

Bio - Technology patents – Protection available under International Agreements

S. K Tannan

Allabar School of Management, Raffles University,
Neemrana (Rajasthan) India

I INTRODUCTION

Bio-technology plays an important role in the fields of medicine, food, fertilizer, energy and protection of environment. Bio-technology concerns living organisms, such as plants, animals and micro-organisms, as well as non-living biological material, such as seed, cells, enzymes, plasmids and the like. Bio- technology is one of the most research intensive industries in the world. In the U.S alone, the bio-tech industry reportedly spent \$9 billion in research and development in 1997. This industry is also very sensitive to copying and piracy, since many inventions involve the description and function of genetic material where barriers to illegal exploitation are low. Bio-technological inventions fall into three categories. They are the processes for the creation or modification of living organisms and biological materials; the results of such processes; and the use of such results. The level of protection afforded to bio-technology inventions varies widely in throughout the world. For instance, not all countries offer protection comparable to U.S utility patents. On the other hand, many countries that issue utility patents for bio-technology inventions do so only for single – celled organisms. Complex living organisms such as plants, seeds or animals are not always patentable under their national laws.

Fortunately in several countries, the trend is towards more protection for plants and seed and other bio-technology inventions. For example, in 1998 china enacted a comprehensive series of regulations that provide significant protection to plant and seed varieties. The convention on Biological diversity (CBD) defines bio-technology as “any technological application that uses Bio-logical systems, living organisms or derivatives thereof , to make or modify products or processes for specific use.”

II APPLICATION OF BIO-TECHNOLOGY TO FOOD AND AGRICULTURE

Bio-technology in food and agriculture is one of the most promising new technologies of modern age. For example, somehow genetic engineering is essential to addressing food security and malnutrition in developing countries. In United States, the growing use of agricultural Bio- technology is resulting in reduced use of pesticides and increased adoption of environmental friendly farming practices such as “no-till” farming which reduces soil erosion and fertilizer run off. New crops derived from Bio-technology are being used in developing countries such as Argentina, South Africa, china, Philippines and India.

The United Nations Food and Agriculture organization (FAO) has supported bio-technology as a technology that would be beneficial to developing countries if more investment is directed towards it. According to him, new genetic technology for the so-called “orphan crops” such as cowpea, millet and sorghum are critical for food Supply and livelihoods of the world’s poor people.

However, there are a number of barriers preventing the poor from accessing fully the benefits of modern technology including inadequate regulatory procedures, poorly functioning markets and seed delivery systems, weak domestic plant breeding capacity, inadequate research capabilities and complex intellectual property issues.

Western technological, pharmaceutical, and human health care industries have increased their interest in natural products as sources of new bio-chemical compounds for drugs, chemical and agro- products development. Although the interest in traditional knowledge and medicines from developing counties has increased in the past few decades, few if any, benefits have accrued to the source countries and traditional communities- their contribution to plant breeding, genetic enhancement. Bio-diversity conservation and global drug development are not recognized, compensated or even protected.

III BIO- TECHNOLOGY PATENTS

Beginning in the mid-1900’s, nations began to offer plant variety protection (PVP) also known as Plant Breeder’s Right (PBR) to breeders. Under PBR, a breeder could obtain protection for a new variety provided it is novel, uniform and stable. The protection gave the breeder the exclusive right to market the variety, although farmers were able to reuse their seed and breeders had the right to use the protected material in producing new varieties. However in 1991, Treaty provisions permitted nations to prohibit farmers from reusing harvested seeds and gave breeders certain rights over material bred from protected materials and stronger rights over products grown with protected seed.

The International Convention for the protection of New Varieties of plants was introduced in 1978, and the developing countries have been urged to adopt it as a sui generis plant variety protection system. *The system of protection is governed by an International agreement and organization: UPOV (International Union for the Protection of New Varieties of plants).* However, a few developing countries have become members of UPOV. The 1978

version of the convention allows the farmers to re-use propagating material from the previous seasons harvest and to freely exchange seeds of protected varieties with farmers. The 1991 version of the convention is more stringent and a farmer who produces a protected variety from the farm seeds is guilty of infringement unless the national law provides otherwise.

It has also been argued that UPOV is inadequate in protecting traditional knowledge of indigenous and local peoples. The Convention does not contain any provisions for recognizing the knowledge and other contributions the indigenous and local people make to plan breeding programs.

