

TRIPS AND PUBLIC HEALTH SOUTH ASIAN PRIORITIES

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INTRODUCTION

Trade liberalisation in developing countries, including the South Asian nations, has seen an expansion and consolidation of market share by multinational corporations (MNCs) based in the North. Diversification and distribution of market share of firms, particularly small and medium enterprises of developing nations, have narrowed considerably. Such a dynamism in the present day market is not restricted to finance, capital and market share alone, but involves new flows of technology and intellectual property rights (IPRs) as well.

South Asian countries are now concerned that such a market phenomenon is taking place in a sector that is critical to public good, namely the health sector. South Asia's highly concentrated population makes disease control extremely difficult and providing treatment to such population is a far greater challenge than providing similar treatment to populations of nations in other parts of the world. Under such circumstances, the Trade Related Aspects of Intellectual Property Rights (TRIPS) Agreement of the World Trade Organisation (WTO) further poses a serious threat to access to medicines in the South Asian countries.

This briefing paper identifies and examines the key drivers of concerns that countries in South Asia have with respect to TRIPS and public health and discusses the relevance of debates on IPR to the health sectors of developing countries in general and South Asia in particular. Its purpose is to support informed and constructive debate among policymakers and concerned stakeholders by clarifying key issues and highlighting the challenges that South Asian countries face in the context of TRIPS and public health. It begins with an overview of the debate on TRIPS and public health. It then looks into the key issues related to public health under the TRIPS regime, finally moving into the challenges confronted by South Asian countries and the measures that these countries could take to ensure that they are able to effectively mitigate the health challenges posed by the multilateral regime on IPR. However, this paper is not exhaustive.

DEBATE ON TRIPS AND PUBLIC HEALTH

The relationship between intellectual property policies and access to medicines has emerged as one of the most controversial policy debates in the IPR field. Access to affordable medicines is a key priority for developing countries. A range of obstacles, including inadequate public health infrastructure, inefficient marketing and distribution networks, insufficient funding, cumbersome regulatory procedures and high prices of medicines, obstructs access to medicines.

The issue of high prices has generated increasing criticism about the existence of powerful patent monopolies in the health sector. In particular, pharmaceutical companies have been condemned by many non-governmental organisations (NGOs) and several governments, including South Asian governments, for failing to do enough to assist the millions of people dying from HIV/AIDS

for lack of access to anti-retroviral drugs. They are also criticised for deploying an extremely low proportion of research and development (R&D) to diseases affecting poor people, and for putting pressure on developing country governments to prevent the local manufacturing or import of cheaper, generic version of drugs produced in countries where patents are not available or respected.

From a developing country perspective, a key policy priority is to help ensure that drugs are available to doctors, hospitals and individuals at lower and more competitive prices. Promoting early competition from generic medicines is one important way to foster competition, stimulate price reductions and expand access to drugs. In recent years, attention has focussed on the patents and public health related provisions of TRIPS. Prior to TRIPS, no similar obligation existed in international law, meaning that more than 50 countries did not grant any

BRIEFING PAPER

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Post Box No. 19366
254 Lamtangeen Marg
Baluwatar, Kathmandu, Nepal
Tel: 977-1-4415824/4444438
Fax: 977-1-4444570
E-mail: sawtee@sawtee.org
Web: www.sawtee.org

BOX: 1

FLEXIBILITIES IN TRIPS

TRIPS allows certain leeway for WTO members to adopt measures to mitigate the monopolistic rights conferred by patents and promote competition. Such measures, which may lower prices and increase access to drugs, include:

- compulsory licenses, that is, authorisation by the state to a third party to exploit a patented invention, generally against a remuneration to the patent holder;
- parallel imports of patented products when they are obtainable in a foreign country (where a patent also exists) at lower prices; and
- the possibility of establishing exceptions to the exclusive rights, such as the early working exceptions (also known as 'Bolar exception'), which allows generic firms to initiate and obtain marketing approval of a patented drug before the expiry of the patent.

