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DEVELOPING COUNTRIES AND INTELLECTUAL PROPERTY RIGHTS

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INTRODUCTION

The concept of intellectual property rights has never been as controversial as it has become with the rapid advancement in technology, new subject matter for protection, new information and communication technologies and current International Intellectual property Rights Laws/ Systems. There have always been two views about the Intellectual property Rights i.e developed world view and developing world view and both sides extend defensive arguments in their favor.

On the one side, the developed world side, there exists a powerful lobby of those who believe that all IPRs are good for business, benefit the public at large and act as catalysts for technical progress. They believe and argue that if IPRs are good, more IPRs must be better. They argue strongly that IPRs are necessary to stimulate economic growth which, in turn, contributes to poverty reduction. By stimulating invention and new technologies, IPRs will increase agricultural or industrial production, promote domestic and foreign investment, facilitate technology transfer and improve the availability of medicines necessary to combat disease. They take the view that there is no reason why a system that works for developed countries could not do the same in developing countries.

On the other side, the developing world side, there exists a vociferous lobby of those who believe that IPRs are likely to cripple the development of local industry and technology, will harm the local population and benefit none but the developed world. They believe and argue that if IPRs are bad, the fewer the better. They argue that IPRs do little to stimulate invention in developing countries, because the necessary human and technical capacity may be absent. They believe that IPRs are ineffective at stimulating research to benefit poor people because they will not be able to afford the products, even if developed. IPRs limit the option of technological learning through imitation. IPRs allow foreign firms to drive out domestic competition by obtaining patent protection and to service the market through imports, rather than domestic manufacture. Moreover, it is believed that IPRs increase the costs of essential medicines and agricultural inputs, affecting poor people and farmers particularly badly.

The process of implementing Trade Related Aspect of Intellectual Property (TRIPS) has not resulted in shrinking the gap that divides the two sides, rather, it has helped to reinforce the views already held. Those who are in favor of more IPRs and the creation of a level playing field hails TRIPs as a useful tool with which to achieve their objective. On the other hand, those who believe that IPRs are bad for developing countries believe that the economic playing field was uneven before

TRIPs and that its introduction has reinforced the inequality. So firmly and sincerely held are these views that at times it has appeared that neither side has been prepared to listen to the other.

Whether IPRs are good or bad thing, the developed world has come to an accommodation with them over a long period. Even if their disadvantage overweighs their advantages, by and large the developed world has the national economic strength and established legal mechanisms to overcome the problems so caused. Insofar as their benefits outweigh their disadvantages, the developed world has wealth and infrastructure to take advantage of the opportunities provided. It is likely that neither of these hold true for developing and least developed countries. However, the production of a series to workable proposals is not enough by itself. What is needed is an acceptance and will to implement it.

For too long, IPRs have been regarded as food for rich countries and poison for poor countries. However, poor countries may find them useful provided they are accommodated to suit local palates. The appropriate diet for each developing country needs to be decided on the basis of what is best for its development, and that the international community and governments in all countries should take decisions with that in mind.

As new IP regimes will have wide ranging socio-economic, technological and political impact. As per the obligations under the Trade Related Intellectual Property Systems (TRIPS), all the members of World Trade Organization (WTO) are supposed to implement national systems of intellectual property rights following an agreed set of minimum standards. However, there is an increasing feeling that harmonization is demanded from those that are not equal, either economically or institutionally. In this paper I have discussed major concerns of the developing countries, in the health sector, about such harmonization and the new challenge it faces in diverse areas of intellectual property protection and some suggestions about the way ahead are made. This discussion includes the need for a fair play in technology transfer, creation of 'favourable economics' of essential medicines from the point of view of the third world, protection of traditional medicine and knowledge, etc.

Now to understand the point of view of developing countries, firstly we look at the Intellectual Property Rights and a brief history of IPRs with particular reference to the countries which developed in 19th and 20th century.

What are Intellectual Property Rights

Intellectual Property Rights IPRs are the rights awarded by society to individuals or organizations principally over creative works: inventions, literary and artistic works, symbols, names, images and designs used in commerce. They give the creator the right to prevent others from making unauthorized use of their property for a limited time period. Intellectual property is categorized as Industrial Property {functional commercial innovations} and Artistic and Literary Property {cultural creations}. Current technological developments are blurring, to some extent, this distinction, and some hybrid sui generis systems are emerging.

HISTORY OF IPRs

Now we look at the history, particularly from the experience of the developed countries in the 19th century, and the emerging economies of East Asia in the last century.

