TRIPs and Public Health: Ways Forward for South Asia

Introduction

Trade Related Intellectual Property Rights (TRIPs) have always been one of the contentious issues at the WTO. A multilateral agreement was signed at the end of the Uruguay Round, despite the reluctance of many developing countries such as India, Brazil, etc. The growing significance of intellectual property rights (IPRs) is posing policy makers with difficult questions regarding the precise limits of state authority in respect of public health governance structures against the background of global private networks.

There are some pressing issues that policymakers in developing countries face while addressing critical public health problems, like: Are developing countries mere facilitators for the global network of private interests? Or do the governments have to redefine the way they have traditionally conceived their public health role and the mechanisms through which they are realised? According to the Commission on Intellectual Property Rights (CIPR), the global expansion of the IPR was unlikely to generate significant benefits for most developing countries. It is most likely to impose high costs such as highly priced medicines and seeds, making poverty reduction more difficult. In addition, it would also increase the cost of access to many products and technologies, diminishing the degree of competition worldwide for many products and services.

Ever since the TRIPs agreement came into being, poor countries have been suffering at the hands of patent holders. This resulted in signing of a separate declaration on TRIPs Agreement and Public Health at Doha. The declaration acknowledges the member countries' rights to protect public health and promote access to medicines for all. The declaration was a victory for developing countries.

The following paper anchors the discussion of public health and the impact of TRIPs on the social and cultural environment of South Asian region. It also tries to answer one specific question: what genuine choices do policy makers in South Asian developing countries now have, following the link between the trade regime and pharmaceuticals.

The Nature of Problem in Public Health: An Overview

Global public health governance is very much in public spotlight[1]. This is largely the result of high profile actions by the US Government and multinational companies to assert their dominance and competitive advantage in the pharmaceutical industry[2]. For example, the United States Trade Representative (USTR) was instrumental in exerting international and bilateral pressures on Brazil, Thailand and South Africa to adopt stringent intellectual property standards.

Brazil, for example, was hauled to the dispute settlement machinery in the World Trade Organisation (WTO). This action was a response to the decision of the Brazilian Government to increase supplies of its generic medicines to address the AIDS/ HIV epidemic. Brazil was handed to the dispute settlement body in the WTO because of its decision to increase supplies of generic medicines to address the AIDS/ HIV epidemic. The USTR-led initiatives were prompted by the Pharmaceutical Research and Manufacturers of America's (PhRMA) concern that this practice would lead to a serious erosion of its profits from the sale of its blockbuster drugs, which were currently on patent.

Some time back the concerted efforts by the multinational pharmaceutical companies to prevent the South African government from accessing viable alternative supply systems floundered in the domestic court[3]. In another incident, Glaxo and SmithKline (GSK) threatened CIPLA with a lawsuit. It was alleged that the Indian pharmaceutical corporation was supplying the South African government with generic supplies of products, which were manufactured in breach of GSK's patents.

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Such events suggest a growing trend where the emerging private networks of commercial interests are encroaching on the traditional measures employed to address the critical needs in public health. The asymmetries in information regarding health needs, government procurement policies, implementation of national drug policies, inadequate public health infrastructure, national wealth and barriers raised by IPRs, individually and cumulatively, pose challenges to public health governance.

Public health management involves addressing the multiple effects of the above factors and due consideration needs to be given to adopting measures in other forums like policy-making in housing, food and health safety, sanitation and education.

Issues Uncovered

There are certain issues, which seem to be marginalised in debates on TRIPs. These issues are as follows:

- First, that policy-making in public health issues has been given low priority than other national issues like defence, trade, telecommunications and services. Broadly speaking, there is a consensus amongst most governments that capitalism and market mechanism best guarantee economic prosperity. Public health goals have largely been measured in terms of economic prosperity of the nation as a whole and, in turn, shift the responsibility for health security on the individual.
- Secondly, with the increasing pressure on public resources, there has been a clear policy shift, in replacing welfare and collectivism with individual responsibility. Public choice theorists argue that governments, in formulating their national policies, are motivated less by concerns about those who constitute the minority in the electoral register and are worried more about appealing to the majority, who tend to comprise the working and affluent classes in society. Given this, the issue of access to medicine affects a small minority in the population. Therefore, it is not surprising that calls for a more socially responsible approach to public health are usually made by charitable and non-profit making organisations like Oxfam, Action Aid and MSF.
- Thirdly, governments have delegated their responsibility for research, development and distribution to the private sector. Indeed, public health management is largely directed towards maintaining the integrity of the corporate supply chain in ensuring its viability. This is important, since the interposition of the price mechanism defines the primary avenue through which medicines are now accessed.
- Fourthly, it cannot be emphasised sufficiently that public health management requires government investment and commitment, if the causes of the current problems are to be addressed.

