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Compromising TRIPS: Brazil's Approach to Tackle the HIV/AIDS Imbroglio

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The General Agreement on Tariffs and Trade (GATT), of which the TRIPS Agreement was an integral part, mandates the implementation of a harmonized patent system applicable to all member countries. Patents are instruments which provide exclusive rights for a limited period on the patentee for dealing with the product or process of his innovation and prevents others from using them without due authorization. These rights often result in monopolistic pricing of drugs making them unaffordable to large number of populations particularly from economically backward developing countries. A very relevant case is that of HIV/AIDS drugs which are not available at affordable prices to millions of patients living in African, Latin American and South East Asian countries. This article is an attempt to understand the strategies adopted by one such affected country, Brazil. The compulsory licenses provisions under Articles 30, 31 of TRIPS as well as Para 6 of the DOHA Declaration of 2001 which proclaims that public interest will supercede private interests particularly in the area of health and drugs are yet to make an impact on the problem. Whether the Brazilian model is tenable across the cross section of countries similarly affected is yet to be established. Other strategies for making the required drugs available for the control of this and similar life threatening and intractable diseases also need to be explored side by side.

Keywords: TRIPS, Brazilian patent law, TRIPS and AIDS, drugs, HA Declaration

One of the major consequences of the newly emerged Trade-Related Aspects of Intellectual Property Rights (TRIPS) is the impact of patents on providing affordable healthcare to the needy, particularly from the developing countries. The issue has assumed importance in view of the global pandemic of HIV/AIDS which has affected around 40 million people the world over. The majority of drugs useful for treating this disease is still protected by patents and hence is generally available only from the patent holder or his licensee.

Brazil, severely affected by the HIV/AIDS epidemic has taken a pro-active stand to resolve the problem of availability, accessibility and affordability of these drugs. This has been achieved through appropriate legal and commercial approaches for overcoming the monopolistic restrictions imposed by the patent holders on drugs useful for treating HIV/AIDS.

AIDS as a Global Problem[1-9]

On 5 June 1981, the Centre for Disease Control (CDC), Atlanta, reported a strange outbreak of pneumonia affecting homosexual men and based on its aetiology, termed it Gay Related Immune Deficiency (GRID) syndrome. Twenty seven years later, with no cure or vaccine in sight, the disease, now well recognized as AIDS, continues to grow, even though due to various treatment and preventive strategies, many countries including some of the developing countries have been able to control the growth in its incidence. Investigations in the laboratories of Luc Montaigner in Paris and Robert Gallo at the National Cancer Institute in US led to the isolation of the virus and development of a diagnostic kit during the years 1983 and 1986. The first anti-AIDS drug, AZT was approved by USFDA in 1985. Improvements in therapy over the years has resulted in the use of anti-retroviral drugs consisting of Reverse Transcriptase Inhibitors and Protease Inhibitors in combination, often referred to as cocktail therapy. At present, there are around 17-20 drugs which are deemed to be useful for the treatment of

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HIV/AIDS. Through the judicious application of various strategies, it has been possible to control the disease from rapid growth, increase life expectancy of patients and reduce the incidence of opportunistic diseases to which most of the AIDS patients ultimately succumb.

It is interesting that recently, source of the disease has been reportedly traced to 1959 when a Congolese national died of an unidentified disease and in 1999 researchers at the University of Alabama claimed evidence that the disease originated from an infected Chimpanzee in West Central Africa. Of the 40 million infected with the virus, 75% live in Africa and it is estimated by UNAIDS that 70 million patients will die from this disease by 2022 unless some dramatic and positive developments take place on the prophylactic and therapeutic fronts.

The Case of Brazil[10]

Outside Africa, the largest incidence is in the countries of Asia and South America. Of the countries in South America, the largest and the most populous country, Brazil has the highest incidence of the disease.

After three centuries of Portugese rule, Brazil became independent in 1822 and a republic in 1889. The population of Brazil is around 180 million with over 80% of the people living in urban areas. Even though the annual per capita income is over $ 2800, the disparity in earnings between the populations is very wide. Over 30% of the people live below the poverty line. The Government in recent times has taken several measures to improve the living conditions of the Brazilian people.