First, historically IP regimes have been used by countries to further what they perceive as their own economic interest. Countries have changed their regimes at different stages of economic development as that perception and their economic status has changed. For instance between 1790 and 1836, as a net importer of technology, the US restricted the issue of patents to its own citizens and residents. Even in 1836, patent fees for foreigners were fixed at ten times the rate for US citizens and two thirds as much again if one was British. Only in 1861 were foreigners treated on non-discriminatory basis. In his Annual Report for 1858, the US commissioner of Patents noted: "It is a fact, as significant as it is deplorable, that of the 10, 359 inventions shown to have been made abroad during the last twelve months, only forty two have been patented in the US. The exorbitant fees exacted of the foreigners, and the severity of the offensive discrimination established this prejudice, afford a sufficient explanation of the result… it might well be concluded that the Government of this country regarded an invention made beyond the seas as something intrinsically dangerous, if not noxious, the introduction of which it is morally just and politically wise to burden with taxation, just as you would thus burden the importation of some foreign poisonous drug. There is a loftier view of this question, and one deemed more in harmony with the progressive spirit of the age – a view which hails the fruits of the inventive genius, in whatever clime matured, as the common property of the world, and gives them cordial welcome as the common blessings of the race to whose amelioration they are devoted". Until 1891, US copyright protection was restricted to US citizens but various restrictions on foreign copyrights remained in force, for example printing had to be on the US typesets, which delayed US entry to the Berne Copyright Convention until as late as 1989, over 100 years after the UK. It is for this reason that some reader may remember purchasing books which had on the cover the words: "For copyright reasons this edition is not for sale in the USA". Until the adoption of Paris Convention on Protecting Industrial Property in 1883, and its 1886 Berne counterpart on literary and artistic works countries' ability to tailor the nature of their regimes to their own circumstances was unconstrained. Even then, the rules of these Conventions exhibited considerable flexibility. The Paris Convention allowed countries to exclude fields of technology from protection and to determine the length of Protection afforded under patents. It also permitted revocation of patents, and compulsory licenses to remedy abuses.

Secondly, numerous countries have at times exempted various kinds of invention in certain sectors of industry from patent protection. Often, the law has restricted patents on products confining protection to processes for their production. Typically these sectors have been foodstuffs, pharmaceuticals, and chemicals, based on the judgment that no monopoly should be granted over essential goods, and that there is more to be gained by encouraging free access to foreign technology, than by

potentially stimulating invention in domestic industry. This approach was adopted by many countries which are now developed in the 19th century, and for some until late in the 20th century, and also in the East Asian countries such as Korea and Taiwan, until relatively recently. However, TRIPs now forbids discrimination in the grant of patent protection in respect of different fields of technology.

Thirdly, intellectual property, and patents in particular, have been often politically controversial. Between 1850 and 1875, a debate raged in Europe, both in academic and political circles, on whether the patent system was a blight on free trade principles or the best practical means of stimulating inventions.

Opposite of patent protection was advanced on various grounds but was summed up in the words of the Economist in 1851:

> "The privileges granted to inventors by patent laws are prohibitions on other men, and the history of inventions accordingly teems with accounts of trifling improvements patented, that have put a stop, for a long period, to other similar and much greater improvements ... The privileges have stifled more inventions than they have promoted... Every patent is a prohibition against improvements in a particular direction, except by the patentee, for a certain number of years; and, however, beneficial that may be to him who receives the privilege, the community cannot be benefited by it... on all inventors, it is essentially a prohibition to exercise their faculties; and in proportion as they are more numerous than one, it is an impediment to general advancement..."

Again this clearly illustrates a theme that recurs in current discussions. If the system protects one set of inventions, can it avoid deterring those who seek to make improvements upon the first?

Foreshadowing the debates concerning TRIPs, the 19th century argument was also related to the free trade controversy in that the patent system, by conferring monopolies, was seen by some as a contravention of free trade principles. Moreover there was self-interest at work. In Switzerland in the 1880s, industrialists did not want a patent law because they wished to continue to use the inventions of foreign competitors. This opposition was maintained in spite of the fact that the Swiss were enthusiastic patentees in other countries themselves. And because Switzerland had low tariffs, they feared that those competitors would take out patents in Switzerland and then drive out Swiss competition under their protection.

Switzerland did eventually adopt a patent law, with various exclusions and safeguards, not because most Swiss thought there was net benefit to be had from allowing foreign patents, but because Switzerland came under intense pressure, particularly from Germany, to do so and did not wish to invite retaliation from other countries. Safeguards adopted included provisions for compulsory working and compulsory licensing which enabled the government to enforce production in Switzerland by one means or another, if it so desired. In addition, chemicals and textile dyeing were excluded from patent protection. Elsewhere in Europe the, proponents of the patent system also largely won the arguments, just as the free trade movement disappeared in the face of the Great Depression in Europe. Only in

Holland/Netherlands did the movement against patents wholly succeed, and from 1869 until 1912 no patents were issued there. Also, France introduced patent protection in 1960, Germany in 1966, Japan in 1976, South Korea in 1987 and Italy in 1988.

In 1876 when the German industry was in its infancy and the patent law was yet to be evolved, Bismarck appointed a committee to study the likely impact of the patent system on the industry. The committee included the founders of Siemens and Hoechst, whose observations made interesting reading: " Today industry is developing rapidly... monopolisation and abuse of patent rights will inevitably expose large segments of the industry to serious injury. The government must protect industry against these dangers.

Also countries were sovereign in excluding some commodities from such protection to safeguard the interest of the people. Hence many countries excluded pharmaceuticals from the purview of their patent laws at some stage.

Having achieved a high level of technical advancement by extensively copying each other, industrialised countries then started demanding global harmonisation of patent laws under the TRIPs agreement.

Fourth, the best examples in the recent history of development are the countries in East Asia used weak forms of IP protection tailored to their particular circumstances at the stage of their development. Throughout the critical phase of rapid growth in Taiwan and Korea between 1960 and 1980, during which their economies were transformed, both countries emphasized the importance of imitations and reverse engineering as an important element in developing their indigenous technological and innovative capacity. Korea adopted patent legislation in 1961, but the scope of patenting excluded foodstuffs, chemicals and pharmaceuticals. The patent term was only 12 years. It was only in the mid-1980s, particularly as a result of action by the US under Section 301 of its 1974 Trade Act, that patent laws were revised, although thy did not yet reach the standards to be set under TRIPs. A similar process took place in Taiwan. In India, Weakening of IP protection in pharmaceuticals in its 1970 Patent Act is widely considered to have been an important factor in the subsequent rapid growth of its pharmaceutical industry, as a producer and exporter of low cost generic medicines and bulk intermediates. In Pakistan there was no per se protection for pharmaceutical products before the enforcement of the current Patents Ordinance, 2000 due to which number of local pharmaceutical industries were established to manufacture much more cheaper medicines.

