THE LAW RELATING TO AGRICULTURAL BIOTECHNOLOGY WITH THE SPECIAL REFERENCE TO IPR: NEED OF AN HOUR

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ABSTRACT

Biotechnology can be applied to all classes of organism - from viruses and bacteria to plants and animals, and it is becoming a major feature of modern medicine, agriculture and industry. Modern agricultural biotechnology includes a range of tools that scientists employ to understand and manipulate the genetic make-up of organisms for use in the production or processing of agricultural products. Biotechnology is being used to address problems in all areas of agricultural production and processing. This includes plant breeding to raise and stabilize yields; to improve resistance to pests, diseases and abiotic stresses such as drought and cold; and to enhance the nutritional content of foods. Agricultural Biotechnology is being used to develop low-cost disease-free planting materials for crops such as cassava, banana and potato and is creating new tools for the diagnosis and treatment of plant and animal diseases and for the measurement and conservation of genetic resources. It is also being used to speed up breeding programmes for plants, livestock and fish and to extend the range of traits that can be addressed. Animal feeds and feeding practices are being changed by biotechnology to improve animal nutrition and to reduce environmental waste.

***KEYWORDS:* Agriculture, Biotechnology, Genetically, India, Intellectual property Rights.**

INTRODUCTION

Biotechnology, in its modern form is a relative new comer to the areas of science, industry, and trade, but its impact has been growing throughout this century and will almost certainly continue to grow at an accelerating rate.[2]Biotechnology is most briefly defined as the art of utilizing living organisms and their products for the production of food, drink, medicine or for other benefits to the human race, or other animal species. Technically speaking, humans have been making use of biotechnology since they discovered farming, with the planting of seeds to control plant growth and

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[2] Klaus Bosselmann, *Plants and Politics: The International Legal Regime Concerning Biotechnology and Biodiversity*, 7 Colo. J. Int'l Envtl. L. &Pol'y 111, 119 (1996).

crop production. Animal breeding is also a form of biotechnology. More recently, cross-pollination of plants and cross-breeding of animals were macro-biological techniques in biotechnology, used to enhance product quality and/or meet specific requirements or standards.[3]

The Convention on Biological Diversity (CBD) defines biotechnology as: *"any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use"*.[4]

Biotechnology is an area of production and research in which biological systems and biological principles are employed to solve technological problems. During the last decade the advancements in biology have led to the development newer areas like, cellular engineering, biochips and biomaterial science, stem cells, nano-biotechnology etc. Biotechnology is a vast subject and covers Gene and genome analysis: analysis of genes and gene networks showing the potential for industrial application; gene expression studies; biotech plant breeding, e.g. marker assisted breeding. Transgenic technologies: Production and analysis of transgenic crops; gene insertion studies; gene silencing; factors affecting gene expression; post-translational analysis; molecular farming; field trial analysis; commercialisation of modified crops; safety and regulatory affairs Functional genomics: bioinformatics; gene function studies for applied uses Comparative genomics: applications to crop species; use of current crop databases Physiological studies: pathways relevant to an application; secondary metabolites; manipulations of physiology for stress resistance – abiotic and biotic stress resistance including salinity and drought stress[5].

For thousands of years, biotechnological processes have been used in creation of agricultural products. Biotechnology, a modernized concept has been revolutionizing production in areas of industry and agriculture. Two sectors where biotechnology has already made significant contributions are pharmaceuticals and agriculture. This technology has been dominated by several developed countries like US and Europe, however it's significant in solving several problems existing in developing countries cannot also be overseen. However, many of the new products formed by biotechnology and products which are protected by Intellectual Property Rights (IPRs) in relation to ethics, morality and access to these technologies tend to arose debate in many developing countries

[3]Theresa Phillip, *An Introduction to Modern Biotechnology*, available at http://biotech.about.com/od/whatisbiotechnology/a/whatisbiotech.htm

[4]Article 2*, International Convetion on Biological Diversity*, (CBD, 5June 1992, 31 ILM 818).

[5]Ashwini Kumar, *Recent advances in plant biotechnology: Applications in Agriculture*, available athttp://www.scientificblogging.com/humboldt_fellow_and_science/blog/recent_advances_plant_biotechnology_applications_agriculture

at national level and also at international level by organizations such as World Trade Organisation and agriculture biotechnology is one of those.

Agricultural biotechnology is one promising device heralded to be valuable in ensuring food security.[6] Agricultural biotechnology research intended to enhance food security in developing countries includes creating GM crops that reduce the use of pesticides, improve stress tolerance, and provide better product quality and increased nutritional value.[7]

Need of Agricultural Biotechnology – Farmers and pastoralists have manipulated the genetic make-up of plants and animals since agriculture began more than 10 000 years ago. Farmers managed the process of domestication over millennia, through many cycles of selection of the best adapted individuals. This exploitation of the natural variation in biological organisms has given us the crops, plantation trees, farm animals and farmed fish of today, which often differ radically from their early ancestors.

