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## TRIPS-Plus intellectual property rules: impact on Thailand's public health

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### Abstract

Thailand has proved that a well-funded, politically-supported public policy could be effective in preventing the spread of HIV/AIDS on a national scale. It is currently facing increased pressure to accept higher standards of intellectual property (IP) protection (the so-called TRIPS-Plus) under bilateral free trade agreements (FTA) proposed by the United States. The proposed US FTA threatens to restrict the measures the country can take to pursue affordable drugs, and will affect ability of Thailand to continue its successful ARV treatment and other healthcare programmes. The paper argues that the TRIPS-Plus regime generates a negative impact on poor people's access to medicines, and the ARV treatment programme in Thailand is presented as an illustrative example.

### Keywords

TRIPS, Plus, intellectual, property, rules, impact, Thailand, public, health

### Disciplines

Law

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## **Abstract**

Thailand has proved that a well-funded, politically-supported public policy could be effective in preventing the spread of HIV/AIDS on a national scale. It is currently facing increased pressure to accept higher standards of intellectual property (IP) protection (the so-called TRIPS-Plus) under bilateral free trade agreements (FTA) proposed by the United States. The proposed US FTA threatens to restrict the measures the country can take to pursue affordable drugs, and will affect ability of Thailand to continue its successful ARV treatment and other healthcare programmes. The paper argues that the TRIPS-Plus regime generates a negative impact on poor people's access to medicines, and the ARV treatment programme in Thailand is presented as an illustrative example.

### **Key Words**

Thailand  
TRIPS-Plus  
FTA  
access to medicines

## **TRIPS-Plus Intellectual Property Rules: Impact on Thailand's Public Health**<sup>\*</sup>

Jakkrit Kuanpoth<sup>\*\*</sup>

### **Introduction**

Anti-retroviral (ARV) drugs have the potential to dramatically improve the health and extend the lives of many people living with HIV/AIDS (PLWHA). However, the high price of these drugs put them out of reach of the vast majority of PLWHA in many developing countries. The problem is acute for example in Thailand, where HIV infection levels are high and public financial resources are limited. The importance of pharmaceutical pricing has become more crucial since the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), which is part of the World Trade Organisation (WTO) multilateral agreements, requires all member states, including developing countries, to provide patent protection for pharmaceuticals and effectively enforce patent rights. In addition, the developing countries are now facing increased pressure toward higher standards of intellectual property (IP) protection (the so-called TRIPS-Plus), which appears in the form of bilateral free trade agreements (FTA).

Such high-level IP standards may be inappropriate for developing countries and would restrict access to essential medicines to fight HIV/AIDS and other pandemics. The fundamental question that faces the pharmaceutical world today is how best to provide drugs to the general population and how to do so cheaply. This note reviews some major issues relating to the controversial TRIPS-Plus rules under various FTAs that pose many challenges to the developing countries. The paper argues that the

TRIPS-Plus regime generates a negative impact on poor people's access to medicines in general, and the ARV treatment programme in Thailand is presented as an illustrative example.

## **1. Access to Medicines: Legal and Moral Rights**

### *i. Restricting access to medicine – violation of human rights*

The right to health has been recognized as a fundamental human rights. It is enshrined in a number of treaties, including the Constitution of the World Health Organization (WHO), the United Nations Charter (Arts. 1, 55 and 56), the Universal Declaration on Human rights (Art.25), and the Convention on the Rights of the Child (Art.24). The most important human rights instrument that explicitly recognizes the right to health is the International Covenant on Economic, Social and Cultural Rights (ICESCR). Article 12 of the ICESCR creates a legally binding right to health on the State, and Article 2 imposes legal obligations on all State parties to co-operate internationally to realize this right.

The right to health was defined as “a right to the enjoyment of a variety of facilities, goods, services and conditions necessary for the realization of the highest attainable standard of health.” which includes “a system of urgent medical care in cases of accidents, epidemics and similar health hazards,” as well as “the provision of essential drugs” for prevalent diseases (UN Committee on Economic, Social & Cultural Rights 2000: paras.9 and 12). This interpretation was reiterated in April 2001 when the 57<sup>th</sup>

Session of the United Nations Commission on Human rights adopted Resolution 2001/33 on “Access to Medication in the Context of Pandemics such as HIV/AIDS”, which confirmed that “access to medication in the context of HIV/AIDS is one fundamental element for achieving progressively the full realization of the right of everyone to the enjoyment of the highest attainable standard of physical and mental health” (UN Commission on Human rights 2001).

*ii. The right to health and access to medicine under the constitution*

Thailand ratified ICESCR on 5 September 1999, and under Article 12 it has an obligation to make sure that its people have access to pharmaceuticals and healthcare services. The right to health under international law is guaranteed by the Thai constitution. The 1997 Constitution, which is known as the people constitution, recognizes the right to health in Article 52. The constitutional right to health was outlined and implemented in the eighth National Economic and Social Development Plan and the National Plan for AIDS Prevention and Alleviation. The link between the national AIDS plan and the national development plan reflected the view of the Thai government that HIV/AIDS epidemic was not only a medical crisis, but also a threat to sustainable, social and economic development of the country.

