Winter 1996). [Available at: http://epn.org/ippp/sagoff1.html].

4.2. An international focus:

In June 1992, more than 150 countries of the world (except the U.S.) signed the U.N. Convention on Biological Diversity, stating their commitment to "*the conservation of biological diversity, the sustainable use of its components and the fair and equitable sharing of the benefits arising out of the utilization of genetic resources.*" One of the methods to reach these goals is by ensuring "*appropriate access to genetic resources and by appropriate transfer of relevant technologies, taking into account all rights over those resources and to technologies, and by appropriate funding.*" However, this emphasis on rights is placed in perspective: parties to the Convention are "*to ensure that such rights are supportive of and do not run counter to its objectives.*" [33]

The Convention is thus the first global, comprehensive agreement to address all aspects of biological diversity: genetic resources, species, and ecosystems. It recognizes for the first time, that the conservation of biological diversity is "*a common concern of humankind*" and an integral part of the development process. To achieve its objectives, the Convention - in accordance with the spirit of the Rio Declaration on Environment and Development - promotes a renewed partnership among countries. Its provisions on scientific and technical cooperation, access to genetic resources, and the transfer of environmentally sound technologies form the foundations of this partnership.[34]

President Bush refused to sign the Biodiversity Convention in 1992 in Rio, making the U.S. the only major industrialized country not to support it. Urged by EDF and other environmental organizations, President Clinton signed the treaty, and sent it to the Senate for ratification. However, the Clinton Administration sought approval from biotechnology industry representatives before signing the Convention in June 1994. At that time, the Administration published an Interpretive Statement redefining the IPR provisions of the Convention. It declared U.S. patent law provisions an adequate and effective protection of intellectual properties, and that the U.S. will not recognize patent laws which restrict patenting nor allow compulsory.[36] However, the United States remains the only major country not to have ratified the convention. The Republican-controlled Senate has blocked approval despite efforts by the Clinton administration.[37]

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[33] Convention on Biological Diversity. [Available at: http://www.biodiv.org/index.html].
[34] *Id.*
[35] *EDF Letter*EDF Letter. [Available at: http://www.edf.org/pubs/EDF-Letter/1994/Mar/k_biodiversity.html].
[36]*Fact Sheet: U.S. Biodiversity Policy*. U.S. Department of State - Bureau of Public Affairs, June 9, 1996. [Available at: http://usembassy.or.cr/biofacen.html].
[37]*GE - various articles & updates on Biosafety protocol*. [Available at: http://data.free.de/gen.free.de/snowball/1999/Feb/msg00138.html].

Under the General Agreement on Tariffs and Trade (GATT) which took effect January 1, 1995, all member countries must bring their national IPR laws into conformity with certain provisions of the new agreement on Trade-Related Intellectual Property Rights (TRIPs). This agreement obliges member governments to provide for "the protection of plant varieties either by patents or by an effective sui generis system[38] or by any combination thereof." Simultaneously, governments are given the option to exclude from patentability "plants and animals other than micro-organisms" and the "essentially biological processes for the production of plants or animals other than non-biological and microbiological processes." These provisions were so controversial during the GATT negotiations that the final agreement states that they shall be reviewed four years after the date of entry into force.

The Biosafety Protocol negotiations, underway since 1996 under the Convention on Biological Diversity, were due to be completed in Cartagena, Colombia in February 1999, but disagreement over a number of critical issues prevented agreement. One of the central points of disagreement, however, centers around whether "living modified organisms" that are "intended for food, feed or processing" (rather than deliberate release) should also fall under "advance informed agreement." The US, Canada, Australia, Argentina, Uruguay and Chile argue that agricultural commodities should be excluded from "advance informed agreement", because they will not be released into the environment, and therefore cannot have an adverse impact on biodiversity. Developing countries insist that all first-time transboundary transfers of "living modified organisms", including commodities, should be covered under the informed consent procedure, as the only way to monitor what is entering one's borders, and to also allow for consideration of human health impacts. The European Union (EU) wants labeling for commodities, rather than a full-fledged informed consent procedure. [39]

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[38] Sui generis is a Latin phrase meaning “of their own kind.”

[39] Gupta, Arthi. 1999. *Biosafety in a Transnational Context.* Cambridge MA: Harvard University, 1999.