INTELLECTUAL PROPERTY RIGHTS - RETROSPECT AND PROSPECT

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This paper reviews retrospectively and prospectively the evolution and development of IP analysing the impact that IP protection can have on pharmaceutical sector, traditional knowledge, food security and biotechnology.

The notion of property with all its controversies has an evolutionary history and complemented by the legal regimes in various countries of the world. In such sense, if not settled, the legal regime has a basis to deal with it based on the socio-political-economic milieu of a particular period in the history of a country. Contrary to that, the protection of the same by legal regimes is not only new but also throws up deeper contradictions *vis-à-vis* the physical property.

It is not the philosophical intellect that is in question but intellectual activity in the sphere of economic activity and its fall out that is the core issue. A simplified defence of Intellectual Property (IP) stems from the fact that there are paradigm shifts in economic modes of production. One such is hunting-gathering-agrarian-industrial in the recent past. The present and near future is based on technology driven economy and hence Intellectual pursuit, its fruits and benefits to be treated as 'Property' is held as defence.

IP serves as an incentive for invention, creation and business confidence which will benefit society. However the antithesis of such a thesis poses the questions of private interest vs. public interest, the north- south divide, as well as the real beneficiaries of invention and creation.

Apart from the fundamental questions of the Intellectual Property Rights (IPR), it is argued that some form of IP protection is a must in an inter-connected world where nations are competing for trade and commerce. Such a move is expected to bring the much needed investments in the third world if a reasonable system of IP protection is in place.

The Global Architecture for IPRs

For centuries IP systems grew and developed sporadically in response to national needs. The process of inserting IPRs on the trade agenda and International agreements concerning IPRs occurred in the later part of the 19th Century. The role of IP protection has expanded at an unprecedented pace during the last two decades. In the process IP rights have been modified or new provisions have been created in order to cover new areas of Science & Technology, such as Information Technology, Biotechnology, and now service sector.

All the members of the World Trade Organisation [WTO] during the Uruguay round of trade negotiations committed to comply with the requirements of the Agreement on Trade related aspects of Intellectual Property rights [TRIPS]. TRIPS Agreement is an integral part of the WTO Agreements, which create binding international obligations among WTO Member States. TRIPS lay down minimum standards of protection for IPR and their implementation is mandatory for every WTO member. TRIPS do not establish

a uniform International law, but sets out minimum standards of protection that must be met by all WTO members[1]. Least-developed countries are not obliged to do so until 2016. TRIPS attempt the arduous task of balancing private and public interests.

The scope of TRIPS is quite extensive, as it covers copyright and related rights (i.e., the rights of performers, producers of sound recordings and broadcasting organisations); trademarks, including service marks; geographical indications, including appellations of origin; industrial designs; patents, including the protection of new varieties of plants; the layout designs of integrated circuits; and undisclosed information, including trade secrets and test data. The Agreement's objectives establish that, the protection and enforcement of IPRs should balance rights with obligations to the mutual advantage of both producers and users of technological knowledge[2]. It was the first comprehensive agreement to establish minimum, enforceable standards for the protection of IPR and, as a result, is a significant step in harmonizing national IP systems.

The global architecture of the IPRs regime has now become really complex, and includes a diversity of multilateral agreements, international organisations, regional conventions and bilateral arrangements. In brief, the International law on IP, in its present form, consists of three types of agreements namely multilateral treaties, regional treaties or instruments and bilateral treaties. Of these, the agreements that affect the greatest number of countries are the TRIPS Agreement and some of the multilateral treaties administered by WIPO. Moreover, agreements between developed and developing countries also include mutual commitments to implement IP regimes that go beyond TRIPS minimum standards. Hence, countries like India are under pressure to increase the levels of IP protection in their own regime, based on standards in developed countries.

IPRs & Access to Medicine

Following the end of World War II, many developing countries shed their colonial status and became sovereign states. One area in which developing countries desperately needed technology was pharmaceuticals. Developing countries had no research and development capability in the pharmaceutical sector. They either imported drugs or left their citizens to rely on varieties of traditional medicine. Prior to the TRIPS Agreement, most IP systems, in both developed and developing countries had refused to grant patents over pharmaceuticals in order to fulfill health and developmental objectives.[3] Article 27(1) of the TRIPS Agreement requires members to provide patents over all inventions, whether products or processes, in all fields of technology. This broad obligation encompasses a requirement to provide patent protection of pharmaceuticals.