The OECD Corporate Pharmaceutical Model

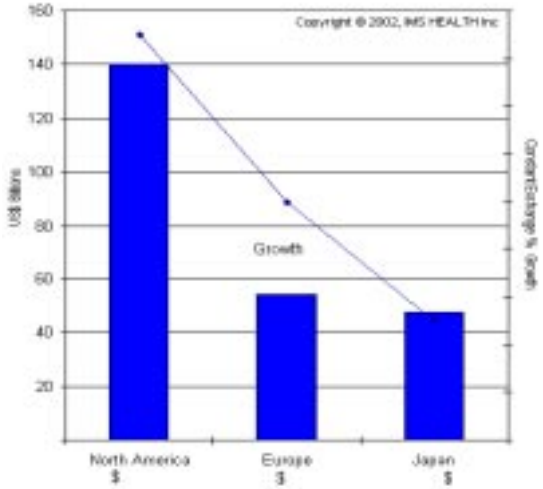
Before examining this system in detail and its implication for pharmaceuticals, we briefly summarise some of the key outcomes of health as a public good in the private sector:

- First, the emphasis by the Organisation for Economic Co-operation and Development (OECD) countries on deregulation and privatisation of the pharmaceutical sector is reflected in the view that the market and the private sector are creators of wealth, resulting in an increase in prosperity.
- Second, the obligation on the government to discharge their role as a custodian of public health is now limited to facilitating the process of establishing a sustainable and affordable supply system.
- Third, by characterising medicines as private goods, the governance structure set in place by governments makes no allowance for the concept of essential medicines. Access to essential medicines is determined by the same norms as those which apply to all consumables.
- Fourth, the equivalent of the minimal role of the government is that the primary responsibility for development, manufacture, distribution and sale is left to the private sector.

It is claimed that the economies of scale and control over the supply chain are critical to ensuring the viability of the corporate pharmaceutical model. The use of the private sector to supply health goods has also led to the emergence of a lucrative industry. Global sales have now reached US$1.3tn.

Central to the viability of the corporate pharmaceutical model in developing new medicines is the patent system. The importance attached to this property regime is illustrated by the fact that transnational corporations, like Merck, Pfizer, Glaxo-Welcome and Bristol Myers, not only own majority of patents, but

Regional Breakdown of Sales in US$bn
(12 months to January 2002)



Source: IMS Health's Drug Monitor, 2002

also are now the key actors in the global pharmaceutical industry.

The patent system is the creation of political patronage. The availability of this system is based on the premise that without appropriate incentive systems and control over the knowledge created during R&D, a sustainable and affordable system of medicines could not be made available by the private sector. For example, the pharmaceutical sector, unlike other sectors, is resource-intensive and time-consuming. It is generally understood that the discovery-to-market phase can take up to a period of 6.5 years and, results in some cases, the R&D cost of US$300mn. Doubts have been expressed whether high costs have been the result of extensive marketing and advertising incurred. This is contradicted by the pharmaceutical industry that claims that the high prices charged for its medicines reflect the cost of R&D.

A better way of approaching the relationship between the patent system and the dominance of the OECD corporate model lies in understanding the importance of standard-setting and its implications for competition and the creation of alternative supply systems. With the advances in science, multinational corporations have invested in skilled personnel and sophisticated technology to undertake research in genetic engineering, sequencing and other techniques like growth hormones and interferon. The patent system enables investment in this process of knowledge creation.

If the underlying policy were to promote technological advance and new therapeutic drugs, it would be in public interest to have a broad definition of each of the requirements for patentability. The reverse holds true if it is felt that a patent might inhibit further R&D or curb legitimate competition. Standard-setting for patentability is important since it can have important implications for competition from generic drug manufacturers. The successful application results in the creation of patent enclosures over the pool of knowledge in public domain.

