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RIS Policy Briefs

Cancun Agenda: TRIPs and Development

Implications and an Agenda for Action

Implications of the TRIPs Regime for Developing Countries

The international environment with respect to intellectual property has changed considerably with the conclusion of the TRIPs Agreement in the Uruguay Round. The TRIPs Agreement accommodates the demands of the industrialized countries for higher international standards of protection by mandating the extension of patentability to virtually all fields of technology recognized in developed country patent systems, by prolonging the patent protection for a uniform term of twenty years, and by providing legal recognition of the patentee's exclusive rights to import the patented products. The patent rights are enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced. All the signatories to the trade negotiations are, therefore, obliged to adhere to the minimum standards prescribed by TRIPs Agreement and to provide product patents for pharmaceuticals and chemicals. The coverage of the patent protection has also been expanded by the provision for patents on micro-organisms and protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof.

The full implementation of the TRIPs Agreement is likely to have an important bearing on the patterns of development in developing countries. This Policy Brief reviews some of the important dimensions of these effects and in their light makes some proposals for action at the international and national level to minimize the adverse effects of TRIPs for developing countries.

Local Technological Capability Building

The strengthening and harmonization of IPR regimes worldwide has considerable implications for the process of acquisition of local technological capability by developing countries. The provision of product patents on chemical and pharmaceutical products, for instance, would adversely affect the process of innovative activity of the developing country enterprises in the manufacture of chemicals covered by patents. The development of new chemical compounds is generally beyond the capability of most developing country enterprises in view of the huge resources involved. Therefore, they focus attention on process innovations for the known chemicals and bulk drugs. This imitative duplication or reverse engineering activity is an important source of learning in developing countries. Indeed, most industrialized countries of today and newly industrialized countries encouraged local learning through soft patent laws and the absence of product patents in chemicals in the early stages of their development as highlighted earlier. It means that the poorer countries of today will not be able to benefit from an important source of total factor productivity growth (viz. absorption of spillovers of foreign inventions) that was available to countries that have developed already. In that respect the TRIPs Agreement is highly inequitable. The probability of stronger IPR regime encouraging innovative activity in developing countries is very small.

Industrialization, Technology Transfers and Trade

Recent trends suggest a reversal of trend of the growing importance of arm's length licensing as a mode of technology transfer as MNEs prefer to internalize the technology transactions. The strengthening of IPRs regime may further limit the access of technology by developing country enterprises. Studies have documented a number of examples of developing country enterprise being denied technology licenses by patent holders in the Western world forcing them to reverse engineer the products. A number of local enterprises in developing countries will come under pressure to close down or form alliances with larger firms, resulting in a concentration of the industry. Dependence on imports may go up. Studies, for instance, find that TRIPs could affect import volumes significantly; e.g. in Mexico, the anticipated rise in manufactured imports could be of the magnitude of $ 6.3 billion, amounting to 9.4 per cent of its real manufactured imports in 1995.

Prices of Medicines and Loss of Consumer Welfare

A number of studies have examined the effect on prices of medicines after introduction of product patents and have simulated welfare losses for consumers in developing countries. It is widely believed that drug prices will go up upon introduction of product patents as happened in China which introduced them in 1993. A study finds the welfare losses to 6 developing countries (Argentina, Brazil, India, Mexico, Korea and Taiwan) from introduction of product patents to be between US$ 3.5 billion to $10.8 billion depending upon the assumptions. The gains to the patent owners from such introduction would range between $ 2.9 billion to $ 14.4 billion. The welfare loss

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RIS 20 Years (1984-2004)

to India could be between $ 1.4 billion to $ 4.2 billion in a year. Another study simulates the likely increase in pharmaceutical prices and decrease in welfare in India with the introduction of product patents in 22 existing pharmaceutical products and finds that weighted mean drug price in India could increase between 26 per cent to 242 per cent while another one estimates the range of price increase between 182 to 225 per cent. That suggests that introduction of product patents would affect prices of medicines significantly and unless new drugs are more efficient, there will be a decline in the health levels of population. The recent case of huge differences between prices of HIV Aids drugs sold by patent holders in South Africa and their generic substitutes just provides a further evidence to the potential of price increases following the introduction of product patents. It may be argued that the vast majority of drugs are out of patent protection and hence will not be affected. Yet the AIDS drugs controversy shows that effective treatment for many of scourges of the day such as cancer, cardiac failures, renal problems, among others, may be affected.