Source: ICTSD and UNCTAD, 2003.

protection for pharmaceutical products, and many more granted much weaker protection than that called for by TRIPS.

New obligations in TRIPS include granting patent protection for at least 20 years from the date of patent application, limiting the scope of exemptions from patent rights and obligations, and effectively enforcing patent rights through administrative and judicial mechanisms. These rules have dramatically changed the global framework for the commercialisation of drugs and affordable access to them in developing countries. While TRIPS provides certain leeway through a number of flexibilities (See Box: 1), it is not crystal clear as to how they should be applied in practice.

DOHA DEVELOPMENTS

Following the Doha Ministerial, trade ministers tabled a special declaration that recognised the rights of countries to take measures to protect public health and promote access to medicines, over and above the obligation to protect IPRs (See Box: 2). The Doha Declaration on TRIPS and Public Health enshrined the principles of the primacy of protecting public health above economic and market interests. The idea was also to promote access of medicines to all. It was thought that the evolution of TRIPS would not prevent governments from taking such measures.

Within the Doha Development Agenda (DDA), a number of allowances and principles surrounding development were included for developing nations to enable them to better benefit from trade liberalisation. With regard to TRIPS, countries have been allowed to restrict the field trials of new products if they are deemed harmful to human, animal and plant life, as outlined in the Convention on Biological Diversity (CBD).

To date, many claim that the spirit of those efforts has not materialised. The concerns of that spirit having not manifested itself within the market are expressed against a regional public sector picture outlined in Table: 1. At least

one third of South Asians live on less than US\$ 1 a day and public sector health spending is at levels that are incapable of supporting or subsidising the needs of the poorest segments of the population.

Civil society continues to struggle for cheaper versions of patented medicines to be made available to the poor and the sick of developing countries. Policy activists also propose that the state of public health be altered in a manner that insulates it from private sector forces of large pharmaceutical firms and the prices they set to justify R&D of new drugs, which, in turn, are protected by the current global IPR regime.

Developed nations, on the other hand, argue that pricing is not the issue; drugs are cheap enough. It is in fact access and infrastructural problems that are responsible for keeping prices high. This has been argued in Africa, but not as much in South Asia, where complaints on pricing come from urban and rural areas where access levels vary. Compulsory licensing has been allowed to enable local manufacturers to produce cheaper versions of life saving drugs, but where there is no manufacturing capacity, there is an impasse.

Naturally, developed nations see DDA's paragraph 6 as a trade threat, whereby developing nations that are allowed to export to adjacent markets through a compulsory license, may use the allowance to export to nations that are not in need of cheap drugs and thereby steal market share away from patent holders who ostensibly keep prices high to pay for R&D efforts. The DDA's paragraph 6 on compulsory licensing issue also needs to be addressed and managed in a manner that allows for import of drugs from adjacent or parallel markets, without compromising commitments to free and fair trade agreements signed by South Asian nations.

KEY ISSUES

The relationship between patents and public health is, indeed, complex. Beneath the policy and trade negotiations that take place within the WTO are the market realities of pricing, public access, availability, distribution, domestic sectoral health and firm strength, to name a few, that drive developing country concerns. The following issues are nested within the market and are of major concern to developing countries, including South Asian nations.

Patent capture: High drug prices and lack of choice are likely to lead to a dependence on high priced drugs produced by a limited number of manufacturers to treat a select group of diseases. Most developing countries experience drug prices to be quite expensive with respect to the average purchasing power of a citizen. Furthermore, a shift from holistic medicine to specialised drug development and research is feared with increased patent capture. The result is that firms that own a number of patents may choose to develop those drugs that show market potential in the short term while leaving the development of patented drugs that may be of interest to developing nations' public health agencies on the wayside.

Another issue related to patent capture is the extent to which patents will be applied. Biotechnology is a concurrent vein of research, which has been fuelling innovations within the pharmaceutical field. As the patenting of life processes has been left out of the debate until now and remained largely within

DOHA DECLARATION ON TRIPS AND PUBLIC HEALTH

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.
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.
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.
4. We agree that 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.
In this connection, we reaffirm the right of WTO members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose.
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.
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.
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 1 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.

