The Impact of the Global Trade Regime on Access to Medicines: A Case Study of HIV-AIDS Treatment Access

Towards the National Health Assembly II
Booklet - 1

The Impact of the Global Trade Regime on Access to Medicines: A Case Study of HIV-AIDS Treatment Access

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- All India People's Science Network (AIPSN)
- All India Drug Action Network (AIDAN)
- Asian Community Health Action Network (ACHAN)
- All India Democratic Women's Association (AIDWA)
- Association for India's Development (AID India)
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- Ramakrishna Mission (RK)
- Voluntary Health Association of India (VHAI)

About the Jan Swasthya Abhiyan

In 1978 at Alma Ata, the governments of the world came together to sign the Alma Ata Declaration that promised "Health for All by 2000". However this promise was never taken very seriously and was subsequently marginalised in health policy discussions.

As the year 2000 approached it appeared that "Health for All by 2000" was quietly being forgotten by governments around the world. To remind people of this forgotten commitment the First People's Health Assembly was organised in Savar, Bangladesh in December 2000 . The People's Health Assembly was a coming together of people's movements and other non-government civil society organisations all over the world to reiterate the pledge for Health for All and to make governments take this promise seriously. The assembly also aimed to build global solidarity, and to bring together people's movements and organisations working to advance the people's health in the context of policies of globalisation.

The national networks and organisations that had come together to organize the National Health Assembly, decided to continue and develop this movement in the form of the Jan Swasthya Abhiyan (People's Health Movement). Jan Swasthya Abhiyan forms the Indian regional circle of the global People's Health Movement..

Despite medical advances and increasing average life expectancy, there is disturbing evidence of rising disparities in health status among people worldwide. Enduring poverty with all its facets and in addition, resurgence of communicable diseases including the HIV/AIDS epidemic, and weakening of public health systems is leading to reversal of previous health gains. This development is associated with widening gaps in income and shrinking access to social services, as well as persistent racial and gender imbalances. Traditional systems of knowledge and health are under threat.

These trends are to a large extent the result of the inequitable structure of the world economy, which has been further skewed by structural adjustment policies, the persistent indebtedness of the South, unfair world trade arrangements and uncontrolled financial speculation - all part of the rapid movement towards inequitable globalisation. In many countries, these problems are compounded by lack of coordination between governments and international agencies, and stagnant or declining public health budgets. Within the health sector, failure to implement primary health care policies as originally conceived has significantly aggravated the global health crisis. These deficiencies include:

- A retreat from the goal of providing comprehensive health care
- A failure to promote participation and genuine involvement of communities in their own health development.
- A lack of insight into the inter-sectoral nature of health problems and the failure to make health a priority in all sectors ofm society.
- A failure to promote participation and genuine involvement of communities in their own health development.

- Reduced state responsibility at all levels as a consequence of widespread and usually inequitable policies of privatisation of health services.
- A narrow, top-down, technology-oriented view of health and increasingly viewing health care as a commodity rather than as a human right.
- It is with this perspective that the organisations constituting the Jan Swasthya Abhiyan have come together to launch a movement, emerging from the Peoples Health Assembly process. Some objectives that this coalition set for itself (which are set out in detail in the Peoples Health Charter) can be listed briefly as below:
- The Jan Swasthya Abhiyan aims to draw public attention to the adverse impact of the policies of iniquitous globalisation on the health of Indian people, especially on the health of the poor.
- The Jan Swasthya Abhiyan aims to focus public attention on the passing of the year 2000 without the fulfillment of the 'Health for All by 2000 A.D.' pledge. This historic commitment needs to be renewed and taken forward, with the slogan 'Health for All - Now!' and in the form of the campaign to establish the Right to Health and Health Care as basic human rights. Health and equitable development need to be reestablished as priorities in local, national, international policy-making, with Primary Health Care as a major strategy for achieving these priorities.
- In India, globalisation's thrust for privatisation and retreat of the state with poor regulatory mechanisms has exacerbated the trends to commercialise medical care. Irrational, unethical and exploitative medical practices are flourishing and growing. The Jan Swasthya Abhiyan expresses the need to confront such commercialisation, while establishing minimum standards and rational treatment guidelines for health care.
- In the Indian context, top down, bureaucratic, fragmented techno-centric approaches to health care have created considerable wastage of scarce resources and have failed to deliver significant health improvements. The Jan Swasthya Abhiyan seeks to emphasize the urgent need to promote decentralisation of health care and build up integrated, comprehensive and participatory approaches to health care that places "Peoples Health in Peoples Hands".

The Jan Swasthya Abhiyan seeks to network with all those interested in promoting peoples' health. It seeks to unleash a wide variety of people's initiatives that would help the poor and the marginalised to organise and access better health care, while contributing to building long-term and sustainable solutions to health problems

The Jan Swasthya Abhiyan is being coordinated by National Coordination Committee consisting of 21 major all India networks of peoples movements and NGOs. This is the sixth book in a series brought out by the NCC for the NHA II.

Contents

Background

HIV-AIDS – How Much of a Problem?

HIV/AIDS is a global problem. While the epidemic has been most destructive in Sub-Saharan Africa, it is now rapidly spreading in many other regions. We know that there are 40 million people living with HIV/AIDS, of whom 37 million are adults and 3 million are children. Last year, 5 million people contracted HIV, of whom 4.2 million were adults, and almost 1 million were children. In 2003, HIV/AIDS killed 3 million people across the world. Over half a million of these deaths were children.

An estimated 2% of deaths in India were caused by HIV-AIDS in 1998. This is lower than deaths by diseases like T.B. However the alarming news is that deaths due to HIV-AIDS are projected to rise to almost 20% of all deaths within the next 25 years, if the epidemic is allowed to advance at the same rate as of today. HIV-AIDS would become the major killer disease in India where Africa did twenty years back – on the HIV-AIDS epidemic. In twenty years the epidemic has ravaged the continent of Africa and has pushed its economies back. Africa is poorer today than it was twenty years back. The contributor has been the HIV-AIDS epidemic.

experience and take urgent steps to control the epidemic. The Table (following page) gives the current status of the epidemic in India.

Table: Estimated Number of People with HIV/AIDS in India

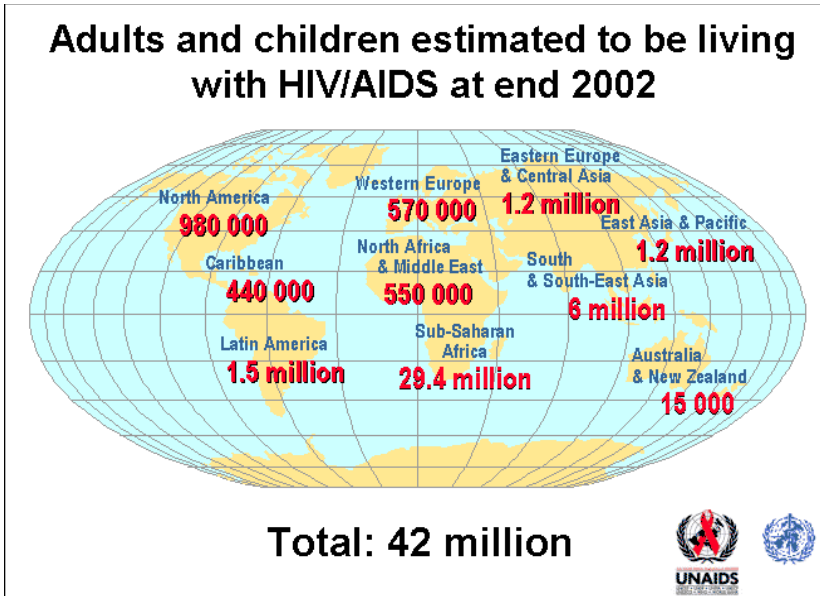
State	No.	State	No.
A and N Islands	538	A.P.	752,204
Arunachal Pradesh	2,336	Assam	44,905
Bihar	35,214	Chandigarh	6,346
Chhatisgarh	28,142	D & N Haveli	292
Daman and Diu	259	Delhi	58,328
Goa	7,920	Gujarat	155,723
Haryana	45,000	HP	2,323
J&K	10,782	Jharkhand	8,898
Karnataka	414,519	Kerala	33,866
Lakshadweep	211	M.P.	85,503
Maharashtra	852,901	Manipur	48,906
Meghalaya	4,626	Mizoram	2,990
Nagaland	9,437	Orissa	35,052
Pondicherry	2,116	Punjab	58,913
Rajasthan	137,432	Sikkim	840
Tamil Nadu	514,513	Tripura	3,680
Uttar Pradesh	317,172	Uttaranchal	18,044
West Bengal	57,545		
Total	**3,757,477***		

Source: National AIDS Control Organisation 2002.

** Since 2002 there has been an estimated 33% rise in the estimate for HIV-AIDS infections, and currently about 5 million people are believed to be infected by the HIV AIDS Virus in India*

What are the Different Determinants of the HIV-AIDS Epidemic?

