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Review

An overview of intellectual property rights in relation to agricultural biotechnology

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The majority of the population in developing nations depends on agriculture. Agricultural biotechnology involves genetic modification and promises a number of important benefits, such as improving agricultural yields by increasing the resistance of crops to pests and facilitating them to flourish in harsh natural environments, improving the productivity of crops, and reducing pesticide use. Also, concerns have been raised about the potential negative impacts of genetic modification. To promote research and development in agricultural biotechnology, intellectual property rights (IPRs) are one of the primary tools. Based on the fact that high investment is required to develop new genetically modified (GM) technologies and products, stronger intellectual property protection is necessary to stimulate research and to allow recovery of investment. As international rules increasingly raise the level of intellectual property protection, there is rising concern about the potential negative impacts on the dissemination of knowledge and important products, further Research and Development, food security, and the conservation of biodiversity among other fundamental areas of public policy. It is thus an important policy challenge to determine application of laws, rules and legislations to agricultural biotechnology. IPRs are woven into innovations, enable entrepreneurship and they allow the leveraging of private resources for resolving the problems of hunger and poverty.

Key words: Biotechnology, intellectual property rights, patents, genetic modification.

INTRODUCTION

Biotechnology has been one of the emerging fields for the past two to three decades and is a rapidly growing life sciences research, product development and intellectual property based sector. It also helps to develop novel products and lots of value addition to agriculture system. Biotechnology includes biopharma (vaccines and therapeutics), agro-biotech (plant breeding, biocontrol of plant disease and pests), biofuels, industrial biotech (industrial enzymes, fermentations, bioprocessing etc.), bioinformatics, research services (clinical research) and other biotech suppliers. An important, challenging area of intellectual property rights (IPRs) in agricultural biotechnology relates to the genetic engineering of plants and animals through applied nucleic acid chemistry and related technologies. This technology includes materials and methods for isolation, modification and combination of genetic materials which in turn are used for invention of new combinations of genetically recombinant vaccines, drugs and other pharmaceutical products. It also helps in invention of genetically modified organisms/plants and foods, hybrid varieties of plants, seeds and other agricultural products. These products provide better solutions in healthcare (diagnostics; prevention, treatment and management of diseases), develop enhanced agricultural quality and productivity (food security and bio safety concerns). They also contribute to the overall economy which affects the market mechanisms. The

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Abbreviations: GM, Genetically modified; **R&D,** Research and Development.

production of increased levels of beta-carotene (the precursor, lycopene) is shown to have physiological chemo-preventive effects with regard to various cancers. Lycopene, commonly found in various carotenoid containing plants such as tomatoes and carrots, is an essential ingredient in maintaining eye health and vision (Daneshyar et al., 2006). Utilization of plants as bio-factories for the production of vaccines in developing countries has been examined (Brink et al., 1998). Many of the principles of intellectual and biological property-based management in plant-based agricultural biotechnology also apply equally to animals and microbes. Fermentation is typically affected by bacteria and yeasts which facilitates preservation and storage (Ahmed et al., 2000). Improvement and optimization of fermentation and bioprocessing is applicable in improving the quality and functions of foods. For example, milk undergoes fermentation due to bacterial action which results in formation of curd, thus separating it from the thin watery part. Modern cheese makers inoculate the milk with lactic acid bacteria (*Lactobacilli*) and other enzymes such as rennet to curdle the casein. This rennet is found in gastric juices produced in the fourth stomach of calves and other animals. Another applicable enzyme, cellulase which hydrolyses cellulose is produced by microorganism *Trichoderma konigi*, that aids in digestion (Daneshyar et al., 2006).

Modern technology that is, nano-biotechnology can play an important role in increasing production and improving quality of food, fibre produced by farmers. They secure the growing needs of the world as well as deliver a huge range of environmental sustainability, health and economic advantages (Kershen, 1999; Wheeler, 2005).

There are potential benefits of IPRs in agricultural biotechnology. Investments in IPRs play a facilitating role, influencing the potential impacts of many other investments in agricultural development. Innovations in many instances created strong incentives and hence IPRs can be fostered for agricultural development. IPR protection is important for agricultural biotechnology, as it creates additional incentives and benefits. Today even *Bacillus thuringiensis* (Bt) maize and Bt cotton is sold under license. IPR holders could license their technologies to public institutions in exchange for a share. Of late, consideration of IPRs has become increasingly important in many areas of agricultural development such as foreign investment, technology transfer, trade, investment in innovation, access to genetic resources and the protection of traditional knowledge. The role of IPRs is widening as it ensures that developing countries benefit from the introduction of new technologies that could radically alter the welfare of the poor. IPRs are used in practice in agricultural development. IPRs are woven into innovations, enable entrepreneurship and allow the leveraging of private resources for resolving the problems of hunger and poverty.