Thailand has to ensure that its law and policy will be supportive of public health policies which promote broad access to safe, effective and affordable medicines. The breach of state power by the introduction of the TRIPS-Plus rules under an FTA that would undermine Thailand’s substantive ability to deal with public health problems is

clearly a violation of the right to health of the Thai population, which is not only the constitutional right but also a legally-binding human rights obligation of Thailand.

*iii. The right to health and access to medicine under patent law*

The right to health is safeguarded by various mechanisms, including those under the patent legislation. While the first patent law of Thailand, the Patent Act B.E. 2522, provides protection and exclusivity over pharmaceuticals, it ensures that the essential products will meet a domestic demand at reasonable and affordable prices by incorporating some possible legal measures to combat abusive practices and enforce local working of patents. The mechanisms include compulsory licensing and parallel import.

The system of compulsory licensing is envisaged as a mechanism to improve free competition, and to authorize the use of patented article for public interest. A compulsory license may be granted to a private competitor or a State agency to use patented substances for meeting public needs. Both in the legal and economic context, it could make a compelling case for the grant of such license, or at least for threatening to do so should the patent holder not lower the prices of its products. Although the mechanism is important and can be used to enhance access to medicines, there are still practical difficulties in applying those provisions due to the incongruity of the Thai legal system and political pressure coming from the West.

In December 1999 a group of PLWHA and NGOs staged a massive demonstration outside the the Ministry of Public Health demanding the use of compulsory licensing

of one important patented ARV drug, ddI (see further below). But this was not accepted by the Thai government which faced a great deal of hostility and threats from the United States government (Kuanpoth 2002: 344-345). Just as everywhere, political factors play an important part in the use of compulsory licensing in Thailand. One factor to reckon with seems to be the lack of political will by the Thai government to actually invoke the scheme of compulsory licensing in the public interest.

The incorporation of the international exhaustion doctrine<sup>1</sup> and the large variation in drug prices in the world market has led to the evolution of a marketing practice, called “parallel importing”, in which drugs sold in a country with low prices are exported to another country where prices are high at lower prices. While the pharmaceutical company tends to use legal rights under patents and other IP rights as territorial restrictions to enhance revenue, developing countries may adopt a policy of encouraging parallel import of foreign-made drugs in order to lower the price level of drugs in their local market (Maskus 2000). The possibility for the entry of foreign drugs into the domestic market will confront the licensed distributors with competitive pressure in setting prices (Abbott 1998; Beal 1998).

In Thailand the principle of international exhaustion was incorporated into the patent law in 1999 in order to permit parallel importing of patented articles. While in principle compulsory licensing and parallel imports could enhance access to medicines, the use of these two mechanisms would be restricted by the introduction of TRIPS-Plus rules under an FTA that Thailand is negotiating with the US.



## **2. HIV/AIDS and ARV Treatment Programme in Thailand**

### *i. History and status of HIV/AIDS in Thailand*

The first case of HIV/AIDS was reported in Thailand in 1984. From 1984 to 2005, 283,668 cases of HIV/AIDS were reported in Thailand, and there were 79,218 deaths because of the disease during the period. However, it has been estimated that the number of PLWHA in the country could be as high as 700,000 and that the number of death resulted from HIV/AIDS-related illnesses were 300,000. The rate of new infections is still high, estimated to be around 29,000 annually (UNDP 2004).

The widespread transmission in Thailand occurred in the late 1980s. Between 1988 and 1989, the rapid transmission of HIV was apparent among injecting drug-users who had tested with over 50 percent HIV prevalence in some provinces. During 1993 to 1997, 8,325 cases were reported, but it was believed that HIV infections had been rapidly spread among sex workers. It was found that during the early 90s almost half of sex workers in Chiang Mai, a northern province of Thailand, were infected with HIV (Weniger *et al* 1991: S71). The high rate of infections among sex workers led to the rapid transmission of HIV/AIDS among the male clients of sex workers, and from infected males to their wives and partners, and their children. Now there are signs that HIV/AIDS has attained epidemic proportions among the general population, as evidenced by the increase in HIV positive diagnoses among military recruits and young people. For example, the rate of HIV infections among teenagers rose from 11 percent in 2001 to 17 percent in the following year (UNDP 2004).

Women were heavily affected by the pandemic. At the early stage of the pandemic, around one-third of adults living with HIV/AIDS in Thailand were women, who were usually infected by their husband or boyfriend who had earlier acquired the virus during commercial sex. The number is rising as half of new adult infections are now occurring among women. The current figure shows that 70 percent of young people between the ages of 15 and 24 who are living with HIV/AIDS are girls and women (UNICEF 2004: 9). While the majority of HIV transmission in Thailand in the early 1990s occurred between sex workers and their clients, around 50 percent of new infections are currently taking place between spouses (Thai Working Group on HIV/AIDS Projections 2001). The rate of HIV infection among pregnant women is relatively high and tends to be variable. From 0.5 percent in 1990, the number of HIV prevalence among women who get pregnant increased to 2.4 percent in 1995, but decreased to 1.18 and 1.09 in 2003 and 2004 respectively (UNDP 2004: 21).