HIV-AIDS has been called the worst human crisis in the modern era – in terms of death and destitution its toll far exceeds the combined effects



of the two World Wars of the last century. HIV/AIDS today is not a mere disease, it is a global catastrophe. A human tragedy of global proportions, the main brunt of which is being felt by virtually the entire continents of Africa – but which now threatens to engulf other countries like India. The numbers are so staggering that we often tend not to comprehend them. It would not be incorrect to say that human society has never seen a tragedy that has taken such a large toll on such a sustained basis. The HIV/AIDS tragedy has set back the continent of Africa by more than two decades.

HIV/AIDS is rooted not merely in the a causative agent and any fight against it does not lie only in addressing the disease by medical remedies. **HIV/AIDS is a political, social, legal and health issue.** It is a political issue because if you have HIV/AIDS in the North of the globe it is a chronic disease, the same disease kills in Africa and other poor regions of the world. This is so because political decisions

determine access to services, resources and knowledge to combat HIV/AIDS in different parts of the globe. It is a social problem because HIV/AIDS sharpens existing social inequities and targets women and children. It festers in situations of social instability, conflict and forced displacement and migration. It is a legal issue because treaties which are iniquitous, such as the TRIPS Agreement, perpetuate this unacceptable situation. The rights of HIV/AIDS patients and those at risk also require special attention. Finally, of course, it is a Health Systems issue. If HIV/AIDS is to be fought back, the fight needs to be located in a fully resourced public health delivery system, that is able to provide facilities for diagnosis, treatment and follow up for all those who require such facilities, irrespective of their social or economic status.

In this booklet, while underlining that control of HIV-AIDS needs to be located in all the above dimensions, we examine in detail the impact of the global trading regime on HIV AIDS (specifically on access to HIV-AIDS treatment) .

Section I

HIV-AIDS and Global Trade

The Trade Related Intellectual Property Rights (TRIPS) agreement, signed as a part of the WTO agreement, was the most bitterly fought during the GATT negotiations. Till 1989 countries like India, Brazil, Argentine, Thailand and others had opposed even the inclusion of the issues in TRIPS in the negotiating agenda. They did so based on the sound argument that Intellectual Property Rights — which includes Patents over medicines — is a non trade issue. India and others had argued that rights provided in domestic laws regarding intellectual property should not be linked with trade. They had further argued that the history of IPRs shows that all countries have evolved their domestic laws in consonance with the stage of economic development and development of S&T capabilities. Laws that provide strong Patent protection limit the ability of developing countries to enhance their S&T capabilities and retard dissemination of knowledge. Japan, for example, was able to enhance its domestic capabilities through the medium of weak patent protection for decades — well into the second half of the twentieth century. Italy changed to a stronger protection regime only in 1978 and Canada as late as in 1992. It was thus natural that many countries like India had domestic laws that did not favour strong protection to Patents before the WTO agreement was signed. It was illogical to thrust a single patent structure on all countries of the globe, irrespective of their stage of development.

Till 1989 countries like India, Brazil, Argentine, Thailand and others had opposed even the inclusion of the issues in TRIPS

These arguments were however systematically subverted during the GATT negotiations, leading to the signing of the TRIPS agreement. The TRIPS agreement required countries like India to change over to a strong patent protection regime. A regime that would no longer allow countries to continue with domestic laws that enabled domestic companies to manufacture new drugs invented elsewhere, at prices that were anything between one twentieth and one hundredth of global prices.

TRIPS Agreement: Features

The TRIPS Agreement covers two categories of intellectual property; *industrial* (trademarks, patents, geographical indications, industrial designs and trade secrets) and *literary and artistic* (copyright and neighbouring rights). It establishes minimum universal standards in all areas of intellectual property with the aim of implementing these standards globally through an enforcement mechanism established in WTO. The Agreement requires universal patent protection for any invention in any field of technology. All WTO member countries are required to adopt in their laws minimum standards of protection for patents, trademarks, copyrights and other intellectual property rights. These relate to the protection of products and processes.

It should be noted that the majority of members of the WTO already had some form of intellectual property protection in existence prior to the TRIPS Agreement. For example, as of January 1995, fewer than 20 of the current WTO developing country and least developed country members excluded pharmaceutical products *per se* from the grant of patents. The key difference that came about after the adoption of TRIPS agreement in 1995, was that countries were bound to certain universal standards of Patent protection. The TRIPS accord, thus, impinges on national sovereignty and prevents countries from changing their laws to suit national interests. Further, as TRIPS is part of the WTO system, there is now also the possibilty of cross-sector retailiation in the event

of non-compliance by any country of its provisions. This implies that any member country failing to bring its patent law into conformity with TRIPS, if challenged by another member country, is subject to the WTO dispute settlement system.

Even before the TRIPS agreement was signed in 1995, countries like Republic of Korea, Mexico, Chile, Thailand, Indonesia and the Andean Group countries (Bolivia, Colombia, Ecuador, Peru and Venezuela) had succumbed to US pressures and amended their patent laws during the late 1980's or early 1990's to allow patents for pharmaceutical products. Argentina, Brazil, Guatemala, Morocco and Turkey introduced pharmaceutical product patents since 1995, well before the end of the 10 year transitional period allowed by TRIPS for developing countries. Brazil, for example, was persuaded to introduce a new patent law in 1996, nine years before it needed to. India, was actually the last significant country to hold out and make use of the full 10 year transition period, but had to allow product patents by January 1st 2005.

There are several ways in which the TRIPS agreement impinged on the pharmaceutical sector and on the manufacture and sale of medicines. Article 27.1 entails that patent owners enjoy the same exclusive rights with respect to imported products as for products manufactured locally. This is contrary to what countries like India and Brazil allowed for – by making the local manufacturing of Patented drugs mandatory. Such a provision has major consequences for the development of domestic industry in developing countries, as now, imports by MNCs are to be treated on par with local manufacturing.

The TRIPS agreement also bars countries from discriminating between sectors, i.e. it compels countries to provide protection in all sectors – both for products and processes. Many countries, like India, had kept medicines and food out of the purview of Patents, but the TRIPS agreement does not allow this any more. The agreement (Article 33) allows a minimum 20 year Patent period, in contrast to countries

like India providing for much shorter Patent protection before implementation of the Agreement.

To summarise, the TRIPS agreement took away the sovereign right of nations to legislate based on public interest, forced countries to provide for 20 year patent protection even for areas like health care and food security, opened the way for MNCs to enter developing country markets even if there was domestic manufacturing capability, and put in place mechanisms for trade retaliation and sanctions if countries did not comply with provisions of the Agreement. It was designed to maintain the monopoly control of a handful of Transnational pharmaceutical companies over manufacture and trade of medicines. It must be remembered that the TRIPS Agreement was signed around the time when countries like Brazil, India and China were emerging as major centres for generic drug production. Today, an estimated 50% of drugs used to treat HIV-AIDS patients in the developing world are manufactured in India. The TRIPS Agreement was, thus, also a means to dampen the challenge to the monopoly of US and European pharmaceutical companies. The importance of this challenge would be obvious from the fact that Indian companies today offer a cocktail of anti-retrovirals at $200 per year in contrast with $10,000 - $12,000 charged by MNCs less than four years back. This is the advantage that will now be lost to the world, as the TRIPS Agreement prevents countries like India from manufacturing cheap generic versions of new anti-retroviral drugs that are in the pipeline today. The high cost of patented medicines can also be gleaned from the fact that the Brazilian National AIDS Programme has 14 ARV medicines, but 3 patented products account for 63% of the total programme expenditure.

HIV-AIDS Crisis

In 1995 the global pharmaceutical industry achieved a major victory through the signing of the TRIPS Agreement. Few had anticipated then the huge public opprobrium that was to be heaped on the industry in

Table: Life Expectancy and HIV/AIDS rates in Selected sub-Saharan African Countries

Country (HDI rank)[1]	1990	2002[2]	HIV prevalence (% ages 15 49)
Central African Republic (169)	47.2	39.8	13.5 %
Lesotho (145)	53.6	36.3	28.9 %
Mozambique (171)	43.1	38.5	12.2 %
Swaziland (137)	55.3	35.7	38.8 %
Malawi (165)	45.7	37.8	14.2 %
Zambia (164)	47.4	32.7	16.5 %
Zimbabwe (147)	56.6	33.9	24.6 %

[1] Human Development Index 2004 (175 countries, plus Hong Kong and the Occupied Palestinian Territories)
[2] Latest available verified data, incorporated in 2004 Human Development Index

the ensuing ten years. A major reason for this has been the galloping spread of the HIV-AIDS epidemic and the utterly callous response to it by the Pharmaceutical Industry which controls access to medicines required to treat HIV-AIDS.