According to the UNDP Report on Human Development, the positive steps taken by Brazil include strategies to improve access to education and healthcare. Universal access to healthcare is one of the central tenets embodied in the country's constitution. As a leader among the countries of Latin America, Brazil is negotiating finance and trade relations with many other countries including India and South Africa. In 1997, Brazil's Ministry of Health set up a working group to develop a National Drug Policy whose recommendations were accepted for implementation in 1998. The Government adopted an essential drugs list on the lines of WHO's list, set up a more efficient drug regulatory system and promoted increased production of drugs and their rational use. Under the Government's health scheme, patients enrolled under the scheme are entitled to receive drugs for a number of diseases such as HIV/AIDS, Tuberculosis, Blood diseases, Diabetes, Chagas disease, Schistosomiasis, Filariasis, Leishmaniasis, Malaria, etc. For meeting the drug requirements, the Government procures needed drugs from private and public companies and distributes them through outlets in various states.

Problem of HIV/AIDS in Brazil[11-13]

The first case of AIDS in Brazil was suspected and reported in 1981 and during the last two and a half decades the accumulated cases of AIDS by 2004 were reported to be around 3,62,364, even though the numbers quoted by UNAIDS are twice as much. In 2001, there were 10941 deaths from AIDS which rose to 11047 in 2002. However, since 2000, annual incidence of new cases has been, though marginally, declining in Brazil. Thus, while in 2000, there were 27,000 new cases, it came down to 25,521 in 2001 and further down to 22295 in 2002. By 2003, a total of 3,10,310 cases had been reported in Brazil of which 48% had died. Despite the decline in overall numbers between 2000 and 2003, the incidence of positive cases is on the increase among women and children compared to homo and heterosexual males. It is a fair assumption that the overall decline is due to the adoption and implementation of a number of approaches including broad-based awareness creation and distribution of free condoms as well as treatment with anti-retroviral and protease inhibitor drug cocktails. Even with these strategies, only half the number of HIV positive cases is still being treated.

TRIPS, Patents and Brazil[14,15]

Brazil as a country has a long history of having a patent law going back to 1809, which received constitutional acceptance in the Imperial Chapter in 1824. It was a founding Member of the Paris Convention of 1882 which allowed patenting of products and processes for all innovations regardless of the technology sector they belonged to. In 1945, a new legislation was brought in, which excluded patenting of pharmaceuticals, food items and products made using chemical processes. Additionally, another amendment brought about completely excluded all inventions that involved pharmaceutical substances. The next major change was only after the establishment of WTO (1995), in 1996 when Brazil introduced the new industrial property law. As per the provisions under TRIPS, Brazil had in fact, time till 1 January 2005 (a total of 10 years from 1995) to

implement a TRIPS compliant patent system by virtue of it being a developing country and had no product patent protection in its patent law. Brazil, however decided to enact legislation ahead of its required deadline unlike many other countries including India. The basic tenets in the 1996 Act (Law 9.279) which came into force in 1997 had incorporated all the features dictated by the TRIPS Agreement. While Article 27 on patentability requirements as per TRIPS was incorporated, the law in addition provided for protection of utility models requiring lower standards of inventiveness and protection period of only 15 years from the date of filing. Living matter, including natural materials and germ plasms were deemed to be non-patentable. However, isolated and purified products from natural materials if they satisfied the condition of industrial utility and are the result of use of human ingenuity are patentable as per the Brazilian Patent Law.

According to Article 18 of the Brazilian Patent Law, among the microorganisms, only transgenic organisms which satisfy the requirements of novelty, utility and involve an inventive step are patentable. In other words, the patented subject matter should, due to a direct intervention in their genetic composition, express a characteristic that cannot normally be achieved in the species under natural conditions.

In practice, in view of Brazil's 1996 Patent Law which permitted grant of product patents on all pharmaceutical products, the law forbids manufacture and/or marketing of any products patented after 1996 by third parties except under license from the patent holder.