Other rights and human rights have been discussed in detail by many authors (Bagde, 2007; Bagde et al., 2012; Bhargava, 2009b). However, Intellectual property rights with special reference to Agricultural Biotechnology have not been extensively studied so far. Hence, this particular study envisages critical analysis of perspectives of Intellectual property rights in relation to agricultural Biotechnology.

INTELLECTUAL PROPERTY RIGHTS AND PATENTS

Intellectual property laws in biotechnology covers many issues such as the range of the products, patents and patentability of genes, gene sequences and parts of gene sequences derived from humans, animals, plants and microorganisms. Patents, material transfer agreements and plant breeder's rights are the main types of IPRs used in agricultural biotechnology (Kowalski et al., 2002). Patents provide the strongest protection for knowhow and genetically modified plants. A patent may protect a process used to obtain the transgenic plant or plant itself and its uses. A material transfer agreement is a contract between two parties exchanging biological materials like cell lines, plasmids and vectors. Such agreements can be used for chemicals, software's and other research materials. Free exchange of information for research is common in the academic community, where research institutions/universities share material for the purpose of improving research. Researchers are required to maintain confidentiality in sharing their research with others, or to delay their publication until a patent has been secured.

INTELLECTUAL PROPERTY RIGHTS (IPRS) AND TRADITIONAL KNOWLEDGE

The characteristics of IPRs and its effects are inequitable and exploitative of indigenous peoples, whose knowledge and innovations play a key role in the conservation and sustainable use of biodiversity. First, IPRs have characteristics that lead to injustices *vis-à-vis* traditional knowledge holders. Second, to what extent can IPRs be used to protect their rights?

Traditional knowledge is characterized among others by continuous evolution that leads to generation improvement and orients itself to practical solutions and survival. It has not been subjected to "Western" scientific methods. The religious, moral, cultural, political and commercial value which is held by collective or individual subjects has intimate relation with the habitat and the environment. In many cases, it lacks material incorporation. It is a private right, held either collectively or individually depending on the prevalent customary norm or law. It tends to generate informal products.

These special features make traditional knowledge a very particular object for protection, especially considering that existing IPRs regimes do not cover all aspects of traditional knowledge. Therefore, traditional knowledge is best protected by an effective *sui generis* system capable of consolidating and reflecting its particular nature, which takes into account the rights and interests of the indigenous and local communities who developed traditional knowledge.

A possible way of rebalancing the trade-related intellectual property rights (TRIPS) Agreement and protecting all types of innovation systems would be an amendment of Article 27.3(b) of the TRIPS Agreement requiring World Trade Organization (WTO) members to provide the protection of traditional knowledge and folklore by an effective *sui generis* system. Such a protection should be designed in light of the Convention on Biological Diversity (CBD), the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) and existing regional and national regulatory frameworks.

AGREEMENT ON TRADE-RELATED INTELLECTUAL PROPERTY RIGHTS (TRIPS AGREEMENT)

At the international level, the minimum standards of intellectual property protection are established by the TRIPS Agreement. The TRIPS Agreement determines the cases in which patents must be granted, obliging countries to grant patents for all fields of technology, including biotechnology. However, the TRIPS Agreement provision also allows countries some flexibility, allowing them, for example, to establish exceptions to patentability, including plants and animals other than micro-organisms (Ravishankar and Archak, 2000).

The conclusion of Uruguay Round of General Agreement on Tariffs and Trade (GATT) negotiations that included an agreement on TRIPs was a major step in terms of establishing legal binding of international intellectual property regimes. There are seven forms of IPRs recognized in the Trips Agreement. These include copyright and related rights, trademarks including service marks, geographical indications including appellations of origin, industrial designs, patents including the protection of new varieties of plants, the layout-designs (topographies) of integrated circuits and protection of undisclosed information including trade secrets. It also might be possible to develop a *sui generis* regime for effectively protecting the contents of indigenous knowledge databases, which in turn protects knowledge. Such rights are instituted and enforced on a country-by-country basis and thus their scope varies across countries. This agreement also covers provisions related to control of anti-competitive practices in contractual licenses, although, it does not directly relate to IPRs. In future, when application of various types of IPRs in different areas of agriculture is put into practice, we may face serious problems unless timely remedial measures are taken by awaring and emphasing IPRs literacy, higher education and capacity building in the country (Ravishankar and Archak, 2000).