Source: www.wto.org

the area of traditional medicine, proponents of the retention of knowledge within the public good fear that this will enable pharmaceutical firms to extend property rights into the area of agriculture.

Polarity in harmonisation: The harmonisation of patent laws that leads to universal standard for patent protection is claimed by developed nations and pharmaceutical lobbies to be of benefit to developing nations. Their argument is based on the premises of new drug development by local pharmaceutical firms, increased technology transfer and flow of foreign direct investment (FDI), and better health due to a wider variety of product availability. Developing nations, on the other hand, fear that harmonisation will lead to higher drug prices, reduced access to medicines, weakening of local pharmaceutical firms, increased dependence on multinational corporations (MNCs) and decreased transfer of technology and FDI. The pivotal issue here is the effectiveness of developing nations to manage and monitor patent laws and allow for sufficient policy space to direct and encourage the growth of domestic pharmaceutical industry.

Drug availability: Critics of the TRIPS Agreement feared

that new drugs would be scarce by the end of the transition period at which time developing nations would have to be in compliance with TRIPS. The concerns stemmed from threats that new diseases and drug resistant strains of viruses and bacterial diseases would pose to developing nations. Besides, TRIPS would further restrict the expansion of health infrastructure, which would be forced to operate using old equipment and medical innovations. Patent periods of 20 years would also prevent non-patent holders from accessing and producing generic versions of those drugs until the passing of 20 years.

Preventable deaths: Lack of access to medicine and emergency relief can potentially lead to hundreds of deaths in developing countries, including South Asia. Delays in provisioning inexpensive medication as a result of the implementation of the TRIPS Agreement may result in substantial spreading of diseases and loss of life. An alarming statistic involves the number of children who die from waterborne diseases in Karachi and Mumbai. The figure is comparable to the total number of infantry casualties absorbed by Pakistan and India during the course of their conflicts.

TABLE: 1

KEY SOCIO-ECONOMIC INDICATORS OF THE SOUTH ASIAN COUNTRIES

Indicators	India	Pakistan	Bangladesh	Nepal	Sri Lanka	Bhutan	Maldives
Population in million (2003)	1065.4	153.5	146.6	25.2	19.1	2.25	0.32
GDP in US\$ billion (2002)	510.2	59.1	47.6	5.5	16.6	0.6	0.6
GDP per capita (2002)	487	408	351	230	873	695	2182
Population earning below US\$ 1 per day (2002)	34.7	13.4	36	37.7	6.6	-	-
Human Development Index (2002)	0.595	0.497	0.509	0.504	0.740	0.536	0.752
Public health expenditure as share of GDP (2001)	0.9	1	1.6	1.5	1.8	3.6	5.6
Private health expenditure as share of GDP (2001)	4.2	3.0	2.0	3.6	1.9	0.4	1.1
Per capita health expenditure (in terms of PPP, US\$) (2001)	80	85	58	63	122	64	263
Percentage of people with HIV/AIDS (2001)	0.8	0.1	<0.10	0.5	<0.10	<0.10	0.06
Malaria cases per 100,000 (2000)	7	58	40	33	1110	285	-
Tuberculosis-related mortality rate per 100,000 (2002)	344	379	447	271	73	205	46
Access to affordable medicines (2000)	very poor	poor	poor	very poor	good	moderate	poor
Patents granted to residents per million (1999)	1	-	-	-	0	-	-
Receipts of royalties & license fees in US\$ per person (2001)	0.1	0	0	-	-	-	12.8

Compiled from Human Development Reports.

Drug resistance: Current drugs and treatments exist in developing nations for a number of seasonal and year round diseases and illnesses. However, these medications need to be updated and refined on a regular basis to counter the evolution of drug resistant strains of certain bacterial and viral infections. Patenting may delay, once again, the timely provision of such drugs to the poorest of the poor, who are unable to pay high prices for patented remedies. So, while the middle class and rich, touted as the beneficiaries of successful globalisation of South Asia, may be able to afford access to such medicines, it will still be out of reach for many.

