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**IPR Implications vis-à-vis Developing Countries**

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## ABSTRACT

This paper discusses the implications of intellectual property system in the scientifically capable developing countries. The debate concerning the economic implications of intellectual property rights (IPRs) has gained attention in the context of the World Trade Organization's (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), and the subsequent increase of regional and bilateral free trade agreements in the TRIPS-plus era. TRIPS aim to narrow the gaps in the way that IPRs are protected around the world, and to bring them under common international rules. The rapid proliferation of regional and bilateral free trade agreements include elements of IPRs building on and raising minimum standards defined by TRIPS. These agreements indeed integrate TRIPS-plus norms, including undertakings by developing countries not to use specific TRIPS flexibilities. Developing countries are under increasing pressure to strengthen their national intellectual property (IP) regimes, in order to harmonise them with those of developed countries. The international protection of intellectual property has always been a contentious issue between developed and developing countries. Intellectual property rights have never been as much in the news as they are today. Several developmental issues like foreign direct investment, public health, agricultural biotechnology, traditional knowledge & folklore have attracted controversy. Many drugs manufacturing companies of developed nation have been taking advantage of their patent rights by charging exorbitant prices for life-saving medicines such as AIDS drugs. The most significant effects are limited *access* to patented drugs in poor countries. Indigenous peoples and advocacy groups supporting their rights condemn corporate 'bio pirates' for making money out of their knowledge and claiming patent rights for 'inventions' essentially identical to knowledge acquired from tribal healers. Concerns are raised that patenting plants, animals, genes and gene fragments is not only unethical but may also be stifling innovation. So, these developing countries need to evolve a pragmatic policy model that would comprehensively address the integration of IPRs into their national system for continuous and balanced economic growth.

## **INTELLECTUAL PROPERTY RIGHT – AN INTRODUCTION**

Intellectual Property (IP) pertains to any original creation of the human intellect such as artistic, literary, technical or scientific creation. Intellectual Property Rights (IPR) refers to the legal rights given by the State to the inventor/creator to protect his invention/creation for a certain period of time. Interestingly, the term intellectual property in the Convention Establishing the *World Intellectual Property Organization*, or "**WIPO**", does not have a more formal definition.<sup>1</sup> The scope of intellectual property is expanding very fast and attempts are being made by persons who create new creative ideas to seek protection under the umbrella of intellectual property rights.<sup>2</sup> Over the years, the rather elastic IPR concept has been stretched to include not only patents, copyright, industrial designs and trademarks, but also trade secrets, plant breeders' rights, geographical indications, and rights to layout-designs of integrated circuits.<sup>3</sup> These legal rights confer an exclusive right to the inventor/creator or his assignee to fully utilize his invention/creation for a given period of time.

Intellectual property rights illustrate the nation's ability to translate knowledge and thereby creating social good and wealth through innovations. These innovations hold the key to any nations' prosperity as well as processing of knowledge. It is very well settled that intellectual property play a vital role in the modern economy. It has also been conclusively established that the intellectual labour associated with the innovation should be given due importance so that public good emanates from it.

The Systems of governance of Intellectual Property and promotion of social welfare through innovation and knowledge creation is an old concept but recent changes in international legal and trade structures have stirred up public debates. IPRs have never been more economically and politically important or controversial than they are today. Patents, copyrights, trademarks and geographical indications are frequently mentioned in discussions and debates on such diverse topics as human rights, public health, agriculture, education, trade, industrial policy, biodiversity

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<sup>1</sup> The States that drafted the Convention chose to offer an inclusive list of the rights as relating to: "Literary artistic and scientific works; performances of performing artists, phonograms, and broadcasts; inventions in all fields of human endeavor; scientific discoveries; industrial designs; trademarks, service marks, and commercial names and designations; protection against unfair competition; and "all other rights resulting from intellectual activity in the industrial, scientific, literary or artistic fields." (Convention Establishing the World Intellectual Property Organization, Signed at Stockholm on July 14, 1967; Article 2).

<sup>2</sup> P.Narayanan, Intellectual Property Law, p.1 (3<sup>rd</sup> Ed.2002).

<sup>3</sup> United Nations Conference on Trade and Development (UNCTAD) and the International Centre for Trade and Sustainable Development (ICTSD). 2002.

management, biotechnology, information technology, the entertainment and media industries, and increasingly the widening gap between the income levels of the developed countries and the developing, and especially least-developed countries. Strong IPRs for all countries whether it leads to transfer of wealth from poor countries to rich countries to further widen the economic divide is a major ethical concern.