The international protection of intellectual property has been a contentious issue between developed and developing countries. The protection of IPRs in agricultural biotechnology is the latest sign of the dispute with both developed and developing countries accusing each other of bio-piracy. TRIPs were the only agreement, which was reluctantly agreed by developing countries at the Uruguay Round of WTO negotiation. Following establishment of the international institutional mechanisms, such as, the CBD and the WTO, and further, signing of ITPGRFA, the growing importance and the global scope of IPRs in agriculture is well realized and recognized (Moschini, 2004).

The Trips Agreement contains some very precise provisions concerning competition law. It allows fair use (Article 30, TRIPS Agreement) and the possibility of compulsory licensing (Article 31, Trips Agreement) or granting of dependent patents (Article 31 (l) and 34, Trips Agreement), that is, granting of a right by public authorities, and against the will of a patent owner. In order to make use of a patent to an extent, it is necessary to develop a new product. In practice the fair use of provision allows countries to permit limited use of innovation achievements for private and non-commercial purposes, like research and/or experiments. The facility of compulsory license allows countries to create involuntary agreements between patent owners and the government or its contractors to serve specific public interest needs. Further, Article 40 provides considerable discretion to members in curtailing licensing practices that may constitute an abuse of IPRs and have an adverse effect on competition. The three examples of potentially abusive licensing practices in the article include exclusive grant-back conditions, conditions preventing challenges to validity and coercive package licensing.

TRIPS, CBD, ITPGRFA, their derivative laws and relationship with general international law have created a thick network of obligations that state parties have to attentively analyze and comply with (Buzzini, 2001). There are various degrees in the acceptance of these treaties that are often monitored by different international organizations, thus revealing the complexities of the contemporary highly interconnected world.

MODERN AGRICULTURAL BIOTECHNOLOGY

The beginning of modern agriculture biotechnology was in 1983 when the first plant gene was transferred from one species to another. Interestingly, the first biotechnology product to receive widespread attention was a number of modified bacteria which were the subject of the patent application by Chakrabarty (1981). The product was developed to assist in the rapid clean up from oil spills, thus demonstrating the direct relevance of biotechnology to environmental safety. Thus both agricultural and environmental applications are two areas of great expectations for the benefits of ecosystem. Directly, biotechnology will contribute to better nutrition and replace at a far higher degree of safety of many pesticides and herbicides which are in use worldwide (Pray et al., 2005).

Agricultural biotechnology in the private sector will be interested in and concentrate on crop protection technologies and environmental sustainability rather than crop improvement technologies. This is to be viewed in a relative sense, since the quantum of basic research, germplasm requirement and other associated costs for varieties with enhanced yields is far higher than that for disease-pest resistant varieties (Bent, 1987). None theless, some observations were made with respect to the rapid growth of this sector in recent years and conscious intervention made by the government. The advance agricultural biotechnology is predominantly taking place in the industrialized countries and their research and development capacity is higher. The ownership and exploitation of IPRs are the key factors in determining the success of any technological innovation introduced in the market that provide the means of technological progress to continue, to support the competitiveness of industry of the country.

BIODIVERSITY

India has great commercial potential in agricultural biodiversity which could be sustainably exploited for socioeconomic development of the continent. Therefore, the commercialization of useful plants and animals remains a viable option for reducing poverty in India. India produces about 10% of total world agricultural production, yet it accounts for less than 1% of agricultural trade, due to agricultural protectionism (Sharma et al., 2003). In biotechnology, the microbial processes and plant varieties are granted patent protection in some developed countries such as the United States and Australia. The protection of new forms of life in particular has proved to be difficult and there are substantial variations among countries. This shift of patenting new forms of life has generated intense debate at regional, national and international flora. The critics of patenting of life forms have argued that it is inappropriate to use the patent system to reward scientific work in the field of biological resources and processes, as living organisms are qualitatively different from non-living materials. In addition, there are provisions needed for prior consent and sharing of benefits for indigenous and local communities that have historically safeguarded the resources. The negative impact of patents, as private rights, granted over genetic resources raises an alarm for many biodiversity-rich countries, *sui generis* system or by any combination thereof.