Emergence of new diseases: The emergence of new diseases, such as HIV/AIDS, will require access by developing nation health infrastructure to the latest and most up to date medications. TRIPS and a powerful pharmaceutical lobby of the North are being blamed for delays and red tape in accessing such medications to nations in South Asia, South East Asia and Africa. As HIV/AIDS pandemic and other diseases spread through tropical biomes, timely availability of up to date drugs will be required to counter widespread and catastrophic losses of life. As drug use within richer elements of society increases, new strains of existing viruses may then

evolve and target poorer segments of society. Such a trend should also be monitored.

Access to medicines: Chronic and acute diseases currently present in many developing nations are priced higher than other medications. If pricing of medications reflects IPR commitments, then the distribution of such medication will be affected as only upper income segments of society will be able to afford them. Hence, some drugs will only be available in towns and/or cities where enough rich consumers live to make distribution worthwhile. Rural areas where a majority of the poor reside would be cut out of the distribution networks due to the lack of ability to pay.

Local health needs: Beyond several diseases, many water-borne diseases not problematic in developed nations are of serious concern to developing nations, and remedies to such diseases would be deemed life saving. The TRIPS Agreement has no binding commitments regarding the flexibility for drugs for new diseases, drugs for existing diseases and drugs for ineffective drugs and drug resistant strains. At the holistic level, the guiding principle and sovereign development agenda of health care systems tailored to the needs of each nation will

be captured by market forces, driven more by market potential rather than health needs. Basic health care development will be overshadowed by the demands created by wealthier consumers and R&D needs that those market segments show.

DEVELOPMENTAL ISSUES

Apart from the key issues outlined above, there are other concerns that stem in relation to the pharmaceutical industries of developing countries. The impact of TRIPS on R&D, growth of pharmaceutical industries, flow of FDI and technology transfer and the hegemony of the North are the most prominent ones.

Health and growth of local pharmaceutical industry:

Since the ushering of trade liberalisation, pharmaceutical firms in developing countries have been experiencing a weakening in support from their once protective governments. A study in the Republic of Korea found that changes in IPR policy created a market loss for most firms. Only those that had higher and more sophisticated technologies gained. Similarly, a study in India in 1996 found that annual profit transfer to foreign firms increased from US\$ 101 million to US\$ 839 million. This means a substantial flow of resources from developing countries to developed countries (See Box: 3). The natural fear from these trends is that developing economy pharmaceutical sectors risk being made redundant and obsolete by foreign competition if they do not establish and maintain some comparative advantage either in research, manufacturing and/or distribution. Should they fail to establish some competitive capability, they would eventually be bought out and their assets used to manufacture and distribute MNC drugs.

Impact on transfer of technology: Prior to the implementation of the TRIPS Agreement, developing nations required MNCs to manufacture drugs within the countries of distribution which ensured some degree of technology transfer. With the TRIPS Agreement, MNCs will be able to decide whether to manufacture or simply import, which will not add to green field investment or new development within existing developing nation sectors. Only India in the South Asian region is capable of replicating and engineering existing drugs from formulae. Other nations in South Asia will need significant degrees of technology transfer in order to advance their pharmaceutical sectors to a more sophisticated level.

Impact on R&D: With regard to the mechanics of intellectual property, it is feared that technology transfer will cease and MNCs will focus their R&D efforts on catering to the wealthy consumers in Organisation for Economic Cooperation and Development (OECD) markets. In the process, MNCs may shackle resources in the South to stagnant patents that are not being developed in a manner to suit the more holistic health needs of their populations. Countries in South Asia, as in other developing countries, already suffer from a lack of intellectual and financial capacity to conduct research, and a need, therefore, exists for substantial investment. A key issue on the domestic side is that developing country firms that do not invest much in R&D will lose current and future opportunities to grow, as products as well as processes are being included in patent regimes.