Another feature about the nature and scope of the patent system is that governments tend not to provide prescriptive standards. It may be the case that, in those countries where a premium is placed on encouraging inventions, there may be willingness to embed greater flexibility in the patent system. The flexibility of the criteria of patentability makes it malleable to fit into any particular political or social mould. For example, under the UK Patents Act, 1977, an invention to be patentable must be 'new'.

The ability of the patent system to fulfil the public interest goals is dependent on government funding of a judicial and administrative system. Their importance lies in ensuring that legitimate competition is not stifled. The effect of the patent is that it vests in its right holders commercial rights of excludability in respect of the data captured by the instrument as well as the use of the product or process. The patent system enables the right holders to preserve imperfect market conditions to recoup their investment, by enabling them to charge prices above the marginal costs and maximise the economic value of the knowledge captured by the patent.

Given that knowledge management is an important part in maximising the commercial value of a patent, it might be useful to briefly outline some of the techniques employed by the corporate pharmaceutical model. It is difficult to state conclusively whether the patent system stifles future research and development[4].

Compound extraction is a common technique employed. These are mainly known compounds. If it is extracted or developed by a known method but put to a new use, patent protection may be available for that specific purpose.

Another strategy used by the industry is to alter the composition of the compounds so that it can be marketed as a superior drug or declassify particular drugs, with the approval of the health authority or any other government body so that they could be made available over the counter or repackage their delivery and distribution systems. This poses two access issues.

- First, the high prices charged may prevent those least able to access the market from purchasing the medicines directly or limit the supplies that can be acquired, owing to limited government resources.
- Second, patent enclosures may be employed strategically to prevent data from being made freely available for commercial exploitation without prior authorisation.

OECD countries have captured much of the economic gains from globalisation. There has been a commensurate rise in investment in public health infrastructure. Access to essential medicines is facilitated in most of the OECD countries through some form of public or private insurance. The increase in economic prosperity has led to a significant decrease in the levels of poverty and the types of epidemics and diseases, which are labelled as 'poverty-related illnesses'.

Globalisation, TRIPs and South Asian Developing Countries

The emergence of global privatised networks and access regimes in health care products is part of the process by which capitalism is now redefining the global landscape, traditionally dominated by sovereign nation states. The mobility of capital and the emergence of global financial networks, coupled with the pervasive nature of the industrial policies adopted in economies like the US and the EC, have an immediate significance in developing countries as they attempt to manage their domestic affairs effectively.

Comments

1. The dominance and competitive advantage enjoyed by multinational corporations from OECD countries would not have been possible without extensive support from the member governments.
2. The emergence of privatised networks in OECD countries is the result of adopting market structures and industrial policies, which marginalise the role of the government.
3. The pharmaceutical industry has a commercial, not a philanthropic, motive. Governments in OECD countries acknowledge this. At the same time, checks and balances are placed to ensure that abuses do not subvert the role of the government in promoting health security.
4. Access problems are minimised if the democratic process is allowed to function in its normal mode.
5. Standard-setting in the patentability of pharmaceutical industry is critical to determining the level of competition and the pool of knowledge that is at the disposal of competitors.

It would be a mistake to isolate the multiple effects of globalisation on national public health governance. Institutions like the World Bank and the IMF link the grant of substantial aid and liquid loans to developing countries adopting a programme of structural reform and market discipline. In the World Development Report 2003, calls have been made for these countries to adopt structural adjustment programmes. In a previous report, the World Bank was particularly critical of policy makers who defer to the protectionist industries and rent-seeking groups in their countries. For example, the report draws attention to the experience between 1990 and 1999, which, it says, illustrates the general rule stated as follows:

> *"Over that decade the number of people living in developing countries on less than $1 a day fell from 1.3 billion to 1.2 billion, and the proportion of people living in extreme poverty fell from 29 percent to 23 percent. Most of these gains were made in the two fastest growing regions – East Asia and Pacific and South Asia".*

Loan obligations and structural adjustment measures imposed as conditions for grants also impose costs, notably in the form of interest repayments and policy change. It is arguable whether any significant and effective use is made of these financial packages to eradicate poverty-related illnesses and increase access to essential medicines. More importantly, the repayment obligations are likely to reduce resources available for any projected state expenditure on public utilities and programmes. The activities of all these institutions now can be said to supplant the WHO in determining the question of promoting public health governance in a global marketplace.