In the process of implementing the TRIPS Agreement, India had to revise several of the main aspects of its patent regime.[4] Before the recent amendment Section 5 of the Indian Patents Act, 1970 expressly prohibited product patents and only permitted process patent relating to pharmaceutical, drug, food and chemicals. After the implementation of TRIPS, the Patents (Amendment) Act, 2005 repealed it and therefore gave way to product patents as well for pharmaceutical, drug, food and chemicals.

The Indian pharmaceutical industry has changed remarkably over the last 50 years, from being traders in imported drugs in the fifties, to major bulk drug producers by the eighties. The industry is set to scale new heights in the fields of production,

development, manufacturing and research. In 2008, the domestic pharma market in India was US$ 10.76 billion and this is likely to increase at a compound annual growth rate of 9.9 per cent until 2010 and subsequently at 9.5 per cent till the year 2015.[5] Globally, India ranks third in terms of manufacturing pharma products by volume.

India's ability to provide low cost generic medicines was primarily due to its IP laws, particularly trade related aspects of patent law, which allowed for generic production of safe and efficacious medicines. But some aspects of the EU-India draft Free Trade Agreement (FTA) which are currently in negotiation between India and the EU threaten this system and this could prevent people from all over the world from gaining access to life saving and life prolonging medicines. EU proposals for IP provisions on data exclusivity, patent extensions, IP enforcement, and in particular, border measures can have disastrous effects on access to medicines; weakening competition from generic medicines and sustaining monopoly prices.[6] Much of the developing world depends on India for generic medicines at affordable costs. Restrictions on generic drug production will have a devastating public health impact and affect the right to health for millions of people. Most importantly, the FTA dismantles the flexibilities reaffirmed by the WTO Doha Declaration on TRIPS and Public Health such as compulsory licensing or parallel importation, and introduces rules that curtail India's ability to take measures to reduce the cost of medicines. Hence provisions pertaining to IP in the draft FTA should be reconsidered and Governments in both developed and developing countries should ensure that any free trade agreements comply with the Principles of the Doha Declaration.

Intellectual Property and Traditional Knowledge

Traditional and indigenous knowledge (TK) has been used for centuries by indigenous and local communities under local laws, customs and traditions. It has been transmitted and evolved from generation to generation. The protection under IPR of traditional and indigenous knowledge (TK) has received growing attention since the adoption of the Convention on Biological Diversity (CBD) in 1992.

The definition of TK used by the World Intellectual Property Office (WIPO) includes indigenous knowledge relating to categories such as agricultural knowledge, medicinal knowledge, biodiversity-related knowledge, and expressions of folklore in the form of music, dance, song, handicraft, designs, stories and artwork. India does not have any specific legislation for protecting TK. But the Patents Act, Plant Variety Protection and Farmers Rights Act, Biological Diversity Act, 2002 and Geographical Indication of Goods (Registration and Protection) Act, 1999 have provisions that can be utilised for protecting traditional knowledge.

The development of new technology and the new use of TK based products today is the major threat to the survival of many of these communities. Attempts to exploit TK for industrial or commercial benefits may lead to prejudicial misappropriation of the same from its rightful holders. The modern cultural industries as well as the manufacturing industries now commercially exploit the traditional knowledge based products using new technology without the permission and sharing of profits with the communities. The developing nations and TK holders were alarmed at the instances of biopiracy and wanted a global solution for the same[7]. Hence it becomes pertinent to develop ways and

means of protecting and nurturing traditional knowledge thereby ensuring sustainable development compatible with the interests of the traditional knowledge holders.

Different strategies may be followed to protect TK under IPRs, including the application of existing modes of protection, the development of a sui generis regime, or a combination of both. The most practical method of protection is the prevention of unauthorised use by third parties beyond the traditional circle. This form of protection focuses on the use of any indigenous knowledge as technical, ecological, scientific, medical or cultural by a traditional community. The demarcating standards in this case are:

- The content or substance of the knowledge
- The use of such knowledge
- The nature of the user

TK should be afforded effective protection especially in developing and under-developed countries. Such protection should be primarily with regards to, the recognition of the rights of the original TK holders and secondly, the unauthorised acquisition of rights by third parties over traditional knowledge. Due to the prevailing trends of globalisation a great degree of international coordination and cooperation is necessary to effectively protect and develop TK and any such protective strategy needs to consider the community, national, regional and international dimensions. Further the mechanisms sought to be implemented with regards to TK must give subjective consideration to the original holders of the knowledge. Economic aspects of development need to be addressed by such mechanisms. Most importantly such protection should be affordable, understandable and accessible to TK holders.[8]