Lesson from the History

The general lesson that aforesaid history shows is that countries have been able to adapt IPR regimes to facilitate technological learning and promote their own industrial policy objectives. Because policies in one country impinge on the interests of others, there has always been an international dimension to debates on IP. The Paris and Berne Conventions recognized this dimension, and the desirability or reciprocity, but allowed considerable flexiblitiy in the design of IP regimes. With the

advent of TRIPs, a large part of this flexibility has been removed. Countries can no longer follow the path adopted by US, Switzerland and Korea in their development.

Now we look, in detail, at the concerns of the developing countries in health sector about Intellectual Property Rights:

Intellectual Property Rights and Health Sector in developing countries

It is often argued by the developed countries that IPRs i.e Patents perform an essential role in stimulating the development of essential drugs, including anti-AIDS drugs, by offering incentives for investing in expensive and long-term research and development of new drugs. Without patents, drugs such as existing anti-AIDS drugs would not have been produced. Without patents, new and better drugs that are needed to overcome the increasing resistance of the AIDS virus would not be developed. At the same time, the patent system also contributes to society as a whole by accumulating and making available human knowledge to fight against the AIDS crisis. The patent system requires significant disclosure of the information leading to the invention of new drugs. Without the patent system, such key technical information would remain unavailable or even secret. Many health care researchers and drug manufacturers, who depend heavily on such information for their work, would have to reinvent the wheel. Given the severity of the crisis, no one can afford to spare such resources and time.

However, the above is not fully true for the poor people of developing countries and the impact of intellectual property rights on the Health Sector in developing countries has generated substantial controversy in recent years especially after TRIPs agreement.

First, the patent holder can exclude direct competition as the patents rights are monopoly rights, and charge higher prices for patented medicines than would have prevailed in a competitive market. International comparisons show that unpatented drugs or generic drugs are much cheaper than the patented drugs. In the Pakistani market, a drug manufactured by a local pharmaceutical industry is much cheaper than the same drug which is patented and manufactured by a multinatioal pharmaceutical industry. There are number of cases pending in the Pakistani courts where a multinational pharmaceutical industry, who was selling its product very expensive, has filed suits against local manufacturers for the infrigements of its patent rights where the local manufacturer was selling the same drug many a times cheaper than the multinational company. Also, one of the studies indicated that for twelve drugs covering a range of conditions US price range from four to fifty six times the price of equivalent formulations in India, and yet still a large number of people in India cannot obtain access to them. In relation to the treatment of HIV/AIDS patented version of anti-retroviral therapies which are used to keep HIV in check, and other drugs effective against the diseases which accompany HIV and cause opportunistic infections, typically cost 3 and 15 times as much as their generic equivelants.Also, prices for non-patented (generic) versions of antibiotics used to treat major childhood killers such as diarrhoea and chest

infections are often marketed at prices less than one-eighth of those for equivalent patented products. If Kenya, where one quarter of the adult population is HIV positive,were able to import the drug fluconazole, used in the treatment of cryptococcal meningitis (an opportunistic infection associated with HIV/AIDS), from Thialand, it could reduce the annual cost of treatment from over US$3000. A global econometric study estimated that the effect of eliminating patent is a cross-section of developing countries would be to increase access to Anti-Retro Viral (ARVs) by 30%, albeit from the very low existing level. Price comparison between Pakistan and India (which has one of the world's strongest generic-drug industries) are interesting. They show that prices for ciprofloxacin, a safe anti-infective medicine used in the treatment of illnesses such as resistant bloody diarrhoea in children, are upto eight times more costly in Paksitan. Becacuse generic-drugs industries are able to market products at a fraction of the costs associated with patentes brands, they provide a life line to low-income households. Current intellectual property rights threatens to cut the lifeline. At a time when millions of lives are at risk from newely-virulent diseases, and from the increasing drug resistance to old killers, trade rules threaten to make basic medicines even less affordable to the poor. Hence, life-saving drugs can then be made unaffordable, as has been seen particularly in the case of HIV/AIDS in sub-Saharan Africa. The importance of prices of medicines to poor consumers in developing countries is perhaps obvious. If a sick person has to pay more for a pharmaceutical product as a result of a patent, it means that he or she will have less to spend on other essentials of life such as food or shelter. Alternatively, foregetting the medicine because it is unavailable or unaffordable may result in long term ill health, or death. In Zambia, where two-thirds of rural households live below the poverty line, it costs one such household US$9 to treat a single case of childhood pneumonia-an amount equivalent to half the family's monthly income. That is why it is essential to consider the impact of the introduction of an IP regime on prices.

A prolonged and strengthen patent protection for two decades as per the minimum requirement according to TRIPs for both processess and products would mean that drugs would remain inaccessible (due to higher prices) to a majority of people in developing countries for two decades. In case of essential drugs this can have catastrophic public health effects. In developing countries where a majority (80-90%) of the people make out-of-pocket expenditures to buy medicines, the high prices of drugs can be a dividing line between life and death.