Article 68 of the Brazilian Patent Law[15]

One of the disputed issues in the 1996 Brazilian Patent Law was the condition imposed that in order to maintain a patent, the patent holder must work the patent in the country. In other words, import of a patented product would not be deemed to be adequate to satisfy the requirement of local working of the patented invention. Thus according to Article 68(1), a compulsory license could be granted for 'failure to manufacture or incomplete manufacture of a patented product or failure to completely use a patented process except for failure to work due to lack of economic viability, in which case, importing shall be admitted'. It is noteworthy that in cases where local production is not economically viable, import is permitted as per the law. According to Article 68(2), if the patented product marketed in the country does not fully satisfy the market needs, compulsory licenses could be invoked.

Of all the conditions stipulated under the law for grant of compulsory licenses, the requirement of local working of the patent is the one that has caused considerable mistrust of the country's intentions by the R&D based industrial corporations in US and Europe. According to US, this provision is in clear violation of Article 27.1 of TRIPS which prohibits members of WTO from requiring local production for protecting their patents. The US also argued that if the purpose was to enable grant of compulsory licenses for meeting health needs, Article 71 of the Brazilian Patent Law could be invoked which is specific for meeting national health emergencies. Brazil, on the other hand claimed that Article 68 is strictly within the purview of WTO's provisions, according to which compulsory licenses are allowed if the product under patent protection is not made in the country within three years after the grant of the patent. It is a moot point whether Brazil's stand is tenable and it is certainly a matter which deserves to be further debated. Even though the US submitted documents to the Dispute Settlement Board substantiating its objections on these issues on 1 February, subsequently it decided to withdraw its petition in June 2001.

Even though Brazil had threatened to invoke compulsory license clause in case of non-working of a patent for three years, this provision has actually never been implemented in practice. It has been largely used as a negotiating tool for price reduction of anti-AIDS drugs. The US on its part continues to keep Brazil in the watch list of the US Government's 301 and super 301 provisions.

Patents and Transfer of Technology[14]

One of the cardinal objectives incorporated in TRIPS is that 'protection and enforcement of intellectual property rights (IPR) should contribute to transfer of technology'. TRIPS does recognize that measures may be taken to prevent abuse of IPR and resort to practices which adversely affect international transfer of technology. TRIPS allows countries to provide limited exceptions for the exclusivity conferred by a patent provided such exceptions do not unreasonably prejudice the legitimate rights of the owner and at the same time take into account legitimate interests of the users.

This in a way implies that access to technology contents of a patent is a legitimate right of those who seek it, particularly countries in the developing world.

This provision has a bearing on the terms of voluntary or even compulsory licenses when granted to third parties.

Compulsory License Provisions[14-17]

Provisions for grant of compulsory licenses in the Brazilian Patent Law of 1996 are consistent with the TRIPS Agreement. They include abuse resulting from exclusivity conferred by a patent. This provision has been a part of the Paris Convention Article 5A (2) which includes 'failure to work' as one of the abuses. Article 30 of TRIPS also provides for grant of compulsory licenses for production for experimental purposes or as directed by the judicial or administrative provisions in anti-competition proceedings or for meeting national emergencies. A matter which has been under dispute with reference to making patented drugs available in the country is related to the issue of parallel imports justified under the exhaustion of rights provisions. The Brazilian Act permits parties to import the goods provided the patentee imports the product subject to the condition that patented goods have been put in the market by the patent holder himself or by his agent. The Brazilian law also stipulates that innovations developed and patents granted through financial support and funding by Government agencies are to be worked locally by the patent . Compulsory licenses can also be issued in cases where a patent holder prohibits the working of a dependent patent by not granting a license for its working.

Yet another point of contention is related to the official amendment introduced in 1999 according to which the National Sanitary Supervision Authority (ANVISA) has to approve pharmaceutical patents before they are issued by the patent offices. [9] Thus, pharmaceutical patents are subject to yet another approval agency outside the purview of the patent offices. It is not clear whether this approval body also considers issues connected with the grant of compulsory licenses.