Women often face a disproportionate burden caring for sick family members or younger siblings, restricting their job or education opportunities. In many cases girls are much more likely to be withdrawn from school to perform caring tasks.

*ii. The Thai treatment programme against HIV/AIDS*

a) Preventive programme

Thailand's initial efforts in tackling HIV/AIDS have proved remarkably successful (Piot 2001: 1106–1112). Comprehensive prevention campaigns adopted by the Thai government in the 1990s were the main factor that slowed down the rate of HIV infections. In response to AIDS epidemic in the early 1990s, the Thai government launched large-scale preventive action. In 1991, the Anand Administration declared that HIV/AIDS was a government priority. The National AIDS Prevention and Control Committee was set up and the AIDS control programme was moved from the Ministry of Public Health to the Office of the Prime Minister. The government also increased the 1993 budget for HIV/AIDS to US\$ 44 million, almost a twenty-fold increase from the previous year (UNDP 2004: 16-17). The political commitment at the top level helped to mobilize not only financial resources but also a wide range of sectors of government and society to fight against HIV/AIDS.

b) ARV treatment programme

The initial policy response was limited to preventing the spread of the epidemic. Medical treatment was for the prevention of opportunistic infections only. No ARV treatment was provided to HIV-related patients at the early stage of the HIV/AIDS campaign. The Thai government subsequently realised that while preventing new HIV infections was crucial, it also needed to treat those who had already contracted the virus.

In 1992, the Ministry of Public Health started to subsidize the ARV treatment programme which covered only a small number of PLWHA. At the beginning, mono-ARV therapy (*i.e.* AZT or zidovudine) was provided. When this drug proved to be

inefficient and ineffective as the virus tended to mutate and became resistant to the medication, the Ministry of Public Health in 1995 switched to dual therapy (*i.e.* a combination of two ARV drugs), and two years later to triple drug therapy (*i.e.* a combination of three ARVs).

In 2000, the Ministry of Public Health created a project “National Access to Antiretroviral Program for People living with HIV/AIDS” (NAPHA) which provided a wide range of triple drug ARV therapy. Under the project, around 400 public hospitals are dispensing ARV drugs to selected PLWHA. The committee bases its decision to select the HIV-related patients on medical grounds (*e.g.* a patient with a CD4 count of less than 200). The PLWHA selected by the committee will receive ARV drugs free of charge, which the Ministry of Public Health allocates to the hospitals based on a quota system. Each small state-funded hospital (*i.e.* a 60-bed hospital) receives ARV drugs for 20 persons at a time. Larger hospitals receive a quota of drugs for 40 persons.

As mentioned earlier, the new constitution recognizes the people’s right to healthcare and social welfare which subsequently led to the introduction of the universal healthcare system. The health insurance system or the “30 baht” scheme, which currently covers approximately 95 percent of the population, was introduced in April 2002 by the Thaksin Shinawatra government. The universal healthcare system, under which the poor and the uninsured persons are charged 30 baht per treatment at the government’s health service units, does not include ARV treatment, due to the country’s financial constraints and the high cost of drugs. As a result, only a very small percentage of Thai AIDS patients were receiving the drug therapy under the

government project. There are scant data on how many PLWHA in the country are actually receiving treatment, but it seems less than five percent of an estimated 700,000 PLWHA have access to HIV treatment.

c) Budgetary pressures

A shortage of funds has been a major obstacle to HIV treatment programme in Thailand. The 1997 economic crisis had strong negative consequences on government programmes, budget and activities and led to a significant reduction and reorientation in the budget for HIV/AIDS prevention and treatment. While Thailand spent over 1,418.5 million baht (US\$ 37.3 million) on HIV/AIDS programmes in 1996, the government budget for HIV including funding for medical interventions such as ARV drugs and drugs for treatment of opportunistic infections was reduced to 1,099 million baht (US\$ 28.9 million) in 2002 (Pothisiri, *et al* 1998).

From the total HIV/AIDS budget, a modest amount is allocated for ARV therapy. The 2003 ARV budget was 300 million baht (US\$ 7.7 million), but increased to 800 million baht (US\$ 20.5 million) in 2004. The limited budget makes it impossible for the Ministry of Public Health to extend its ARV treatment programme to all PLWHA who require the drugs.

d) Local production of generic ARV drugs

In 2002, the Government Pharmaceutical Organisation (GPO), the state enterprise under the Ministry of Public Health, successfully produced its first ARV cocktail

called GPO-vir. The drug, a fixed-dose combination of three drugs (stavudine, lamivudine and nevirapine), has become a cheap and affordable ARV treatment in Thailand. This success led the Thai government to announce that from January 2006 onwards it would provide ARV drugs free of charge for 70,000 PLWHA through the government healthcare system. The Global Fund to fight AIDS, TB and Malaria has also promised to allocate US\$ 209 million for ARV treatment for 10,000 people in Thailand. With the funds from the government and the Global Fund, the government could achieve its target in providing treatment to 70,000 PLWHA (about 10 percent of PLWHA in Thailand) by the end of 2005 (Bangkok Post 2004).