Developed countries and business corporations who may benefit directly from IPRs regime insist on strong IPRs for all countries in the globalization process under TRIPs (Trade Related Aspect of Intellectual Property Rights). Most of the innovation (97%) is in the hand of developed countries and only 3% of global patents are owned by developing countries. The 93% patents on biotechnology are from USA, European Union and Japan and rest 7% from other countries. Hence the criteria for measuring the social benefit of IPRs are deferent. A recent world bank analysis suggests that the major beneficiary of TRIPs on term of enhanced value of patents are the developed countries with USA alone expected to make an annual gain of US\$ 19 billion while developing countries face loss of US\$ 7.5 billion on royalties and license fees.<sup>4</sup>

## **INTELLECTUAL PROPERTY AND FOREIGN DIRECT INVESTMENT**

Traditionally, attracting FDI in general, and in R&D in particular, has been high on the policy agenda of many countries, as inward flows of R&D are believed to provide net benefits for the host country.<sup>5</sup> Acquiring modern technology may generate important spillovers for the host country economy, which result in more and better competition, upgrade domestic innovative capacity, increase R&D employment, give better training and support to education, and reverse 'brain drain' effects.<sup>6</sup> However, inward FDI may have negative effects on the host country, such as loss of control over domestic innovative capacity, potentially impacting the technological competitiveness of domestic firms and leading to job loss. In addition, outward direct foreign investment has negative effects on the home country, such as loss of jobs and technological capacity.<sup>7</sup> Despite the possible costs of FDI for the home country and the host country, FDI is perceived often by policymakers to be an important engine for economic growth, especially in developing countries.

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<sup>4</sup> Arif Hossain & Shamima Parvin Lasker, Intellectual Property Rights and Developing Countries, Bangladesh Journal of Bioethics 2010.

<sup>5</sup> Organisation for Economic Co-operation and Development (OECD), 2008.

<sup>6</sup> Caves, 1974; Borensztein et al., 1998; Veugelers and Cassiman, 2004.

<sup>7</sup> Organisation for Economic Co-operation and Development (OECD), 2008.

## **INTELLECTUAL PROPERTY AND TRADE**

International trade is viewed as an important instrument to reduce poverty in developing countries<sup>8</sup> for most developing countries, exports allow them to acquire goods through importation that are necessary for economic growth and poverty reduction, but are not produced domestically. In turn, exports can make it possible to transform underutilised natural resources and surplus labour into foreign exchange, in order to pay for imports to support economic growth. But in recent multilateral and bilateral agreements, international trade remains unfair to developing countries, as the majority of gains from trade are accrued to developed countries.<sup>9</sup> Patent rights tend to influence insignificantly the total exports of developing and least developed countries. However, two industries in which exports in developing countries were moderately affected were pharmaceuticals and computer and office equipment. In contrast, in the case of the least developed countries, exports were affected negatively and significantly by patent rights.<sup>10</sup>

## **INTELLECTUAL PROPERTY AND INNOVATION**

Harnessing R&D and innovation has been a priority for policymakers in developed countries<sup>11</sup> particularly as technological progress is considered to be key driver for economic growth in the long run.<sup>12</sup> In an open economy, technological progress can be driven either by technology creation, or technology diffusion and absorption. It is reasonable to assume that the respective contribution of creation and diffusion to technological progress depends on countries' level of technological development.<sup>13</sup> In less advanced economies, diffusion and absorption can drive economic growth, because countries at the forefront of technology act as a driver for growth by expanding the set of attainable knowledge, pulling others through a 'catch-up' effect. However, the strength of the catch-up effect at the technology frontier decreases with the level of technological development, to the benefit of technology creation. Indeed, the creation of more advanced technology becomes progressively more important as a country moves closer to the technology frontier, because catching up translates into increasingly smaller technological improvements. Developing countries over the period 1975–2000, showed the positive impact of IPRs on innovations in developing countries. From 1989 to 2005, Indian firms evidence more innovation-

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<sup>8</sup> United Nations Conference on Trade and Development(UNCTA), 2004

<sup>9</sup> Stiglitz, 2003; Samuelson, 2004

<sup>10</sup> Comprehensive econometric study, Park and Lippoldt (2003)

<sup>11</sup> Solow, 1957; Romer, 1990; Grossman and Helpman, 1991; Aghion and Howitt, 1997

<sup>12</sup> Jones, 2002; OECD, 2003; OECD, 2004; Aghion and Howitt, 2009).

