

# IPR, Biotechnology and Biodiversity: Issues and Options before Developing Countries

The conclusion of Uruguay Round of GATT Negotiations that included an Agreement on Trade related Intellectual Property Rights (TRIPs) was a major step in terms of establishing a legally binding international intellectual property protection regime. During the Negotiations there was an interesting debate about the scope of patenting being extended to life forms. The sharp differences between the European Union and the United States led to the inclusion of a provision enabling a review of Article 27.3 (b) after four years of TRIPs coming into force, that is by 1999. This Article basically allows national governments to exclude certain inventions from the patent regime especially ones based on plants, animals and 'essential biological processes', including micro-organisms and non-biological and micro-biological processes. During the review process the scope of the debate expanded considerably. At the Doha Ministerial the developing countries also joined the debate. As a result, the issues related to indigenous knowledge system (IKS) and access and benefit sharing (ABS) were also included. As a result the Doha Development Agenda (DDA) (Paragraph 19) provides for the relationship between the UN Convention on Biological Diversity (CBD), which explicitly acknowledges IKS and ABS and seeks to look into the relationship between TRIPs Agreement and the CBD.

In this debate several developing countries have contributed through their submissions issues including like biodiversity and indigenous knowledge system and thus have expanded the scope of the debate itself. In between, the WIPO General Assembly also established an Inter-governmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore. The conclusion of

International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) under the aegis of FAO further encouraged protection and promotion of farmers' rights and indigenous knowledge system.

However, one finds that the advances in agricultural biotechnology to some degree are paralleled by enhancement in the IPRs under TRIPs and at times in addition of TRIPs as well. This has brought under sharp focus the optimal patent scope and its coverage. This is now being discussed at length in the TRIPs Committee and the debate is largely around patentability and non-patentability of plant and animal inventions and the protection of plant varieties. In fact the TRIPs Agreement introduce the option of an "effective sui genesis" system for the protection of plant varieties.

The Checklist of issues submitted to WTO by Brazil, Cuba, India and Peru among others is a recent example of the kind of documents that are needed at this stage to delineate the concept of disclosure requirements and related issues so as to bring out the negotiating process from the current state of 'status quo'. The Switzerland proposal of making disclosure requirement an optional one under the national legislation rather than a mandatory provision at the international level may be explored for further facilitating the movement of the debate. The African group wants the TRIPs agreement to prohibit patenting of all life forms, including micro-organisms and wants *sui generis* protection for plant varieties to preserve farmers' rights. The US position is closer to that of Switzerland in the sense that the US proposal argues for national legislations to address CBD objectives on access to resources, traditional knowledge, benefit sharing.

In case of India at least some of these objectives have been included in the national legislations and guidelines. However given the emerging trend of free trade agreements across various countries and the IPR provisions in them, it is important that one looks into the IPR regime beyond the TRIPs framework as well. One may find this trend completely opposed to the spirit and objective of Article 7 of TRIPs. The objective of TRIPs as stated is "the protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations". Here we briefly mention three broad trends in the patent

regime important from the standpoint of the developing countries in context of their access to biotechnology per se.

### **Moving from PVP to Plant Patents**

In recent past, plant variety protection (PVP) and the patents have emerged as two important forms of intellectual property rights. In context of developing countries, PVP has been there for some time but patents for plants is a recent phenomenon. Both patent and PVP provide exclusive monopoly rights over a creation for commercial purposes over a period of time. A patent is a right granted to an inventor to prevent all others from making, using, and/or selling the patented invention for 15-20 years. The criteria for a patent are novelty, inventiveness (non-obviousness), utility, and reproducibility. Although patents were designed for industrial application, with biotechnology, patent offices now grant patents on microorganisms and, in some countries, on all life forms, which has become a major concern as these countries are now entering in FTAs with IPR provisions much more stringent than TRIPs.