Despite having been unable to treat all PLWHA, Thailand's ARV treatment programme can be regarded as a success. The achievement of Thailand in providing access to these drugs for a wider group of people stemmed from the fact that Thailand has been able to develop its healthcare systems and its drug-manufacturing base. The programme could be a model for other developing countries to tackle the HIV/AIDS crisis.

### *iii. Benefits of the ARV treatment programme*

#### a) Treatment programme expanded

At the early stage, most of the drugs distributed under NAPHA were branded drugs which cost more than 380,000 baht (US\$ 10,000) per person per year, far beyond the limited government budget. Since the ARVs are now locally produced and sold at

much cheaper prices, the Ministry of Public Health has been able to expand its treatment programme significantly. For example, during 2001 to 2003 the HIV-treatment programme was expanded more than eight-fold with only a 40 percent increase in budget. The number of people on ARV treatment also increased, reaching 50,000 at the end of 2004 (UNAIDS and WHO 2004: 23). With the use of GPO-vir, which costs 1,200 baht (US\$ 31) per patient per month compared to 18,620 baht (US\$ 490) per patient per month for the imported drugs, the Thai government would be able to meet its aim to provide affordable ARV treatment and treat 70,000 HIV-positive people and poor patients in the early 2006.

While drug accessibility is not a complete solution to the problems posed by HIV/AIDS, access to affordable ARV therapy provides medical and social benefit to the HIV-infected people. It prolongs the lives of patients and extended families members, and in turn strengthens their ability to support their families and communities. Since ARV treatment reduces the discrimination and stigma associated with HIV/AIDS, it also creates an incentive for HIV testing which will enhance AIDS prevention and control efforts.

#### b) Benefiting women

Thailand was the first developing country that implemented a programme preventing mother-to-child HIV transmission (UNICEF 2004: 22) The programme has particularly positive outcomes for women, because the administration of ARV agents to mother and child around the time of birth may be the most effective means of an intervention to reduce viral transmission (Kanshana and Simonds 2002). The

programme, which currently runs under the 30-baht scheme, provides free ARV drugs and other health services to all HIV-positive women during pregnancy and their newborns.

c) Benefiting foreign PLWHA

Thailand has successfully developed its capability to produce cheaper ARVs. The GPO is currently able to supply a whole range of ARVs to its neighbouring countries (*i.e.* Vietnam, Cambodia, Myanmar, and Laos). The poor patients in those countries benefit tremendously from Thailand's capability in drug production, as they rely on Thailand as the significant source of cheap generic medicines (Kuanpoth and Duong 2004).

d) Obstacles remain

While Thailand's healthcare systems and its drug-manufacturing base benefit a wide group of people at home and abroad, there are still a large number of people who still miss out and do not have access to the essential medicines. Apart from the Thai PLWHA who are excluded from the government ARV treatment programme because of insufficient funds, the Thai government is still unable to fulfil its human rights obligation to treat foreign migrants who are HIV positive and require treatment.

There are approximately more than one million immigrants working illegally in Thailand. Most migrant workers are from Cambodia, Laos and Myanmar, who cross over the border in search of work and trading opportunities. Among these, there are



girls and women drawn into the commercial sex industry, and those foreign sex workers are at significant risk of contracting the disease from their sexual activities. HIV prevalence among these women is likely to be higher than among their Thai counterparts. While the Thai government healthcare system is already serving the health needs of the local people, these illegal immigrants do not have access to health and other social services in Thailand and miss out on the ARV treatment programme.

*iv. Patents and prices of ARV medicines*

a) Patented ARV medicines in Thailand

Access to medicines implies not only actual availability but also financial affordability. Affordable prices are fundamental for improving access to medicines. Although the prices of many ARVs have significantly fallen in recent years, they remain too high for Thailand. For example, the cost of a standard three-drug ARV regimen in Thailand in 2000 was 324,000 baht (US\$ 8,100) per person per year. The total cost for providing AIDS drugs to all PLWHA could have been over US\$ 8 billion (UNDP 2004: 38). The high level of medicine prices stems from several factors. The most significant factors that lead to high drug prices are the lack of price competition, a non-transparent mark-up system, and the fact that health professionals and consumers prefer branded products instead of cheaper generics but alternative sources are not available for patented medicines.

