

Draft

INTELLECTUAL PROPERTY, COMPETITION AND DEVELOPMENT

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1. Introduction

This paper outlines some of the issues relating to intellectual property, conditions affecting competition, the public interest and the requirements of the development objective and process.

It discusses the relation between IPRs, monopoly and competition and the public interest (section 2) and the shifting of the balance towards the IP right holders (section 3) before examining the conditions and circumstances of developing countries (section 4). Examples are given on the effects of IPRs on competition and development (Section 5). Section 6 discusses policies and methods to prioritise competition principles in relation to IP, while a brief conclusion is in Section 7.

2. IPRs, monopoly and competition, and the public interest

There are inherent tensions between IPRs and competition. In a market economy, competition is seen by most as generally important and indeed essential to curb market distortions, induce efficiency in use of resources, prevent monopoly or oligopoly, maintain prices at fair levels, as low as possible, prevent excessive or monopoly profits and promote consumer interests and welfare.

An IPR is seen by many as a privilege granted in recognition of the need of the holder to recoup costs incurred in the research and innovation process, so as to maintain incentives for further innovation. Thus an IP entails an exclusive right for a limited time, enabling the holder to charge a higher price than the marginal cost of production. That higher price reduces access of consumers to the product, and access of other producers to production inputs and methods. The monopoly granted prevents or deters competition from rivals that can sell at lower prices. These are costs that are seen to be short-term (since the exclusive right is of limited duration), but which are supposed to be outweighed by the long-term benefits brought about by the innovation which IPRs encourage.

As noted by CIPR (2002: p15), “the optimal degree of protection (where social benefits are judged to exceed social costs) will also vary widely by product and sector and will be linked to variations in demand, market structures, R&D costs and the nature of the innovative process. In practice IPR regimes cannot be tailored so precisely and therefore the level of protection afforded in practice is necessarily a compromise. Striking the

wrong compromise – whether too much or too little – may be costly to society, especially in the longer term.”

There is thus a balancing required between the monopoly privilege granted to the IP holder and the public interest (including consumer welfare, the competition from other producers, and national development prospects). The appropriate balance requires the right policies that enable that IPs be appropriately given for correct reasons and to the correct parties, and that they be of an appropriate period, and that flexibilities and exemptions and exclusions are provided to safeguard vital public interests. If the balance is tilted excessively to the IP holder, then one consequence is that the IP facilitates a stream of monopoly profits beyond what is justified for recovering the costs of innovation, and society bears the costs unreasonably. These may include prevention of access to goods and services (including essentials such as medicines, food and information, and important inputs for production), curbing of industrial development, an overall reduction in competition and its benefits for resource allocation, and a monopolization in products, sectors or the economy as a whole.

Especially for developing countries, it is thus important that the standards of IPs be appropriate, that there be adequate exclusions and flexibilities, and that the framework enables IPs to be awarded appropriately for the right inventions and to the right parties, and that there be sufficient provisions policies and legal provisions that counter abuse of IP privileges when they occur.

3. Shifting of the balance between IP, monopoly and development

There are benefits to be derived from an appropriately designed and implemented IP policy geared to the public interests and to development needs, that takes account of the factors requiring balancing, and that attains the right balance. However, when the policy is inappropriately designed, or when the proper balance is not struck, there can be adverse effects of IPs on competition, the public welfare and development requirements.

Due to the TRIPS Agreement, several flexibilities that countries had in their IP policies have been narrowed. For example, TRIPS mandates that national treatment be provided for patents and patent applications; patents have to be given for both products and processes, and there cannot be different treatment on a sectoral basis. This has affected many developing countries that had previously excluded from patentability certain sectors (such as medicines, food and chemicals) or certain categories (especially product patents in medicines). TRIPS sets minimum standards for a wide range of IPs that are mandatory to implement. Many analysts have concluded that TRIPS has very significantly tilted the balance in favour of IPR holders, most of who are in developed countries, vis-à-vis consumers and local producers in developing countries and vis-à-vis development interests.

Recent trends in major developed countries have shifted the balance further in favour of IP rights holders. A recent study (Jaffe and Lerner 2004) analyses recent developments in the US patent system and their effects. In the early 1980s, the judicial appeal system for patent cases in the federal courts was changed so that the appeals are all heard by a specialized appeals court; and in the early 1990s the structure of fees and financing of the US Patent and Trademark Office was changed so that costs of operations are covered by patent application fees. These two developments resulted in US patent practice. The new appeals court has interpreted patent law to make it easier to get patents, to enforce patents against others and obtain large financial awards from such enforcement, and harder for those accused of patent infringement to challenge the patents' validity.

The results are that: (a) The new orientation of the patent office combined with the court's legal interpretations make it much easier to get patents. Patents on inventions that are trivially obvious, such as the process of making a particular type of sandwich, or a method for swinging on a swing, are being given. (b) Patents have become weapons for firms to harass its competitors. (c) Patents have enabled companies to win huge damages awards and put rivals out of business. (d) Patent approvals are extended to new areas including purported discoveries that are actually familiar, such as patents on previously well-known option pricing formulas. (Jaffe and Lerner 2004: p2-3). While some innovators who obtain the patents are rewarded, the activities of many others who are competitors are inhibited or even stopped, including their potential innovation activities.

IP policy and practice in developed countries have been exported to the rest of the world through international harmonization programmes and treaties. The TRIPS is the best example of these. The agreement was mainly prompted by and even designed by representatives of certain industries in developed countries, which succeeded in getting their governments to successfully advocate their cause in the Uruguay Round, overcoming the initial strong resistance of many developing countries. (This is well documented for example in Raghavan 1990, Drahos 2002 and Sell 2003).