Brazil is the only country in the world which has an ANVISA kind of provision and USA and some other countries feel that this is inconsistent with the non-discriminatory clause under Article 27.1 of TRIPS.

Drugs for AIDS[3-6]

The first drug approved for the treatment of AIDS was AZT in 1987 and the first combination drug was of AZT and Dideoxycytidine (DDC) approved in 1992. The drugs which are currently used for the treatment of AIDS fall under three categories of Nucleoside Reverse Transcriptase Inhibitors (NRTIs), Non Nucleoside Reverse Transcriptase Inhibitors (NNRTIs), Protease Inhibitors (PIs) and Fusion Inhibitors (FIs). Eleven NRTIs, 3 NNRTIs, 10 PIs and 1 Fusion inhibitor have so far been approved by the USFDA for treatment of AIDS. Almost all of them have been discovered and developed by R&D based multinational corporations, the leading companies being Abbotts, Glaxo Smith Kline, Bristol Myers Squibb, Merck, Gilead Sciences, Hoffman La Roche and Boehringer Ingelheim. About half a dozen drugs used are combination drugs consisting of 2 or 3 drugs in one single formulation. Combination drugs are preferred to single drug therapies since the former enable better compliance and convenience and could be less expensive. In addition, incidence of resistance also could be less. In 1996, FDA approved use of combinations of Reverse Transcriptase Inhibitors and Protease Inhibitors to initiate the first cocktail drug therapy. Apart from drugs for treating AIDS, drugs are also required for opportunistic diseases including bacterial, fungal, protozoal and viral infections, cancer, neurological disorders etc. which are a natural sequel to HIV/AIDS infections. Drugs are also needed to handle adverse reactions that AIDS drugs produce in patients.

On the research front, many approaches are being actively followed such as development of Integrase inhibitors, Cellular Inhibitors, Maturation Inhibitors and Immune based therapies. Many products are in various phases of pre-clinical and clinical development.

Except for 3 or 4 of the above drugs, all of them are still patent protected in countries where patent applications have been filed. The problems of availability and affordability of drugs for the treatment of AIDS in developing countries including Brazil are primarily due to the monopoly enjoyed by the patent holder and the total control he can exercise on their supply.

Brazil's Resolve to Tackle the AIDS Crisis[11,15,16-20]

During the early eighties, Brazil initiated a major social reform process with immediate and primary emphasis on education and healthcare for her citizens. In 1988, a national integrated health service system was established which guaranteed comprehensive and free healthcare to the entire population, regardless of whether they had benefits from employment or insurance policies. While this provision of universal

healthcare was applicable to all diseases, it became particularly significant to HIV/AIDS patients due to the threat of an emerging pandemic and low access to drugs for the treatment of this disease. The social stigma which affected those who were shown to be infected with HIV added yet another dimension to the problem. The Government on its part also found this new health crisis most challenging and to a large extent beyond its immediate capabilities. However, social pressures assisted by a pro-active judiciary which chided the Government of its constitutional obligations, made it imperative that the commitments had to be met and drugs for HIV/AIDS among others were made available to the needy. Thus in spite of the heavy financial burden, distribution of the first generation drug AZT started in early 1990's. In November 1996, a Presidential decree guaranteed that all HIV positive patients in Brazil will have free access to drugs and in 1997, Protease Inhibitory drugs were added to the supply regimen. By 2001, the Ministry of Health created a list of 12 drugs for treatment of HIV/AIDS which was later extended to a total of 17 anti retroviral drugs in 35 different formulations.

Along with drug distribution, the Government also set up a net work of state-of-the-art testing laboratories for TD4 + lymphocyte counting and for quantifying HIV load to assess and gather information on who would need drug treatment for HIV/AIDS as well as consequent opportunistic infections.