Currently there are six triple drug ARV therapies being used under the Ministry of Public Health's NAPHA programme. The drugs distributed in Thailand are listed below:

- 1) GPO-vir (stavudine+lamivudine+nevirapine)
- 2) d4T+3TC+EFV (stavudine+lamivudine+efavirenz)
- 3) AZT+3TC+NVP (zidovudine+lamivudine+nevirapine)
- 4) AZT+3TC+EFV (zidovudine+lamivudine+efavirenz)
- 5) d4T+3TC+IDV/RTV (stavudine+lamivudine+indinavir/ritonavir)
- 6) AZT+3TC+IDV/RTV (zidovudine+lamivudine+indinavir/ritonavir)

In the six triple drug therapies, there are seven ARVs (different chemical entities). As of December 2005, only two chemical entities (*i.e.* efavirenz and indinavir) are patented in Thailand. One formulation (*i.e.* GPO-vir) is under a petty patent, which is owned by the GPO. There are no patents over lamivudine, nevirapine, ritonavir, stavudine, and zidovudine. The lack of patents on the majority of ARV drugs makes it possible for the GPO to produce cheaper generic medicines. For example GPO-vir pills can be produced because stavudine, lamivudine and nevirapine are not under patents in Thailand. The Thai government can run its ARV treatment programme successfully as it can obtain the generic versions of the drugs at much cheaper prices than the ones offered by the multinationals.

b) Second-line drugs – worsening impact

It may be noted that all the drugs currently distributed under the ARV treatment programme are WHO-recommended first-line ARVs most of which are non- patented

as they have been on the market for some time. The government programme will face difficulties in the future when the Ministry of Public Health has to switch a large percentage of patients to considerably more expensive second-line therapy if patients become allergic to the first-line drugs or when the HIV virus becomes resistant to the current drugs.

A search in the Department of Intellectual Property database found that several WHO-recommended second-line drugs are under patent protection in Thailand. Only two of seven second-line drugs (*i.e.* abacavir and ritonavir) are not patented. Three important second-line ARVs (*i.e.* didanosine, lopinavir, and lopinavir/ritonavir) are all under patents. The search could not confirm whether or not two compounds (*i.e.* tenofovir and saquinavir) are patented. They may be patented or have patents pending in Thailand. Assuming they are the subject of pending applications, five out of seven WHO-recommended second-line ARVs could become patented in Thailand in the near future.

When the Ministry of Public Health needs to dispense those patented drugs, it will significantly raise the cost of the ARV treatment programme as the production and importation of generic drugs would not be possible. Available data indicate that the prices of branded and patented ARVs are generally much higher than those offered by the generic companies. For example, the prices of two non-patented first line ARVs currently used by the Ministry of Public Health (*i.e.* lamivudine and stavudine) are considerably lower than those offered by the originator companies. While the originator's lamivudine 150 mg and stavudine 40 mg are priced at 6,046 baht (US\$ 159) per 60 capsules and 5,660 baht (US\$ 148) per 60 capsules respectively, the same

drugs are available in the same quantities from the GPO at much cheaper prices: 600 baht (US\$ 15.60) for lamivudine and 270 baht (US\$ 7.10) for stavudine.

As regards the patented drugs, the price differentiation is much greater. For example, lopinavir/ritonavir 113.3/33.3mg, a WHO-recommended second-line ARV, is sold in Thailand by the originator company at 17,762 baht (US\$ 467) per 180 capsules, while the same drugs could be imported from an Indian generic company at the price of 5,930 baht (US\$ 156).

Since the cost of the branded ARV drugs is beyond reach for Thailand, without the capability to produce generic ARV drugs the Thai government's treatment programme could not have lasted long. The experience of Thailand in the production of generic drugs, particularly GPO-vir, has demonstrated that generic production and competition can reduce drug prices to well below those charged by multinational pharmaceutical companies. The Thai government should apply all possible legal options currently available under the patent law such as compulsory licensing to enhance generic competition, particularly for second-line ARV drugs which are under patent protection in Thailand. In an attempt to do this, Thailand has to keep in mind that the TRIPS-Plus rules would preclude its ability to enforce compulsory licensing and it should not accept any TRIPS-Plus provision that might be proposed in the FTA negotiation.

v. *Patents on ARV didanosine (ddI)*

Didanosine (ddI) is one of the anti-retroviral drugs that WHO recommends for HIV/AIDS treatment. The drug when used with zidovudine and lamivudine, has been proved to be an effective reverse transcriptase inhibitor against the disease, especially for patients intolerant to zidovudine, or in whom zidovudine has failed. The ddI drug was developed in the US by two scientists working for the National Institute of Health, a US public research institution. In 1989, two patents (US 4861759 and US 5616566) were issued by the US Patent Office to ddI substance. The owner of the patents is the Department of Health and Human Services. The patents on ddI were then licensed to Bristol-Myers Squibb (BMS), a company incorporated in Delaware, to produce and market the product worldwide under the trademark 'Videx'. A patent application was filed by BMS with the Department of Intellectual Property of Thailand on 7 July 1992 for the ddI drug. It was claimed in the application that the invention related to pharmaceutical components providing the improved oral dosing formulations of ddI. The claims were directed to the method of adding buffer (antacid) that provides special advantages for the treatment of HIV/AIDS.