The most widely used *sui generis* system for plant variety protection is the International Convention for the Protection of New Varieties of Plants (UPOV Convention). Even though plant variety protection developed separately from patent protection and is considered to be more appropriate for the particular nature and characteristics of agricultural innovation, higher levels of protection have raised similar concerns as those in the patent field. Revisions to the UPOV Convention, for example, have generally served to progressively strengthen plant breeders' rights (Ravishankar and Archak, 1999; Alston and Venner, 2002).

Ex situ conservation and sustainable development of technologies includes tissue culture, field-based propagation, protoplast fusion and cryopreservation. Common mechanisms for transferring technologies include joint Research and Development (R&D), the training of nationals in foreign universities and other institutions, and technology partnerships undertaken under biodiversity-prospecting arrangements.

The exception to patentability in Article 27.3(b) also gives rise for offering *sui generis* protection over plant varieties. This also provides that members must provide protection for plant varieties, either in the form of patents or an "effective *sui generis* system". The interpretation and application of these provisions on plant variety protection will have significant implications for the implementation of the CBD. The rights to information, allocated under the Trips Agreement, will have an impact on the benefits from the use of genetic resources being shared. For example, although a high proportion of *in situ* biodiversity and related traditional knowledge, innovations and practices, are found in developing countries, most patents relating to biological resources are granted for research undertaken in developed countries. *Sui generis* protection may, if appropriately defined, provide a tool for implementing the CBD's objectives, including access and benefit sharing, and technology transfer.

THE PROTECTION OF NEW VARIETIES OF PLANTS (UPOV) CONVENTION

The International Convention for the Protection of New Varieties of Plants (UPOV Convention) was signed in Paris in 1961 and enforced in 1968. It was revised in Geneva in 1972, 1978 and 1991. The 1978 Act was enforced in 1981, and the 1991 Act was enforced in April 1998. UPOV has 38 member states of which 29 are parties of 1978 Act and eight are parties of 1991 Act.

UPOV provides a framework for intellectual property protection of plant varieties. These rights are most often referred to as plant variety rights or plant breeders rights (PBRs). To be eligible for protection, the plant variety must be distinct, stable, and uniform in its relevant characteristics (UPOV, 1991), or homogeneous with regard to the particular feature of its sexual reproduction or vegetative propagation (UPOV, 1978); and novel, that is, have not been offered for sale or marketed, with the agreement of the breeder or his achievement or in title, in the source country, or for longer than a limited number of years in any other country (Wright and Parley, 2006; Das, 2011).

UPOV (1978) defines the scope of protection as the breeder's right to prior authorisation for the following acts: the production for purposes of commercial marketing; the offering for sale; and the marketing of the reproductive or vegetative propagating material, as such, of the variety (Article 5). UPOV (1991) version extends the scope of the breeders' rights in two ways. Firstly, it increases the number of acts for which prior authorisation of the breeder is required so that these include production or reproduction; conditioning for the purpose of propagation; offering for sale; selling or marketing; exporting; importing; and stocking for the above purposes (Article 14). Secondly, such acts are not just in respect of the reproductive or vegetative propagating material as with the 1978 version, but also encompass harvested material obtained through the use of propagating material, and so-called "essentially derived" varieties (Dutfield, 2002; Das, 2011).

The International Convention for the Protection of New Varieties of Plants (UPOV convention) is significant because it provides a legal mechanism for the protection of plant varieties developed by commercial plant breeders through the introduction of "plant breeders' rights." Plant breeders' rights are a hybrid form of intellectual property rights, which give the seed industry similar incentives to those offered by patents, without establishing a complete monopoly (Cullet and Raja, 2004).