Income Transfers from Developing Countries

Given the near complete domination of developed countries on technology generation as evident from the 95 per cent ownership of US patents, the strengthening and harmonization of IPRs regime will lead to a substantial increase in flow of royalties and license fees from developing countries to developed countries. Studies suggest that the net patent rents derived by the US for the year 2000 (in current US$) could add up to over $ 19 billion, to Germany $ 6.7 billion, and Japan $ 5.7 billion. Among the developing countries, China could see an outflow of patent rents of the order of $5.1 billion, India $ 903 million, Israel $ 3.8 billion.

Furthermore, the extension of IPRs to plant varieties could further increase the outgo of royalties for the breeder lines of the seed companies even though the basic raw material for the development of these varieties, viz. genetic diversity which is largely found in developing countries and is based on the work of generations of farmers in these countries, is generally available to them free.

Impact on Global Technological Activity and Availability of Drugs

One of the arguments in favour of a stronger IPR regime is based on the premise that expenditures on R&D were significantly determined by appropriability conditions. Hence, ensuring adequate appropriability with more stringent IPR protection was deemed to be a necessary condition for sustaining the pace of innovation in the global economy. The empirical literature, however, does not support this presumption as patent protection was found to be instrumental for only a small proportion of innovations. On the other hand, studies show that spillover effects of R&D activity of other firms to be a lot more important in inducing firms to undertake R&D compared to appropriability. The R&D outputs of other firms form valuable inputs for the R&D efforts of these firms. Hence, tightening of IPRs is likely to affect innovative activity adversely by stifling these spillovers. Therefore, it is by no means clear that strengthening of IPRs will increase innovative activity even in the developed world especially for solving the problems and diseases faced by developing countries. Furthermore, the research priorities of MNEs are determined by the purchasing power and very little R&D is currently done on tropical diseases. Unless some steps are taken by the international community, such as those discussed by the recent report of WHO's Commission on Macroeconomics and Health (CMH), the pattern is not likely to change significantly in the future.

Issues for National and International Action

The preceding discussion suggests that the ongoing trend of strengthening and harmonization of IPR regime under TRIPs is going to affect the process of development of poorer countries in a significant manner by choking an important contributor of growth that has been variously described as imitative duplication, reverse engineering or knowledge spillovers from abroad. It is also likely to affect the prices of a large number of important drugs and thus affect the health systems in poorer countries. It would lead to income transfers from poorer to richer countries. It is likely to adversely affect the manufacturing activity in developing countries and may increase their imports but does not guarantee increased in FDI inflows, access to technology or R&D investments in tropical diseases. These challenges require a response at the national policy levels as well as a response from the international community. In what follows, we outline some of the policy responses that could help in moderating the adverse effects of TRIPs Agreement on developing countries.

Policy Responses to be taken at the National Level

Incorporating the Provisions of Compulsory Licensing in the IPR Legislation

Developing countries should build adequate provisions for compulsory licensing in their IPR legislation in order to safeguard them from possible abuses of monopoly power obtained by patent owners. The compulsory licenses are permitted under Article 31 of the TRIPs Agreement. The Agreement does not limit the grounds upon whch compulsory licenses may be granted and only sets forth the conditions to be applied in the case of granting. This includes specification of grounds of compulsory licensing and the reasonable rates of licensing fees. Recent withdrawal of proceedings by the US against Brazil's compulsory licensing provisions show that intelligently crafted domestic patent laws can meet national objectives and yet be TRIPs compatible.

Incorporating the Research Exception

Developing countries could incorporate provisions allowing researchers to use a patented invention for research, in order to understand the invention more fully. Experimentation on a patented invention is clearly admissible as an exception to exclusive rights under Article 30.

Early Working Exception or 'Bolar' Provision

It is possible to make provision for allowing manufacturers of generic drugs to use the patented invention to obtain marketing approval without patent owner's permission

and before the expiration of patent. This facilitates the generic manufacturers to market their products as soon as the patent expires. This provision is sometimes called the regulatory exception or Bolar provision under Article 8. The US, Canada, Australia, Israel and Argentina have adopted Bolar exception in their patent legislation.