Intellectual property rules are driven through by the world's largest and most powerful pharmaceutical companies: Merck, Pfizer, GlaxoSmithkline, and Eli Lilly etc. The financial power of these companies is enormous. Taken collectively, the larest five drugs companies have a market capitalisation greater than the economies of Mexico or India-and twice the GNP of sub-Saharan Africa. These pharmaceutical companies have helped lead the way to TRIPs that will increase the profits accruing to drugs patent holders: namely, themselves and their shareholders. From 2000, most developing countries are required to ensure that their national legislations protects the IP of foreign pharmaceutical companies or

face the prospect of WTO-sponsored trade sanctions. TNCs account for over 90 per cent of global patents on pharmaceutical products. During 1998 and 1999, the South African government faced the constant threat of trade sanctions from the USA. Its crime: amending its law to allow importation of copies of patented anti-retroviral HIV/AIDS drugs from generic-drugs suppliers. The copies cost less than one-half of the patented versions. GlaxoSmithKline challanged the legality of imports anti-HIV/AIDS generic drugs to Ghana and Uganda from India. The threat of trade sanctions has played a pivotal role in the development and implementation of the TRIPs regime. Following complaints from the Pharmaceutical Research and Manufacturers of America (PhRMA), an industry body representing the world's largest pharmaceutical companies, the Government of the United States has threatened unilateral trade sanctions against over 30 countries under the 'special 301' provision of the country's trade law. Countries such as India, Egypt, and Argentiana, all of which have strong generic-drug industries, have been among the prime targest. The Pharmaceutical Research and Manufacturers of America (PhRMA), is one of the world's most politically influential and well-financed industrial lobbies. The primary source of PhRMA's power is its influence over the office of the United States Trade Representative (USTR). PhRMA's political influence comes at a price. Between 1997 and 1999, PhRMA's members spent US$236m lobbying Congress and the executive branch of government. Another US$14m was provided to political parties in 1999 alone. Almost two-thirds of corporate investment in political lobbying in the USA is directed towards the Republican Party. One of the negative implication of the TRIPs agreement is on local pharmaceutical companies. Unable to compete with resourceful Northern transnational corporations (TNCs), which they will have to because of a national treatment clause, local companies would be badly effected and governments in developing countries would not be able to rescue them. We have number of examples in Pakistan where the multinational firms filed suits against local companies on the basis that local companies were making a medicine with their patented processes,but the local industries were not able to litigate due to lack of financial resources, lack of qualified lawyers and judges in Pakistan in the field of IP.

According to an estimates by the WHO, about one-third of the world's population lacks access to essential drugs. Pakistan truly reflects this global scenario where morbidity thrives and mortality rises for want of needed treatment. The poor suffer the most, becoming poorer as poverty and disease alternate with each other as cause and effect. TRIPs is one of such factor that is damaging equity in health and health care. The main industrial demanders for incorporating intellectual property issues into the GATT framework were the pharmaceutical transnational companies, computer software and motion picture industries. Chakravarthi Raghavan in his book " Recolonisation: GATT, Uruguay Round and the Third World" has provided a detailed account of behind the-scene manoeuvres, pressure tactics and arm twisting by the industralised countries to make developing countries fall in line.

The announcement by the president Bush that the United States could seek to greatly expand access to HIV treatment at prices charged by generic manufactures was only the latest in a string of policy pronouncements favoring the wider use of generic drugs to enhance access to medicine. The Doha Declaration on TRIPs and Public Health, the World Health Organization efforts to promote the use of generic drugs and the announcement by President Bush that the USA would seek to reduce barriers to entry by generic copies of drugs in the USA market are other such examples. These measures are designed to promote access to lower cost generic drugs and in principal, each will have an impact on private incentives for research and development.

Sir John Sulston, Co founder of the Human Genome Project, in an article said that:

> "It is very disturbing that the monopoly rights of the producers of technology are being strengthened. The new global patent rules, introduced by the World Trade Organization, will raise the costs of vital medicines, with potentially disastrous implications for poor countries. In the pharmaceutical sector the winners will be the large northern-based transnational companies, which as a result of the lengthened patent protection of 20 years, will be able to sell their new medicines at higher prices. The losers are likely to be millions of people who will be unable to afford vital new medicines, and hard pressed government health services"

Second, the claim that reinforced patent protection will stimulate large scale investment in finding cures for diseases is not of much interests for the poor people of the developing countries. Pharmaceutical industries do invest in R & D focus mainly on the diseases likely to yield the highest return for their shareholders. It is widely acknowledged that there is too little investment in R & D for diseases of the poor such as malaria, tuberculosis and bloody diarrhoea . R & D for "neglected diseases" is appallingly low given the suffering and death that is involved. According to one study, of the 1393 new drugs approved between 1975 and 1999, only 16(just over 1%) were specifically developed for tropical diseases and tuberculosis, diseases that account for 11.4 % of the global disease burden. The Global Forum for Health Research's reports describe this as follows:

> "every year more than US$ 70 billion is spent on health research and development by the public and private sectors. An estimated 10% of this is used for research into 90% of the world's health problems. This is what is called the 10/90 gap"

Public health groups note that the financial incentives that patents are supposed to provide " will not stimulate R&D into neglected diseases because the people who suffer from neglected diseases do not have substantive purchasing power and do not constitute a profitable market. In looking towards new tools from genomics, Carlos Morel, who directs search on tropical diseases for the WHO, warns that "if this challenge is left exclusively in the hands of market forces, or addressed by scientific and technological policies, genomics will increase the divide between

the rich and the poor, instead of bridging it". That is market driven investment will ignore the needs of those who suffer from diseases that primarily afflict the poor.