The knowledge relating to biological processes and biological material is not the inventions. Under the Trips Agreement, member countries may be excluded from patentability of plants and animals and essentially biological processes for the production of new plants and animals. Meanwhile, member countries of the Trips Agreement are required to apply some form of protection to plant varieties either by patents or an effective *sui generis* system or combination of the two systems. The technology transfer is an important mechanism for stimulating the formation and growth of high-technology entrepreneurial start-ups, regional economic development for firms, research and development centers and universities. The commercialization of patent in agriculture biotechnology sector is nothing but the working patent for the industrial use, where the prerequisite of the patent get fulfilled and the technology transfer rate shows the quality of research to grow a successful and high technology economy. Intellectual property issues go beyond the scope and levels of protection. Other relevant issues include enforcement capacities, which are critical to manage the regulation and trade in genetically modified (GM) crop varieties. In addition, the "privatization of science" brings a new management challenge for research institutions, particularly in developing countries, as many are not well equipped to deal with proprietary knowledge. The lack of negotiating skills and the administrative and bureaucratic limitations of research institutions have an impact on their ability to acquire, negotiate, and protect IPRs, and often represent tangible barriers for accessing certain strategic technologies. Moreover, intellectual property policies are also necessarily linked to broader economic policies, such as the creation of the appropriate environment for direct foreign investment and greater participation by foreign firm in domestic markets. The technology transfer is a related issue of IPRs, which play vital role in the research and development in academic area and its goal is to facilitate the transfer of knowledge that could have direct economic value from research and development institutes to the industry. The genomic-centric biology by producing hybrid varieties is taking away the invention and innovation to commercial market. The discovery of Human Genome Sequence, Incyte, and Sequena shifted the new genomic framework with IPRs in reshaping the balance struck among the interests of biomedical researchers, private sector market participation and the public good (Ramasami, 2009).

SCOPE OF PATENTABILITY

The scope of patentability therefore has an impact on safeguarding the investment and access that others will have to the invention. Indeed, because many developing countries do use these exceptions and also have problems with enforcing existing patents, many foreign investors feel they lack assurance for property rights in GM technologies that will be adequately protected. On the other hand, high levels of patent protection may result in food security and bio- safety; conserve biodiversity, and socio-economic problems. For example, there is considerable debate about the actual impact of patent protection on innovation and diffusion in agricultural biotechnology (International Centre for Trade and Sustainable Development, 2008). The patenting of many GM crops innovations by private companies and universities-particularly when an innovation is covered by multiple patents creates so-called "patent thickets" and veritable legal gridlocks for further research (Yamin, 2003). In this regard, patent protection mechanisms are not a new issue with respect to agricultural research, but now proprietary claims are not only increasing but are rapidly enveloping research tools. As many developing countries focus their R&D on marginal innovations and minor improvements in existing technologies, their efforts may be blocked by strong patent protection (Rangasamy and Elumalai, 2009).

Patenting is still not cheap, hence patents are usually registered only in countries where a large return is to be expected from the commercial use of the patented subject matter. Country of manufacture or residence of competitors is additional criteria for filing. Patents applications on key biotechnologies are rarely filed in developing countries, except where major crops such as soyabean, canola and cotton are extensively planted, e.g. Argentina, Brazil, and China (Mayer, 2003).

In addition, more extensive patent protection is also considered problematic for achieving the objectives of other international agreements, particularly the 1992 Convention on Biodiversity. The CBD recognized the sovereign right of States over their natural resources, including genetic resources. Access to such resources thus can only take place on the basis of prior informed consent and mutually agreed terms. In addition, there are provisions on the need for prior consent and sharing of benefits for indigenous and other local communities that have historically safeguarded the resources. The negative impact of patents, as private rights, granted over genetic resources is thus a cause of alarm for many biodiversity-rich countries (CBD, 1999; International Centre for Trade and Sustainable Development, 2008).

CONCLUSION AND FUTURE PROSPECTS

As pressure increases to find ways of adapting current agricultural products to an environment altered through climate change, more emphasis will be placed on the application of biotechnologies to increased efficiency in breeding crops and increases in the productivity of varieties. Researchers will need to draw physical and informational databases to identify research targets that can respond best to environmental change. Simplified and standard material transfer agreements and intellectual property licence agreements will be required to sustain this research effort. Developing country's research institutions will be drawn into research out of both politics and necessity to make sure that developed products are adapted not only to physical environment, but also to the social and political environment. As the large developing countries become increasingly sophisticated in their science and technology, we expect their researchers, industries and governments to act more like their developed country counterparts than like their developing world partners. We thus envision a large biotechnology gap separating the richer from the poorer developing countries. This gap will be expressed by an increasing convergence of intellectual property policies between the large developed and the successful developing countries (Spielman et al., 2006; Richard and Matthew, 2007; Bhargava, 2009a, b). It is thus an important policy challenge to determine application of laws, rules and legislations to agricultural biotechnology (Laxmi et al., 2007).

Nano-biotechnology has the potential to revolutionize agriculture and food systems. Agricultural and food systems security, disease treatment delivery system, new tools for cellular and molecular biology, new material for pathogen detection, protection of environment, and education of the public and future workforce are examples of the important links for biotechnological application of agriculture and food systems (Scott and Chen, 2003; Seyed et al., 2011).

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