The aim of modern breeders is the same as that of early farmers - to produce superior crops or animals. Conventional breeding, relying on the application of classic genetic principles based on the phenotype or physical characteristics of the organism concerned, has been very successful in introducing desirable traits into crop cultivars or livestock breeds from domesticated or wild relatives or mutants. In a conventional cross, whereby each parent donates half the genetic make-up of the progeny, undesirable traits may be passed on along with the desirable ones, and these undesirable traits may then have to be eliminated through successive generations of breeding. With each generation, the progeny must be tested for its growth characteristics as well as its nutritional and processing traits. Many generations may be required before the desired combination of traits is found, and time lags may be very long, especially for perennial crops such as trees and some species of livestock. Such phenotype-based selection is thus a slow, demanding process and is expensive in terms of both time and money. Biotechnology can make the application of conventional breeding methods more efficient.

International Overview

[6]BarunMitra et al., *31 Critical Questions In Agricultural Biotechnology*, http://www.agbioworld.org/biotech-info/articles/agbio-articles/critical.html

[7] Joel I. Cohen, Poorer *Nations Turn to Publicly Developed GM Crops*, 23 Nature Biotechnology 27, 31-32 (2005).

TRIPS and Biotechnology

At the time of the TRIPS negotiations in the Uruguay Round, the US and EU differed in their approaches regarding the issue of patenting of biotechnological Conventions. This was because the reason that US believed that 'anything under the sun made by man', except human being was patentable, however EU at the sometime was grappling with strong resistance to patents on living organism. During this debate, WTO members agreed to a minimal agreement committing to revisit the provision within four years from the entry into force of TRIPS. Article 27.3 (b) of TRIPS incorporate this minimal agreement.

Article 27 of TRIPS require that patents be made available for both processes and products, I all fields of technology. Under Article 27.3(b), which specifically talks about biotechnology states that, plants and animals, and essential biological processes for their production may be excluded from patentability. However, microorganism and microbiological or non biological processes must be protected.

Though, there exist uncertainty regarding the definitions of these terms such as 'non biological' or essentially biological. Furthermore, it can also be inferred from this Article that microorganism and microbiological processes are not clearly excluded from patent protection despite of resistance from some developing countries during negotiations.

The definition of term microorganism as it was not interpreted in TRIPS, so the respective Member State made their own definition of the term and applied accordingly. Like Canada in its definition recognizes microorganism as cell lines and hybridomas in addition to unicellular organism. However, in the absence of the clear definition under TRIPS, WTO members have freedom to define microorganism in reasonable way.

There are three universally recognized criteria of patentability which were incorporated in Article 27.1 of TRIPS, which are novelty, non obviousness and industrial applicability or utility, which apply to all inventions including biotechnology. However, application of these standards to biotechnology has given rise to peculiar set of problems and several controversies as the concept of invention in biotechnology is itself controversial. However, TRIPS give no guidance on these controversial concepts.

International Conventions

Apart, from several National Legislations, there also exist Conventions on plant varieties. UPOV, is one such convention. It was not until 1968, with the entry into force of an international agreement for administering the rules on plant variety protection of this type, named after its French acronym, UPOV[8]. UK was the first country to become the member of this convention. Apart from it, several other countries like Denmark, Germany etc, are also its members. This convention was revised in 1978 and 1991. The main advantage of this convention was that it offers reciprocal national treatment or the same treatment to foreign right holders as accorded to national for the protection of new plant varieties from member countries.

UPOV, 1978, was not entirely compatible with TRIPS, as it permits reciprocal protection for a limited number of species of plants but it may no longer be possible for WTO members to incorporate clauses based on the reciprocity of protection to foreign nationals as it would be violative of Article 3 of TRIPS.

Plant Variety Protection in India

India while framing its legislation on protection of plant varieties took the base from UPOV, 1978 although the concept of essentially variety is taken from UPOV in 1991. The main controversy, due to which the framing of legislation has been delayed, was on the question of incorporating the concept of farmer's right from the proposed legislation.

India framed the Protection of Plant Varieties and Farmers' Rights Act, 2001 (Plant Variety Act) which constitutes India's direct response to its commitments under Article 27(3) b of the TRIPS Agreement. Parliament has passed the Plant Variety Protection and Farmers Rights Bill. With this has ended a long and arduous struggle waged for the recognition of the rights of farmers in India's sui generis legislation. India has now put in place a law to grant Plant Breeders Rights on new varieties of seeds, for the very first time. Farmers Rights, long resisted by successive governments, have finally been included in the legislation as a result of the determined and sustained campaign by NGOs, spearheaded by the Gene Campaign. Gene Campaign's position right from the start has been that if the status quo has to be changed and we have to grant Plant Breeders Rights, our

[8]*Union International pour la protection des ObtentionsVegetales* or The International Union for the Protection of New Varieties of Plants.

legislation will have to grant a strong Farmers Rights at the same time. As against the generally articulated demand that Farmers Rights should constitute the right to save seed from the harvest to sow the next crop (plant back rights), however, it was maintained that plant back rights were no rights, only exemptions. Such exemptions, referred to as Farmers' Privilege, were granted by Breeders under UPOV. The key demand was for the farmer to retain the right to sell seed to other farmers, even if the variety was under a Breeders Right. This right to sell seed was crucial to maintaining the livelihood basis of the farming community and the nation's self reliance in agriculture. The pivotal importance of the farmer having the right to sell seed has to be seen in the context of seed production in India where the farming community is the largest seed producer, providing about 87% of the country's annual requirement. Denying the farmer the right to sell seed would displace the farming community as the country's major seed provider. Their only replacement would be the Life Science corporations since budget cuts have seriously weakened the capacity and output of the other player, the public research institution. Any development that would give MNCs a significant share in seed production in India was fully unacceptable to civil society groups.