WIPO has also been an active forum for IP harmonization, for example through its 1996 Copyright Treaty. The present negotiations for possible new treaties relating to patents and to broadcasting are other examples. In fact, WIPO has become a more active forum for negotiations for new treaties aimed at harmonization of IP systems and rules than the WTO. If current patent harmonization negotiations proceed along the lines advocated by the developed countries in the substantive patent law treaty process, there is a strong possibility that the results of recent developments in the major countries (such as the relaxing of criteria of patentability and the much easier granting of patents) will be disseminated to the rest of the world. There is thus a danger that what many analysts consider a dysfunctional system will be disseminated to developing countries.

Bilateral and regional agreements, that involve developed countries with developing countries, are other channels through which new aspects of IP are being transferred to developing countries. Many of these arrangements have TRIPS-plus provisions, requiring the parties to undertake obligations that narrow their policy space to choose between options. For example, they may contain conditions for compulsory licensing

that are more restrictive than permitted under TRIPS, or that require parties to commit to a provision on data exclusivity preventing the use of test data in the drug approval process relating to generic drugs that is not required by TRIPS.,

4. The situation of developing countries and the development context

The models and practices that serve as the basis for harmonization are generally tilted in favour of IP holders, with serious implications also for competition. When they are transferred to developing countries, so too are the imbalances. However, the effects on developing countries are even more serious, as there are systemic reasons why upward harmonization towards developed countries' IP standards are inappropriate and damaging for most developing countries.

The overwhelming share of patents in developing countries are held by foreigners, and thus most of the commercial benefits of IP accrue to these foreign institutions. There are large and growing patent rents transferred from developing to developed countries. Since the patents are owned by foreigners, local researchers and enterprises are blocked or restricted in their use of the patented materials. Local industries will also find it difficult or impossible to produce similar products as those patented. In terms of effect on competition, the situation confers monopoly rights on foreigners, and local enterprises are placed in a situation in which they face high or even insurmountable obstacles to compete. The kind of reverse engineering undertaken by today's now-developed countries during their development phase, or by industrially successful developing countries such as South Korea, when they did not have to adhere to the TRIPS agreement's high IP standards, will be extremely difficult or impossible to undertake today (See, for example, Ha Joon Chang 2004 on this point).

Thus the problem is more serious for developing countries. The recent IP trends in the US may make it harder for other US firms to compete with those US firms owning IP; however the market concentration takes place within the same country. But the developing countries have problems with a whole different dimension: their local firms are unable to develop as the IPs in their own territory are owned by foreigners. For a developed country the issue is mainly the degree of concentration or monopoly among firms within the country, for a developing country the issue is the very existence and viability or otherwise of local industries in sectors in which patents proliferate and where most are owned by foreigners.

Moreover, whilst developed countries may have instruments within their IP system or outside of it (for example in anti-trust regulation and competition law) to curb anti-competitive practices and other abuses by IP holders, most developing countries lack the capacity to have or use similar instruments.

In other words, the anti-competitive effects of high IP standards in developing countries are serious, and may become even worse if they lose even policy space for using existing

flexibilities due to further “upward harmonization” through new international treaties or through bilateral and regional trade and economic agreements.

Recent studies show the high extent of costs incurred by developing countries. The former chief of trade policy research in the World Bank, Michael Finger (2002), estimates that the obligations on developing countries to implement TRIPS will result in increased payments by them of US\$60 billion a year. A report by the World Bank (2002) estimates that the net annual increase in patent rents resulting from TRIPS for the top six developed countries in this field will be US\$41 billion (with the top beneficiaries being the US with \$19 billion, Germany \$6.8 billion, Japan \$5.7 billion, France \$3.3 billion, UK \$3 billion and Switzerland \$2 billion). Developing countries that will incur major annual net losses include South Korea (\$15.3 billion), China (\$5.1 billion), Mexico (\$2.6 billion), India (\$903 million) and Brazil (\$530 million).

Weisbrot and Baker (2002) argue that the World Bank’s patent rents estimates, already high enough, significantly understate the actual costs to developing countries, as these only measure the direct outflow of patent rents from these countries. In addition there are economic distortions as the IP protection causes goods to sell at prices far above their marginal costs, thus giving rise to “deadweight costs.” Citing other studies, they estimate the deadweight costs to be twice the size of the estimated patent rents.

In addition, there are costs for administering and enforcing IP laws and policies, requiring law reform, enforcement agencies and legal expertise. According to Finger (2002), WorldBank project experience indicates that it will cost a developing country \$150 million to get up to speed on three new WTO areas (IPRs, SPS and customs valuation. He notes that this amount is more than a full year’s development budget in many LDCs.

Many analysts believe the developing countries received a bad deal in accepting TRIPS in the Uruguay Round. “Through TRIPS developing countries took on as legal obligation a cost of \$60 billion per year, but there is no legal obligation in the agreement on any Member to provide anything in exchange.” (Finger 2002: p11). Finger adds that the Uruguay Round ‘grand bargain’ was that developing countries would take on obligations in the new areas and in exchange developed countries would provide better access to their markets, particularly on agricultural products and on textiles and clothing. He concludes that compared with the outcome of the market access negotiations, the TRIPS amounts (ie net rents) are big money. The US obtained 13 times more benefit from annual patent rents arising from TRIPS than from liberalization of industrial tariffs with Germany, France and UK gaining 3.6 times more. Conversely, the loss from TRIPS obligation is 18 times greater for Korea than gains from Uruguay Round tariff liberalization, and the costs outweigh benefits 7 times for Mexico and 4.7 times for China.