The U.S will grant a regular protection to a variety with the probable implication that the maternal cannot be reused by farmers or used by third party for further breeding. The U.S and probably Europe also grants patents on all plants of a particular species into which a specific new gene has been inserted by biotechnological means, in this sense it is possible to patent a gene which typically involves legal claims over the isolated gene and DNA sequences, over the genetic engineering tools that use those sequences and over plants that have been transformed with such tools. The rights of the plant holder do not extend to plants in which the genes occur naturally.

The U. S and Europe have also granted patents on wide categories of transgenic plants, for example, all transgenic Colton or soybean. Many other nations grant patents on processes for genetic transformation of plants. Although many developing countries have been hesitant about adopting such forms of intellectual property protection, the trade related intellectual property right (TRIPs) agreement requires all members of the WTO to make patent available in all fields of technology. However, members may exclude from patentability, the plants and animals, other than microorganisms and the processes used for the production of plants and animals that are essentially biological. All members must provide an effective sui generis system for the protection of plant varieties.

Because the private sector will hold many of the advanced technologies, the publicly funded agricultural research community must also develop an effective approach in cooperation with the private sector in research and product development. International pressure is likely to ensure that national governments make an effort to comply with TRIP's. But such efforts should mean more than simply passing TRIPs complaint legislation.

The intellectual property legislation must be supplemented with appropriate training in the Courts, law firms and law schools so that law can be used effectively. Effective legislation for managing intellectual property rights for products of governmental research also must be passed.

IV INTELLECTUAL PROPERTY RIGHTS IN PLANTS

Plants have long been object of Private Property; Germplasm has not. But most-jurisdictions now recognize IP rights in plant genetic information. Law creates IP by separating an abstract idea like for molecularly engineered gene, for its physical vessel such as the gene itself contained in a plant or seed. Property Right in the abstract object may come as patents, Plant Breeder's rights or both. Innovation like bio-technology has magnified the philosophical instability of property rights in ideational resources. Thus IP is typically measured against public interest or occasionally society's rights are crystallized as common property.

There is a overlap between IP and classic property rights. Monsanto to markets agricultural systems; the farmer provides land and labour, and it provide seeds, chemicals or other tools for crop growing. Monsanto's system involves "Round Trip" glyphosate herbicide which kills plants. Monsanto has also engineered a gene that causes plant and the progeny to be glyphosate resistant. Farmers can therefore, spray "Round up" on a growing crop, killing weeds but leaving the genetically modified (GM) plants unharmed. Monsanto has a Canadian patent for glyphosate resistant plants including "Roundup Ready" Canola.

Monsanto has accused Percy schmeiser, a saskatchewan farmer of marking using and selling its patented inventions without license. Monsanto's private investigators discovered glyphosate resistant Canola in schmeiser's 1998 crop, which he had planted with seed saved from the previous year, as was his customary practice. Sehmeiser never purchased seeds from Monsanto that would have required contracting not to save new seeds generated from his crop. He argued that he was not responsible for, nor did he want, "Round up Ready" Canola on his land. He proposed various explanations for its presence including adventitious spread by wind or insects.

The Trial Division did not accept schmeiser's explanation. However, he declined to decide how and why Monsanto's gene did appear in schmeiser's crop. He held that growing and selling the GM seed under these circumstances made Sehmeiser liable for infringement of Monsanto's patent. The Court of Appeal and on may 21, 2004, five of the nine Judges of the Supreme Court of Canada, upheld this ruling.

Sehmeiser made many arguments to the Supreme Court. **First**, he argued that Monsanto's plant is invalid as it concerns a higher life form, which is not patentable in Canada. **Second**, because he did not spray has crop with "Round up" herbicide, he claimed that he did not "use" or exploit the patents' only moved utility. Sehmeiser also argued that the correct damage, if any, represent only has encroachment from exploiting the patent, not his entire profit.

The majority of the Supreme Court held that the patent was valid as it did not concern a higher life form, but merely a gene and cell contained within a higher life form. In a compelling dissent, four Judges held that this is a distinction without a distinction. This dissent is especially persuasive given the majority's finding that possession of a plant containing patented gene constitutes "use" and therefore, infringement. Schmeiser's failure to spray his crop with herbicide was immaterial because of the patent's stand-by utility as a consolation. However, the majority did accept Schmeiser's argument regarding damages.

But Schmeiser made another argument that is most interesting. He had argued that Monsanto forfeited its IP rights by virtue of the unconfined release of its product; that innocent by-stander should not suffer from the adventurous spread of Monsanto's gene, and that solution to this dilemma is through the doctrines of waiver or implied license. The upshot is that Schmeiser's classic property rights in the plants and seeds should not be subordinated to Monsanto's IP rights.