<sup>13</sup> Aghion and Howitt, 1997; Acemoglu et al., 2006.

intensive industries increased their R&D expenditure after TRIPS. The estimated increase in annual R&D spending after TRIPS was on average 20 percentage points higher in an industry with a one standard-deviation higher value of innovation intensity. But it is not necessary that strengthening IPRs in developing countries necessarily encourages domestic innovation. The existence of non-linear function (i.e. a U-shaped curve) between IPRs and economic development, which initially falls as income rises, then increases<sup>14</sup> after that stresses that countries at different levels of industrial and technological development face very different economic costs and benefits from stronger IPRs. This suggests that while IPRs encourage innovation in high-income countries and technology flows to low-income countries, middle-income countries may have offset losses from reduced scope for imitation.

## **INTELLECTUAL PROPERTY AND PUBLIC HEALTH**

Pharmaceuticals have brought immense health benefits to developing countries, but one third of the world's population does not have access to existing essential drugs<sup>15</sup> and this estimate has remained unchanged since the mid-1980s. The proportion reaches 50 per cent in the poorest parts of Africa and Asia.<sup>16</sup> *The Commission on Health Research for Development (1990)* showed that less than 10 per cent of global health research is directed towards diseases that afflict 90 per cent of the world's population – the so called '10/90 gap'.

Large empirical studies have found consistently that patents are extremely important for the pharmaceutical sector.<sup>17</sup> It estimated that pharmaceutical R&D outlays would be reduced by 64 per cent in the absence of patent protection; while for other industries, the corresponding reduction was only 8 per cent. The reason behind R&D is so costly in the pharmaceutical industry is that most drug candidates fail to reach the market.<sup>18</sup> Normally, less than 1 per cent of the compounds examined in pre-clinical stages are cleared for testing on humans. Only 22 per cent of the compounds entering clinical trials endure the development process and achieve FDA<sup>19</sup> approval.

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<sup>14</sup> Maskus, 2000;Primo Braga et al., 2000.

<sup>15</sup> The concept of essential drugs, as unanimously endorsed by the World Health Assembly, consists of "those that satisfy the health care needs of the majority of the population and should therefore be available at all times in adequate amounts and in appropriate dosage forms".

<sup>16</sup> World Health Organisation, 2002 report.

<sup>17</sup> Scherer, 1959; Cohen et al., 2002.

<sup>18</sup> Failure can be due to the compound's toxicity or carcinogenicity, manufacturing difficulties, inadequate efficacy, inconvenient dosage characteristics, economic and competitive factors and various other problems.

<sup>19</sup> US Food and Drug Administration; DiMasi,1995.

Moreover, the complete R&D process from synthesis to FDA approval involves undertaking successive trials of increasing size and complexity. Further in pharmaceuticals, manufacturing plants are expensive, costing between US\$50 million and US\$200 million, and unique manufacturing requirements usually mean that they are suitable for only one product.<sup>20</sup> These expensive R&D costs are compensated by patent-protected profits: profitability in the pharmaceutical industry and investment in R&D was found to be strongly correlated.<sup>21</sup> In the absence of patent protection, imitators can free-ride on the innovator's regulatory approval and duplicate the compound for a small fraction of the originator's costs. Imitation costs in the pharmaceutical industry are exceptionally low, relative to the innovator's costs for discovering and developing a new product.<sup>22</sup> Generic compounds need only demonstrate that they are bio-equivalent to the pioneering brand in order to receive market registration. This process only takes a few years and costs US\$1 million to US\$2 million. The prospect of success is reflected by the fact that many generic firms typically receive FDA approval and enter the market within a short time of the patent expiration of the pioneer brand. In the case of *Praziquantel*<sup>23</sup> – discovered, developed and licensed by Bayer, was immediately copied, improved and sold at a lower price by a Korean pharmaceutical company.