More than 3 million people died of AIDS and nearly 5 million people became newly infected with HIV in 2004. There were just under 40 million people living with the disease – nearly half of them women – yet fewer than 1 in 5 people at high risk of infection had access to proven prevention interventions. The number of AIDS orphans climbed to 15 million, 12 million of whom live in sub-Saharan Africa. The table above shows the devastating impact of the epidemic in sub-Saharan Africa – the worst affected region of the world.

One would have expected a crisis of such massive dimension to have elicited a focused and rapid response. In a manner the crisis did evoke such a response – medical science rapidly developed a number

Table: Number of people (15-49 years) with access to antiretroviral drug treatment for AIDS, and estimated number who are in need, by country[1]

Country	Need for Treatment[2]	People Receiving Treatment[2]	Percent	Country	Need for Treatment[2]	People Receiving Treatment[2]	Percent
Angola	34,500	3,000-3,500	9.4%	Argentina	35,500	30-33,000	88.7%
Botswana	75,000	36-39,000	50.0%	**Brazil**	**179,000**	**154-160,000**	**87.7%**
B. Faso	45,000	3,000-3,500	7.2%	Burundi	40,000	3,000-4,000	8.8%
Cambodia	22,000	4,500-6,000	23.9%	Cameroon	95,000	12-15,000	14.2%
C. African Republic	40,500	1000 2.5%		Chad	30,000	500	1.7%
China	122,000	7,500-9,500	7.0%	Colombia	25,000	11-13,000	50.0%
Côte d'Ivoire	84,000	4,000-5,000	5.4%	Congo	167,000	3,500-4,500	2.4%
Ethiopia	211,000	10-13,000	5.5%	Ghana	55,000	1,500-2,000	3.2%
Haiti	42,500	3-4,000	7.8%	**India**	**770,000**	**20-36,000**	**3.8%**
Kenya	220,000	24-33,000	12.5%	Lesotho	56,000	2,500-3,000	4.9%
Malawi	140,000	10-12,000	7.9%	Mali	20,500	1,000	4.9%
Mexico	39,500	26-32,000	73.4%	Moz'bque	199,000	6,500-8,000	3.6%
Myanmar	46,500	1,500-2,000	3.8%	Namibia	32,000	7,500	23.4%
Nigeria	558,000	12-15,000	2.4%	Russia	92,000	3,000-3,500	3.5%
Rwanda	39,000	6,000-7,500	17.3%	South Africa	837,000	47-62,000	6.5%
Sudan	50,000	500	1.0%	Swaziland	36,500	5,000-6,500	15.8%
Thailand	114,000	45-55,000	43.9%	Uganda	114,000	40-50,000	39.5%
Ukraine	45,000	1,000	2.2%	Tanzania	263,000	2,000-3,500	1.0%
Vietnam	27,500	500	1.8%	Zambia	149,000	18-22,000	13.4%
Zimbabwe	295,000	7,500-9,000	2.8%				
Total	**5,800,000**	**700,000**	**12.1%**				

[1] Developing and transitional economy countries where estimated people needing treatment > 20,000
[2] Estimates from UNAIDS/ WHO for December 2004

of drugs to control the infection. Treatment of AIDS with a combination of drugs — called Highly Active Anti-retroviral Treatment (HAART) — decreased mortality from AIDS by 84% in a country like Switzerland between 1992 and 1998. This relative fall is greater than the 72% fall produced by penicillin in the treatment of severe pneumonia between 1930 and 1965, and of course occurred in a much shorter period of time. Unfortunately if an HIV +ve patient lives in

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see Tableon previous page) chance that
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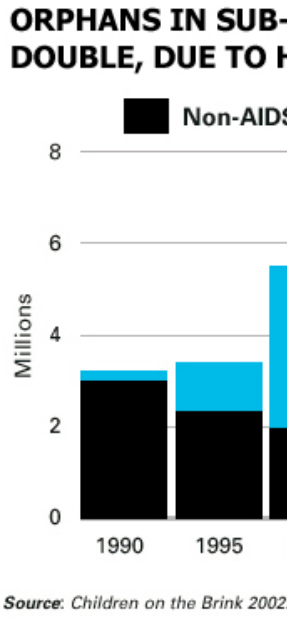
iscussion. Brazil is clearly the leader in
V-AIDS patients. Brazil's success can be
willingness to use its Patent Law with
provisions to bargain with big pharma to

negotiate lower prices, and pledging of public resources for HIV-AIDS treatment. It should however be mentioned that Brazil too has been unwilling to go all the way and actually issue a compulsory license to its domestic companies – a step which would have further brought down prices of ant-retrovirals in Brazil. A contrast in this case in India. Till India enacted its new law in 2005, pharmaceutical products were not protected by patents. As discussed earlier, this allowed Inida to export cheap anti-retrovirals to a number of developing countries. But India's record of treating it own HIV +ve population is poor – essentially a function of its poor public health facilities. **The short point is, that while Patents (or the absence of Patent protection) are very important in determining access to anti-retroviral treatment, there are also other very important factors that play a major role.**



Source: *Children on the Brink 2002*

Trade and Access to Medicines: Some International Examples

The manner in which the TRIPS agreement restricted (and continues to restrict) access to medicines is illustrated by two widely publicised cases involving South Africa and Brazil.

Medicines Case in South Africa

In December 1997 South Africa legislated on the "South African Medicines and Medical Devices Regulatory Authority Act" The Act was designed to enhance access to essential medicines through authorisation to revoke patents and allow for compulsory licenses to manufacture generic versions of anti retrovirals. The Act also provided for Parallel Imports, i.e. imports from sources offering cheaper prices than that charged by companies in the country. The Act immediately provoked a reaction from the US, with the US Commerce Secretary denouncing it squarely. In 1998, the European Commission too joined the US in pressuring South Africa to repeal the Act.

In February 1998, the South African Pharmaceutical Manufacturers Association and 39 pharmaceutical companies filed a suit in Pretoria High Court against the Act. alleging that the Act violated the TRIPS agreement and the country's Constitution. The case drew wide attention and the action of the pharmaceutical companies was condemned by activists across the globe. Sensing public sentiment the US announced that the USTR would refrain from pressuring South Africa on this issue. However the companies remained adamant till the time the case came up for trial in March, 2001. The huge outcry caused by the case forced the companies to with draw the case.

Access to HIV Drugs in Brazil

The Brazilian Governmemt health system treats by far the largest number of HIV-AIDS patients – far more than in any other country.

Central to this programme is Brazil's attempt to indigenously manufacture most of the drugs required for its HIV-AIDS programme. A key component of the Brazilian Patent Law is a provision that requires manufacturers to produce a Patented drug in the country. The law stipulates that a Compulsory License may be issued if this provision is not complied with.

In February 2001, this provision (Article 68) of the Brazilian Law was challenged by the US at the WTO Dispute Settlement Body (DSB). The US claimed that the Brazilian law violated the TRIPS agreement. Brazil replied that its law did not violate the TRIPS agreement and was actually in line with Art.5.4 of the Paris Convention, which in turn is incorporated in the TRIPS agreement through its Art. 2.1. This action by the US provoked a strong global reaction and in June, 2001 the US withdrew its case against Brazil.

Both these cases highlighted the differences in approach while interpreting the TRIPS agreement. It was in this background that developing countries pressed for a discussion on the issue of Public Health and TRIPS. This proposal, which was sponsored by a number of African countries, wanted the TRIPS Council to clarify that countries have the flexibility under TRIPS to impose comulsory licenses or take recourse to parallel imports, in order to address the problems associated with any public health crisis. Initially this was opposed by a number of developed countries, including, the US, Japan and Switzerland. With no resolution in sight, the matter was taken up in the WTO Ministerial meeting in Doha, in November 2001.

The Doha Ministerial issued a declaration on Declaration on the "TRIPS Agreement and Public Health". The declaration was hailed as a landmark in the negotiating history of the World Trade Organisation as this was the first instance, since the signing of the WTO Agreement in 1994, that a portion of that agreement has been interpreted in a manner that was favourable to developing countries.

The declaration noted: "*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*". It also said: "*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*". It further added: "*Each Member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted*".

While the Doha declaration constituted an advance for developing countries. Para 6 of the declaration pointed to an area that remained unresolved. The declaration clarified that comulsoty licenses could be issued to domestic manufacturers for medicines under Patents, so that they could manufacture generic versions of these drugs and sell them at much cheaper prices. As a majority of countries who were reeling under the impact of HIV-AIDS, fell under this category, the declaration was in many senses a hollow victory for developing countries. However this was of little or no help to countries without domestic manufacturing capability. The Doha meeting authorised the TRIPS Council to find a solution to this problem.[4]

Having failed to get their way in Doha, developed countries saw this as an opportunity to nullify the gains made by developing countries through the Doha declaration.

In August 2003, the WTO General Council finally resolved the issue by adopting what is known as the Perez Motta text. The Motta text, was a far cry from what developing countries had wanted. They had argued that the TRIPS agreement should be amended (amendment of Art.30 of the TRIPS text) to treat exports to countries without manufacturing capacity as "exceptions" to patentability, i.e. patent protection would not be valid in such cases.