It is worth recalling that the intellectual property regime for plant variety protection emerged with a strong commitment for larger public interest in mind. The whole provision for compulsory licensing was introduced with this intention only. Under the provision of compulsory licensing, a holder of plant breeders' right, can neither refuse any applicant nor can offer unreasonable terms for access. Plant variety protection has worked well as a mechanism to promote the interests of the plant breeders for developing new varieties through giving them proprietary rights on the one hand and as custodians of public rights of access and use of genetic material on the other hand. PVP gives patent-like rights to plant breeders. What gets protected in this case is the genetic makeup of a specific plant variety. The criteria for protection are different: novelty, distinctness, uniformity, and stability. PVP laws can provide exemptions for breeders, allowing them to use protected varieties for further breeding, and for farmers, allowing them to save seeds from their harvest. In plant breeding, thus PVP is the weaker sister of patenting mainly because of these exemptions. Plant variety right also encourages cross licensing between a holder of PVR and a holder of a patent. Under the breeders' exemption of plant variety rights anyone may use protected material for breeding purposes.

However, the patent regime does not reciprocate this. Moreover, the growing usage of much more stringent instruments such as Utility Patents to protect biotechnological advances is another major concern.

### **Utility Patents**

In the US the extension of IPR's to new plant varieties and biological inventions, including the development of biotechnologies, has stimulated private companies to invest in plant breeding. The Plant Patent Act of 1930 and the Plant Variety Protection Act (PVPA) of 1970 established plant breeders' rights for new plants and plant varieties. In 1980, a Supreme Court decision (*Diamond v. Chakraborty*) authorized the use of patents for biological inventions, specifically microorganisms. However, several recent decisions by the Patent and Trademark Office have further broadened the use of patents for plants and have created space for Utility Patents in plants (ex parte Hibberd in 1985) and animals (ex parte Allen in 1987). Utility Patents are for any, "new and useful process machine, manufacture, composition of matter or any new and useful improvement therefor." Utility Patents can protect all the parts of the plants including genes, seeds, physiological and physical traits. Utility Patents have a larger coverage than PVPs in the sense that they cover not just a single variety as in PVP but also all other varieties having same traits and functional properties. Further, in Utility Patent not only is a single claim allowed, it also provides protection for covering plant parts including flowers, fruits and cuttings, etc. Apart from this, protection is not dependent on whether the plant is sexually produced or asexually produced. The share of Utility Patents among all other IPR instrument has gone up with the highest growth rate. Apart from plants now it covers research tools as well which in a way proposes to foreclose options for late comers in the technology race.

### **Patenting of Research Tools**

One of the major trends in patenting which is emerging in US patent system is their broad nature. This is also one of the features as mentioned in the US-Singapore FTA. At times, it even encompasses research tools necessary for further downstream research and development. Some of the research tools, patenting of which have attracted attention are expressed sequence tags (ESTs), restriction enzymes, screening systems, technique related to DNA sequencing and single nucleotide

polymorphisms (SNPs). As these research tools by definition have the power to control the downstream research of pharmaceuticals, they can wield an extremely large influence when patented.

A related problem is that of broad patenting which has actually grown over the years. For instance, Agracetus patent on all transgenic cotton (US patent 5, 159, 135) or similar patents on all transgenic soybean. Some of these patents are subject to reexamination or litigation to determine their validity. Similarly, a new US patent awarded to Monsanto in 2001, giving an exclusive monopoly right on crucial method identifying modified plant cells in laboratory. US Patent No. 6, 174, 724 covers all practical methods of making transformed plants that employ antibiotic resistance markers. The technique has been used in virtually all commercial GM crops. An earlier patent granted to another major US firm, Syngenta, covered a marker, which enables plants cell transformation and selection without the use of antibiotic resistance marker. This technology was first developed in a very small firm, Danisco in Denmark. This company sold the patent to Sandoz in 1998, which later became Novartis, which in 2000 became Syngenta.

## **Present Issue**

In this issue of *Asian Biotechnology and Development Review*, we take a stock of this debate with an eminent panel of contributors from academia and policy world. Dr. K.K. Tripathi discusses the contours of biotechnology patent regime and its implications for India while Prof. Pranav Desai and Dr. Balakrishna Pisupati have linked up the debate with the wider developmental concerns especially in context of CBD and provision for plant variety protection. Prof. Dinesh Abrol and Dr. Malathi Lakshmikumaran have discussed at length the latest bill passed by the Indian Parliament amending Indian Patent Act 1970 and its implications on the biotechnology sector. Dr. Anitha Ramanna has analysed the current debate on access to technology and proliferation of illegal Bt cotton.

The usual columns of the journal also have a focus on IPR and licensing related issues. The Bio Stats presents brief comparative analysis of trends in biotechnology patents in major economies while in the Document section we provide OECD draft guidelines for licensing of genetic inventions, which at present is open for discussion.