Well known trade economists who advocate free trade have also written harshly on the imbalances of TRIPS and the adverse effects on competition caused by the upward harmonization of IP standards induced by TRIPS. Jagdish Bhagwati (2001), Economics professor at Columbia University, in a letter to Financial Times, argued that the WTO must be about mutual gains in trade whereas IP protection is a tax on poor countries’ use

of knowledge, constituting a wealth transfer to the rich countries. “We were turning the WTO, thanks to powerful lobbies, into a royalty-collecting agency by pretending, through continuous propaganda that our media bought into, that somehow the question was ‘trade related.’ He advocated that the TRIPS agreement be removed from the WTO.

T.N. Srinivasan (2000), Economics professor at Yale University also advocates taking TRIPS out of WTO altogether or at least renegotiating some of its provisions. The arguments put forward as benefits to developing countries of high IP standards are that this would encourage local innovation, and foreign enterprises would be more willing to transfer technology and to invest. “These a priori arguments are based on the premises that first IPR protection of the type imposed by TRIPS is needed to encourage innovation and second that foreign enterprises place a significant weight on the strength of IPR protection regime. The theoretical justification for and even more importantly the empirical evidence in support of both these premises is not at all strong....It would appear that patent protection as a spur to innovation does not appear to be powerful in the real world. And the cost to the general public of restricting access to new technology through patenting may be high.”

In relation to balance of gains and losses and to the effect on competition, Sreenivasan states: “Most of the gainers from TRIPS are in rich developed countries and only a few, if any, in poor countries. This being the case, even if gains outweigh losses, international transfers would be needed to compensate losers. No such transfers from gainers to losers are envisaged as part of TRIPS. Besides, TRIPS, unlike tariff reductions, involves the creation or strengthening of the monopoly position of developed country producers in the markets of poor countries. Thus, TRIPS creates a distortion of monopoly in developing countries, the rents from which accrue to the rich. Besides, any acceleration of innovative activity, which is the only rationale for granting monopoly rights, if it comes about at all, will take place mostly in rich countries. Whether some of the benefits from any acceleration of innovation in the rest of the world will accrue to poor countries is arguable. In any case the benefits, if any, are uncertain and in the future, but the costs to developing countries are concrete and at the present.”

Another free-trade economist, Arvind Panagariya (1999) has argued that upward patent harmonization, as carried out under TRIPS, resulted in reduced welfare for developing countries and the world as a whole. His thesis is summarized as follows: “Suppose the world is divided into two regions, North and South. North is much bigger than South in economic terms and has a comparative advantage in innovations. Initially the patents are given a life of 20 years in North and 5 years in South. This means that innovators are able to exercise monopoly power over the product they innovate for 20 years in the North and 5 years in the South. The introduction of TRIPS which extends patent life in South from 5 to 20 years has two main effects. First, it extends the monopoly distortion in South on all products innovated from 5 to 20 years. The resulting inefficiency lowers the welfare of South as well as world. In addition, the extension of the patent transfers a part of Southern consumers’ income to Northern innovators through higher producer prices. This redistribution further lowers the income in South and raises that in North. The loss to South is larger than to the world as a whole.

“The second effect of the extension of the Northern patent system to South is the generation of some additional innovations. Prospects of the monopoly power in South for an extra 15 years may encourage some more products to be innovated. Benefits from these innovations counteract the loss due to increased monopoly distortion on products innovated under the old regime. But given the small size of South, extra innovations generated are likely to be few. The loss from monopoly distortion for additional 15 years is almost guaranteed to dominate the benefit from the extra innovation.”

5. Examples of effects of IPRs on competition and welfare

As earlier stated, a proper balance is required between the monopoly granted to IP holders and the needs of the public to use the inventions. The upward harmonization of IP standards has shifted the balance adversely for the public interest and for development needs in developing countries. Recent developments in developed countries have also tilted the balance much more towards the IP holders. There have been adverse effects on competition as well as consumer access. Below are examples.

(a) Effects on competition and market structure

The monopoly provided by patents enables the patent holder to block or otherwise discourage rival firms entering the market, or even in some cases to undertake research and innovation. This may be justified if the patents are given correctly, and for the right duration, and moreover if the IP holder does not abuse his right (for example by harassing competitors).

The trend in some developed countries in relaxing the criteria, standards or practice of granting patents, and the practice of some companies owning patents in harassing rivals is increasing the anti-competitive effects of IPs. The study by Jaffe and Lerner (2004) provides useful insights. The number of patents tripled from 1983 to 2002 (from 62,000 to 177,000), accompanied by a proliferation of patent awards of dubious merit, for example “inventions” that are not new or are trivially obvious. There has also been a corresponding explosion in patent lawsuits. One recent trend is that an established firm with many patents demands rivals to take out licenses to its patents and many of the rivals choose to settle rather than fight (even if they do not believe they infringe) as they do not have the means to fight expensive cases. Many large companies engage in this patent enforcement activities as a line of business; for example, Texas Instruments is netting almost \$1 billion annually from patent licenses and court settlements due to an aggressive enforcement policy, and in some years this source of revenue has exceeded net income from product sales. Besides paying royalties, the small firms may reduce their R and D investment, shying away from innovations in areas where big firms have patents. Thus, the effect is the suppression of innovation by younger and smaller firms, and the reduction of competition in the market. A second trend is the emergence of individual

inventors who hold up established firms. The individuals have been granted patents of dubious validity, with overly broad claims. The established firms often choose to settle rather than face the uncertainty of a court case.

One example of a “trivial” patent affecting competition is the case of giant jam and jelly maker J.M. Smucker (which holds a patent for a “sealed crustless sandwich” with fillings in between pieces of bread) threatening to sue Albie’s Food, a small grocery in Michigan state U.S. for selling crustless peanut butter and jelly sandwiches. The case went to federal court, with Albie arguing that this type of sandwich had been popular in Michigan since the 19th century. Eventually the two parties reached a settlement. Other examples of dubious patents are “method for exercising a cat” and “method of swinging on a swing.” According to Jaffe and Lerner (2004: p 34-35), the US Patent Office has become so overtaxed and its incentives so skewed to granting patents that the tests for novelty and non-obviousness (to ensure only true inventors get patents) have become largely non-operative. Simultaneously, changes in the court system have made patents more powerful legal weapons than they used to be, with a patentee more likely to win an infringement suit against a broader array of possible infringers than before. “The result has been a dangerous and expensive arms race, which now undermines rather than fosters the crucial process of technological innovation.”