Resisting the Attempts to Evolve TRIPs Plus Regime and Ever-greening of Patents

Developed countries are constantly putting pressure on developing countries to implement stricter patent legislation than required under TRIPs, exclude compulsory licensing, parallel imports provisions and include provisions that would result in increasing the life of the patent (ever-greening), as well as grant data exclusivity to them. The TRIPs Agreement however, is clear that a new use for an old formulation does not constitute an inventive step (Art. 27(1)). Therefore, member countries are within their rights not to permit the practice of ever-greening of patents.

Allowing Parallel Imports or Grey-Market Imports

Since 'exhaustion of rights' issue cannot be raised in the dispute settlement under TRIPs Agreement, developing countries should allow parallel imports or grey-market imports. The experience of several countries suggests that substantial costs savings could result from such imports because of differential pricing strategy practiced by MNEs depending upon the extent of competition in different markets.

Competition Policy

The patent system grants temporary monopolies to the firms that introduce innovations. The national competition or antitrust policies are needed to prevent the build up of excessive monopoly power of certain enterprises and to deal with possible abuse of monopoly power emanating from patent protection. The TRIPs Agreement (Articles 8 and 40, Section 8) explicitly provides for appropriate measures to prevent the abuse of IPRs or the resort to anti-competitive practices. Apparently in the US, 'compulsory licensing has been specified as a remedy in more than 100 anti-trust cases making available some 40,000 to 50,000 patents at reasonable or no royalties'.

Incorporating Breeders Exceptions and Farmers Exceptions in sui generis *Plant Variety Protection*

TRIPs Agreement allows flexibility to member countries to exclude plant varieties from the scope of patent protection and instead opt for an effective *sui generis* system. In order to minimize the adverse effect on the plant breeding programmes and protecting small and marginal farmers from buying seeds who typically save them for the next crop, developing countries could build provisions for exceptions for farmers and plant breeders. They should also participate effectively in the mandated Reviews of the Agreement under Article 27.3(b) to protect their interests.

Price Controls for Essential Drugs

To protect the poor masses from the price increases following the introduction of product patents, governments may impose regulation of prices of essential drugs. To keep the price controls effective, transparent formula for evolving them could be made providing for a reasonable mark-up over the cost. Indian experience shows that price controls have proved to be effective means of keeping prices of life saving essential drugs under check. However, given the possibility of transfer pricing manipulation, there may be complications in administering price controls for imported drugs.

Introduce Utility Models and Industrial Design Patents

The experience of several East Asian countries suggests that utility patents and industrial design patents could be effective means of encouraging domestic enterprises to undertake minor adaptive innovations and foster a innovation based rivalry among them. In any case, few developing country based enterprises will be able to generate inventions that can be patented in different countries. Utility models and industrial designs may encourage developing country enterprises, especially small and medium enterprises, to undertake minor incremental adaptations and innovations. The cumulative impact of these minor or incremental innovations on growth and total factor productivity improvement could be substantial. Besides Japan, Korea and Taiwan, they have been fruitfully employed by many countries. In Brazil, utility models helped domestic producers gain a significant share of the farm machinery market by encouraging adaptation of foreign technologies to local conditions. Developing countries could consider to introduce utility models and industrial design patents, tailored appropriately to their requirements.

Policy Responses at the International Level

The recent controversy concerning the HIV AIDS drugs in South Africa, among other factors, has helped to focus attention of the international community on the possible adverse effects of the implementation of TRIPs Agreement on poorer countries. Over the past year a number of international initiatives have been taken to deal with the matter. These include establishment of the Commission on Macroeconomics and Health by the WHO and Commission on IPRs by the British Government. WHO and WTO organized a Workshop on Differential Pricing and Financing of Essential Drugs at Hosbjor, April 2001. The Fourth Ministerial Meeting in Doha in November 2001 adopted a Declaration on TRIPs Agreement and Public Health. UNDP's *Human Development Report 2001* as well as World Bank's *Global Economic Prospects 2002* reports focused on the IPRs and their impact for developing countries. However, these initiatives are yet to lead to a concrete outcome addressing the many problems that are raised by the TRIPs Agreement. In what follows we summarize a few avenues for possible international action.