Schmeiser tried to show how the law traditionally reconciles competing property claims. Indeed this is not a novel exercise. By the early 19th century, the law of the admixture recognized that "if a man" puts corn in my bag in which before there is some corn, the whole is mine because it's impossible to distinguish what was mine from what was his.

There are some noteworthy passages in response to Schmeiser's classic property argument. Justice McKay said in the trial division "for the defendants' it is argued that Monsanto has no properly interest in its gene, only intellectual property rights. While I acknowledge that the seed or plant containing the plaintiff's patented gene and cell may be owned in a legal sense by the farmer who has acquired the seed or plant, that owner's interest in seed or plant is subject to the plaintiff's patent rights including the exclusive right to use or sell its gene or cell and they alone may license others to use the invention.

Thus a farmer whose field contains seed or plants originating from seed may own the seed or plants or his land even if he did not set about to plant them. He does not, however, own the right to the use of the patented gene or of the seed or the plant containing the patented gene or cell.

In the court of appeal Justice Sharlow remarked; "I am prepared to assume, without deciding, the owner of the real property has legal title to any volunteer plant on his land and generally has a right to save the seed from such a plant and to plant and harvest the seed for profit in subsequent years. However, there is no authority for the proposition that ownership of a plant must necessarily supersede the right of the holder of patent for a gene found in the plant. On the contrary, the jurisprudence presents a number of examples in which the right of ownership of property are composed of extent required to protect the patent holder's statutory monopoly.

But most disapprovingly, the majority of the Supreme Court missed the point entirely "the issue is not property rights, but patent protection. Ownership is no defense to a breach of the Patent Act". Actually reconciling intellectual and classical property right is exactly the issue.

Also, unfortunately, the majority also failed to mention any countervailing interest including Society's interest. They cited no purpose for patents except "to prevent others from depriving the inventor, even in part and even indirectly, of the monopoly that the law intends to be theirs"

Schmeiser may not have been responsible for the initial presence of Monsanto's invention in his crop, yet Schmeiser was distinguished from an "Innocent by-stander" Nevertheless, Schmeiser was forced to give up or destroy all of his plants and seeds. He was also injected from saving or replanting any seed that he knows or should contain Monsanto's gene. So a farmer who knows of a patented gene in his crop cannot replant particular seeds known to contain the gene. That is perhaps a regrettable constraint on an owner's classical property rights.

But a worse, if a patented gene has infiltrated an entire crop, or even if it is sparsely distributed throughout the crop, all seed saving rights are in effect extinguished. Farmers who suspect GM plants on their land are in a very difficult position. For one, every farmer knows that Monsanto's gene spreads adventurously so they may not test spray the entire crop, killing if they were mistaken. If, however, they were correct, they could not save any of their seeds without being branded as an infringer. Not testing, but nevertheless saving seeds might make them willfully blind. The only viable option is to discontinue the practice of saving seeds. Not surprisingly, it has been said that Schmeiser sets a "troubling general precedent"

V IMPLICATIONS OF IPR IN PLANTS FOR DEVELOPING COUNTRIES

Over a long period of time, farming communities in developing countries have bred and developed their own crop varieties improved on the varieties through selective breeding and sold them locally under names which have found widespread local acceptance.

Over the last few decades, some of these local varieties have also been exported. Intellectual property protection in developing countries however is poor and in many cases, the government is opposed to granting monopoly rights in agricultural crops.

In such a situation, an agricultural biotechnology company from a developed country can acquire samples of the crop. As these varieties are not produced using bio-technology, the company can make use of the exemption for plants and animals allowed under the World Trade Organization (WTO)

VI AGREEMENT ON TRADE RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS (TRIPS) ON BIOTECHNOLOGY

Beginning in 1999, the TRIPS Council commenced its review of Article 27.3 of TRIPS that related to biotechnological inventions. Article 27.3 permits countries to exclude plants, animals and biological processes from patent protection (although microorganisms and non-biological and microbiological processes are eligible for patents). Article 27.3(b), however, requires member countries to provide for the protection of plant varieties either by patents or through a system created specifically for that purpose (*sui generis*), or a combination of both.

In November 2001, the Doha Declaration linked the issues of biotechnology, biodiversity and traditional knowledge and declared that further work by the TRIPS Council on these review should be guided by the TRIPS objectives and principles and must take development into account.

Since the Doha Ministerial Conference, a number of proposals have been submitted on bio-diversity. On October 17, 2002, the EU submitted a proposal to examine the requirement that patent applicants disclose the origin of genetic material. Switzerland submitted a proposal on May 28, 2003 suggesting an amendment to WIPO'S Patent Cooperation Treaty, which would require domestic law to ask the patent applicants to disclose the origins of genetic resources and traditional knowledge.