Jaffe and Lerner proposes that the way to get the system back on track is to restructure the incentives of all the parties (patent office, potential applicants, other inventors, and patentees) to reduce the flow of applications, improve the rigor of examination and reduce the incentive to use patent litigation as a competitive weapon.

(b) Effects on competition, prices and access to essential goods

The monopoly rights granted to patent holders enables them to restrict competition and charge monopoly prices. Proponents of IP point to the need for innovators to recoup the cost of research, and thus a mark up on normal profits is needed. However, critics claim that in some cases the balance is tilted in favour of the patent holders, who make excessive or even exorbitant profits by over-charging consumers excessively high prices, even after taking account of the need to recoup research costs. In order for policy makers to be able to judge whether the balance is struck, or how far it has been missed, it is important to be able to obtain data on costs and prices from the companies that hold the patents.

In medicines, the effect of patent monopolies on prices is demonstrated by data that compare prices of patented/branded and generic products; the prices of the same product sold in different countries; and the prices of raw materials used in producing medicines in the open competitive market and in transfer-pricing practices of TNCs. The following are some conclusions.

(i) Prices of branded or patented products are often far higher than prices of generics. A comparison of HIV/AIDS medicines in 2001 show that the US price of 3TC (lamivudine)

by Glaxo was \$3271 per patient per year while the Indian generic producer Cipla's price was \$190. For viramune (nevirapine), the branded product sold in the US for \$3,508 while the Cipla generic price was \$340 (Kavaljit 2001).

(ii) When generic competition is introduced, prices of the patented product will fall. For example, the drug simvastatine was sold in branded version in Malaysia (where there was no generic competitor) for \$1050 per 100 units; in India the same brand was sold for \$18 as there was a generic competitor which sold for \$11. (K. Balasubramaniam 2002). In Brazil, when the government started producing generic versions of AIDS drugs, the prices of equivalent branded products dropped by 79%. (Medicins sans Frontieres 2001).

(iii) When a drug company sells the same product in different countries, it differentiates the prices according to "what the market can bear." Where alternative or generic medicines are available, a branded product is usually priced lower; the same brand will sell at higher price levels in countries where there is no competition. The same brand zantac sold cheaply in India (\$2 for 100 tablets) because it faced generics competition. It sold at \$3 in Nepal, \$9 Bangladesh, \$30 Vietnam, \$37 Thailand, \$55 Malaysia, \$61 Sri Lanka, \$63 Philippines and \$183 Mongolia. It also sold at \$23 in Australia, \$77 Canada, \$196 Chile, \$132 El Salvador, \$150 South Africa and \$97 Tanzania. (Health Action International 1998).

(iv) TNCs practice transfer pricing in the trade of raw materials used in the drugs, raising the cost of medicines in developing countries. A study in Pakistan found that TNCs exported raw materials to their subsidiaries in Pakistan at much higher prices than the prices of the same raw materials if purchased from the open international market at competitive rates. In the case of a drug produced by a German company, the price for raw materials charged to the company's subsidiary in Pakistan was \$11,092 per kg whereas the competitive international price was \$320, a price difference of 3,360%. An Italian company charged its Pakistan subsidiary for raw materials at a price 7.044% more than the international market price.

(v) Some surveys show that drug companies can charge more in developing countries than in developed countries for the same branded products. For example, in 1998, retail prices of 10 out of 13 commonly used drugs were higher in Tanzania than in Canada; the average retail prices of 20 commonly used drugs in 10 countries of Central and South America were all higher than the average retail prices of the same drugs in 12 OECD countries (Health Action International 1998).

(c) Patenting of lifeforms

An example of abuse of the patent system is in the patenting of biological resources and the misappropriation of these resources and associated traditional knowledge. The patenting of these resources can lead to monopolization of these resources by corporations mainly of developed countries, thereby affecting the competitiveness of developing countries.

Article 27.3(b) of TRIPS lacks clarity as to the rationale of differently treating categories of life forms as to their possible exclusion from patentability. There is an artificial distinction made between plants and animals (which may be excluded) and micro-organisms (which may not be excluded); and also between “essentially biological” processes for making plants and animals (which may be excluded) and non-biological and microbiological processes (which may not be excluded).

TRIPS thus obliges WTO members to grant patents for micro-organisms and non-biological and micro-biological processes for the production of plants and animals. There is no reason why these have been singled out for patentability, whereas members are given the discretion to prohibit patents on plants and animals, and on biological processes.

By stipulating compulsory patenting of micro-organisms (which are natural living things) and microbiological processes (which are natural processes), the provisions of Article 27.3 contravene the basic tenets on which patent laws are based: that substances and processes that exist in nature are a discovery and not an invention and thus are not patentable. Moreover, by giving Members the option whether or not to exclude the patentability of plants and animals, Article 27.3(b) allows for life forms to be patented.

In recent years, there has been a great patent race among companies and institutions (mainly in developed countries) to obtain patents for genes, microorganisms and other biological substances. This "gene patent rush" was the subject of an investigation by GeneWatch UK and The Guardian (London), and the Guardian published a special report on The Ethics of Genetics on 15 November 2000. Using a comprehensive commercial database, its study covered the patents on DNA sequences (partial and complete gene sequences) in 40 patent authorities worldwide including the US, European, World, Japanese and German patent offices.