Intellectual Property and Food Security

Food security is about filling each individual's human right to food. The introduction of IPRs in the plant varieties is justified by the need to foster food security in the long-term. IPRs have progressively been introduced in agriculture in two main phases. Firstly, a number of developed countries adopted overtime a form of IP protection for plant varieties - plant breeders' rights – which is derived from the patent model. Secondly, in the context of the development of genetic engineering, the progressive introduction of patent over life forms has constituted a major incentive for the overall growth of agro-biotechnology.[9] At present TRIPS say that all WTO member countries must provide IPR protection for plant varieties, either in the form of patents, or through a *sui generis* (i.e. of its own kind) system. In principle, the *sui generis* provision allows countries to develop their own system for protecting plants. India has adopted a *sui-generis* system for the protection of plant varieties which is "non-patent" based. Article 27.3(b) of TRIPS is of great importance to India as this provides for comprehensive and focused plant variety protection legislation. The main reason behind adopting a *sui generis* system is that India has a vast diversity of landraces of agricultural resources and indigenous and traditional knowledge.

The introduction of IPRs in agriculture must also be examined in its broader context which includes, for instance, the impact of IPRs in agriculture and biodiversity management. Biodiversity in particular, is of importance for the sustainability of agricultural systems in the long term. They are contentious issues for third world

countries namely India. The international conventions and TRIPS do talk about safeguards and provisions to challenge them. It is a well known fact that the resources and expertise needed to challenge them in the home country where such violations and infringements occur. If north is technology driven economies, south is driven by agrarian or labour intense sub-contracting economies. In general, Patents or Plant Breeders Rights seeks to give incentives to the private sector. The Patents Act, 1970, introduced series of measures restricting the rights of patent holders, to encourage innovations in India[10] and also to foster the availability of essential items like food and medicine, by keeping the prices as low as possible for the fulfillment of basic needs[11].

Biotechnology and IPR

Biotechnology is a field of applied biology that involves the use of living things in engineering, technology, medicine and other useful applications. Intellectual Property (IP) is central to the biotechnology industry, and brings with it a dimension, facilitating collaborative activity, whether it is a drug discovery or clinical or market-related trials. This intellectual property right protection granted to a biotechnological invention, being the subject matter of the intellectual property may be in the form of patent protection having great importance and value commercially.

For developing countries the TRIPS agreement gives some choices on the IPR protection of biotechnological inventions. TRIPS make no reference at all to biotechnology, but Article 27.3(b) of the Agreement deals with IPR protection of life-forms. It allows Members to exclude from patentability "plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof."

Conclusion

Intellectual property law has travelled from the 14th century *letters patent* to its present form. It really has the capability of influencing almost all spheres of human life. Patents and other proprietary rights granted on life like genes, micro-organisms raise a lot of issues which only time can answer. At the same time a proper balancing of public and private interests is paramount to maintaining the equilibrium. The fact that even a country like USA, is contemplating measures to regulate patenting of life forms shows the sensitivity of the issue. Thus it is very important for our policy makers to keep abreast of the rapid changes happening globally in this sensitive field so that they can perform the perfect "balancing act" which adequately protects creativity and safeguards the interests of the public. Developing countries like India need more *balancing acts* which can propel their creativity to new heights and at the same time promote public interests.

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1 Will the lifeline of affordable medicines for poor countries be cut? Consequences of medicines patenting in India" External Briefing document of Médecins Sans Frontières February 2005 available at http://www.who.int/hiv/amds/MSFopinion.pdf last visited on 13 September 2010

2 The TRIPS Agreement, Article 7.

3 Salazar, S., "Intellectual Property and the Right to Health", in WIPO/OHCHR, Intellectual Property and Human Rights, A Panel Discussion to commemorate the 50th Anniversary of the Universal Declaration of Human Rights, Geneva, Switzerland, 1999, p.71

4 India, being a developing country, was allowed 10 years from 1995 to make the transition to a full patent regime.

5 http://business.mapsofindia.com/pharmaceutical/

6 http://www.imaxi.org/content/right-health-includes-access-generic-drugs

7 Gavin Stenton, Biopiracy within the Pharmaceutical Industry: A Stark Illustration of How Abusive, Manipulative and Perverse the Patenting Process Can Be Towards Countries of the South, 26 Eur. Intell. Property Rev. 1, 17-26 (2004);

8 http://www.legalserviceindia.com/article/l98-Intellectual-Property-and-Traditional-knowledge.html

9 http://www.iprsonline.org/resources/docs/PCull.Food_sec_IPRs_7.11.03.pdf

10 Compulsory licensing provisions in India

11 Suman Sahai, "Indian Patents Act and TRIPS",28,Economic and Political Weekly ,1993