Industrial power of the North and South: Japan spends US\$ 411 per capita whereas Bangladesh spends only US\$ 1

BOX: 3

TRIPS AND RESOURCES FLOW

If TRIPS were fully implemented, estimates indicate that annual transfers to major technology-creating industries – particularly those in the US, Germany and France – in the form of royalties and licensing fees for pharmaceutical patents, computer chip designs, and other intellectual property, would amount to more than US\$ 20 billion.

Stated crudely, this means that TRIPS represents a US\$ 20 billion-plus transfer of wealth from the technology-importing country (most of which are developing countries) to technology-exporting countries (few, if any, of which are developing countries) that may or may not be outweighed by future gains.

For example, potential benefits such as FDI may take quite a long time to accrue, and their scale is difficult to predict, particularly in the light of the variety of policy issues and economic conditions that influence FDI decisions. Moreover, IPRs can inhibit, rather than enhance, the flow of trade by limiting market access opportunities for foreign competitors.

Source: ICTSD and UNCTAD, 2003.

per capita on public health. Seventy five percent of the world's population, living in developing countries, consume only about 11 percent of the globally available drugs. In 1980, more than 90 percent of global drug production took place in seven industrialised countries. This trend coincides with the concerns expressed by developing nations that an increasing concentration of global public health is taking place in a small number of nations. The concern is that pricing regimes as well as the direction of R&D will be determined by developed nations and their firms with little or no knowledge of the socio-economic conditions of developing nations where they intend to export their products.

CHALLENGES CONFRONTING SOUTH ASIA

The challenges confronting South Asia as a result of the TRIPS regime are enormous. One of the broad challenges relates to increasing space and adaptability to the new trade environment in order to ensure that TRIPS benefits nations in South Asia. Other specific challenges include good governance in public health, attracting investment in enhancing domestic intellectual capacity, understanding South Asian market dynamics beyond the generic power in India, monitoring the activities of MNCs and supporting public and private health sectors, among others. The most important challenge for South Asia, however, exists on using the flexibilities provided by TRIPS to ensure sustainable access to cheaper drugs. Besides, challenges in the South Asian context can also be elucidated in terms of governments' capacities and pharmaceutical strength. There is a need for the countries in the region to effectively mitigate these challenges.

Using the TRIPS flexibilities

As already shown in Box 1, TRIPS provides a number of flexibilities for developing countries to ensure access to medicines. The Agreement allows the granting of compulsory licenses to override patents so that generic manufacturers may

produce cheaper versions of patented life saving drugs.

Countries without domestic manufacturing facilities, however, are faced with a problem. And except for India, which has a strong generic manufacturing base, no other country in the South Asian region have any viable manufacturing base. These countries hence would need to import drugs. However, the supply of drugs may be limited and insufficient because of constraints placed by TRIPS on nations that have the capacity to produce such drugs. So a country, for example, will be able to produce only enough for its domestic population and any excess for export to a neighbouring country would not be allowed. Article 31(f) of TRIPS requires that production of generic drugs is 'predominantly for the supply to the domestic market'.

Paragraph 6 of the Doha Declaration addresses this particular concern with TRIPS. It is concerned with increasing the utility of compulsory licenses as a policy tool in overcoming some of the barriers to access. However, most South Asian countries are not in a position to effectively utilise this flexibility given their capacity. Countries like Bangladesh, Sri Lanka, Nepal and Pakistan are least equipped to maximise the potential of this instrument as they lack human and institutional infrastructure.

Besides, 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 license export to such countries confronting crisis in the public health sector. In the absence of domestic manufacturing capacity, imports become a critical means for increasing access to essential medicines. South Asia must unite with other developing countries and pressure the developed countries, particularly the US, to back down from their hardline stance on access to drugs (See Box: 4). Also, countries in the region must work collectively to expeditiously find a solution to the paragraph 6 problem.