Moratorium on Further Strengthening of IPR Regime

There is tendency in some developed countries to treat provisions of TRIPs as the minimum standards and are constantly attempting to evolve stronger norms through unilateral or bilateral approaches. A consensus needs to

be built on the need to put a moratorium on such approaches for the next couple of decades or so.

Granting Flexibility to Developing Countries in Implementing the Provisions of TRIPs

Most of the adverse effects concerning TRIPs on poor countries arise not because of IPR regimes per se but from the attempt to harmonize them across the countries at different levels of development. There is also a discussion whether TRIPs should fundamentally belong to WTO. However, the least that could be done is allowing flexibility to developing countries to implement the provisions of the Agreement as and when their level of development has reached a certain stage. This could be achieved if a consensus among the developed countries is built on the differential need of developing countries for IPR regime. A possible revision of TRIPs could incorporate a provision that grants to developing countries a flexibility to implement the TRIPs obligations until they reach a certain level of development defined in terms of some objective criteria such as per capita income. One possibility in this respect is to adopt a threshold of US$ 1000 of per capita income as the Agreement on Subsidies and Countervailing Measures (SCM) adopted, as it would be easier to agree to, having been adopted in one of the WTO's Agreements. This would bring in an element of graduation in the treatment of countries as the preferential treatment would cease as they cross the developmental threshold. Another possibility could be to shorten the term of product patents applicable to low income countries. This way the Agreement would have incorporated development dimension.

Incorporating Specific Provisions for Transfer of Technology

Although transfer and dissemination of technology is an explicit objective of TRIPs Agreement (Article 7), and provides for appropriate measures to prevent practices that adversely affect international transfer of technology (Article 8), the Agreement leaves the provisions for transfer of technology quite vague. The access to technology is increasingly becoming difficult for developing countries, as observed earlier. There is need for defining conditions, norms and practices for facilitating transfers of technology for production of essential drugs and other critical inputs. A review of the Agreement could address the important issue of transfer of technology and conditions under which technologically less advanced countries could seek transfer of technology from patent owners.

International Funding R&D Activity in Low Income Countries

One of the ways of compensating the low income countries for the adverse effects of strengthened IPR regime is to provide increased technical assistance and R&D funding to local enterprises to help them build local capabilities. One possibility in this respect could be that governments of developed countries donate a sum equal to (or a substantial proportion of) technology license fees collected from low-income countries to a fund created in the respective countries to assist inventive activities of domestic enterprises. This provision will neutralize the adverse balance of payment effects of the additional income transfers resulting from strengthening of the IPR regime. In addition it will moderate the adverse effect on the local technological activity of domestic enterprises by providing additional financing for undertaking such activity.

Furthermore, there is need to address the issue of funding R&D on special problems and tropical diseases that concern low income countries. It has been widely acknowledged that global pharmaceutical industry has neglected research on tropical diseases. The CMH has recommended a donor commitment of $ 27 billion per annum for the health needs of low-income countries including $ 3 billion per annum for R&D for diseases of the poor. It is arguable that this funding of $ 3 billion could also help to moderate some adverse effects on the inventive activity in low-income countries if it is awarded to institutions and enterprises based in these countries. Therefore, an additional recommendation could be made in conjunction with those of CMH that the funds would be allocated to eligible and competent institutions and companies of low income countries.

Differential Pricing

There has been a lot of discussion on the possibility of improving the access of poorer countries to patented medicines through differential pricing. There are a number of practical issues concerned with the differential pricing that need to be resolved. However, this is certainly one of the options to be explored along with compulsory licensing, parallel imports and other measures.

Implementation of the Agreement on TRIPs and Public Health

A 31 December 2002 deadline was proposed for signing of the proposed Agreement on TRIPs and Public Health in the Doha Mandate that recognizes the supremacy of public health over IPRs and grants flexibility to poorer countries, having no domestic capability to produce, from the provisions of TRIPs. However, the Agreement could not be concluded due to pressure on the US government from its pharma industry. The US government should honour the commitment made at Doha in letter and spirit in the interest of long-term sustainability of the world trading system.

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