In the context of TRIPs, we need to understand how the interaction of its provisions with the corporate business model potentially creates a formidable instrument for OECD industrial countries and multinational corporations. This agreement suggests that though TRIPs does mark an important change in governance structures in public health, its significance should not be overstated. This is true since member states are under no obligation to set in place systems of property protection that OECD industrial countries have in place. The only requirement is that some measure of protection is made available for 'any inventions, whether products or processes, in all fields of technology'. It means that the previous references to the growing consensus amongst all governments about the dominant role of capitalism and their recognition of the pivotal role of the corporate pharmaceutical model are too important to ignore and still leave unresolved the question of creating a viable supply system or framework for developing countries with critical public health problems.

The debate on TRIPs and the implications of linking IPRs with goods must be considered against the demographics of the crises in this region. Poverty is endemic and is often a key determinant of access, which, in turn, raises wider issues of the levels of government funding of public health and, more importantly, ensuring the effective implementation of their national drug policies. The South and East South Asian regions have at least 50 percent of the world's poor. Poverty increases the risk of poor health. For example, those who are deprived of the basic amenities like housing, sanitation and water are likely to have poor health and vulnerability increased. This susceptibility is underscored by poorly resourced public health infrastructures and the lack of national health insurance.

Non-communicable diseases, like diabetes, cardiovascular diseases and cancers, are equally problematic. The cost of addressing the public health needs through public insurance, in the absence of established private sector insurance, cannot be emphasised sufficiently. India, for example, has the world's second-largest population and over 400,000 cases of cancer registered annually. It is well-known that apart from HIV/AIDS, other diseases like malaria, tuberculosis, cancer and cardiovascular respiratory problems continue to stretch the under-resourced health care and administration system in developing countries. Reduced prices of essential medicines and access to data to produce cheaper alternatives are critical to any pro-poor national health policies.

Conclusions

This Paper focused on one question: *what genuine choices do policy makers in South Asian countries now have, following the link between the trade regime and pharmaceuticals?* This question was answered by focusing on the business model of pharmaceuticals. The Paper proceeded to describe how OECD countries, in particular, have obtained a crucial head start.

The Paper has provided a partial response to the way some of the problems can be overcome through judicious interpretation of the flexibilities in the TRIPs agreement. Clearly, much empirical work is needed to document the extent to which the economies considered in South Asia are adversely affected and the extent to which the promises in the preamble in TRIPs are realised in tangible terms.

This Paper concludes that it is too easy to demonise the WTO. Multinational corporations and TRIPs lead to a mischaracterisation of the real challenge of finding an alternative system in which medicines neglected by the market are developed and also takes measures to ensure that essential medicines are not subject to market mechanism.

Thus, the question is, *if we do not have TRIPs, would the communities in South Asian countries, who are at least able to access the market of life saving drugs, find their governments even more responsive to their needs?* The ambivalence here does not defeat the limited goal of this Paper, which is to provide a foundation for the contention mentioned at the outset.

Recommendations

- ***Standard Setting***

  The impact of TRIPs in terms of the economic and social costs of establishing patent systems should not be underestimated. Inadequate systems for the processing of the patent applications, examination of patent specifications and claims and supervision of the exercise of patents rights can increase barriers to access.

  It is therefore recommended to increase dialogue and partnership programmes with Export Promotion Organisations. Also, empirical studies to be undertaken to customise the patent legislation to reflect the level of skilled workforce, the dependence on foreign export earnings and the necessary trade-offs.

- ***Compulsory Licensing and Export/Import Restrictions***

  Article 31(f) of Compulsory Licensing and Export/ Import Restrictions enables the issuance of compulsory licenses for domestic production. The requirement that the products manufactured under compulsory licence must be supplied predominantly to the domestic market renders the value of the provision illusory. Equally, countries like India, which have the domestic capacity, may be reluctant to supply to least developed countries since the latter does not possess markets, which enable the former to derive the necessary economies of scale to make the production viable.

  The need is to ensure that the patent legislation contains TRIPs compliant compulsory licensing provisions. It is imperative that developing countries draw on the Preamble in TRIPs and articulate the specific grounds where governments may issue compulsory licenses. Also, Article 31(f) should be amended and the framework suggested by the African Group, which has been made available to the TRIPs Council, should be adopted.

- ***Technology Transfer***

  Article 7 specifically states that the protection and enforcement of IPRs should contribute to the promotion of technological innovation and transfer and dissemination of technology. It is unclear whether this is more than an aspiration since the provision envisages that this transfer must be to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.