Access to HIV/AIDS Drugs[4,9,10]

As already mentioned, majority of AIDS drugs which are in the list for free supply to patients in Brazil are still protected by patents in countries where they have been granted and are valid in other countries in the context of TRIPS' transitional provisions. Thus in Brazil, only patents granted in the country after 1996 when the new Brazilian Patent Law came into force would be valid. Prior to that time, Brazilian Patent Law did not allow grant of product patents for pharmaceuticals and hence earlier products were free to be manufactured and marketed in Brazil without infringing any of the product patents granted elsewhere. While resolve of the Brazilian Government to provide free access to all drugs was not only extremely praiseworthy but also unique among all the countries, the programme had many inherent and seemingly insurmountable problems to overcome if it was to be effectively implemented. The main concerns were:

(1) Brazil being a Member of WTO, she was obliged to work within the provisions of TRIPS with regard to honouring the validity of patents.
(2) Mechanisms for accessing the drugs from the patent holders at prices which are affordable.
(3) Ensuring that drug prices could be negotiated with the manufacturers to make them affordable.
(4) Manufacturing products which are outside the ambit of patent protection with indigenous or licensed–in technologies.
(5) Finding adequate funds to meet the requirements for accessing the drugs.
(6) Usage of the drugs for the most effective outcomes including appropriate distribution channels.
(7) Invoking clauses under Articles 30 & 31 dealing with the conditions under which compulsory licenses could be granted.
(8) Access to process technologies required for the manufacture of patented products for which compulsory licenses have been granted.

Brazil's Handling of TRIPS Provisions[11,16,17-20]

Article 7 of TRIPS Agreement recognizes that protection of IP 'should contribute to the promotion of technological innovation and transfer and dissemination of technology to the mutual advantage of users and producers of technological knowledge and in a manner conducive to social and economic welfare and to a balance of rights and obligations'.

Similarly, Article 8 of TRIPS specifies that 'WTO Members may in formulating or amending their rules and regulations adopt measures necessary to protect public health and nutrition provided that such means are consistent with the provisions of the Agreement'.

The emphasis in both these Articles is on the need to consider social and economic welfare as well as public health and nutrition of the primary stakeholders, the patients, while upholding the exclusive rights to 'exploitation' by the patent holder. A liberal interpretation of these Articles is a valid and seminal response to much of the debates and disputes which have arisen in the last decade between the Brazilian Government and the innovator companies in USA and Europe. The only moot point is whether pro-active steps taken by Brazil are consistent not only with the spirit of TRIPS, but also legal texts.

Prices of AIDS Drugs[21]

Disputes between Brazil and the innovators of AIDS drugs, Merck, Abbott, Roche, Gilead Sciences

and others, started in 2001 ever since Brazil announced her intention to supply patented drugs through the compulsory license route. There were proposals even to disregard product or process patents on HIV/AIDS drugs. They continued right up to 2005 when it threatened three companies with invoking compulsory licenses if the prices of Kaletra ((Abbott), Efavirenz (Merck) and Tenofovir (Gilead Sciences) were not reduced to levels affordable to the Brazilian Government. The US Government filed petitions with the Dispute Settlement Board of WTO and decision of the US Government to later withdraw its complaint was a strategic move to protect USA's overall trade interests. In fact, Brazil had the option to bring in the compulsory licensing clause declaring HIV/AIDS as a national emergency, which would have been detrimental to US companies' interests. Some experts at the University of St. Paulo even advocated issue of compulsory licenses for HIV/AIDS drugs as a cross retaliatory measure to counter another trade issue affecting Brazil, namely US's cotton subsidy policy.

TRIPS Provision for Compulsory Licenses[14,16,18]

Article 31 of TRIPS stipulates that each case for a compulsory license should be considered on its own merits and in cases of national emergency or extreme urgency, even prior authorization of the rights holder is not required. However, any forceful imposition of the compulsory license issue has a flip side, since, while the rights of the patentee over his patented product could be overcome through this approach, the working of the patent still would require access to the appropriate technology for production, which may not be readily available or accessible from other sources. Brazil therefore used the provisions for grant of compulsory licenses as an instrument for price negotiations with the patent holders. Such a strategy eventually worked and Brazil has been able to successfully negotiate with the patent holders' price reductions by as much as 65% for some patented drugs leading to considerable savings to the country's budgets for AIDS programme. That the negotiations have been successful and have served Brazil's purpose is obvious from the fact that Brazil has not resorted to grant of any compulsory licenses for patented drugs so far. In fact, of the 15 drugs used for treatment of AIDS in Brazil only 7 are locally manufactured and these are drugs which are outside the protective ambit of the patent system. The rest are all purchased at negotiated prices, mostly from the innovator companies.