The text allowed WTO Members to issue compulsory licenses for export to countries with little or no manufacturing capability. Thus it

allowed countries like India and Brazil, with developed manufacturing facilities, to issue compulsory licenses to authorise domestic manufacturers to produce generic versions of patented drugs for export to countries without manufactring capability. Potentially this should benefit a large number of developing countries in Africa and Asia, many of whom are reeling under the impact of the HIV-AIDS epidemic. However, the Motta text places onerous conditions on countries who wish to avail of the facility. Both exporting and importing countries will have to seek a "case by case" clearance. Given this, few manufacturers in countries like India appear to be interested in making use of the new provision. Given the complexities now built into the process, there is unlikely to be much activity taking place in this area. The lack of interest would also have to do with perception in the generic industry regarding the size of the market in countries with no manufacturing facilities and their willingness to pledge resources to set up manufacturing facilities for a market that is plagued with uncertainty – given that there will be no blanket provision available to export.

Monopoly Power of Pharmaceutical Companies

Proponents of the TRIPS Agreement argue that Patent protection promotes innovation and ultimately benefits everybody. They contend

that without Patent protection new drugs (such as for HIV-AIDS) would

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in diseases such as tuberculosis and malaria and also in finding appropriate

treatment and diagnostic aids for HIV-AIDS in poor countries. It has been estimated that less than 10% of global spending on health research is devoted to diseases or conditions that account for 90% of the global disease burden.

Patent monopolies also serve to perpetuate the concentration of the industry in a few hands. The leading 100 pharmaceutical manufacturers produce about 70 per cent of all drugs and the bulk of pharmaceutical production occurs in Japan, Switzerland, the US and the EU (particularly the UK). Despite enormous shifts in its core technologies, the industry continues to be dominated by companies founded before World War II.

Patents on Medicines out of the Global Trading Regime

Clearly we have a situation that is unacceptable. The issue of how we address the TRIPS Agreement needs to be firmly addressed. While the battle to ensure that the flexibilities in the TRIPS Agreement are allowed to be used by developing countries must continue, it is also necessary to understand that the TRIPS is and shall remain an inequitous Agreement. No national legislation in the area of patents can meaningfully address the legitimate interests of its citizens while remaining within the framework of TRIPS. The TRIPS agreement needs to be taken out of the WTO and this is where terrain for future struggles must shift. The developing countries had argued precisely this in the GATT negotiations before the WTO Agreement was signed, and it is time now to return to this argument once again. **The HIV-AIDS saga is a powerful reminder that Patents and Health care cannot be mixed together.**

Section II

Patents for Profits

Intellectual property means property that is a creation of the human mind. Because ownership over Intellectual Property cannot be ensured through means that are used for other forms of property, special mechanisms are used in the case of intellectual property. In the case of ideas that lead to inventions that have industrial applications, the ownership over the new idea is protected by Patents. The first patent law was enacted in 1623. Patent Rights are monopoly rights allowed by the Government under certain conditions. The idea behind Patent rights is that the details of an invention are made public by an inventor, and in exchange for this disclosure the inventor — for a limited time — has the exclusive right to make, use or sell the invention. Inventors are thought to deserve special reward because of the benefit of inventions to society.

Patent Rights reduce the freedom to use new ideas because the original inventor is allowed a monopoly over the use of his idea for a certain period of time. It has been argued that the concept of Intellectual Property Rights (IPRs) in general and Patent Rights in particular, is built on a contradiction. It is a contradiction that says that in order to promote the development of ideas, it is necessary to reduce the freedom with which people can use them. Laws on IPRs by attempt to strike a balance between public interest and rights of the inventor. Unfortunately, since the signing of the Trade Related Intellectual Property Rights (TRIPS) agreement in 1995 as part of the WTO agreement, the balance has shifted in favour of those who hold the rights over new inventions. How this has happened is discussed at greater length elsewhere.

We are now entering an era where major parts of the world economy are based on ideas and knowledge, i.e. goods that take no material

form. The central distinction between information or knowledge or ideas and physical property is that information can be transferred without leaving the possession of the original owner. Unlike physical goods, there are no physical obstacles to providing an abundance of ideas. Intellectual property Rights are an attempt to create an artificial scarcity of ideas in order to give rewards to a few at the expense of the many.

IPRs today bring into force another kind of problem. Open ideas can be examined, challenged, modified and improved. But IPRs, by converting scientific knowledge into a commodity, arguably inhibits science. There are innumerable examples to show that IPRs have been used to suppress innovation. Companies may take out a patent, or buy someone else's patent, in order to inhibit others from making use of new ideas. As far back as in 1875, the US company AT&T collected patents in order to ensure its monopoly on telephones: an act that is beleived to have slowed down the introduction of the radio by almost 20 years. In a similar fashion, General Electric used control of patents to retard the introduction of fluorescent lights, which were a threat to its market of incandescent lights.

Do IPRs Promote Creativity and New Inventions?

It is argued that Intellectual Property Rights promote creativity and innovations. This was probably true at the time when the concept of IPRs developed. The earliest Patent and Copyright Laws were designed to benefit the individual artisan, or the author of a literary piece or a musical score. In the last hundred years, however, protection of IPRs has become something very different. We are no more talking about protecting the property of a single, or a group of artisans who have laboured to produce something useful to society. Intellectual products, today, are social products. Individual creators have now ceased to be the beneficiaries of Patent rights, and have been replaced by large multinational corporations. Most individual creators do not actually

Table: Profitability by Industrial Sector (1999)

Sector	Net Profits as % of Assets	Net Profits as % of Revenues
Pharmaceuticals	**14.7**	**18.3**
Beverages	11.1	10.1
Tobacco	8.0	8.5
Specialty Retailers	6.0	2.6
Telecommunications	5.5	10.2
Computers, Office Equipment	4.9	6.6
Food	4.8	2.2
Aerospace	4.1	4.3
Petroleum Refining	4.0	3.6
Forest & Paper Products	3.8	4.2
Food & Drug Stores	3.7	1.9
Chemicals	3.6	3.3
Wholesalers	3.5	1.2
Airlines	3.4	3.4
Electronics, Elect. Equipment	2.9	3.0
General Merchandisers	2.8	1.4
Energy	2.3	2.2
Publishing, Printing	2.3	2.5
Motor Vehicles & Parts	2.2	2.2
Utilities: Gas & Electric	2.1	2.5
Entertainment	2.0	5.6
Health Care	1.9	2.8
Diversified Financials	1.5	11.1
Mail, Package, Freight	1.1	1.7
Securities	0.9	10.7
Industrial & Farm Equipment	0.8	0.9
Mining, Crude Oil Production	0.8	1.0
Banks: Commercial/Savings	0.6	5.4
Insurance: P & C	0.6	3.5
Insurance: Life, Health	0.5	2.3
Engineering, Construction	0.4	0.5
Railroads	0.4	1.3
Trading	0.4	0.2
Metals	-0.7	-0.4

Source: Fortune 500

stand to gain from protection of intellectual property today. When employees of corporations and governments have an idea worth protecting, it is usually copyrighted or patented by the organisation, not the employee. Since intellectual property can be sold, it is usually large corporations who benefit.

IPRs now help create massive monopolies that place enormous power in the hands of a handful of corporations. It is a power that allows corporations not only to reap huge profits, but more importantly, to determine the direction of research. Microsoft, for example, with its virtual monopoly over software that is used on Personal Computers (PCs) has consistently obstructed the development of new products by its competitors. A handful of Pharmaceutical corporations, given their monopoly over the control of knowledge, can decide the kind of drugs that will be developed — drugs that can be sold to people with the money to buy them. Thus on one hand we have the development of "life-style" drugs, i.e. drugs like viagra which target illusory ailments of the rich. On the other hand we have a large number of "orphan" drugs — drugs that can cure life threatening diseases in Asia, Africa and S.America, but are not produced because the poor cannot pay for them.

The importance of the knowledge based sectors to the US (and global) economy can be gauged from the performance of large companies today. Among the top fifteen companies with the highest returns (profits) on Revenues (turnover), six are pharmaceutical companies and five are from the information technology sector.