The impact of IPR specifically on price – is one factor among several that affect poor people's access to healthcare. Weaknesses in country-level physical, medical, financial and political infrastructures mean that many existing products, needed by people in developing countries, are not being purchased by patients, healthcare facilities, governments or non-governmental organisations. For example, many patients with AIDS in Africa would not benefit automatically from antiretrovirals, even at dramatically lower, affordable prices. Antiretrovirals require diagnosis, monitoring and long-term maintenance of demanding treatment regimens (so as to minimise drug resistance) that are difficult to sustain without adequate infrastructure and support. In many developing countries, access is a particularly complex problem, requiring political will and commitment of new resources. Even for diseases that affect developed countries as well as developing countries (such as cancer), the characteristics of poor countries make the products

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<sup>20</sup> Pisano, 1996; Douglas, 2004.

<sup>21</sup> Frank (2001) adds a more dynamic dimension to Scherer's observation that R&D outlays are affected significantly by changes in profitability, by emphasising that the link is to do more specifically with R&D investment today and expected, but uncertain, future profits.

<sup>22</sup> While R&D may cost in the region of US\$1 billion, imitation costs are around US\$1million. There are few other comparable industries where there is such a large disparity between the costs of innovation and imitation.

<sup>23</sup> Reich and Govindaraj, 1998.

designed for developed markets unsuitable. For example, developing countries have weak infrastructure and need vaccines that can withstand breaks in refrigerated distribution chains and survive a long shelf-life. They also need products that do not require intense supervision by medical Personal. While Europe has 39 trained physicians per 10,000 people and the USA has 27 but the developing countries has only one.<sup>24</sup> The choice between vaccines and drug therapies is such an example. An HIV/AIDS vaccine would be far easier to deliver in a poor country than a combination of drug therapy cocktails, but efforts to develop a vaccine have been minimal in comparison to investment in treatment.<sup>25</sup> For the health problems facing developing countries, a chronic lack of scientific and technical understanding suggests a severe state of under-investment in R&D that is only just beginning to be addressed. This can be best estimated from the fact that only 1 per cent of biomedical research papers make reference to tropical diseases or neglected disease of developing countries.<sup>26</sup>

## **INTELLECTUAL PROPERTY AND GENETIC RESOURCE**

Genetic resources from plants, animals and micro-organisms are widespread in developing countries, amounting to 90 per cent of the world's genetic resources.<sup>27</sup> These genetic resources have been utilised by communities and individuals in developing countries through generations and as such their use is embodied in what is referred to often as traditional knowledge. However, the use of such knowledge and resources is not limited to local contexts and many innovations relate to and draw on them.<sup>28</sup> For example, 45 per cent of all herbal-based patents were hosted in China alone in 1996 and 80 per cent of modern plant-based medicines have the same function as their original use by Aboriginal peoples.<sup>29</sup> The use of genetic resources, both inside and outside of their local context, raises the prospect that they may play an important role in driving development. The issue for policymakers is how this prospect might be realised best, particularly when the use of traditional knowledge and genetic resources is becoming increasingly subject to governance by various, and sometimes contradictory, IP systems.

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<sup>24</sup> World Bank Report, 2008.

<sup>25</sup> Yaqub, 2009.

<sup>26</sup> Lanjouw and Cockburn, 2001.

<sup>27</sup> Desai, 2007.

<sup>28</sup> World Intellectual Property Organisation, 2009.

<sup>29</sup> Farnsworth and Kaas, 1981.



To illustrate the complexity which surrounds intellectual property in genetic resource, consider the following scenario. Over a long period of time farmers in a developing country breed a crop variety which is adapted to local climatic conditions and which has characteristics that appeal to local consumer tastes. Over the last few decades, local plant breeders improve on the varieties through selective breeding and release strains using a name which has widespread local acceptance. These local varieties also appeal to niche market consumers in other countries and a considerable export trade develops. Intellectual property protection in the home country, however, is poor and, in any case, the government is opposed to the granting of monopoly rights in agricultural crops. Seeing the international market potential of the local crop variety, an agricultural biotechnology company in a developed country acquires samples of the crop. As these varieties are not produced using biotechnology, the firm convinces its government to make use of the exemption for plants and animals allowed in the TRIPs by claiming these are natural varieties where no inventor can be identified. This is strictly correct because the developing country did not provide intellectual property protection for the varieties. The use of the exemption voids any rights on the part of the developing country to the natural varieties. The agricultural biotechnology company then genetically engineers a close substitute for the "natural variety" which maintains its desirable consumer characteristics. This genetically modified variety can be patented and its name copyrighted, which makes it eligible for intellectual property protection under the TRIPs. This means that the biotechnology firm can license the production of the crop in any climatically friendly country, export the product in competition with the natural varieties and prevent the natural varieties from being sold in importers' markets using their traditional names. In the extreme, the biotechnology firm could ask for protection of its intellectual property in the original developing country to prevent both seeds and the outputs of the natural varieties from being sold under the traditional name. A close variant of this scenario is being played out for Jasmine rice from Thailand and Basmati rice from India. In both cases, variants of the two rice varieties have been patented and copyrighted by United States (US) firms. There has been an adverse reaction to this perceived "biopiracy"<sup>30</sup> in both India and Thailand.