The solution to this problem is essentially a waiver of Article 31(f). With this waiver in force, it means that a predominant portion or even the total amount of production under a compulsory license could be exported to a country wishing to import. It is very apparent that the US and its pharmaceutical lobbies do not want generics to gain a stronger foothold. The flexibility provided by TRIPS should be allowed to be used in good faith to minimise abuse. In order to guard from negative effects, least developed countries (LDCs) are automatically eligible for such rights, whereas developing nations will have to establish that there is insufficient or no manufacturing capacity.

Besides, compulsory licensing is subject to a number of terms and conditions. They include limit on distribution, marketing and supply, apart from ensuring transparency with regard to quantities supplied to each importing country. The concern is that too many hurdles would be presented to generic manufacturers for them to feel it worthwhile to manufacture such drugs. Competition, which would be worthwhile to keep costs low, is then not practical as economies of scale will be required to overcome hurdles in order for production to remain viable.

Government capacity

One of the most important challenges faced by South Asian nations is the historically weak legislation not just in regulat-

ing intellectual property, but in defining limits to liberalisation and patent exemption in a manner that will ensure high prioritisation of national public health goals. Most governments in the region are not strong enough to minimise monopoly behaviour, which in turn are yet to be investigated in the light of private and public sector dynamics. There is also a general lack of institutional and independent watchdogs to monitor the impact of TRIPS-related national and provincial policies on the poorest of the poor.

Besides, the governments in the region are weak in their capacities to negotiate on IPR issues at the multilateral level. There is also a lack of regional position and strategy on whether or not intellectual property should remain in the WTO. In essence, there is a serious dearth of cooperation amongst South Asian nations in increasing regional production of drugs, sharing of technology and issuance of compulsory licenses, among others. Likewise, there is a serious shortage of consultative mechanisms involving NGOs, social movements and private sector local generic drug producers or potential producers so that a coordinated response on TRIPS issues can be made. At the intra-government level, there is a need for establishing institutional arrangements for coordination of policies and measures between different ministries and departments, such as Ministry of Health, Ministry of Industry, Ministry of Commerce, Patent Office, Attorney General's Office, etc., on issues related to TRIPS.

Except for India, most of the South Asian countries are yet to properly examine their national situations regarding patents and prices of medicine in relation to the prevalent diseases, and devise measures such as government use, com-

BOX: 4

WHY THE US IS UNMOVED ON TRIPS?

Though the Doha Ministerial recognised the need to ensure access to medicines to all, the US has continued to contravene the goal of the Doha Declaration - 'access to medicines for all' - by pressurising developing countries to implement TRIPS-plus measures. The US is spearheading a pro-patent agenda that is unacceptable to developing countries.

As a matter of fact, the US government is taking this agenda seriously and actively at the behest of its powerful pharmaceutical lobby, PhRMA. The industry has an interest in strong patent protections, which limit generic competition and, therefore, protect its market share and profits. And the US government has a strong political interest in the industry.

In 2000, the industry contributed approximately US\$ 20.14 million in election campaign contributions. In 2003, the industry gave US\$ 29.37 million, out of which with over US\$ 21 million went to the Republicans. In addition, the industry spends an additional US\$ 120 million each year on lobbying. This is a drop in a ocean compared with its annual sales, which stood at a whopping US\$ 400 billion in 2002. The 10 largest US drug companies made US\$ 35.9 billion in profit in 2002, with a rate of return of 27.6 percent for shareholders, more than two and half times the Fortune 500 average rate of return of 10.2 percent.

Source: Oxfam, 2003.

THE HEGEMONY PREVALENT IN DRUGS BUSINESS

Global public health governance is very much in public spotlight. This is largely the result of high profile actions by the US and MNCs to assert their dominance and competitive advantage in the pharmaceutical industry. For example, the US 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 WTO. This action was a response to the decision of the Brazilian government to increase supplies of its generic drugs to address HIV/AIDS 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 profits for its members from the sale of blockbuster drugs, which were on patents.

Some time back the concerted efforts by the pharmaceuti-

cal MNCs to prevent the South African government from accessing viable alternative supply systems floundered in the domestic court. In another incident, Glaxo and SmithKline (GSK) threatened CIPLA, an Indian pharmaceutical corporation, with a lawsuit. It was alleged that the corporation was supplying the South African government with generic supplies of products, which were manufactured in breach of GSK's patents.