Also in a number of areas, public health and private sector priorities differ when it comes to R&D. One illustration is the SARS outbreak, which has the possibility of becoming a widespread health care crisis. This story from the washington post illustrates the different perspective between the public and private sector:

> "While the sudden emergence of SARS, the severe acute respiratory syndrome, is a global health emergency of the highest order, it's not at all clear yet that it represents a commercial opportunity. Scientists are announcing breakneck progress, including isolation and genetic mapping of a new SARS virus, that may, under the right circumstances, lay the groundwork for new treatments. But executives in the pharmaceutical and biotech industries say those won't come automatically or quickly-- and may not be needed at all, if public health experts succeed in controlling the virus through the simpler expedient of quarantine. only if quarantine fails and the virus becomes widley established in the human population, the executive say, will the numbers of victims rise to the point that it makes sense to launch programs to discover new drugs and vaccines. while many experts fear the virus has already spread too widely to be eradicated, they are not yet certain. Scores of companies are looking at the prospects, but few, so far, appear to be committing large sums to SARS research. "its only a good commercial opportunity if worst cases are realized," said William A. Haseltine, chairman and chief executive of Human Genome Sciences Inc.

Patents and IPR regimes are most effective at attracting investment in products that have commercial prospects, leaving important gaps where R&D is most risky, research outputs would be a general increase in scientific knowledge, or where products serve poor populations. Public sector or donor funds, or research mandate often addresses gaps in research that is not adequatley or efficiently provided for IPR incentives.

The patent system itself is subject to serious misuse. Companies have developed a high level of expertise in prolonging the life of patents through minor improvements or modifications such as new crystalline forms, isomers, combinations and formulations which may not amount to genuine scientific invention and a significant part of industry's R & D expenditure goes not on developing new drugs but on expanding the coverage and life time of patent protection for existing ones. Also patent system itself is a costly mechanism to fund R&D . For Example, the USA six months extension of patent rights as a reward for conducting pediatric testing on medicines costs consumers billions of dollars and yet only a tiny fraction of the increases cost in medicines is being reinvested in pediatric clinical trials. **Also, in the US market, it has been estimated that US consumers pay atleast $150 billion per year in higher prices on pharmaceutical products, in order to fund an estimated $20 billion in private sector R&D. While this may or may not be an acceptable degree of**

efficiency in funding R&D in a wealthy country like the United States, it may be too wasteful to justify in countries where high prices prevent poor persons from obtaining access to essential medicines.

Third, despite some theories and expectations to the contrary, the TRIPs agreement has not stimulated direct investment or technology transfer in pharmaceuticals production in developing countries. Technology transfer is essential to all developing countries. Developing countries do not possess a large amount of protected technology upon which they can built new technology and research. Also, they lack a sufficient pool of trained personall to perform research and development in new technologies. Consequently, they need technology from developed nations to assist their growth.

The two gap theory descibes constraints limiting a developing country's ability to gain technology. first, developing countries are unable to save enough capital to create and maintain their own technological base to promote growth. Second, the cost of importing technology far exceeds export revenues.

If technology from developed country is imported and protected too strongly, the developing country-the importer of technology-will not be able to lay its own technological groundwork. That is why least developed countries view patents as inhibitors to technology transfer. They bring about high fees for the use of beneficial technology and hinder attempts to foster the development of high technology industries domestically. **Additionally, because most patents are owned by corporations in the industrialized world, patents are regarded as instruments used by industrialized countries to exert control over economic growth of developing countries.**

Currently, developing countries believe-and with good cause that the dominant international treaties, such as TRIPs, are not geared to suit their long term interests. Namely, the current policies will not help the developing countries grow out of complete dependence upon the technology of developed countries, in the long term.

Case study: Thailand

To see an example of these modern international policies in action, we turn our attention to Thailand's experience in international technology transfer.

Thailand had no laws regarding patent until its Patent Act of 1979. Thailand a developing country during that time, clearly favored patents as vehicle for economic growth, rather than a source of legal rights for inventors and these ideals were reflected in the Patents Act. The Act limited patents exclusively to inventions of industrial application. In effect, this meant machinery and electronics, and effectively excluded pharmaceuticals from patent protection.

After 1979, a trickle of foreign investment, mostly from United States, started to make its way to Thailand. Since by Western Standards, Thailand's patent law was still quite weak, the technology transfer which occurred was of very low quality because companies could not risk bringing advanced technologies into such

a legal enviornment. Nevertheless, Thailand became quite dependent on technology transferred from the western world.

Drug companies in the US filed a complaint with the US government in 1989 about the exclusion of pharmaceuticals from protection in Thailand. In 1990 US government opened an investigation into the matter and put heavy political and economic pressure on Thailand to amend its laws. Thailand's government was reluctant to comply, but had no choice because of the threat of trade sanctions by the US, whom Thailand depends upon heavily for technology.

In 1992, as a result of pressure from the US, Thailand enacted Patent Act Number Two, which provided much stronger patent protection. specifically, the Act broadened the domain of patentable subject matter and extended patent protection to drugs patented after September of 1992. The protection of drug patents was later extended to include those patented after 1986, to satisfy the pharmaceutical companies of the US.

After second Patent Act, Thailand experienced an increase in technology transfer and FDI. However, most ventures to date have been "turnkey" projects, where technology is imported and controlled by foreign experts for a limited purpose. So, this has failed to foster growth in domestic technology R&D and Thailand remains dependent on technology from industrialized nations.