  OECD industrial countries should provide market incentives to MNCs to encourage joint ventures and collaborations with domestic industries in developing countries. This is particularly important to address the lack of R&D in developing medicines and treatments commonly found in South Asia like malaria, diarrhoea etc.

  All developing countries need to have in place TRIPs compliant legislation by the end of 2005. Besides this, there is a need for the developing countries to undertake a review of their infrastructures to ascertain what constitutes a realistic target period.

Endnotes

1 See Gary G. Yerkey and Daniel Pruzin, "United States Drops WTO Case Against Brazil Over HIV/AIDS Patent Law" WTO Reporter (June 26, 2001) and C Raghavan, 'US beats a (tactical) retreat over Brazil's patent law' (visited 7 February, 2002) http:// www.twnside.org.sg/title/tactical.htm.

2 See Brazil - Measures Affecting Patent Protection WT/DS1991/1, G/L/385. IP23 (Request for Consultations by the US,8 June 2000) and Brazil-Measures Affecting Patent Protection WT/DS199/39 (Request for the Establishment of a Panel by the US, January 2001).

3 See a summary of the South African Medicines Act Court Case in http://www.tac.org.za/newsletters/ns010424.txt. See however Phrma's response: PhrMa supports USTR on Brazil http://www.phrma.org/press/newsreleases//2001-06-25.238.phtml. (last visited, 6 February, 2002)

4 The following account is taken from A Gupta, "Enigma of Intellectual Property Rights: How Long Shall We Miss the Opportunities?" Paper presented at the 49th Indian Pharmaceutical Congress in Trivandum 20 December 1997. Available at www.iprcommission.org.

APPENDIX A

DOHA MINISTERIAL DECLARATION ON TRIPs AND PUBLIC HEALTH

The Ministerial Declaration on TRIPs and Public Health issued at the 4th WTO Ministerial Conference in Doha, Qatar represents the latest phase in the efforts to address some of the legal and policy issues accompanying the implementation and enforcement of patent rights in the global market of pharmaceuticals. India and Pakistan have recently enacted TRIPs compliant legislation. It is expected that Bangladesh and Sri Lanka will follow suit. Nepal, with the assistance of World Intellectual Property Organisation (WIPO), will have the relevant legislation in place.

Member states during Doha agreed that there was a need for a co-ordinated effort, which included the WTO, to enable developing countries address the public health needs. That said, it will be the height of naivety to ignore the fragility of the consensus, since OECD countries and PhRMA will not readily relinquish their interests in maintaining an effective property protection system.

That said, in a special discussion on patent rights and access to medicines, developing countries embarked on a co-ordinated strategy and presented arguments before the TRIPs Council of the need for the entire WTO community to demonstrate their share of the responsibility for the public health problems in developing countries. With these brief points in mind, we can now turn to the key provisions in the Doha Declaration to ascertain whether a consensus is beginning to emerge that economic imperatives should not trump humanitarian concerns.

Key provisions of the Doha Declaration	***Comments***
Paragraph 1: "We recognise the gravity of the public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics."	This is a reflection of one of the consequences of the linkage between public health governance and trade. It marks an important stage in the evolution of the international trade regime where the WTO now provides a strategic lead in global public health governance.
Paragraph 2: "We stress the need for the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs Agreement) to be part of the wider national and international action to address these problems."	The WHO and the World Bank have been particularly supportive of the efforts of the WTO. The important point here, and which is often glossed over, is that global public health governance is not purely a trade issue but one which requires greater co-ordination amongst all international organisations and stakeholders. The use of this vocabulary is significant.
Paragraph 3: "We recognise that intellectual property protection is important for the development of new medicines. We also recognise the concerns about its effects on prices."	This is the first indication that the exercise of patent rights may lead to increases in prices. Concerns about prices need to be balanced with the overall need for a sustainable supply system.
Paragraph 4: "The TRIPs Agreement does not and should not prevent members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPs Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all."	This paragraph would seem to add nothing new to an obvious feature in public health management. Culture, tradition and history have long characterised the State as the political and moral custodian of the community's health security. The concluding sentence can be interpreted as rejecting any suggestion that TRIPs obstructs public health initiatives. This stage setting is important, not the least that it circumscribes the policy prescriptions that are specifically identified in the remainder of the memoranda.