The principal arguments of the pharmaceutical industry are related to its claims that it invests huge amounts in the development of new drugs and hence deserves returns for such investments. The important point to be underscored is that after the claimed investments are made on R&D the pharmaceutical sector has consistently been the most profitable sector. A perusal of the profitability in different sectors based

on data from the top 500 globally, shows that profitability in the pharmaceutical sector is way ahead of all other sectors. (***see Table***)

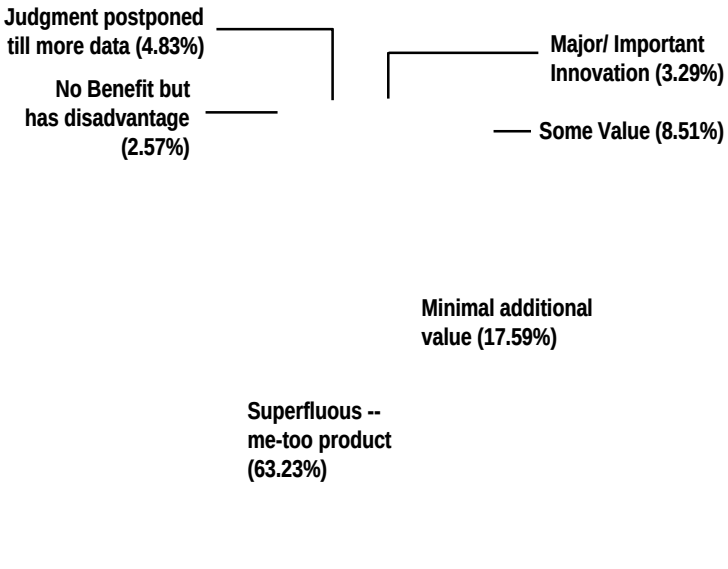
To look at it in another way, if profit margins of top pharmaceutical companies were to have been less by a third of current levels — which would still make them more profitable than any other sector — a benefit of about 11 billion dollars could have been passed on to consumers. That is in fact more than the projected 10 billion dollars that are required to provide access to anti-AIDS drugs to <u>all</u> HIV positive patients in the world!

Innovations for Whose Benefit?

High prices, are just one part of the story. The other part of the story is that **drugs which sell in the market have little to do with the actual medical needs of the global population**. As there is nobody to pay for drugs required to treat diseases in the poorest countries, or even to treat the poor in developed countries, such drugs are rarely researched. Research and patenting in pharmaceuticals are being driven by the search for the next "blockbuster" drug — which in industry parlance means a drug with global sales of over one billion dollars. This is a major reason for the trend towards global mergers, as individual Cos. wishing to retain the huge growth rates from the 1970s to the 90s, try to pool resources for R&D. As a consequence, we are looking to a situation, where 10-12 conglomerates will survive as "research based" companies. The bulk of drug manufacturing will be done by smaller companies. In the US today, this trend is already discernible. While the volume of sales of large pharmaceutical companies has stagnated in the past decade, the sales of small companies producing generic drugs has shown a double digit growth. However the profitability of these companies have not suffered — rather they have increased. Clearly these companies are able to thrive on "rent incomes" made possible by strong IPR protection, while not enhancing their manufacturing activities.

The frantic search for the next "blockbuster", consequently, skews drug development in favour of new drugs for which there are buyers who are willing to pay prohibitive amounts. Attempts are also focused at carrying out minor modifications on proven "blockbuster" in order to maintain dominance over particular market segments after the patent on the original money-spinner runs out. Thus Schering has recently introduced its "son of Claritin" to replace its anti-allergic drug, Claritin, (loratidine) that produced returns to the tune of 9 billion dollars in the last decade. Eli Lily tried the same with its hugely succesful anti-depressant drug, Prozac, (fluoxetine) by trying to introduce R-fluoxetine — an attempt which failed in the penultimate stage due to the "new" drug's unacceptably high cardiac effects.

Assessment of New Drugs Introduced Between 1981-2000 ***(Source: Prescrire International)***



This trend has converted the whole business of new drug development into farcical exercise with tragic consequences. The basic qualification for the next "blockbuster" is that it should be possible to sell it in the market, not that it should address real medical needs. Hence, more and more drugs being introduced are "copycat" drugs or drugs like Pfizer's Viagra that address "lifestyle" needs and not medical needs and do not significantly alter prevalent therapeutic practices (**See Chart on previous page**).

The problem, thus, is not merely one of high prices. Consumers are being forced to pay higher prices based on the specious plea that these prices are warranted because of high research costs. But the drugs that are being introduced do not address real medical needs in an overwhelming majority of cases. What, one may legitimately ask, then justifies such high research costs — the burden of which are finally passed on to consumers.

It also needs to be noted that many new drugs are initially researched in public funded institutions. For a major proportion of newly introduced drugs it is virtually impossible to trace the precise step which is innovative. Beta-blockers, H2-blockers, Taxol, ACE inhibitors — therapeutic groups which spawned a host of "blockbusters" were initially researched in public funded institutions.

It is but natural that an industry driven by rent incomes will bypass the needs of the income poor across the globe. The most severely affected are the poor living in developing countries. Tuberculosis kills half a million people in India alone, but the last new anti-TB drug was introduced more than two decades back. Just four per cent of drug research money is devoted to developing new pharmaceuticals specifically for diseases prevalent in the developing countries. Some drugs developed in the 1950s and 1960s to treat tropical diseases, on the other hand, have begun to disappear from the market altogether because they are seldom or never used in the developed world. These drugs are termed, appropriately, as "orphan" drugs.

The pharmaceutical industry argues that patented drugs constitute less than 10% of drugs that are being used in developing countries. The statement is possibly true when taken at its face value. But what it hides is the fact that this is because drugs addressing the real medical needs of developing regions are seldom addressed by pharmaceutical companies. So the reason why so few commonly used drugs in developing countries are under patents is not because new drugs are not necessary, but because pharmaceutical countries do not develop appropriate drugs.

The Poor Spend More on Medicines

There is a truism about pharmaceutical consumption — those who need drugs the most are the least likely to be able to pay for them. So even if it is claimed that efforts by the pharmaceutical industry places life saving drugs in the market, the mere presence of such drugs does not ensure access. This is a fact that has been consistently highlighted in the campaign on ant-AIDS drugs and needs little elaboration here. It needs to be underlined, however, that as we move towards poorer countries as well as towards the income poor in rich countries, drug costs

Table : Regional Comparison of Private Expenditure on Pharmaceuticals

	TotalPharmaceutical Expenditure		Pvt. as % of Total
	Per capita (US$)	% GDP	
Sub-Saharan Africa	8	0.9	65
Asia	12	0.6	81
Middle East	27	0.7	74
Latin America	26	0.9	72
Mkt.Economies	138	0.6	40

Source: Selected Topics in Health Reform and Drug Financing, WHO

form a higher proportion of total medical costs. For example, in countries such as China, Indonesia, and Thailand, this share ranges from 35-45%. In several African countries, it is believed to exceed 50% [*Public-Private Roles in the Pharmaceutical Sector, 1997, WHO*]. US Cost of prescription drugs is about 10% of health care costs but have risen much more rapidly than physician costs and costs of hospitalisation. Moreover, in developing regions, a much larger percentage of drug costs are paid for privately (***See Table on previous page***).

Patents Make for Bad Science

Strong patent protection now extends to protection of test data generated by companies while researching new products. The pharmaceutical industry argues that granting data exclusivity for test data is crucial, since the development of these data is expensive. Allowing other companies to rely on data developed by the innovator, instead of having to develop their own clinical data, would give them an unfair economic

advantage. But the net result is that there is less and less disclosure of information when patents are filed. We now have an emerging trend that is contrary to the standard argument in favour of strong patent protection: that such protection ensures early disclosure of innovations and thus promotes faster dissemination of knowledge.

"Full disclosure" usually means providing enough detail for a "person skilled in the same or the most clearly related area of technology to construct and operate" the patented object. Strong patent protection is now moving the pendulum away from the concept of "full disclosure" and it is a matter of grave concern for the scientific community. Can information provided by patients acting in the public interest legitimately be considered the intellectual property of a pharmaceutical company? In practice, to support the marketing of their new products, most manufacturers make some of their intellectual property generally available by publishing some of the reports upon which their successful licens1e applications were based. Unfortunately, these reports are not generally representative of all the evidence. A report in 1980 showed that studies submitted in support of applications for new licenses for drugs in which side-effects had been shown were less likely than others to be published. There have been a number of recent instances of suppression of vital information by companies. Clearly, patents have ceased to be a vehicle of dissemination of knowledge and have become the tools to constrain its spread — quite the antithesis of what good science requires.

Patents Retard Domestic Industries in Developing Countries

Domestic industries outside the developed countries have been able to develop in places where strong patent production has not been allowed. India is representative of such a situation, where the Indian Patents Act of 1970 allowed the development of a strong vertically integrated pharmaceutical industry. It was facilitated by the ability of Indian

companies to develop and market generic versions of patented drugs. The issue is not just that it allowed cheaper versions of patented drugs to be sold in the Indian market. More importantly, it led to the development of world class manufacturing facilities in a developing country.

Today the campaign on access to drugs draws strength from Indian companies like Cipla who are offering anti-AIDS drugs at one tenth to one fortieth of the prices being charged by large pharmaceutical countries. It also draws strength from the ability of Brazil to indigenously manufacture 8 out of the 12 anti-AIDS drugs and also to distribute them to all those who require these drugs. Let us not forget that this could not have happened if the TRIPS accord had been signed in 1975 and not in 1995! It is this that we stand to lose as we move towards "harmonised" standards of strong patent protection.