The investigation found that as of November 2000, patents were pending or had been granted on more than 500,000 genes and partial gene sequences in living organisms. Of these, there were over 9,000 patents pending or granted involving 161,195 whole or partial human genes in early November 2000. The remainder of the genes where patents are pending or granted are related to plants, animals and other organisms.

This “gene patent rush” indicates that the corporations believe they can make substantial profits from owning patents to genes and micro-organisms. However, people in developing countries are adversely affected. Most of the patents are to institutions in developed countries and they obtain the monopolies and the benefits. The granting of patents prevents developing countries not having the patents from making use of the patented materials. Moreover, many of the genes and micro-organisms may originate in developing countries, and thus “misappropriation” or biopiracy is taking place. Also, the genetic material may be inserted via vectors such as bacteria into plants and animals, and all these living things (the genetic material, the genetically-modified bacteria, and the

genetically-modified plants and animals) may then be patented. The result is a concentration of ownership of patents and a concentration of the benefits from owning the patents in a few people or institutions, with detrimental effects on competition and on social and economic situation (including food security and livelihood of farmers) especially in developing countries.

(d) Agriculture, biological resources and traditional knowledge

Before TRIPS, developing countries were able to deal with agriculture, food and genetic resources in their own way. Several countries excluded agriculture and food from IP protection. However, TRIPS Article 27.3(b) provides for protection of plant varieties by either a patent, a sui generis system or a combination of both.

In several developed countries, patenting of plants, plant varieties and traditional knowledge associated with their use is already taking place. In that process, “biopiracy” or the misappropriation of biological resources and traditional knowledge is taking place, as plants and seeds originating in developing countries are being patented, usually without the knowledge or consent of these countries of origin.

According to ActionAid (1999), between 1985 to 1999, about 11,000 patents on plants had been registered in the US. In the European Union, patent law has been extended to microorganisms and genes of plants, animals and humans. Thus, if a company has a patent on a gene from a rice variety, it can obtain a patent on new rice plants engineered with that gene.

The ActionAid study stated that techniques to decode and identify the best plant genes are accelerating and the biotechnology industry is racing to map the genomes of the world's staple food crops with a view to patenting the vital and most interesting genes. The farmers of developing countries that developed the world's food crops would have no effective rights over the varieties, due to the patenting being carried out by the transnational companies. According to the study: "Only 10 per cent of seed is bought commercially in the developing world and many poor farmers buy seed only once in five years... We believe the right to livelihood--a basic human right--is threatened by patents on life in food and agriculture. Our analysis is that these patents pose a threat to farmers' livelihoods and global food security. They may decrease farmers' access to affordable seed, reduce efforts in public plant breeding, increase the loss of genetic diversity and prevent traditional forms of seed and plant sharing."

The study also found that companies were seeking patent protection on gene sequences, proteins, plants and seeds. Three quarters of patents on plant genes were by the private sector, and almost half of 601 patents on plant DNA were filed by just 14 multinational companies. The study commented: "Although patented plants and genes may have evolved in developing countries, there is no system of informed consent to notify the communities involved of the intentions of genetic collectors. This is the case even if the

"invention" relies upon the knowledge and insight of local people. This is characterised by countries in the developing world as '*theft*' of knowledge and natural living material."

In assessing cases of patents involving "biopiracy", the study lists in two tables patents that have been claimed for naturally occurring compounds, genes or gene sequences with a variety of functions. They include:

(i) 62 patents on genes or natural compounds from plants which are traditionally grown in developing countries. The plants include rice (34 patents), cocoa (7), cassava (2), millet (1), sorghum (1), sweet potato (2), jojoba (3), nutmeg, camphor and cuphea (4), and rubber (8); and

(ii) 132 patents on genes in staple food crops which originated in developing countries but which are now grown globally. The crops include maize (68 patents), potato (17), soybean (25) and wheat (22).

In some of those countries where there are patents on plant varieties, farmers are being prosecuted for alleged violation of IPRs. These developments could be reproduced in developing countries in the future.

A report by the Center of Food Safety based in Washington (January 2005) documents how American farmers have been impacted by litigation arising from the use of patented genetically engineered crops produced by Monsanto. The report notes that, to date, Monsanto has filed lawsuits against 147 American farmers and the company has a staff of 75 devoted solely to investigating and prosecuting farmers. The report expresses concern that in its quest to be source for staple crop seeds in this country and around the world, the company will overturn centuries-old farming practices through lawsuits. The largest recorded judgment that was found thus far in favor of Monsanto as a result of a farmer lawsuit is US\$3,052,800 farmers have paid an average of US\$412,259 for cases with recorded judgments. Many farmers have to pay additional court and attorney fees as well as costs of the company.

The study found that farmers even have been sued after their fields were contaminated by pollen or seed from someone else's genetically engineered crop; when seed from a previous year's crop has sprouted, or "volunteered," in fields planted with non-genetically engineered varieties the following year; and when they never signed Monsanto's Technology Agreement but still planted the patented crop seed. In all of these cases, because of the way patent law has been applied, farmers are technically liable. It does not appear to matter if the use was unwitting or if a contract was never signed.

According to a press report (Inter Press Service 14 January 2004), a Tennessee farmer named Kem Ralph spent four years in jail for saving and replanting Monsanto's Roundup Ready soy seed in 1998 and he also had to pay the company 1.8 million dollars in penalties. The report says that even if a farmer decides to stop using Monsanto seeds, the GE plants self-seed and some will spring up of their own accord the following year. These unwanted "volunteers" can keep popping up for five or more years after a farmer

stops using the patented seeds. Under U.S. patent law, a farmer commits an offense even if they unknowingly plant Monsanto's seeds without purchasing them from the company. Other countries have similar laws.