Such events suggest a growing trend where the emerging private networks of commercial interests are encroaching 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 in South Asia.

Source: CUTS-CITEE, 2003.

pulsory licensing and parallel imports in order to effect importation or production of medicines. Challenges also remain with the governments to examine their respective legislation and do away with the inadequacies and weaknesses to maximise the rights that each country can enjoy under the TRIPS regime.

Besides, TRIPS involves huge costs. All countries must put in place patent protection systems and legislation. This will impose considerable costs on countries like Nepal and Bangladesh which 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.

Pharmaceutical strength

Pharmaceutical firms in the South Asian region spend relatively very little on R&D as compared to foreign MNCs, and hence are in a weak position to acquire and apply for new patents. In general, South Asia seriously lags behind in utilising the intellectual capacity of scientists and engineers to ensure that some indigenous intellectual capacity is translated into patents. That would at least induce some comparative advantage for domestic pharmaceutical firms.

Besides, TRIPS is a complex issue altogether. When even academicians completely devoted to it find hard to understand and interpret TRIPS provisions, there is no logic how businesspersons would do the same with ease. As such South Asian pharmaceutical firms and entrepreneurs find it hard to understand the TRIPS flexibilities that will benefit them, in particular the timelines, anti-piracy laws, exemptions, technological innovations and transfer of technology allowances. There is a need to understand the comparative advantage. That would be necessary not just to increase exports, but also to ensure access of medicines to the domestic populace and to cater to the needs of the health sector as a whole.

Drugs market in South Asia, which is host to a number of

killer diseases, is not immune of MNCs' decisions and patents. MNCs have the muscle to put substantial pressure on governments of developed countries. As such, MNCs and powerful governments in the North have the potential to wreak havoc in South Asian markets if their activities are not monitored closely. Though the WTO espouses the principles of fairness in trading, the TRIPS provisions have the potential to make global pharmaceutical companies more profit driven rather than welfare, and which exactly is the case in the global drugs market today.

There are some glaring examples of use of force and bullying by MNCs and developed countries (See Box: 5). Most markets in South Asia, apart from India, which has a fairly strong generic market, are susceptible to unfair gaming of MNCs. Besides, inability of these countries to consolidate their own pharmaceutical industries increases their vulnerability further.

Also there is a severe limitation on what the governments could do to protect the pharmaceutical sectors of respective countries in South Asia. Enacting protective legislation alone is not enough since countries 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 capacity. It is still unclear as to what extent the Indian generic industry would be affected by TRIPS. 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.

It is, however, clear that among the South Asian countries, India will be significantly affected if it is unable to exploit the economies of scale, especially under the case when parallel imports are prohibited under the agreement. This is the reverse of the local working requirement where MNCs located in developing argue that parallel imports of cheaper versions of patented products produced locally are being discriminated against.

CONCLUSION

The emergence of global privatised networks and access regimes in health care products is a part of the process by which MNCs are now redefining the global landscape, traditionally dominated by sovereign nation states. The debate on TRIPS and the implications of linking IPRs with goods must be considered against the backdrop of crisis faced by the South Asian region on the health front. This is more important in the light of the fact that South Asia houses at least 40 percent of the world's poor. MNCs have mischaracterised the real challenge of finding an alternative system in which medicines neglected by the market are developed. Besides, South Asia is confronted by multiple challenges, not just in terms of using the TRIPS flexibilities but also in terms of the capacity of governments and the strength of the pharmaceutical sector. South Asia must take measures to ensure that essential medicines are not subject to the vested desires and designs of MNCs and are not subject to market mechanisms.