Paragraph 5: "Accordingly and in the light of paragraph 4 above, while maintaining our commitments in the TRIPs Agreement, we recognise that these flexibilities include: (a) In applying the customary rules of interpretation of public international law, each provision of the TRIPs Agreement shall be read in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles. (b) Each member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted. (c) Each member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/ AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency. (d) The effect of the provisions in the TRIPs Agreement that are relevant to the exhaustion of intellectual property rights is to leave each member free to establish its own regime for such exhaustion without challenge, subject to the MFN and national treatment provisions of Articles 3 and 4."	Paragraph 5 enumerates some familiar features of the TRIPs Agreement. Members can, for example, determine the grounds under which compulsory licenses can be granted. Its reach in both quantitative and qualitative terms is important, since it purports to point to the way the flexibilities in TRIPs can be best maximised to correspond with the pubic health needs in developing countries. For instance, public health crisis is not to be viewed restrictively. Paragraph 5(c) accepts that members should have the right not only to determine what constitutes 'national emergency' but also may adopt measures to alleviate crises in 'circumstances of extreme urgency'. This is not to be limited to diseases like HIV/AIDS, tuberculosis and malaria but can cover any other epidemic that visits a particular community. The reference to expediency is important. Procedural or administrative frameworks lack the lightness of touch where time is of the essence to ensure that medicines can be made available to avert potential fatalities. Finally, paragraph 5(d) makes available to members another policy instrument. Members can now manage their public health by constructing their own regime on exhaustion of intellectual property rights. This is, however, said to be subject to Articles 3 and 4.
Paragraph 6: "We recognise that WTO members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPs Agreement. We instruct the Council for TRIPs to find an expeditious solution to this problem and to report to the General Council before the end of 2002."	Paragraph 6 is solely concerned with increasing the utility of compulsory licenses as a policy tool in overcoming some of the barriers to access. At present, two problems are particularly prominent: (i) capacity and (ii) design. It has been shown that countries like Bangladesh, Sri Lanka, Pakistan and Nepal are, perhaps, least well-equipped to maximise the potential of this instrument, as they are sorely lacking in human and institutional infrastructure. Article 31, as presently constituted, has not anticipated the consequences for these countries in implementing TRIPs. In the absence of this option and as the costs of patented medicines increase, access is likely to be insurmountable. The second 'design' issue arises from the condition that the issue of compulsory licences under Article 31(f), is a response to overcoming domestic health needs. It is true, of course, that TRIPs still permits imports of generic medicines from other countries, so long as patent rules are not in force in these countries. Similarly, a country like India, after implementation of TRIPs, will not be permitted to export on patent medicines produced under a compulsory licence to alleviate the public health needs in Bangladesh or Nepal. The effect of a rigid application of TRIPs is that genuine public health needs are foreclosed by purely geopolitical

	considerations. It was agreed in Doha that the TRIPs Council should formulate an expeditious solution before the end of 2002. Paragraph 6 falls short of permitting countries with little or no capacity to engage in parallel imports; a corollary being that countries cannot unilaterally or with licence export to such countries with public health crises. Finally, it should be noted that TRIPs is to be now interpreted in the light of customary rules of interpretation of public international law (paragraph 5(a). When interpreting the particular provision, the TRIPs Agreement shall be read in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles. The requirement that least developed countries implement TRIPs compliant legislation is somewhat of a puzzle. Countries like Nepal and Bangladesh neither have a strong economic presence or basic institutional infrastructures that would have led to the competitive advantage of OECD countries being undermined. It could be argued that an embracing market liberalisation policy, without addressing questions of capacity and human resources, may prove to be counterproductive and, consequently, divert scarce resources from priority sectors. Indeed, in the absence of domestic manufacturing capacity, imports become a critical means for increasing access to essential medicines. Given the poor economic prospects and the demands on public health services as a mechanism for access, two immediate problems emerge. Production and R&D of developing countries' diseases are likely to be limited, if not expensive. This is likely to create a market failure, which can only be addressed by increased government role in creating market incentives. The other would be the relative expense of acquiring on-patent medicines.
Paragraph 7: "We reaffirm the commitment of developed-country members to provide incentives to their enterprises and institutions to promote and encourage technology transfer to least-developed country members pursuant to Article 66.2. We also agree that the least-developed country members will not be obliged, with respect to pharmaceutical products, to implement or apply Sections 5 and 7 of Part II of the TRIPs Agreement or to enforce rights provided for under these Sections until 1st January 2016, without prejudice to the right of least-developed country members to seek other extensions of the transition periods as provided for in Article 66.1 of the TRIPs Agreement. We instruct the Council for TRIPs to take the necessary action to give effect to this pursuant to Article 66.1 of the TRIPs Agreement."	Paragraph 7 can be regarded as emphasising this rethinking about the place of least developed countries within this new international community. Members now restate their commitment to providing incentives to their enterprises and institutions to promote and encourage technology transfer to least-developed country members pursuant to Article 66.2. More significantly, least-developed countries will not be obliged, with respect to pharmaceutical products, to implement or apply Sections 5 and 7 of Part II of the TRIPs Agreement or to enforce rights provided for under these Sections until 1st January 2016. This statement is, however, made without prejudice to the right of least-developed country members to seek other extensions of the transition periods, as provided for in Article 66.1 of the TRIPs Agreement. To this end, the TRIPs Council was instructed to take the necessary action to give effect to this pursuant to Article 66.1 of the TRIPs Agreement.