In the case of Canadian farmer Percy Schmeiser, pollen from a neighbour's GE canola fields and seeds that blew off trucks on their way to a processing plant ended up contaminating his fields with Monsanto's genetics. The trial court ruled that no matter how the GE plants got there, Schmeiser had infringed on Monsanto's legal rights when he harvested and sold his crop. After a six-year legal battle, Canada's Supreme Court ruled that while Schmeiser had technically infringed on Monsanto's patent, he did not have to pay any penalties. Schmeiser says it cost 400,000 dollars to defend himself. Another North Dakota farmer, Tom Wiley, said: "Farmers are being sued for having GMOs on their property that they did not buy, do not want, will not use and cannot sell."

The reports above show a trend in developed countries that may be replicated in other countries, including the developing countries, should these countries also adopt particular systems of plant varieties protection.

Developing countries that do not want to allow patents for plant varieties may wish to introduce their own version of *sui generis* protection, which provides for the rights of farmers. However, there may be pressures placed on them to accept a certain definition and model of a "sui generis system" for plant varieties protection. These pressures may be partly caused by the lack of clarification as to the flexibility that Members, especially developing country Members, may have in instituting their own sui generic system of protection.

(e) Patents and the transfer and use of technology

It has been argued that higher standards of IP can lead to transfer of technology as foreign firms would be encouraged to invest in developing countries and make use of their technologies. However, there is also a counter-argument that foreign firms that have obtained patents in developing countries are able to make inroads and profits in these countries without having to produce the patented products there, as they can import the products and sell them at monopoly prices.

On the other hand, there are several ways in which a strong IPR regime can hinder access of developing countries to technology (See Khor 2002: p87-101). Obstacles to technology transfer make it difficult for developing countries and their firms to upgrade productivity which is necessary for them to compete successfully. They thus impede competition.

Firstly, a strict IPR regime can discourage research and innovation by locals in a developing country. Where most patents in the country are held by foreign inventors or corporations, local R&D can be stifled since the monopoly rights conferred by patents could restrict the research by local researchers. Strict IPR protection, by its apparent bias, may actually slow the pace of innovation in developing countries, and increase the knowledge gap

between industrial and developing countries. In such situations, the IPR system favours those who are producers of proprietary knowledge, vesting them with greater bargaining powers over the users (Oh 2000). The CIPR report (2002: p126-130) also provides analysis and examples of how the patent system might inhibit research and innovation.

As pointed out by Dr Gahuur Alam (1999): "The proposed changes to the IPR policies of developing countries have raised a number of important issues. One of the most important of these is the likely impact of these changes on a developing country's ability to undertake research and development in agriculture. We are particularly concerned about the impact of a strong IPR system on research aimed at the development of new plant varieties and genetically engineered plants." In relation to biotechnology research, Dr Gahuur states: "The research in this area is completely dominated by firms in developed countries, while public sector research institutions (both international and national) are very weak. The adoption of an IPR system which includes patents for biotechnology based techniques and products will be extremely detrimental to local research. As our study of cotton and rice research in India has shown, most of the important techniques and genes used in the development of genetically engineered plants are already owned by firms in developed countries. As these patent rights are not applicable in developing countries, local researchers are able to undertake research on local problems. However, once these rights become applicable in developing countries, research and its commercialisation will face serious problems."

Secondly, a strict IPR regime makes it difficult for local firms or individual researchers from developing or making use of patented technology.

Thirdly, should a local firm wish to "legally" make use of patented technology, it would usually have to pay significant amounts in royalty or license fees. As pointed out earlier, TRIPS increases the leverage of technology-suppliers to charge a higher price for their technology. Many firms in developing countries may not afford the cost. Even if they could, the additional high cost could make their products unviable. Moreover, there could be a large drain on a developing country's foreign exchange from having to pay foreign IPR holders for the use of their technology. Many developing countries with serious debt problems will be unable to afford to pay the cost of using the technologies.

Fourthly, even if a local firm is willing to pay the commercial rate for the use of patented technology, the patent holder can withhold permission to the firm, or impose onerous conditions, thus making it impossible or extremely difficult for the technology to be used by the firm. Patent holders can refuse to grant permission to companies in the South to use the technologies, even if they are willing to pay market prices; or else the technologies may be made available at high prices (due to the monopoly enjoyed by the patent holders). Companies in the South may not afford to pay at such prices, and if they do their competitiveness could be affected.

An example of IP hindering technology diffusion to developing countries was the experience of some Indian firms in trying to produce substitutes for chloroflourocarbons (CFCs), chemicals used in industrial processes as a coolant, that damage the atmosphere's

ozone layer. Under the Montreal Protocol, countries have committed to phase out the use of CFCs and other ozone-damaging substances by certain target dates.

Under the Montreal Protocol, developed countries originally agreed to eliminate production and use of CFCs by the year 2000, whilst developing countries are given a ten-year grace period to do the same. A fund was set up to help developing countries meet the costs of implementing their phase-out, and the protocol's article 10 provides for technology transfer to developing countries. Each Party is obliged to take every practical step to ensure that the best available and environmentally safe substitutes and related technologies are expeditiously transferred to developing countries, under fair and most favourable conditions.

A study of the effect of IPRs on technology transfer in the case of India in the context of the Montreal Protocol has been conducted by Watal (1998). She points out that technology transfer provisions in the Montreal Protocol are particularly relevant for developing countries which are producers of ozone-depleting substances (ODS), such as India, Brazil, China, South Korea and Meico. In India, Korea and China, such production is dominated by local-owned firms, for which the access to ozone friendly technology on affordable terms has become a central issue of concern. The study concludes that: "Efforts at acquiring substitute technology has not been successful as the technologies are covered by IPRs and are inaccessible either on account of the high price quoted by the technology suppliers and/or due to the conditions laid down by the suppliers. This would require domestically owned firms to give up their majority equity holding through joint ventures or to agree to export restrictions in order to gain access to the alternative technology." Moreover, financial assistance to acquire the technology was also not effective.