To overcome the exploding issue of bio piracy in developing countries TRIPs recognises the issue by allowing for *sui generis* protection of genetic resources, specifically plants, animals and biological processes.<sup>31</sup> *Sui generis*<sup>32</sup> protection is a system of protection tailored to accommodate the special characteristics of traditional knowledge. Since TRIPs, there has been pressure for

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<sup>30</sup> the stealing of genetic material and knowledge from communities in the gene-rich developing countries.

<sup>31</sup> Commission on Intellectual Property Rights, 2002.

<sup>32</sup> Commission on Intellectual Property Rights, 2012.

increased protection of knowledge linked to genetic resources from plants, animals and micro-organisms. Bilateral agreements encourage countries to join the International Union for the Protection of New Varieties (UPOV) Convention. The UPOV Convention, formed in 1961, acknowledges breeders of new plant varieties through uniform and clearly defined principles for exclusive property rights, based on criteria that the variety is distinctive, uniform, stable and novel.<sup>33</sup>

Geographical Indications are a second measure used to protect diversity in access and benefit-sharing in developing countries. With GIs, this is achieved by making provision for a price premium for the goods produced in a specific locality. Producers in developing countries have begun to use certification marks to develop brands and protection for their products, such as *Jamaican Blue Mountain coffee* or *Juan Valdez and Café de Colombia*. In addition, as evident in, rural communities<sup>34</sup> in developing countries have developed quality brands through interactions between local know-how and particular environmental conditions.

## CONCLUSION

The essay emphasises on the effect of IPRs in developing countries in the context of the WTO TRIPS Agreement and the development of TRIPS-plus standards. TRIPS encouraged the international harmonisation of IPR regimes by providing a minimum standard of protection for IP, and a dispute resolution system for entities to challenge breaches of these standards. Since the establishment of TRIPS, there has been an increase in the number of new deals formed through bilateral and regional free trade agreements to strengthen these minimum standards of protection, the so-called TRIPS-plus standards.

After discussing the impact of strengthening IPRs in developing countries in five main areas – FDI, trade, innovation, public health, and genetic resources and traditional knowledge, the paper concludes the following things:

1. Strengthening IPRs can have positive effects on FDI. Strong rights can create ownership advantages that allow firms to invest abroad. They can also represent a location advantage, which can be used by developing countries to attract new cross-border investment. Moreover, stronger IPRs can provide incentives for multinationals to increase the quality of their investment dedicated to developing countries.

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<sup>33</sup> Commission on Intellectual Property Rights, 2002.

<sup>34</sup> The Light Years project and in a recent World Bank report (Barconcelli et al., 2004).

2. IPRs can positively affect trade, at least with countries with high technical absorptive capabilities. Moreover strengthening IPRs can increase the market power of foreign firms in developing countries, giving them incentives to increase the price of their products and decrease their exports to developing countries.
3. Stronger IPRs are needed in developing countries to encourage domestic innovation due to market failure and to facilitate international technology transfer from developed countries due to information asymmetries in contracting.
4. IP targeted at health issues of particular relevance to developing countries is of value to commercial product and technology developers only if a viable market can be created. The degree of need (and market size) is high, but creating viable markets entails a concerted international effort. However, pharmaceutical industries, including those in countries such as India, are responding imperfectly to developing country needs. Instead, they often focus on developed country markets.
5. Tailored IP laws are a necessary prerequisite for knowledge protection systems to engage a wider range of people in accessing and sharing the benefits of knowledge in developing countries. Although evidence about implementation is scarce, this could be facilitated by using the provisions in TRIPS for *sui generis* protection and Geographical indication.

So, the Developing Countries have to evolve pragmatic policy model that would comprehensively address the integration of IPRs into their national system for continuous and balanced economic growth. What developing countries need is to nurture a system that generate capable human resources, high valued services and products that are appropriately protected as intellectual property and transferring them at opium value as “value added wealth”.