APPENDIX B

TRIPs COMPLIANT LEGISLATION

Case Study of Patent Legislation in India and Pakistan

TRIPs Flexibilities	India	Pakistan	Comments
Patentability	S2(j) an invention covers "a new product or process involving an inventive step and capable of industrial application". S2(ja) inventive step means a feature that makes the invention not obvious to a person skilled in the art.	S2(i) 'invention' includes any new and useful product including chemical products…and includes any new and useful improvement of any of them; 'process' means any process or manner of new manufacture of a product and includes a new use of a known process or product. S10(1) provides that, subject to sub-section (2), an invention shall be considered to be capable of industrial application if it can be made or used in any kind of industry. The industry shall be understood in its broadest sense. It shall cover, in particular, agriculture, handicraft, fishery and services. S7(2) adopts similar provisions in paragraph (b)	Pakistan's overly prescriptive approach goes beyond the minimal threshold required by TRIPs. For example, it would be easier to patent pharmaceutical patents on the ground of the claim showing 'any' new and 'useful product. Potential discoveries will be brought within the scope of S2(i). The Indian legislation, by contrast, reserves in the Patent Office the residual discretion.
Exclusions	S3(b) "an invention the primary or intended use or commercial exploitation of which could be contrary to public order or morality or which causes serious prejudice to human, animal or plant life or health or to the environment". S3(p) "an invention which, in effect, is traditional knowledge or which is an aggregation or duplication of known properties of traditionally known component or components".		There is no reference in the Pakistan legislation to protect traditional knowledge. The Indian legislation, arguably, limits the scope in which biological organisms can be exploited. The mere fact that traditional knowledge is not publicly known is insufficient. This is an attempt to avoid bio-piracy and ensures that traditional knowledge handed down to the indigenous community or which has been developed is incapable of being captured by patents.

Parallel Imports	S107A now provides that (a) any act of making or using a patented invention within three years before the expiry of the terms of the patent by any person for the purpose of development and submission of information to any regulatory authority responsible for grant of marketing approval for the product of invention; (b) importation of patented products by any person from a person who is duly authorised by the patentee to sell or distribute the product, shall not [be] considered as an infringement of patent rights".	S30(5) provides that the rights of excludability do not extend to acts in respect of articles that have been put on the market by the owner of the patent or with his consent or acts done only for experimental purposes relating to a patented invention.	S30(5) is badly drafted and does not adequately define the reach of the exhaustion principle or the scope of the 'Bolar' provisions. This can be contrasted with section 107A.
Working of Patented Inventions	General Considerations to operationalise Chapter XVI S83 (a) inventions to be "worked in India on a commercial scale and to the fullest extent that is reasonably practicable" (b) "they are not granted merely to enable patentees to enjoy a monopoly for the importation of the patented article" (c) "that the protection and enforcement of patented rights contribute to the promotion of technological innovation.." (d) "do not impede protection of public health and nutrition and should act as instrument to promote pubic interest.." (e) "do not in any way prohibit Central Government in taking measures to protect public health"	S59 provides for the issue of compulsory licence, if the patented invention is not exploited or is insufficiently exploited by working the invention locally or by importing in Pakistan. The right holder may, however, avoid the issue of this non-voluntary licence, if he satisfies the Controller that circumstances exist which justify the non-exploitation or insufficient exploitation of the patented invention in Pakistan.	It may be argued that such prescriptions are tantamount to discriminating against patents as a field of technology contrary to Article 27(1) (i.e., pharmaceutical process or product patents).