A paper submitted by Brazil, Cuba, Ecuador, India, Peru, and Venezuela in June 2003 develops earlier disclosure of the origins of biological resources and traditional knowledge, "Prior Informed Concept" for exploitation, and equitable benefit sharing. Under this proposal, the TRIPS section on biodiversity will be amended to make disclosures of the origins of genetic resources obligatory.

In June 2003, the African Group submitted a paper that proposes to prohibit the patenting of all life forms (plants, animals and microorganisms) and prefers *Sui Generis* protection for plant varieties to preserve farmers and breeders rights to use and share harvested seeds.

By claiming that these are natural varieties where no inventor can be identified – this is correct because most developing countries do not provide Intellectual property protection for their plant varieties. The agricultural bio- technology company can then genetically engineer a close substitute for the natural variety which maintains its desirable consumer characteristics. This genetically modified variety can be patented and its name copy righted, which makes it eligible for intellectual property protection under TRIPS. This means that bio-technology firm can license the production of the crop in any climatically friendly country, export the product in competition

with natural varieties and prevent the natural varieties from being sold in importers markets using their national names. Examples are jasmine rice from Thailand and basmati rice from India; varieties of these two crops have been patented and copyrighted by U.S.A firms.

Some view this system as bio-piracy arguing that if a patent system which is supposed to reward inventiveness and creativity systematically rewards piracy as this to honestly apply criteria of novelty and non-obviousness in the granting of patents related to indigenous knowledge, then this system is flawed and needs to be changed. It cannot be the basis for granting patents or establishing the exclusive marketing rights. The difficulty with protecting patents or crops under patent law is that they confer property rights which are private in nature. This means that under the law, once a patent is granted, the owner enjoys exclusive right to his invention.

VII THE 2001, FAO INTERNATIONAL TREATY FOR PLANT GENETIC RESOURCES FOR FOOD AND AGRICULTURE (PGRIA)

It seeks to facilitate and regulate access to genetic resources for food and agriculture. Contracting parties agree to take the necessary legal or other appropriate measures to provide access to other contracting parties or to legal and natural persons under the jurisdiction of any contracting party in accordance with a set of conditions. These include that a "recipients shall not claim any intellectual property or other right that limit the facilitated access to plant genetic resources for food and agriculture or their genetic parts or components, in the form received from multilateral system" and that "access to plants genetic resources for food and agriculture protected by intellectual and other property rights shall be consistent with relevant international agreements and with relevant national laws".

VIII CONCLUSION

Many developing countries argue that traditional knowledge held by indigenous and local communities now forms part of the product discovery process of the industrialized world, but that this knowledge is not recognized and adequately protected by the conventional IPR system. Therefore, *sui generis* legislation systems needs to be developed that would name the sources of genetic material and traditional knowledge used in new products and allow for the sharing of benefits arising from the use of such genetic material and knowledge. This would be in accordance with the requirements of the Convention on Biological Diversity and the FAO International Treaty on Plant Genetic Resources for Food and Agriculture.

REFERENCES

- [1] The International Business Law and its Environment by Schaffer Earle Augusti, Sixth Edition published by Thomson South-Western.
- [2] "Biotechnology, Intellectual Property Rights and the Rights of Farmers in Developing Countries" by Emmanuel Opoku Awuku published in the Journal of World Intellectual Property Rights, Volume 8, No 1, January 2005.
- [3] "What will TRIPs do for Developing Countries" by Ana Maria Pacon published in the Book "TRIPs and Developing Countries".
- [4] Press Release of the National Seminar on TRIPs-CBD at the WTO jointly organized by the Ministry of Commerce and Industry, Government of India and the United Nations Conference on Trade and Development on August 25, 2005 at New Delhi.
- [5] "How the U.S Interpretation of Flexibilities Inherent in TRIPs affects Access to Medicines for Developing Countries" by Elina Ghanotakis published in the Journal of World Intellectual Property.
- [6] "Compulsory Licensing Imbroglia: Provisions under TRIPs and their Interpretations" by M.D Nair published in the Journal of Intellectual Property Rights, Volume 9, September, 2004.
- [7] Law relating to Intellectual Property Rights by Mr. V.K Ahuja, 2010 published by Lexis Nexis Butterwords Wadhwa, Nagpur.
- [8] Intellectual Property Rights in the Emerging Business Environment by Bharti Thakur, 2010 published by ICAFI University Press.