The patent application that was filed in Thailand claimed the drug dosage, which was limited to 5-100 mg of ddI per dose. In 1997, after the application was published, BMS requested the Department of Intellectual Property to amend its application. The amendment was aimed at removing the limitation on the dosage range mentioned in the claims. The Department of Intellectual Property approved the request for amendment and in January 1998 a patent covering all dosage forms of ddI was granted to the company.<sup>2</sup>

In May 2001, the AIDS Access Foundation, which is an NGO, and two Thai HIV patients filed a lawsuit against BMS and the Department of Intellectual Property seeking an amendment to the descriptions of the scope of the claims in the patent pertaining ddI. It was alleged that the patent was wrongly and unlawfully granted for ddI formulation. The plaintiffs asserted that the decision to allow amendment of the application strengthened the company's ddI manufacturing rights more than what it initially claimed. It was also alleged that the Department of Intellectual Property's decision in allowing amendment of the application was wrong and violated the law and regulation, because the amendment had widened the scope of the invention and gave wider exclusive rights than the company was entitled to.

The Central Intellectual Property and International Trade Court of Thailand ruled on 2 October 2002 against BMS and the Department of Intellectual Property calling the amendment 'unlawful'. The court ordered the Department of Intellectual Property to revoke the invalid claims and restore the original limits to formulation in the patent. The judgment of the court resulted in the company's exclusive rights being limited to 5-100 mg per unit, which permitted anyone to produce generic versions of ddI tablets greater than 100 mg without infringing the patent rights held by BMS. Both BMS and the Department of Intellectual Property appealed the decision.

On 9 October 2002, a second lawsuit was filed by the Foundation for Consumer Protection of Thailand and three HIV patients against BMS and the Department of Intellectual Property. This time the AIDS activists sought revocation of the company's patent. The plaintiffs asserted that the grant of the patent for the ddI formulation was unlawful because the invention was not new. They also argued that

the idea of adding buffer (antacid) to create an improved pharmaceutical formulation in order to reduce acid in stomach and facilitate the oral dosage was obvious to any professional in the field. They also said that the patent covering the ddI formulation was an obvious development of an existing product, rather than an original therapeutic idea. Both lack of novelty and obviousness are a standard legal argument against patent exclusivity under Thai law (Patent Act B.E. 2522, Secs.5 and 54).

Before the trial of the second case began, the company sought settlement with the plaintiffs. After several rounds of negotiation, an amicable agreement was reached and signed by BMS and representatives of the Foundation for Consumers and the three HIV patients. The company agreed to surrender all its exclusive marketing rights under the ddI patent in Thailand and withdrew its appeal in the first lawsuit in exchange for the dropping of the second lawsuit by the plaintiffs (Kuanpoth 2006).

### **3. International Trade Regulation and Its Impacts on Access to Medicines**

#### *i. TRIPS, the Doha Declaration and access to medicines*

The TRIPS Agreement established a new area of trade regulation in the WTO. It contains new multilateral rules and disciplines with minimum substantive standards of IP protection that all WTO Members must implement. WTO Members are required to provide patent protection for pharmaceuticals, but high levels of protection are balanced by various legal measures that WTO Members may take if IP rights are abused. The feasible options include: compulsory licensing and government use

(TRIPS, Art. 31), parallel importing (Art.6), exception to exclusive patent right such as research exemption, Bolar provision, prior users' rights, etc. (Art.30), and competition law and policy (Correa 2000).

TRIPS requires patent protection for pharmaceutical products and processes, and a number of developing countries have expressed increasing concern that exclusivity under patents is leading to substantially higher drug prices, with adverse effects on healthcare services (WHO 2000). The experiences of some countries (*e.g.* South Africa, Thailand, and Brazil) regarding the actual impacts of patent rights on access to medicines, led to the issuance by the WTO of the Doha Declaration on the TRIPS Agreement and Public Health (WTO Ministerial Conference 2001; Correa 2002). The Doha Declaration, which was adopted on 14 November 2001, expresses concern of Member countries over “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 stipulates that TRIPS “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 goes on to recognize that WTO Members are free to use the flexibilities under TRIPS, such as compulsory licensing, in order to promote access to medicines, and are free to determine the grounds upon which to issue compulsory licenses.

The Doha Declaration instructed the WTO Council for TRIPS to recommend a solution to the problem faced by countries with insufficient or no manufacturing



capacities. The problem concerns Articles 31(f) and (h) of the TRIPS Agreement which permits Members to grant compulsory licenses to supply foreign markets but limits exports to less than half of production and requires payment of adequate remuneration to the patent holder when such licenses are issued. It also instructed the Council for TRIPS to recommend a solution to the problem faced by countries with insufficient or no manufacturing capacities, which led to the decision by the WTO General Council in December 2005 to amend the TRIPS Agreement permitting a production for export under a compulsory license and waiving the payment requirement in the eligible importing Member (WTO General Council Decision 2005).

*ii. The proposed Thai-US free trade agreement and TRIPS-Plus rules*

The early 2000s saw the proliferation of FTA, which arose after some WTO Member countries became impatient with slow progress in multilateral trade negotiations. Since trade liberalization was getting more difficult under the WTO framework, some developed country governments, particularly the US government, have used bilateral and regional trade fora to achieve what they could not in the multilateral WTO forum (enforcing inflexible high level IP protection in developing countries).