Fourth, most developing countries are excluded from the benefits of protection for inventions because they lack the scientific infrastructure and the capital needed for research and development. High costs and the need for economics of scale place the development of patentable pharmaceuticals beyond the reach of most of them.

Patent protection may be necessary for future investment and R & D but the lives and well-beings of millions of people in the developing world depend on this protection being effectively integrated with public health concerns. The consensus statement of Global Health Forum I, February 2000, said "The move to globalize the protection of intellectual property is not politically sustainable without, at the same time, making the delivery of health technology more equitable". On April 23, 2001 the United Nations Commission on Human Rights called on governments to ensure the accessibility of pharmaceuticals and medical treatments used to treat pandemics such as HIV/AIDS, as well as "their affordability for all," in accordance with international law and international agreements. The resolution also calls on governments "to safeguard access to such preventive, curative or palliative pharmaceuticals or medical technologies from any limitations by third parties."

Intellectual Property Rights and Traditional Medicines (TM)

Normally when we consider innovation, we refer to only formal systems of innovation, namely that done in universities, industrial R & D laboratories, etc. Often not recognized is the technology innovation that takes place in an informal system of innovation, be it by artisans, farmers, tribes, or other grass-root

innovators. Indeed many societies in the Third World have nurtured and refined systems of knowledge of their own, relating to such diverse domains such as geology, ecology, botany, agriculture, physiology and health. These informal innovators have, generated such a rich store of traditional knowledge.

One of the concerns of the developing world is that the process of globalization is threatening the appropriation of elements of the collective knowledge of societies into proprietary knowledge for the commercial profit of a few. The local communities or individuals do not have the knowledge or the means to safeguard their property in a system, which has its origin in very different cultural values and attitudes. The communities have a storehouse of knowledge about their flora and fauna – their habits, their habitats, their seasonal behaviour and the like – and it is only logical and in consonance with natural justice that they are given a greater say as a matter of right in all matters regarding the study, extraction and commercialization of the biodiversity. A policy that does not obstruct the advancement of knowledge, and provides for valid and sustainable use and adequate intellectual property protection with just benefit sharing is what is needed.

The existing IPR systems are oriented around the concept of private ownership and individual innovation. They are at odds with indigenous cultures, which emphasize collective creation and ownership of knowledge. **There is a concern that IPR systems encourage the appropriation of traditional knowledge for commercial use, and that too without the fair sharing of benefits of the holders of this knowledge. They violate the indigenous cultural precepts by encouraging the commodification of such knowledge.**

The knowledge of and uses of specific plants for medicinal purposes is an important component of TK. Once traditional medicines(TM) were a major source of materials and information for the development of new drugs. In the 20th century, however, new sources for pharmaecuticals led to a decline in the importance of ethnobotany in drug discovery of programs. However, new discoveries of potentially potant anti-cancer agents in plants(such as turmeric and taxol), as well as rapidly growing herbal remedies market, has revived industry interest in traditional medicine knowledge and practises. As interest in traditional medicine is rekindled, indigenous knowledge of the cultivation and application of genetic resources is becoming exploited at an alarming rate. World sales of herbal medicine alone were estimated at US$30 billion in the year 2000.

Intellectual property rights should gurantee both an individual's and a group's right to protect and benefit from its own cultural discoveries, creation and products. But Western intellectual property regimes have focused on protecting and promoting the economic exploitation of inventions with the rationale that this promotes innovation and research. Western Intellectual Property law, which is rapidly assuming global acceptance, often unitentionally facilitates and reinforces a process of economic exploitation and cultural erosion. It is based on notion of individual property ownership, a concept that is often alien and can be detrimental to many local and indigenous communities. An important prupose of recognizing

private proprietary rights is to enable individuals to benefit from the products of their intellect by rewarding creativity and encouraging further innovation and invention. But in many indigenous world-views, any such property rights, if they are recognized at all, should be extended to the entire community. They are means of maintaining and developing group identity as well as group survival, rather than promoting or encouraging individual economic gain.

Problem experienced by indegenous people in trying to protect their traditional knowledge under intellectual property laws stem mainly from the failure of traditional knowledge to satisfy requirements for intellectual protections. Alternatively, where intellectual property protection could potentially apply to such knowledge, the prohibitive costs of registering and defending a patent or other intellectual property may curtail effective protection. There has been a clear bias in the operation of these laws in favor of the creative efforts of corporations, for example, pharmaecutical and other industries in industrialized countries. With in the context of scientific progress, modern intellectual property laws have allowed these industries to monopolize the benefits derived from their use of indigenous knowledge with disregard for the moral rights and material (financial) interests of indigenous people themselves.

Traditional Medicine (TM) play a crucial role in health-care of serves the health needs of a vast majority of people in developing countries. Access to "modern" health care services and medicine may be limited in developing countries. TM becomes the only affordable treatment available to poor people and in remote communities.

World Health Organisation (WHO) defines traditional medicine as "*the sum total of all the knowledge and practices, whether explicable or not, used in diagnosis, prevention and elimination of physical, mental or social imbalance and relying exclusively on practical experience and observations handed down from generation to generation, whether verbally or in writing*". Health care providers worldwide including major pharmaceutical giants are turning to incorporate many of these into their mainstream activities. As traditional medicines are largely based on medicinal plants, indigenous to these countries, where the system has been in vogue for several centuries, the effort is on accessing them either directly or through the use of modern tools of breeding and cultivation, including tissue culture, cell culture and transgenic technology.