On 1 June, 2005, Brazil's lower House of Congress unanimously voted to disregard product and process patents on drugs to treat HIV/AIDS. Whether this means automatic compulsory licenses for these items or change in patentability criteria to exclude these products is not clear. While the former may find legitimacy under Articles 30 & 31 dealing with compulsory licenses and conditions which are to be met for granting them such as declaration of a national emergency, the latter interpretation may violate patentability clauses in Article 27 of TRIPS.

Brazil's AIDS Control Policy- A Success Story[16-20]

A survey taken in 1998 showed that, of the patients treated with AIDS drugs in the 10 Latin American countries participating in the Horizontal Technical Cooperation Programme, 73.3% were from Brazil, 12.4% from Mexico, 11.38% from Argentina and Chile, Panama, Ecuador, Costa Rica, Cuba and Peru fewer than 3%. In 2004, Health Ministers of Argentina, Bolivia, Brazil. Chile, Colombia, Ecuador, Mexico, Paraguay, Uruguay and Venezuela signed a landmark Agreement to lower the costs of AIDS drugs by as much as 15 to 85%. The leadership in all these negotiations was taken by Brazil.

In 1997 after Brazil started providing free treatment with AIDS drugs, the total expenditure on this account was $ 134 million, which rose to $ 220 million in 2004 and currently, it is estimated to be around $ 300 million. That the programme has been successful is obvious from the fact that mortality rates from AIDS had dropped almost 60% in less than a decade and equally importantly, average survival time post-detection has extended during this period from 6 months to 5 years.

The DOHA Declaration and Its Aftermath[22]

The Inter-Ministerial Conference held in DOHA in November 2001 was considered a success, particularly after the aborted meeting two years earlier at Seattle, USA. To a large extent, impetus for addressing the concerns of developing countries with regard to affordability of much-needed drugs at the DOHA Inter-Ministerial Meeting was provided by the success that Brazil had achieved while dealing with this issue and negotiating with the innovator companies of the developed world. One of the significant features of the meeting was the Declaration of a fresh Doha Round of talks of which the one on TRIPS and Public Health (Para 6) addressed the issue of non-affordability of patented

drugs to more than half of the World's population, primarily due to the exclusivity granted for patented product under the TRIPS Agreement was most significant. The Members also agreed on the conditions under which compulsory licenses can be granted and can determine what constitutes 'national emergency' and 'extreme urgency'. Apart from compulsory licenses, the right to establish under their laws, exhaustion of rights clauses also would enable member countries to permit parallel imports from the cheapest available sources without infringement of the concerned patents. Expectedly, the provisions recommended by the declaration on TRIPS and Public Health clearly mandated that public health issues will supersede TRIPS provisions whenever the two are in conflict was not acceptable to countries such as the USA and Japan. Another area of concern for the innovation-driven pharmaceutical companies is the interpretation by most developing countries that the mention of HIV, Malaria and TB in the DOHA Declaration are only illustrative and by no means would prohibit extension to other diseases of grave public health concern while considering the grant of compulsory licenses. It was also agreed that exports of patented drugs to countries which have no capability to utilize their compulsory licenses by those which have the technological strengths would be permitted.

In spite of all efforts by the TRIPS Council to finalize the modalities of implementation of Para 6 of the DOHA Declaration, it was unable to meet the deadline and it was not till 30 August 2003, weeks before the next Ministerial Conference in Cancun, Mexico in September 2003 that the rules were approved. In practice, it is now clear that the rules to be followed for implementation of Para 6 of the DOHA Declaration are very cumbersome to both the countries which need to import under the compulsory licenses granted to them under the TRIPS provisions and those which want to export and hence it would be only in exceptional cases that the benefits of the DOHA Declaration will accrue to those in need.