It is also this that is sought to be taken away by large pharmaceutical companies through the medium of TRIPS. Notwithstanding the rhetoric, the TRIPS accord was not pushed through to access markets of developing countries. These markets represent just a fraction of the global market — India, for example, accounts for 0.8% of the market, in contrast to 33%, 24% and 20% for the US, Europe and Japan respectively. Rather the TRIPS agreement became a necessity to protect the markets of large pharmaceutical companies in the developing world against competition from cheaper generic drugs manufactured in countries like India and Brazil. TRIPS in other words is not about "free" trade, but has to do with protection of markets in developed countries.

Section III

Public Health Safegaurds in the TRIPS Agreement

A patent provides proprietary title over an invention, which allows the patent holder the right to prevent others from using, making, selling, marketing the product for a specified period. There are no international patents, and patent rights are limited to the country in which it has been granted. A patent gives the patent holder a temporary monopoly on using, making and selling the invention as a "reward" for publishing the full details of the invention. In return the public pays a higher price during the patent term, but after expiry of patent, has free access to the invention.

Given the large benefit that accrues to a patent holder through the temporary monopoly that it enjoys, it is legitimate to question what amounts to a good invention to deserve this reward. Patents are a public policy tool - to be balanced against other public policy needs and governments have the power to keep this balance. Ideally health considerations should play a decisive role in defining which inventions deserve protection, but in practice the Ministry of Health is rarely involved in decisions regarding patents.

Patents on Pharmaceutical are for inventions, and not medicines per se. Thus patents may be granted for: a chemical compound or molecule; a medical indication or therapeutic effect of the molecule; the combination of products (e.g., a fixed dose combination of 2 or more molecules); or the manufacturing process (known as a process patent). There could be more than one patent for a single medicine, viz. the chemical compund as well as the process to make it can both be patented. It needs to be kept in mind that while above are the possible kinds of patents that can apply to medicines, national laws may restrict

the kind of patents to be granted for medicines, viz. some laws can explicitly bar the grant of patents for drug combinations.

Patents and Prices

The fact that patents on medicines lead to higher prices has been widely documented, and this is to be expected given that patents confer a monopoly (albeit temporary) to the patent holder. Reduction in prices of patented drugs result when this monopoly enjoyed by multinational drug corporations (who hold the overwhelming majority of drug patents) is curbed and market competition is introduced. **Thus, for example, the cost of triple drug therapy to treat HIV-AIDS was in excess of US$10,000 per patient per year, before the Indian generic manufacturer, Cipla, offered the same therapy in February 2001 at US$350 per patient per year. As a result of generic competition, current prices for first line triple ARV therapy is approx. US$168 in January 2005** (See graphic on next page).

WTO/TRIPS Agreement

The TRIPS agreement under the WTO sets minimum standards for IPR protection and all WTO members are bound to comply. Before the agreement in 1995, countries did not have to grant patents for medicines if they did not wish to. This had allowed a diversity in national approaches to patent protection, in terms of what could be patented (scope), patent term, exceptions to patentability, etc. The TRIPS agreement sets minimum standards for patent protection. It must, however, be underlined that the agreement is not a uniform international law with uniform legal requirements and countries have some leeway in how to implement it. The agreement requires countries to provide patents to protect inventions, in all fields of technology, and for both products and processes. Patents have to be provided for inventions

Generic Competition Reduces Drug Prices Drastically

June 2000 to June 2005

Sample of ARV triple-combination: stavudine (d4t) + lamivudine (3TC) + nevirapine (NVP). Lowest world prices per patient per year. Generic competition has shown to be the most effective means of lowering drug prices. During the last four years, originator companies have often responded to generic competition

Source: Medecens Sans Frontieres: Untangling the web of Price Reductions, June 2005

that meet the three criteria of : novelty, inventive step, industrial application (TRIPS Art.27).

TRIPS flexibilities or safeguards

As the TRIPS is not an international law, countries have the flexibility to interpret it based on their national situation. They can include in national legislations measures that may limit exclusive patent rights, so that the objectives and principles of the TRIPS Agreement may be achieved. Articles 7 and 8 of the TRIPS agreement set out some of the broad objectives of the agreement, including: promotion of technological innovation, transfer and dissemination of technology; and measures to protect public health and nutrition and to promote the public interest. Further, the Doha Declaration (at the time of the WTO Ministerial meeting in 2001) affirmed the right of countries to use to the full, the flexibility in TRIPS

The flexibilities or public health safeguards available in TRIPS and clearly affirmed by the Doha Declaration include the following:

- Government use
- Compulsory licences
- Parallel importation
- Exceptions to patent rights (e.g., Bolar exception)

Government use

This pertains to the government's right to use a patented invention, without consent of the patent holder, and is allowed under TRIPS (Article 31). It permits government agencies or a party authorised by the government to use an invention, for public, non-commercial purposes. e.g., public sector production of generic medicines, or import of generics for use in public hospitals. This provision allows for "fast-tracking" of compulsory licences, i.e. licenses to generic manufacturers can be issued even before the country's law allows generic production in the normal course through issue of compulsory licenses. Government

use provisions are part of many country laws on patent protection, including broad provisions in the laws of developed countries, such as in the US and UK (known as “Crown use”).

Compulsory licences

Compulsory licences are non-voluntary licences granted by the government to permit third parties to use a patented invention, without the patent holder’s consent. Using such licenses local pharmaceutical companies may produce generic versions of patented medicines, or generic versions of medicines may be imported from foreign manufacturers. Governments have the right to determine grounds for compulsory licence, and such grounds are not limited to emergencies. The main conditions for grant of a compulsory license are prior negotiations with the patent holder, payment of compensation and an appeals procedure.

Parallel Import

Parallel import is the import and resale of a patented product in another country, without consent of patent holder. It involves the import of a patented medicine from country A to country B, when the patented product is sold at a higher price in Country B than in Country A. TRIPS does not prohibit parallel imports, Article 6 allows countries to decide which regime for “exhaustion of rights” to adopt. The principle under which exhaustion of rights operates is that the rights of the patent holder are exhausted once the product is put for sale in the market, and a resale of the same does not constitute an infringement of the rights of the patent holder. Many countries, viz. S.Africa, Malaysia, Argentina, India, etc. have provisions in their national laws allowing for parallel imports.

Exceptions to patent rights

Exceptions to patent rights allow limited use of a patent in specific circumstances. TRIPS allows for exceptions to patent rights under

Article 30. For example, the “Bolar” exception allows the production of generic medicine for testing and regulatory approval, to enable speedy introduction of generic product once the patent expires. Other exceptions include exceptions for research, and experimental use. For a country to make use of this flexibility specific exceptions must be provided for in the national law.

Use of safeguards

Most developed countries have TRIPS safeguards in their laws, and have used them (e.g. the extensive use of compulsory licensing in the US). Ironically, many developing countries have not included all TRIPS safeguards in their national laws. The challenge is to make sure that all available safeguards are provided in national laws to enable countries that need such safeguards to use them whenever necessary. In order to use these safeguards countries may need to review, compare and amend their laws to:

- Fully exploit the flexibility in TRIPS;
- Ensure that these flexibilities are implemented through clear, unambiguous, easy to use, regulations
- Adopt clear, easy to apply, and transparent guidelines for setting compensation rates;
- Ensure that appeal procedures that do not suspend execution of licence;
- Adopt straightforward, transparent and speedy procedures.

Section IV

Recent Developments and Implications for Public Health

The TRIPS agreement was instrumental in developing a new set of standards for patent protection. In 1986, 50 countries did not recognise patents in the case of pharmaceutical products.

The TRIPS agreement, thus, obliged massive changes in national laws, including extension of patents to all fields including pharmaceuticals, reversal of burden of proof, 20 years term. This led to an increase in the level of IP protection, especially in the case of pharmaceuticals across the globe. Most countries were inclined to provide for the minimum standards set in TRIPS as the maximum level of IP protection their national laws would provide. Developing countries were in a position to make use of the multilateral framework for dispute settlement in the WTO. This provided them some protection against pressures to provide higher levels of IP protection from developed countries. After the medicines court case in South Africa, developing countries actively pressed for the Doha declaration in 2001, which was designed to clarify that safeguards to public health could be built into national laws dealing with IPRs. The Doha Declaration was a significant landmark, marking the recognition that public health issues need to be kept in mind during trade negotiations.

Free Trade Agreements

The scenario has changed dramatically in the last 5 years. Faced with the reluctance of the multilateral system in the WTO to introduce new changes providing higher levels of IP protection, the US has chosen to increasingly rely on a bilateral approach. A significant number of

countries have signed or are negotiating Free Trade Agreements with the US, attracted by the prospect of access to the large US market for their export products. The price that they have to pay in return includes provisions in the agreements that are designed to open their economies, viz. in the form of reduced import tariffs and liberalised service sector norms that encourage the flow of goods and services from the US, and higher IP standards. These IP measures have been termed as "TRIPS plus", or "TRIPS extra" as areas covered have not been conceived in the TRIPS agreement.