In 2002, the US Congress passed the Bipartisan Trade Promotion Authority Act of 2002 giving the Executive branch fast track authority to conclude bilateral agreements. Since then, the US has negotiated and is negotiating an FTA with a number of countries including Australia, Bahrain, Chile, Morocco, the Southern

Africa Customs Union (SACU) countries, and Singapore. It is also negotiating FTA with Thailand along with many other countries.

The US offers the trade partners concessions in core trade areas like agriculture, textile and other market access preferences in exchange for higher standards for IP protection. US FTA generally includes an IP Chapter containing TRIPS-Plus standards that goes beyond what is already included in the TRIPS Agreement. The TRIPS-Plus provisions in the FTAs signed by the US are of a comprehensive nature. They concern all areas of IP such as patents, trademarks and copyright. On patents, TRIPS-Plus rules generally contain:

- Inclusion of new areas of IP (*e.g.* patenting of life forms, data exclusivity);
- Implementation of a more extensive IP standard (*e.g.* extension of patent and copyright terms);
- Limiting flexibilities that countries have under TRIPS (*e.g.* restricting the right of governments to allow the production, marketing, and import of generic medicines);
- Requiring the parties to the FTA to ratify or accede to a host of WIPO treaties (*e.g.* the Patent Cooperation Treaty, the UPOV Convention, WIPO internet treaties).

When the USTR submitted the draft IP text to Thailand in the sixth round of FTA negotiations in January 2006, TRIPS-Plus provisions appeared in the US proposed text (available at: [http://www.bilaterals.org/article.php3?id\\_article=3677](http://www.bilaterals.org/article.php3?id_article=3677)). If Thailand signs such an FTA with the US, the TRIPS-Plus commitment would have negative

implications for access to medicines in Thailand, especially the country's successful ARV treatment programme, as the following discussions suggest.

a) Patents for any new uses or methods of using a known product

The text of the USTR IP proposal requires Thailand to protect second uses, new use of products already known or existing in the market. For example, Thailand must allow the claim to a new use of an old drug or the claim to a new therapeutic application of the known drug. Given that a single medical product can have multiple uses and formulations, providing patents for the subsequent uses or the new composition of a known drug would allow "evergreening" (*i.e.* granting patents for trivial inventions) which unnecessarily prolongs the monopolistic market enjoyed by the patent holder and deprive consumers of the right to essential medicines.

b) Restricting compulsory licensing

The USTR text introduces language that would undermine the ability of Thailand to make use of compulsory licensing as a means to obtain differentially priced generic medicines. For example, it confines circumstances under which compulsory licenses may be issued to three circumstances only, namely (i) to remedy anti-competitive practices, (ii) in the case of public non-commercial use, and (iii) in the case of national emergency or other circumstances of extreme urgency. The issuance of compulsory licenses in other circumstances than those mentioned above (*e.g.* issuing a compulsory license in case of non-working or insufficient working of patents) is not permissible.

In the case of public non-commercial use, national emergency or other circumstances of extreme urgency, the USTR text provided that a compulsory license can be granted only in accordance with these conditions:

- A compulsory license can be issued only to the public sector or third parties authorised by the government.
- The patent holder shall receive full compensation under the TRIPS provision for compulsory licensing.
- There must be no requirement for the transfer of undisclosed information or for the disclosure of know-how without the consent of the right holder.

The constraints which might be imposed on Thailand threaten to restrict the measures it can take to pursue affordable drugs. Thailand's signing an FTA with the US would result in limited access to medicines not only in Thailand but also in its neighbouring countries like Vietnam, Myanmar, Cambodia and Laos, which have been relying on Thailand as an important source of drug supply. The TRIPS-Plus provision would prevent Thailand from issuing a compulsory license and exporting the compulsorily licensed drugs to those countries that have no or insufficient capacity in drug production, denying their rights as reaffirmed by the Doha Declaration on TRIPS and Public Health (Abbott 2004).

#### c) Prohibiting pre-grant opposition and revocation of patents

The USTR text prohibits Thailand from allowing pre-grant opposition to a patent. The effectiveness of the patent system primarily depends on the quality of the technical

examination. In developed countries, it is not uncommon to find a number of invalid patents being issued each year (Sherwoon *et al* 1999). In view of the weaker patent examination system, it is thus logical to assume that the number of invalid patents granted in the developing countries like Thailand is even higher (Tanasugarn 1999). The case of ddI discussed earlier reflects the policy significance of the pre-grant opposition procedure which permits the invalidation or amendment of patents before the patent office examination. A straightforward administrative procedure is necessary because it allows the patentee's competitors to challenge the validity of the patent at relatively low cost prior to an infringement action. The system also reduces the excessive burden on the court and contributes to speedy proceedings of patent invalidation.

The US text also prevents Thailand from revoking patents on grounds other than those that would have justified a refusal to grant the patent (*e.g.* lack of patentability, insufficiency of or unauthorised amendments to the patent specification, non-disclosure or misrepresentation of prescribed, material particulars, fraud, or misrepresentation). Revocation cannot be undertaken in the cases of abuses of patent rights or non-working which are generally the cause of high drug prices, despite of the fact that the revocation of patents is permissive under the Paris Convention and the TRIPS Agreement.