Global Usage of AIDS Drugs[3]

According to a Report of WHO in 2005, estimates of usage of anti-retroviral drugs among the low and middle income countries showed that treatment coverage in Sub Saharan Africa was only 17%, East, South and South East Asia 16%, Europe and Central Asia 13% and North Africa and Middle East together 5%. The most dramatic increase in usage of drugs, however was in South East Asia with Thailand in the lead, showing a usage increase of 75% between 2003 and 2005. Treatment coverage in Latin America of which Brazil is far ahead of all the others, is the highest of all regions at 68%. Taking all the countries of the developing world, the number of people receiving treatment for HIV infected cases was 1.3 million in 2005, whereas the number requiring treatment was around 6.5 million resulting in average treatment coverage of only 20% in these countries.

On 1 December 2003, the World's AIDS day, WHO and UNAIDS[24] launched the 3 by 5 programme, so christened to highlight the objective of reaching treatment of 3 million additional cases of HIV/AIDS in low and middle income countries by 2005. While the programme was partially successful in over 50 countries as judged by results of the last two years, it failed to reach the overall objectives in majority of countries by a large margin. It is now realized that the gap between available resources and actual requirements for the programme is $ 18 billion for the period 2005 to 2007 and $ 22 billion per year by 2008 to fund comprehensive national programmes for prevention and treatment. During the period 2003 to 2005, global expenditure on AIDS programmes grew from $ 4.7 billion to $8.3 billion. Most of these came from the US President's Emergency Plans for AIDS relief, Global Fund to fight AIDS, Malaria and TB and from the World Bank. It was reported by WHO that the average price of first line treatment of HIV/AIDS decreased by 37 to 53% during this period, depending on the drugs used.

Brazil–A Role Model for Other Developing Countries[18-20]

In many ways the policies adopted by Brazil to tackle the country's HIV/AIDS programme and their implementation provide a role model for other developing countries affected by grave problems of AIDS and similar major pandemics. The multinational pharmaceutical companies are the most powerful corporations which are responsible for the discovery and development of drugs needed by the majority of the World's populations. The costs to be incurred for the discovery and development of a single new drug entity have been estimated to be between $ 800 million to $ 1.5 billion. It is inevitable that such huge investments necessary for this activity need to be recovered from the products which are provided exclusivity in the market place through the patent system administered under the TRIPS provisions. At

the same time, such economic and commercial considerations and compulsions leading to monopolistic tendencies make these drugs outside the limits of affordability for the majority of populations living in poor countries of the World. The consequence is that even when treatments are available for some of the diseases such as HIV/AIDS, they offer very little solace to poor patients in developing and least developed countries, since they cannot be purchased by those patients who need them the most. There have been several proposals to find a solution to this mismatch between the needs of the innovator and affordability to patients of much needed drugs. One way would be is to provide global funds by raising a common resource pool in addition to available public and private funds, as proposed by the Secretary General of the United Nations to subsidise treatments across the Globe. The second is to have a two tier pricing formula for drugs for such diseases where developing countries will have a generic pricing formula while the more affluent patients will pay a higher price for the same product. A more effective and equitable insurance system which essentially follows the principle of the healthy paying for the poor is yet another possible solution. What is redeeming is that countries such as Brazil, Thailand or even Uganda all of them following different strategies to tackle the AIDS issue, have been able to at least control the progression of the disease with their limited resources. What is distressing, however, is the fact that even after two and a half decades of the first identified case, there is no cure or even a prophylactic to prevent further incidence of this dreaded disease. Even more distressing is the fact that there is little light seen at the end of what seems to be a very long and dark tunnel as far as the eradication of this disease is concerned.

Properly interpreted and implemented, the provisions under TRIPS may not be major impediments for making even drugs under patent protection available at affordable prices to large sections of poor populations affected by some of the dreaded diseases. However, in spite of the compulsory licence provisions and the DOHA Declaration and the spirit behind them, no proper and simple modality is yet available for the developing and least developed countries for implementing an effective system for achieving the goals spelt out in the DOHA Declaration.

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