The Act provides following rights:-

a. **Farmers Rights**-In section 39 (iv) of the chapter on Farmers Right, the right to sell seed, even protected seed, has finally been provided:

The farmer shall be deemed to be entitled to save use, sow, resow, exchange, share or sellhis farm produce including seed of a variety protected under this Act in the same manner ashe was entitled before the coming into force of this Act.; Provided that the farmer shall not be entitled to sell branded seed of a variety protected under this Act.

Other kinds of farmers' rights-There are provisions for acknowledging the role of rural communities as contributors of land races and farmer varieties in the breeding of new plant varieties. Breeders wanting to use farmer's varieties for creating Essentially Derived Varieties (EDVs) cannot do so without the express permission of the farmers involved in the conservation of such varieties. A share of profits made from a new variety bred by using farmers' varieties, has to go into a National Gene Fund. Further protecting farmers, the new Act stipulates detailed disclosure about the parentage of the new variety so that farmers are paid when their varieties are used. If breeders conceal the use of farmer's varieties, their certificate stands to be cancelled. Breeders cannot use terminator technology and have to submit an affidavit to this effect.

Clauses that need amendment -The provision for payment for use of farmer varieties in the *Benefit Sharing* clause is welcome but modalities of implementation must be made simpler and less

bureaucratic. There venues earned should only be available for use by farming communities. There is also a clause protecting the farmer against the supply of bad quality seeds but the clause is weakly framed, leaving too much to the discretion of the Authority. There should be specific guidelines. Say, compensation should amount to at least twice the projected harvest value of the crop. In addition, a jail term should be provided for repeated offence.

b. **Breeders Rights -** Breeders Rights over the varieties they have developed are fully protected by the legislation. The Breeder has complete rights of commercialisation for the registered variety either in his/her own person or through anyone he designates. These unequivocal rights include the right to produce, sell, market, distribute, import or export a variety, in short, full control overproduction and commercialisation. The strong protection granted to a plant breeder over his/ her variety is seen in the section dealing with infringement of Breeders Rights where punishment in the form of substantial fines and jail terms has been prescribed for those who infringe the rights of the registered breeder.

c. **Rights Of Researchers -** The new law has provisions for Researchers Rights which allows scientists and breeders to have free access to registered varieties for research. The registered variety can also be used for the purpose of creating other, new varieties.

SUGGESTION

A distinction must be made between the use of biotechnology in industry, which refers to chemical or pharmaceutical substances derived from or processes pertaining to the plant and animal kingdom, and in agriculture, to the use of genetic engineering in producing new plant or plant varieties, which is focused in this project. The recent biotechnology revolution in agriculture is based, for the most part, on the genetic modification of in – situ plant varieties. Thus, among various applications of Agricultural Biotechnology one of them is Genetic Modified Crops. Genetically modified crops, also known as transgenic crops, are crops that include “a gene or genes which have been introduced artificially into the plant's genetic makeup

using a set of several biotechnology techniques known as recombinant DNA (rDNA) technology."[9]

CONCLUSION

Broadly, the scope and applicability of the biotechnology can be witnessed in two spheres mainly i.e. in the Biotechnology is one of the newly emerging fields in the sphere of research and development. However, it has made huge development in the very short span of time. Biotechnology has been growing very rapidly and its development has covered almost every sector by now. The importance and significance of bio technology can be understood by the fact that its development has been associated with almost every field. The biodiversities are huge and thus the applications of technology to these biodiversities are also huge. The developments made in these sphere is basically for the benefit of mankind through these biodiversities.

Apart from that, one also requires to understand that the biological sphere we live in has to be tackled well. With the recent development of mankind, nature's activities and chains have been greatly affected. Thus, the role of biotechnology here becomes to find out the best possible technological measure that does not disturbs nature much and finally proves to be beneficial for the mankind.

There are various kinds of micro organisms and small particles which need to be studied, and can be beneficial to the mankind in various ways, such as they can help in manufacturing of some medicine, or their extractions can be used in as vaccines. It also includes study and disposal mechanisms of various wastes. The waste of any type is studied properly under biotechnology and there after ways are found out to dispose it properly, so that it does not harm any biological diversity.

[9] Stephanie E. Cox, *Genetically Modified Organisms: Who Should Pay The Price For Pollen Drift Contamination?* 13 Drake J. Agric. L. 401 P. 402 (2008)