	(f) "the patent right is not abused…does not resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology" (g) "that patents are granted to make the benefit of the patented invention available at reasonably affordable prices to the public."		
Compulsory Licences	S84 (1) (a) "that the reasonable requirements of the public with respect to the patented invention have not been satisfied" (b) that the patented invention is not available to the public at a reasonably affordable price" (c) "that the patented invention is not worked in the territory of India"	S59 (1) Subject to sub-section (2), where (i) public interest, in particular, national security, nutrition, health or the development of other vital sectors of the national economy so requires; or (ii) the Federal Government has determined that the manner of exploitation, by the owner of the patent or his licensee, is anti-competitive, and the Federal Government is satisfied that the exploitation of the invention in accordance with this sub-section would remedy such practices,the Federal Government may, even without the consent of the owner of the patent, decide that a Government agency or a third person designated by the Federal Government may exploit a patented invention.	It could be argued that this exceeds the limits imposed by Article 31 and, furthermore, any conditions are subject to the due process of mechanisms of judicial review, reasonable compensation, voluntary agreement etc. It is not possible under TRIPs for pharmaceuticals manufactured under compulsory licence to be exported to other countries where TRIPs legislation is already in place.

APPENDIX C

A SUMMARY OF TRIPs ISSUES AND IMPLICATIONS FOR SOUTH ASIA

TRIPs Obligations	Implications for South Asia
Non-discrimination Policies	Enacting protective legislation cannot discriminate against pharmaceutical exports. In practical terms, there will be an increase in foreign pharmaceutical products. This will require governments in Bangladesh, Sri Lanka and Pakistan to assess the impact on welfare loss and the domestic industries, which currently possess some manufacturing capability. It is unclear as to the extent to which the Indian generic industry will be significantly affected. There will, invariably, be some form of contraction in the industry as well as increase in the entry into joint ventures or licensing of domestic manufacturers.
Protection to be made available for product and process patents in pharmaceuticals	All countries must now set in place patent protection systems and legislation. This will impose considerable costs on countries like Nepal and Bangladesh who will need to have in place an entirely modern framework. Sri Lanka, which has previously adopted the WIPO model, may have to undertake minor modifications. India, however, has now to amend its legislation to ensure that process patents are protected.
The interface between Article 27(1) and Article 28(a) is at present unclear.	India, which has a substantial generic industry, may be significantly affected if it is unable to exploit the economies of scale, in case parallel imports are prohibited under the agreement. This is the reverse of the 'local working' requirement where foreign multinationals located in developing countries may argue that parallel imports of cheaper versions of patented products produced locally are being discriminated against.
Standard Setting for Issuing of compulsory licenses.	Domestic legislation must enact the standards prescribed by Article 31(f), which restrict the issuance of compulsory license on the grounds stipulated in the section. The requirement that royalty payments are made presupposes that governments have adequate resources to fund the repayments. Also, there is an assumption that in producing the medicines under compulsory licence, domestic manufacturers do not attach any importance to the economies of scale, particularly where the domestic market is small or not viable.
TRIPs recognises that developing countries may not be able to comply with the obligations. Consequently, transition periods are made available.	Almost all the developing countries in South Asia have in place TRIPs compliant legislation, with the exception of Nepal, which is presently being assisted by WIPO.
FDI and Technology Transfer	It remains to be seen, given the complexion of the corporate pharmaceutical model, whether these aspirations are likely to be operationalised. It must be questioned whether any credible benefit is to be gained in the case of Nepal and Bangladesh, in particular.

This Briefing Paper is an abridged version of a research report entitled 'TRIPs and Public Health: Ways Forward for South Asia'. The abridged version has been prepared by Garima Joshi of and for CUTS Centre for International Trade, Economics & Environment, D-217, Bhaskar Marg, Bani Park, Jaipur 302 016, India, Ph: 91.141.220 7482, Fx: 91.141.220 7486,E-mail: citee@cuts.org, Web Site: www.cuts.org, and printed by KBS Printers, Tonk Road, Jaipur 302 015, India.