The study also showed how the attempts by Indian companies to manufacture HFC 134a (an approved substitute for CFCs, used as a coolant in the refrigerators and air-conditioners (RAC) were blocked by the foreign holder of the patents. Only a few companies in the developed countries control the patents and trade secrets related to HFC 134a, and thus developing countries either have to pay high royalty fees to produce them locally or lose the local and international markets for this alternative. One of the Indian companies that sought to access the technology was quoted a very high price of US\$25 million by a transnational company that produces HFC 134a and that holds a patent on the technology. The supplier also proposed two alternatives to the sale, that the Indian firm allow the supplier to take majority ownership in a joint venture to be set up, or that the Indian firm agree to export restrictions on HFC 134a produced in India. Both options were unacceptable to the Indian company, whilst the quoted price was also unrealistically high as it was estimated that the technology fee should at most have been between US\$2 to \$8 million and not the quoted level.

6. Policies and methods to prioritise competition principles in relation to IP

There are several measures that countries can take to give higher priority to competition principles in relation to intellectual property. Below is a discussion on some of them.

Limit the granting of IPs according to correct criteria

The wrong granting of IP extends monopoly rights needlessly or to the wrong parties, and thus widens the extent of anti-competitive behaviour and market distortions. Perhaps the most important measure to promote competition principles vis-à-vis IP is that governments institute policies that enable or ensure the appropriate granting of IPRs and that the proper conditions are set (for example with regard to duration of patent, copyright, etc). The nature of appropriateness of the grant should be in accordance with the need to attain the right balance between the need for incentives for the right holder, and society's need for access and use of the inventions.

The examination and granting of patents should be in accordance with the principle that they be provided for inventions and not discoveries, and that they meet the criteria of inventive step, novelty and industrial applicability. Thus, patents that do not meet these tests should not be given. An efficient system should be in place to ensure this. For example, applications for trivial or frivolous patents should not be treated favourably. Patents should also not be given for biological materials that are naturally occurring. Moreover, patents should not be given for genetic resources or associated traditional knowledge that belong to other parties or that are in the public domain. For that purpose, the patent regime nationally and internationally should require that applications in this area should be accompanied by disclosure of sources and countries of origin, evidence of prior informed consent of such sources of origin, and evidence of adequate access and benefit-sharing arrangements.

A useful set of guidelines is provided in CIPR (2002: p49, p114) which states that the underlying principle in developing country legislation should be to aim for strict standards of patentability and narrow scope of allowed claims, with the objective of: limiting the scope of subject matter than can be patented; applying standards such that only patents which meet the requirements for patentability are granted and that the breadth of each patent is commensurate with the inventive contribution and the disclosure made; facilitating competition by restricting the ability of the patentees to prohibit others from building on or designing around patented inventions; providing extensive safeguards to ensure that patent rights are not exploited inappropriately; and considering the suitability of other forms of protection to encourage local innovation. The CIPR report also provides details on the implementation of each of the objectives

The duration to be given to patents, copyright and other IP should be appropriate in that it be sufficient to enable the innovator to recover the costs of research and innovation but not so much as to enable excessive profits. Prices can be regulated to ensure that the right of consumers to access to essential good and services is respected.

Providing for and making use of exceptions, exemptions and limitations

There should be policy space, especially for developing countries to have adequate provisions for exceptions, exemptions and limitations to IPs in accordance with development needs and requirements, and the rights to access of essential goods and services.

Where such exceptions and limitations exist or are allowed in international laws such as TRIPS, developing countries should make use of them. This would reduce the extent of monopoly and increase the extent and scope of competition in the economy, as well as catering to the fulfillment of rights and access to essential goods and services.

Organisations like WTO, WIPO and other UN agencies should provide technical assistance to developing countries on how to make use of the exceptions, exemptions and limitations allowed by international laws, by incorporating them in domestic law and thereafter in practice.

Existing international laws should be examined for whether the exceptions, exemptions and limitations are adequate in providing the necessary balance, and to allow the fulfillment of rights and access to essential goods and services. The review should then result in the appropriate clarifications and amendments. Negotiations for new IP-related treaties or new provisions or amendments to existing treaties should fully take these factors into account. Bilateral and regional trade/economic arrangements should not have TRIPS-plus provisions.

The proper design and implementation of flexibilities

Besides exceptions, international frameworks should also contain adequate flexibilities especially for (but not limited to) developing countries to enable or even encourage them to take measures that may be required to offset IPRs that are granted. Such measures are meant to uphold the principles of competition and meeting the needs of access to essential goods and services.

Among these safeguard measures are compulsory licensing, parallel importation and government and non-commercial use. Technical assistance should be provided in (i) raising the knowledge of developing countries and their institutions about their existence, rationale and use, (ii) instituting them in national law and (iii) implementing these measures.

The existing international treaties should also be examined for their adequacy in providing for these safeguard measures, and clarifications or amendments made to strengthen these where needed. Negotiations for new treaties should fully take into account the need for adequate safeguards. Bilateral and regional trade and economic arrangements should not contain provisions that restrict the flexibilities that are allowed by international treaties such as TRIPS.

At the national level, governments should review existing legislation to fully incorporate the flexibilities that are allowed, and then institute policies and mechanisms to implement them,

Competition principles and legal provisions in laws relating to IP and beyond

Pro-competition principles and measures that exist in IP related international treaties should be fully recognized and appreciated and technical assistance should be provided to developing countries to enable them to be aware of these and to incorporate them where possible in national legislation, policy and practice.