The codification of TM varies significantly. A distinction can be made, particularly in Asia, between the *codified* systems of 'traditional medicine' and *non-codified* medicinal knowledge, which includes "folk", "tribal" or "indigenous" medicine. Thus, in Asia folk traditions are handed over orally from generation to generation.

The "folk" medicine is based on traditional beliefs, norms and practices based on centuries old experiences of trials and errors, successes and failures at the household level. These are passed through oral tradition and may be called, "people's health culture", home remedies or folk remedies. TM may be possessed by

individuals. In some cases, for instance, healers use *rituals* as part of their traditional healing methods, which often allow them to monopolize their knowledge, despite disclosure of the phytochemical products or techniques used. The codified tradition consists of medical knowledge with sophisticated foundations expressed in thousands of manuscripts covering all branches of medicine. Examples are ayurveda, siddha, unani and the Tibetan tradition.

The term "Biopiracy" is often used to describe the misappropriation of knowledge and/or biological materials from traditional communities. With today's rapidly globalizing IPR regime, situations of biopiracy are becoming increasingly evident. A few years ago, an American citizen owned a patent on the well known and commonly used Amazonian plant ayahuasca. Traditional Andean uses of meca (Lepidium meyenii)for increased fertility and the Indian use of neem as a pesticides have been patented in name of protift for Western companies. The specific of these examples are complicated and technical, but it is not an understatement to suggest that many more discrepancies will develop between traditional knowledge and the IPR regime negatively affacting indigenous communities across all continents. A major concern is that western corporations will continue to adapt, incorporate built upon or directly claim indigenous knowledge with out acknowledgement or compensation for communities that developed the knowledge.

Biopiracy can refer to:

- unauthorised use of biological resources e.g., plants, animals, organs, microorganisms, genes;
- unauthorised use of traditional communities' knowledge on biological resources;
- unequal share of benefits between a patent holder and the indigenous community whose resource and/or knowledge has been used;
- patenting of biological resources with no respect to patentable criteria (novelty, nonobviousness and usefulness).

When we look at the sample of Biopiracy in WikiPedia, we see how developed countries get profit from local and traditional experiences. In under-developed countries, farmers breed crop varieties adapted to their local soil/climate conditions over several decades. Local plant breeders improve varieties through a circular model: selective breeding, release of the variety, and use of the seeds for further selection. Traditional varieties are not fixed genetic structures, but rather dynamic structures, resulting from collective efforts over generations. Most of the time, improvement and use of crops cannot be separated. An interesting variety may be locally known for its particular properties and identified by a local name, but rarely patented. This may be explained by several facts: the crop does not show the quality of stability and homogeneity required, patenting is a long and expensive process, the selection of the crop is a community work, hence no single holder can be identified, etc. There is a community approach and there are many difficulties for farmers to patent their methods and their products. However, this is not same as

for the big firms: Ethnobotanists from firms and research facilities are prospecting biological resources, which they use for research and making new and improved products (i.e., agricultural, food and pharmaceutical products).

Given the international market potential, an agricultural biotechnological company can decide to ask the indigenous community of the biodiversity-rich country for information on interesting crops availability. Discovering that this variety and its characteristics appeal to a market in developed countries, the company acquires samples of it. The firm, then, genetically engineers a close substitute from the original natural variety, adding an improvement (e.g., pest resistance), and keeping the natural variety's desirable characteristics. As a genetically engineered variety, the new crop can be patented and its name copyrighted. Companies, in particular, are quick to apply for a patent on the collected resource or the new products, so as to prevent competitors from using them. The biotechnological company may license production of the crop in any suitable country, and even export the product in the source-country, in which case the improved variety comes into competition with the traditional one. The company may even ask for the intellectual protection of the modified variety in the original country in order to prevent both seeds from co-exististing, and the natural variety from being sold under the traditional name. In the latter case, the source-country loses its rights to produce or use the original variety for any further breeding.

The grant of patents on non-original innovations (particularly those linked totraditional medicines), which are based on what is already a part of the traditional knowledge of the developing world have been causing a great concern to the developing world. It was CSIR that challenged the US patent No. 5,401,5041, which was granted for the wound healing properties of turmeric. The process of reexamination of a US patent is well laid out . In a landmark judgement, the US Patent Office revoked this patent in 1997, after ascertaining that there was no novelty; the findings by innovators having been known in India for centuries.

The Coordinating Body of Indigenous Organisations of the Amazon Basin (COICA), which represents more than 400 indigenous tribes in the Amazon region, along with others, protested about a wrong patent (US Plant Patent No. 5,751 issued on 1986) that was given on a plant species native to the Amazon rainforest, called B.caapi and its traditional medicinal uses through an indigenous product called 'Ayahusca' in 1999. On reexamination, USPTO revoked this patent on 3rd November 1999. However, the inventor was able to convince the USPTO on 17th April 2001 the original claims were reconfirmed and the patent rights restored to the innovator.

These two cases were followed by yet another case of revocation May 2000. The patent granted to W.R. Grace Company and US Department of Agriculture on Neem (EPO patent No. 436257) by European Patent Office was squashed again on the same grounds that its use was known in India. India filed a reexamination request for the patent on Basmati rice lines and grains (US Patent No. 5,663,484) granted by the USPTO, and Ricetec Company from Texas has decided to withdraw the specific claims challenged by India and also some additional claims.