For example, in separate FTAs with Singapore (already signed) and Thailand (being negotiated) the US has insisted on the incorporation of a chapter on IPRs that provided for strong IP standards. The FTAs incorporate no flexibilities and it is understood that the pharmaceutical and software industries have played a major role in framing these chapters. Some provisions in these chapters that may have negative consequences for Public Health are the following:

- Some FTAs ask for patent terms exceeding 20 years to compensate for delays in patent examination and marketing approval for pharmaceutical products.

- Data exclusivity for pharmaceutical products is provided for in these FTAs. Under CAFTA the period can be up to 10 years. This actually constitutes the creation of a new right sanctioned by the FTAs.

- Drug Regulatory Authorities are not allowed to provide marketing approval pharmaceutical products if there is a patent on the drug. They can block registrations even if the patent is invalid. It provides for them to block registration even in the case of invalid patents if the application has not been examined yet. Such provisions do not exist even in the US or in Europe. In the US, for example, the FDA just informs the patent owner of a request for marketing approval.

Data Protection and Data Exclusivity

Data exclusivity refers to a practice whereby, for a fixed period of time (usually 5 years), drug regulatory authorities may not rely on the data that the originator company files to get marketing approval, in order to register a generic version of the same medicine. It means that if an MNC gets marketing approval for a drug based on data of clinical trials, these clinical trial data cannot be relied on to register a drug by a company. The latter, would have to conduct fresh clinical trials before its version of the drug can be registered, or wait till the end of the exclusivity period.

It is important to be clear that, firstly, Patents and Data Exclusivity are two entirely different concepts. In fact the enforcement of Data Exclusivity can have the biggest impact in situations when Patents cannot or are not being enforced. Secondly, the TRIPS Agreement, which lays down conditions for Patent protection does mention Data Exclusivity. What the TRIPS Agreement requires, is "Data Protection" (explained later), which is very different from Data Exclusivity. However, some parties try to argue that Data Protection is the same as Data Exclusivity.

Medicines, the world over, are subject to two sets of national rules: Intellectual Property Rights (IPRs – which include Patent protection) and registration of drugs before marketing approval. The former is regulated by a country's Patent laws while the latter is regulated by the drug regulation authorities. In the case of Patents it is a private right, that it is a right that the Patentee enjoys and the onus is on the Patentee to ensure that it is not infringed, i.e. someone else does not make the patented substance during the patent period. If such an infringement is alleged, the Patentee has to approach the relevant authorities to take action against the infringer. On the other hand a drug regulatory authority is a body set up as a public authority. Its function is to ensure,

in public interest, that drugs that are provided with marketing approval meet the criteria of safety, efficacy and good quality.

Forcing Drug Regulatory Agencies to Protect Private Monopoly Rights

When implementing Data Exclusivity, drug regulatory authorities are acting on behalf of pharmaceutical companies to safeguard their monopoly right. They are being asked to reject the application for marketing of a drug by another company if it doesn't submit fresh data from its own clinical trials. This is clearly a practice that cannot be within the domain of regulatory agencies. With regards to safety and efficacy, they have already been taken care of when the originator company's drug was given approval.

In relying on the data of innovator companies, drug regulatory bodies are not compromising on quality or efficacy, because they usually do insist that the second company provide data on bio-equivalence – i.e. show that the drug achieves the same concentration in the human body as for the originator company's drug. In addition, regulatory agencies make sure that the second company follows manufacturing practices that ensure a certain quality so that its drug is similar in properties to the original drug.

Data Exclusivity is not a TRIPS Requirement

The TRIPS agreement mentions the need to provide for what it calls "Data Protection" under Article 39(3) of the agreement where it says: " *Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products that utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition, Members shall protect such data against disclosure, except where necessary to protect*

the public, or unless steps are taken to ensure that the data are protected against unfair commercial use".

It may be noted that TRIPS does not mention "data exclusivity" but "data protection". There is a clear distinction that must be made between the two – in the former case it is a concept involving monopoly right for a period over test data whereas in the latter case no such monopoly right is involved. The US is pursuing this issue vigorously, and Data Exclusivity provisions form a part of all Bilateral Free Trade Agreement that it is involved in. Data Exclusivity has thus become the prominent "TRIPS Plus" (i.e. measures that go beyond the TRIPS Agreement) measure that the US is pressing for.

Impact of Providing for Data Exclusivity

There are various factors involved when pharmaceutical companies press for data exclusivity. First, it allows them monopoly power even in situations where a country is not required to provide patent protection. For instance, all Least Developing Countries (LDCs) who, under WTO rules, do not need to allow Patents in medicines till 2016. In their case, Data Exclusivity allows companies to have a "patent like" monopoly for a certain period – usually at least 5 years. While 5 years may seem a small period compared to the patent period of 20 years mandated by TRIPS, it must be understood that data exclusivity comes after marketing approval, i.e. usually with a few years of patent exclusivity. So it really covers up to half or more of a patent period, and importantly, it covers the period when the benefits of monopoly protections are maximum. Further, the US advocates for Data Exclusivity for the new use of an existing drug, which can push the monopoly enjoyed by the originator company beyond the 20 year patent period if the new use is "discovered" just when a patent is about to expire.

For countries like India where Patents on medicines are now allowed the effect can be of a different kind. The instrument available in India to curb the exclusivity of the originator companies is the use

of a compulsory license. It is a license that the Government can issue after 3 years of patent grant, if it is found that the Patented drug is not available, or it is too expensive, or the development of domestic industry or an export market is hampered. Such a license would allow domestic companies to manufacture the Patented drug in the country, after paying a small royalty to the originator company. But if Data Exclusivity is provided for, such a license would be useful as the DGCI would then insist that Indian companies conduct fresh clinical trials before getting marketing approval. Such trials are expensive and would add to the cost of the drug, and would be time consuming and delay the introduction of the drug. Most importantly such trials would be unethical. If we know that a drug is useful and it is safe, to conduct the trials again on human beings is not ethical.

Given the far reaching public health consequences of providing for data exclusivity, it is important that developing countries consider avoiding data exclusivity provisions in the FTAs they may be involved in, but rather just provide for what is required under TRIPS. If unable to avoid data exclusivity provisions, they should limit the duration of data exclusivity, as well as its scope (i.e. only for NCEs, only for undisclosed data etc.). Countries may also consider creating exemption mechanisms, i.e. mechanisms by which they can exempt products to which data exclusivity would apply.

Section V

Implications of Recent Changes in the Indian Patent Act

The TRIPS agreement, once signed, placed a number of obligations on countries like India, specifically related to the Amendment of the Indian Patents Act 1970. The most important of these was the condition that required India to change to a product Patent regime in the area of pharmaceuticals and food, from the earlier system provided in the 1970 Act which did not provide for Product Patents in these areas. It may be noted here that it was this simple provision in the Indian Act which had catapulted India to a position where it is the 4th largest producer of pharmaceuticals and a large supplier of cheap generic drugs to poor developing countries.

In order to conform to these agreements the Government brought in two separate sets of Amendments to the 1970 Act, in 1999 and 2002. The 1999 amendments provided for mailbox applications, as required under TRIPS. The 2002 amendments brought in further changes to make the Act TRIPS compatible but did not provide for Product Patents in pharmaceuticals. Subsequently the Patents Ordinance 2004 was issued in December 2004. This was modified into an Act in March, 2005, incorporating remedies for some major concerns that had been expressed about the 2004 Ordinance.

The major areas in which the final amendments in the Indian Patent Act address these concerns include the following :

1) Restrictions on Patentability

There were serious concerns that after Product Patents are allowed in all areas we would be deluged by Patents that could be granted on flimsy and frivolous grounds. There were concerns also that this would lead to "evergreening" of patents, that is perpetuation of Patents monoploly beyond the stipulated 20 years by repeated Patent grants based on small changes made to the original molecule. The amendments to the Ordinance has now restricted the scope for the granting of Patents on frivolous claims by clarifying that, "*the mere discovery of a new form of a know substance which does not result in the enhancement of the known efficacy*" is not patentable. It is further explained that: "*Salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substances shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy*".

2) Export to Countries Without Manufacturing Ability

The Ordinance had provided for allowing exports of Patented drugs produced through compulsory license in the country, to developing countries with no manufacturing capacity. This was in line with the Doha declaration of 2001 and the subsequent declaration by the TRIPS council. However this clause had been circumscribed by a provision that said that the importing country would have to obtain a compulsory license. Globally this clause caused concern as many developing countries would have been unable to import from India if this clause was retained. The amendments now clarify that the country can import from India if "*by notification or otherwise allowed importation of the patented pharmaceutical product from India*".