For example, Article 8.2 of TRIPS under general principles states that appropriate measures (consistent with the agreement's provisions) may be needed to prevent abuse of IPRs by right holders or the resort to practices which unreasonably restrain trade or adversely affect technology transfer. As pointed out in Roffe (1998), while licensing is a legitimate activity of IPR holders and in most cases can be seen as pro-competitive in legitimizing access to technology to third parties, these activities may also (as noted by the OECD) be "anti-competitive where they are a mere sham for a cartel arrangement, where they restrict competition between technologies that are economic substitutes for one another or where they exclude new technologies from the market."

Section 8 of TRIPS on "Control of anti-competitive practices in contractual licenses" has an Article 40 that recognizes that some licensing practices or conditions pertaining to IPRs which restrain competition may have adverse effects on trade and impede technology transfer and dissemination. Article 40.2 says that nothing in the agreement shall prevent members from specifying in their legislation licensing practices or conditions that abuse IPRs, having adverse effect on competition, and a member may adopt appropriate measures to prevent or control such practices, including exclusive grantback conditions, conditions preventing challenges to validity and coercive package licensing, in light of relevant laws and regulations of that member. Article 40.3 also provides for consultations and cooperation among members (including through supply of non-confidential information) to deal with IPR owners that are undertaking anti-competitive practices in violation of a requesting member's laws.

Several developed countries have laws or regulations that hold certain anti-competitive practices as *per se* unlawful. (See Watal 2001: p304-309). The US Antitrust Guidelines for the Licensing and Acquisition of IPRs 1995 states that among the restraints that have been held *per se* unlawful (by courts in the past) are naked price-fixing, output restraints and market division among horizontal competitors, as well as certain group boycotts and resale price maintenance. To determine whether a particular restraint in a licensing arrangement is given *per se* or rule of reason treatment, the agencies will assess whether the restraint will contribute to an efficiency-enhancing integration of economic activity. The EC in its Technology Transfer Block Exemption Regulation, 240/96, (effective 1996) in general has 8 categories on its black list including restrictions relating to price or

output, competing markets, exports to territories within the common market, customer allocations, R&D activities or full grantbacks of license improvements. Japan's Guidelines for Regulation of Unfair Trade Practices with respect to Patent and Know How Licensing Agreements (introduced in 1989) treats 5 types of restrictions as unfair trade practices, unless specific justification can be shown to the contrary; these are restrictions on domestic prices of patented goods, prohibitions on handling or using competitors' goods or technology or requirements on payment of royalties after license expiry, R&D restrictions and exclusive grant back requirements. Some Commonwealth countries, following the UK, have a provision in their patent laws that certain anti-competitive practices in patent licenses are automatically deemed to be null and void. For example, Australia's Patents Act 1990 holds invalid any conditions that restrict the licensee from purchasing or using a product or process supplied by the licensor's competitors or that requires the licensee to acquire a product not protected by the patent from the licensor; in addition the Australian Trade Practices Act 1974 specifically prohibits 5 activities: anti-competitive agreements (including price fixing and exclusionary provision), misuse of market power, exclusive dealing, resale price maintenance, mergers and acquisitions with a substantial lessening of competition.

According to the above regulations, the mentioned features in contractual IP licenses are anti-competitive *per se* and thus deemed lawful in general; thus it would not require a case-by-case examination to determine whether the mentioned activities are anti-competitive.

Following the example of developed countries, developing countries should specify anti-competitive conditions in IPR licenses to be *per se* null and void. As seen from the above examples, there is leeway for countries to determine what licensing conditions can be considered to have anti-competitive effects *per se* and this flexibility should be retained. However, as pointed out in Watal (2002: p307), in many cases it is not the restrictive nature of IPR licenses that are a cause of concern but the outright refusal to transfer technology without other cross licensing arrangements, to which developing country enterprises may have no access. Also, the question as whether refusal to deal or license a patent by the right holder can be considered a patent misuse, has to be clarified. Roffe (1998) provides a useful account of the evolution of international negotiations in and outside the TRIPS agreement, on restrictive practices, and their implications for interpreting and implementing TRIPS.

There are other provisions in TRIPS that deal with competition issues. For example, Article 31 on use of patents without authorization of the right holder, has a sub-paragraph (k) relating to anti-competitive practices. If a compulsory license is granted to remedy a practice determined after judicial or administrative to be anti-competitive, the obligations in subpara (b) (that before a compulsory license can be given, efforts have to be made to obtain voluntary license) and in subpara (f) (that a compulsory license has to predominantly for the supply of the domestic market) are waived. Moreover "the need to correct anti-competitive practices may be taken into account in determining the amount of remuneration in such cases" and authorities can refuse termination of authorization if and when conditions which led to such authorization are likely to recur. Developing

countries should include this pro-competitive safeguard provision and measure in their national legislation and policy.

Generally, it would be important for developing countries to incorporate the pro-competition principles and elements in their national laws and regulations relating to IP. Moreover, they should establish provisions within national competition law and regulations that prohibit anti-competitive practices in IP-related licenses, as referred to above.

8. Brief Conclusion

The present IP system, international and national levels, should be evaluated in light of the crucial need for “balances” in the IP system, to enable both innovation and the meeting of the public interest and development needs.

In recent years, this balance has shifted worldwide too much to the side of IP holders in both international IP frameworks and in national law or practice of many countries.

This is of concern particularly for developing countries as the characteristics and conditions of such countries make them especially susceptible to adverse effects.

The global harmonization of IP laws (towards the standards and practices of developed countries), especially through the WTO, WIPO and bilateral/regional agreements, has contributed to the imbalances and the spread of conditions that make it more difficult for developing countries and their enterprises and institutions to compete.

Thus, a review of the international IP frameworks is required to determine the sources of the imbalances, while a review of national frameworks are also required so that the existing flexibilities can be properly made use of.

Meanwhile, further harmonization initiatives at international level should be reviewed in light of the need to regain balance.

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