There is a problem on the grant of such patents linked to the indigenous knowledge of the developing world that needs to be addressed jointly by the developing and the developed world. We need to understand that there is a distinction between the patents that are granted based on modern research and patents, which can be categorized as traditional knowledge based patents. A recent study by an Indian expert group examined randomly selected 762 US patents, which were granted under A61K35/78 and other IPC classes, having a direct relationship with medicinal plants in terms of their full text. Out of these patents, 374 patents were found to be based on traditional knowledge. The Governments in the third world as well as members of public are rightly concerned about the grant of patents for non-original inventions in the traditional knowledge systems of the developing world. At International level there is significant level of support for opposing the grant of patents on non-original inventions. For example, more than a dozen organizations from around the world got together to oppose the EPO Neem patent and the entire process took five years. Such a process of opposition is, understandably expensive and time consuming. It is estimated that the Government of India and Pakistan spent around six million dollars to oppose patent on Basmati rice granted at USPTO and it took several years to obtain decision. It can be easily estimated that it is not convenient for most of the developing countries to pass through any such process of opposing a patent in some other country.

CONCLUSIONS

As regards intellectual property rights big problem is that it is not “one size fits all”. Strong IPR protection in poor countries, which are mainly net importers of modern technology, will have a number of negative consequences for the poor and developing countries, including:

- Higher prices of essential items such as medicines, seeds, software and educational material,
- Increased financial transfers to developed, rich countries;
- No significant increase in innovation in areas which may be of interest to poor countries (for example, tropical diseases or subsistence agriculture) owing to small market size;
- Limited or no increase in technology transfer;
- Restricted scope for imitation and reverse engineering which is vital for technological learning.

In order to implement the IPR system to support the needs of the poor countries, developing countries need to be allowed maximum use of the flexibilities in IPR system. Also technical and political support should be provided to help poor countries resist pressures to introduce stronger IPR protection.

The current intellectual property systems were primarily set up for inanimate objects and that too in formal systems of innovation. The time has come to revisit them. The emerging challenge is to look at the systems that will deal with

animate objects (such as plants and animals) and with informal systems innovation (such as those by grass root innovators like farmers, artisans, tribes, fishermen and so on). The standard intellectual property systems will certainly not suit such innovators and their innovations. We, therefore, need innovation in the intellectual property system itself.

It is important to recognize that the principal objective of the WTO system is to promote free trade. This can be done if competitive opportunities are provided across the nations on a non-discriminatory basis. The TRIPS provisions should be interpreted. In other words, the emphasis should be on promotion of competition, and not its restriction. The TRIPS prvisions have to be interpreted in this context alone, and especially with an aim of laying down the foundation of a fair trade system. It is hoped that the third world concerns enumerated in this paper will be addressed by a dialogue to create a new 'TRIPS plus', getting a new meaning of 'TRIPS plus equity and ethics'.

RECCOMMENDATIONS

- **Change IPRs Rules to cut the cost of vital medicines:**

Developing countries should retain the right to produce, market, import, and export affordable medicines. The principles of patent protection set out in TRIPs agreement should not be used in ways which inhibit this right. Provisions in the TRIPs agreement to safeguard public health through compulsory licensing and parallel importing should be strengthened, and the scope for legal challanges by patent holders limited. Under no circumstances should bilateral and regional economic agreements be used to ratchet up patent protection. The duration of patent protection should be shortened and the scope of protection limited.

- **End rich country bullying in negotiations on patents:**

The WTO should prevent industrialized countries from demanding high levels of patent protection in developing countries through the threat or use of unilateral trade sanctions or legal challanges i.e Section 301 of the US trade legislation

- **Invest in a research fund for diseases of the poor:**

Given the lack of commercial interest in researching infectious diseases in developing countries, an international fund should be set up to support a global network of public research institutions dedicated to developing new medicines and vaccines. Public investment and international co-operation, rather than extended patent rights, hold the key to narrowing the global health divide. Also, an international fund for subsidising drug purchases and delivery system in the poorest countries should be established.

- **Pharmaecutical giants should cut the cost of key medicines to developing countries:**

Pharmaceutical companies should reduce the price of key medicines in developing countries so that they are affordable to the poor. Prices should be

determined as part of an international and transparent system of equitable pricing, developed in counjunction with the WHO, with price differential based on the human development index and the country's ability to pay.

- **Pharmaceutical giants should balance public health and their patent claims in poor countries:**

Pharmaceutical companies should exercise social responsibility with respect to their patent claims. They should not seek to enforce patent claims in the poorest countries on drugs essential to public health.

- **Stop patent protection on bio-piracy:**

IPRs should be amended to prevent bio-piracy. As a first step, the TRIPs regime should be harmonised with the other conventions on Biodiversity, with patent holders required to disclose the origion of biological materials and to demonstrate prior informed consent of the original holders of the knowledge applied in the developmentof the patented products.

Finally, International agencies will have to make an effort to bridge the gap between the developed world and the third world. Some laudable efforts are afoot in this direction. WIPO's activities are going to narrow the information access gap that exists between the developed countries and developing countries; improve the flow of information concerning intellectual property rights among WIPO member states, regional intellectual property offices and the International Bureau; to improve access to and exchange of intellectual property information in terms of costs and access time; to improve intellectual property information dissemination; to consider the information needs and filing requirements of applicants and develop electronic services keeping in mind the need to provide benefits to applicants and intellectual property offices, and to other interested parties; to help guide the International Bureau to leverage information technologies and to improve the retrieval of intellectual property information through further development of international classifications of patents, trademarks and industrial designs as efficient search tools.

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