SELECTED REFERENCES

- ADB. 1998. *Key Indicators of Developing Asian and Pacific Countries*. Volume XXIX, Manila: Asian Development Bank.
- ADB. 2003. *Asian Development Bank Outlook: Competitiveness in Developing Asia*, Oxford: Oxford University Press.
- Balasubramaniam, K., O. Lanza and S. R. Karu. 1998. *Retail Drug Prices: The Law of the Jungle*. HAI News. Number 100. April.
- Balasubramaniam, K. 2002. *WTO/TRIPS Agreement and Access to Medicines*. Paper presented during Asia Pacific regional consultation, 17-19 April, Colombo, Third World Network.
- CUTS-CITEE. 2003. *TRIPS and Public Health: Ways Forward for South Asia*. Briefing Paper No. 10. Jaipur: CUTS Centre for International Trade, Economics and Environment.
- ICTSD and UNCTAD. 2003. *Intellectual Property Rights: Implications for Development*. Geneva: International Centre for Trade and Sustainable Development and United Nations Conference on Trade and Development.
- Mahbub ul Haq Human Development Centre. 2004. *Human Development in South Asia 2003*. Karachi: Oxford University Press.
- Mirza, Z. 2000. *WTO, Pharmaceuticals and Health: Impacts and Strategies*. Islamabad: The Network for Consumer Protection and Association for Rational Use of Medication in Pakistan.
- National Institute for Health Care Management Foundation. 2002. *Prescription Drug Expenditures in 2001: Another Year of Escalating Costs*. Washington, D.C.
- Oxfam. 2003. *Robbing the poor to pay the rich? How the United States*

RECOMMENDATIONS

- South Asian governments should collectively seek remedial measures to ensure access to medicines by forming a common position for the purpose of negotiations at the multilateral level.
- Since not all South Asian nations are technically informed and capable to analyse the implications of different TRIPS provisions, they should press for technical and financial assistance for capacity building.
- South Asian pharmaceutical firms and governments should enhance their competence to make use of TRIPS flexibilities for ensuring access to medicines to all.
- South Asian countries should resist any multilateral and bilateral pressures to implement TRIPS-plus measures.
- South Asian governments must engage in consultation with the concerned stakeholders while designing policies and preparing positions for negotiations. ■

- keeps medicines from the world's poorest*. Oxfam briefing paper. November.
- RAFI and UNDP. 1997. *Conserving indigenous knowledge: Integrating two systems of innovation*. New York: United Nations Development Programme and Winnipeg: Rural Advancement Foundation International.
- UNDP. 2002. *Human Development Report*. New York: Oxford University Press.
- UNDP. 2003. *Human Development Report*. New York: Oxford University Press.
- UNDP. 2004. *Human Development Report*. New York: Oxford University Press.
- World Bank. 2001. *World Development Report 2001*. Washington, D.C.
- WTO and WHO. 2002. *WTO Agreement and Public Health*. Geneva: WTO and WHO.
- WTO. 2000. *Trade Policy Review - Bangladesh*. Geneva: WTO.
- WTO. 1995. *Trade Policy Review - Thailand*. Geneva: WTO.
- WTO. 1995. *Trade Policy Review - Sri Lanka*. Geneva: WTO.
- WTO. 2000. *Trade Policy Review - Philippines*. Geneva: WTO.
- WTO. 2000. *Trade Policy Review - Singapore*. Geneva: WTO.
- WTO. 2002. *Trade Policy Review - Pakistan*. Geneva: WTO.
- WTO. 2001. *Trade Policy Review - Republic of Korea*. Geneva: WTO.
- WTO. 2002. *Trade Policy Review - India*. Geneva: WTO.
- WTO. 1998. *Trade Policy Review - Hong Kong*. Geneva: WTO.
- www.wto.org

Launched in December 1994 at Nagarkot, Nepal by a consortium of South Asian non-governmental organisations (NGOs), South Asia Watch on Trade, Economics & Environment (SAWTEE) is a regional network that operates through its secretariat in Kathmandu and 11 member institutions from five South Asian countries, namely Bangladesh, India, Nepal, Pakistan and Sri Lanka. Registered in Kathmandu in 1999, the overall objective of SAWTEE is to build the capacity of concerned stakeholders in South Asia in the context of liberalisation and globalisation.

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