3) Continued Manufacture of Drugs with applications in mailbox

Possibly the biggest concern expressed by many was that after the passing of the Ordinance, drugs which are being produced by Indian companies and for which patent applications are pending in the mailbox, would go off the market once the Patents are granted. This could potentially hike drug prices. This had been seen to happen in the case of an anti-cancer drug called Glivec which was granted an Exclusive Marketing Right (EMR) in 2003 to the Swiss MNC Novartis, leading to a ten-fold hike in prices. The new amendments have now clarified that such Indian companies who are already producing these drugs can continue to produce them after payment of a royalty even if the drug is placed under a Patent. Specifically, it is now provided: "*…the patent holder shall only be entitled to receive reasonable royalty from such enterprises which have made significant investment and were producing and marketing the concerned product prior to 1.1.2005 and which continue to manufacture the product covered by the patent on the date of grant of the patent, and no infringement proceedings shall be instituted against such enterprises*."

4) Export by Indian Companies of Patented Drugs

The Indian Patent Act and its amendment has attracted international attention because today Indian drugs are the principal source for cheap drugs for poor developing countries. For example, about 50% of all drugs used to treat HIV-AIDS patients globally come from India. This concern (that the source of cheap Indian drugs would dry up) had been expressed in the past few months by a large number of international agencies such as the UNAIDS and WHO. The amendments have now provided that when patented drugs are produced under compulsory license in India by Indian companies: "*the license is granted with a predominant purpose of supply in the domestic market and that the licensee may also export the patented product, if need be in accordance with Section 84(7) (a) (iii)*" (i.e. where an export market exists).

5) The 2002 Amendment to the Indian Patents Act had provided for Patenting of microrganisms and microbiological processes – thus opening the door for patent protection to biotechnological inventions both in the agricultural sector (genetically modified seeds, etc) and in the case of pharmaceuticals produced through biotechnology. This provision which follows the TRIPS provisions of the same kind, was one of the most controversial in the TRIPS agreement. As a result, at the time of signing of the agreement it had been agreed upon that this clause would be reviewed within 4 years. The clause is under review in the TRIPS council, but because no consensus has been arrived at, it continues to be a part of the TRIPS agreement. While this clause has not been deleted from the Indian Act, the Govt. has referred it to a an expert committee.

6) Similarly, the Government has given a commitment that the issue of further defining what a "new" pharmaceutical substance is to restrict the scope of patenting frivolous claims would be referred to a committee and further amendments can be considered based on the committee's findings.

Compulsory License – the major area of concern

The one major area that remains a matter of concern is that amendments to streamline the compulsory licensing system were not incorporated by the government. The compulsory licensing system is really the lifeline for domestic companies, now that we have moved to a Product patents system. It is a system that allows manufacture of Patented drugs by domestic companies through a license that is granted by the Government. For the compulsory licensing system to be effective, procedures for granting such licenses need to be simple and effective. The Indian law provides for a number of grounds for the granting of such licenses on grounds of high prices, non-availability, to promote

commercial activity, etc. Unfortunately the procedure for granting has been left ambiguous. This is an area which will require close monitoring, to ensure that such licenses are actually granted within a reasonable time frame and on reasonable terms.

There have been 4 major criticisms on the compulsory licensing system now in place in the Indian Law. These are:

1) The absence of clear time frames within which administrative procedures are to be completed after an application for a CL is received. This might allow for prolonged legal wranglings and inordinately delay the issuing of a CL even where there are clear indications.

2) The absence of a royalty cap, i.e. a cap on the maximum amount of royalty to be paid to the Patentee by the licensee when a CL is granted. Here too the scope for delays in granting a CL exist.

3) The non incorporation of the clause 31(b) in the TRIPS agreement as a clear ground for issuing a CL. 31(b) of the TRIPS agreement says: "*such use may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time*"**.**

4) The provision for a 3 year "lock in" period, i.e. the provision that an application for a CL can be received not before 3 years have expired since the grant of a Patent.

However, in general, country Laws do not lay down time-frames or royalty caps. In most laws the general principle applied is that the economic value and the innovative content of a Patent should determine the royalty amount. So in that sense, the Indian Act is not different in this regard from other country laws.

The 31(b) clause of the TRIPS agreement pertains to what is called the "refusal to deal" argument – i.e. refusal of the Patentee to deal with a request for a voluntary license should be a condition for granting a CL. There is, however, ambiguity regarding whether "refusal to deal" is a *necessary* condition or a *sufficient* condition for granting of a CL. Interestingly at least three countries, Argentina, China and Israel, have clear provisions for this clause as a sufficient ground for issuing of a CL but it must be noted that neither has actually used this clause as a ground for issuing a CL. The "refusal to deal" clause has been invoked in the pharmaceutical sector in the US in a few cases — all pertaining to post-merger situations where the new company was found to have a monopoly situation in a certain therapeutic segment. It would have been useful if the Indian law had incorporated the "refusal to deal" clause as a ground for CL, and then have tested the waters to see if it could have been used to facilitate issuing of CLs. But not doing so India has not attempted to push the envelope of TRIPS, which is something one had expected the leading manufacturers of pharmaceuticals in the developing world to do.

The three-year lock in period in the Indian law is a continuation of what was provided for in the 1970 Act and draws from the Paris Convention. It is generally true that the lag time between the filing of a Patent, its grant, and actual commercialization is at least 4-5 years. So in that context the three-year period may not be too high. But in the context of the necessity of finding rapid cures for diseases of critical importance, viz. HIV-AIDS, and the possibility to put the commercialization of some of these on a fat-track, the three-year lock-in could inhibit early issuing of CLs even if otherwise warranted.

Finding ways to restrict Patents

Another core area where the TRIPS agreement provides some flexibility is the area of Patentability. The TRIPS agreement allows country laws to define what is patentable and also what is not. It is customary for

country laws to incorporate the three principles of novelty, inventive step and usefulness. Thus, for something to be patentable, it must be new, it must involve an inventive step and not be a mere discovery of something already existing, and should have an application that has some use value. Patent regimes that provide strong Patent protection tend to have looser definitions for these 3 criteria, thereby allowing Patenting of a larger number of inventions.

In this regard two portions of the Indian Patents Act has come in for criticism on the grounds that the definitions allow for loopholes that can be used to Patent frivolous claims. These are:

· In the Indian law inventive step has been defined as a feature of an invention that "*involves technical advances as compared to the existing knowledge or having economic significance or both.*" It has been argued that inventive step really should apply only to technical advance as it defines the innovative content in an invention. Thus the incorporation of "economic significance" can dilute the criteria for what is an invention – viz, a trivial invention with little technical advance but of economic value would become patentable by this definition. It is to be seen how this clause will be interpreted while Patents are being granted. It can perhaps be legitimately argued that in this clause "technical advance" is the overriding phrase as the clause.

· In the section in the Indian law defining what is not patentable the following is mentioned: "*Salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isopmers, complexes, combinations and other derivatives of known substances shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy*". While this tightens the definition and is designed to prevent "evergreening" of Patents (i.e. extending Patent periods by making small, therapeutically insignificant, changes in the original molecules or by finding new uses for the same) the phrase "*unless they differ significantly in properties with regard to efficacy*" has caused some concern. It has been argued that this phrase

can be arbitrarily interpreted to allow for some degree of evergreening as what constitutes a significant different in efficacy is subjective. However it is also true that new technologies are emerging, viz. nanotechnology, that can radically change the characteristic of a molecule by tinkering at the molecular level. This, however, remains an area that is likely to see contentious arguments when Patents are granted.

Effect on Drug Prices and Availability

What are the likely effects drug prices and availability? It is an issue that is of crucial importance not just for India but for a large number of developing countries. Drugs introduced into the market till before 1995 would not be affected immediately. By the recent changes in the Indian law it has been ensured that drugs introduced in Indian between 1995-2005, for which Patent applications are pending, can now continue to be produced by Indian companies. They would have to pay royalty to

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uce these drugs has been compromised and they would have to go through the compulsory licensing process to produce these drugs.

Linked to this is the ability of

Indian companies to export these new drugs. There are two options available – both with their own sets of problems. One route would be to export a portion of the drugs being produced through compulsory license – evidently this is entirely dependant on the ability of Indian companies to be granted compulsory licenses to produce newly Patented drugs. The second option is to export drugs through the process that was arrived at after the Doha declaration – it is a process that is reserved for export to countries without manufacturing ability. The process is tied to very painstaking and time consuming conditions, and companies might have major problems in meeting these.

While there would continue to be varying opinions on how far the Indian law has gone in incorporating all possible safeguards that the TRIPS agreement allows, it cannot be denied that the final Act does incorporate several of the TRIPS safeguards. Given India's importance as a supplier of low cost drugs in the global market, one can expect substantial attention to be focused on the extent to which these flexibilities will be utilised to address public health concerns and access to medicines.