#### d) Extending patent term

Extension of patent term is another type of restriction found in FTAs concluded by the US. The TRIPS-Plus standards require patent term extension beyond the twenty years

of TRIPS due to a delay caused by regulatory approval processes or by the granting of a patent. Extending the patent term would delay the potential introduction of affordable generic medicines and defer the day when consumers can reap the benefit of generic competition.

e) Data exclusivity

A company that seeks registration of medicines must submit test data (*i.e.* data relating to the drug's quality, safety and efficacy) to the national drug regulatory authority (Correa 2002). Like all US FTAs, the USTR text requires Thailand to enforce data exclusivity, which prevents the national drug regulatory authority from using the originator's clinical test data for a period of 5 years (in the case of new medicines) or 3 years (for the new use of old products) from initial regulatory approval of the original product. The drug regulatory authority is prevented from granting market approval to generic drugs on the basis of bio-equivalence or on the fact that the original product has got a marketing approval in a foreign country. This provision would delay generic drugs entering the market, as generic companies would have to enter a long and costly testing process and complete the registration trials before the marketing approval of a generic drug can be obtained. It may also restrain the effectiveness of the compulsory licensing system, potentially preventing the drug regulatory authority from registering the generic drug produced under the compulsory license. Thailand would be inhibited from using compulsory licensing to gain access to lower priced medicines.

f) Linkage of drug registration and the patent status of a drug

The text that the USTR has proposed to Thailand contains a provision obligating the Thai drug regulatory authority to inform the patent holder as to any attempt to register a generic drug. The linkage of drug registration with the patent status would impose unnecessary burden on the drug authority and unnecessarily restrain the entry of generic medicines. The TRIPS Agreement makes it very clear that IP rights, including patents, are private rights. The owner of the rights must protect its own interests, not the State. The practice of linking patent status to registration obviously provides legal protection for IP rights that are much stronger than any other rights of the private party. This sort of proposal therefore should be rejected by Thailand.

g) Trade marks

TRIPS-Plus provisions introduced by the US also impose a high level of trade mark protection. Under US FTAs, “trade mark” is defined in the broadest manner, including non-visually perceptible trade marks, such as scent marks. Sound, texture and smell could be registered as trade marks. The new trade mark rule would allow the pharmaceutical companies to create “brand loyalty” for their trade marks and brand names associated with the patented medicines by using intense advertisement and sophisticated marketing techniques. The monopolistic market based on the trademark and consumer loyalty will continue after the expiration of the patent, and will restrict the introduction of generic competition which leads to price reductions on branded medicines.

h) Linkage of IP rights and investment

FTAs introduced by the US also advance the liberalization of investment measures by restricting the sovereign right of states to regulate foreign investments. For example, some US FTAs prohibit the host governments from imposing performance requirements (US-Singapore FTA, Art.15.8). Expropriation or other measures tantamount to expropriation are prohibited except when such measures are taken in the public interest, on a non-discriminatory basis, against payment of prompt, adequate and effective compensation, and in accordance with due process of law. Compensation would have to be paid without delay, equal the fair market value of the investment before the expropriation occurred, and be fully conceivable and freely transferable (US-Singapore FTA, Art.15.6.2). The US FTAs also incorporate provisions for investor-to-state dispute settlement that allows private investors to sue the host state directly in international dispute tribunals for monetary compensation for government policies or actions judged by the tribunal to be in breach of the treaty obligations and to undermine an investor's future profits (US-Singapore FTA, Sec.C: Investor-State Dispute Settlement).

FTAs also link the protection of IP with investment protection by including IP rights in the definition of investment (US-Singapore FTA, Art.15.1.13(f)). The linkage between IP rights and investment would inhibit Thailand to regulate its economy or protect its citizens. For example, US FTAs generally specify that when a compulsory license is issued in compliance with the FTA provisions, which are generally more restrictive than the TRIPS Agreement, it does not violate the investment chapter's limitation on expropriation. That means if the issuance of the compulsory license is a violation of the FTA IP chapter (even though it is in compliance with TRIPS), the



patent holder can directly sue the host government in a special trade tribunal for compensation (US-Singapore FTA, Art.15.6.5). The patent holder can claim much higher compensation than reasonable royalties in case of compulsory licensing under the TRIPS IP rules, as the investment chapter under FTAs requires compensation to be the full market value of a patent. The prospect of paying high compensation to the patent holder would undoubtedly discourage developing country governments from issuing compulsory licenses to protect public health.

## **Conclusion**

HIV/AIDS is devastating many developing countries on a scale unseen in recent history. Thailand has proved that a well-funded, politically-supported public policy could be effective in preventing the spread of HIV/AIDS on a national scale. The comprehensive prevention programmes adopted by the Thai government have saved millions of lives, significantly reducing the number of new HIV infections. The Thai case also demonstrates the importance of generic competition to maintain low price levels and thus makes medicines available and affordable. This in turn means that TRIPS flexibilities are crucial to increase such competition. Any attempt to limit the use of such flexibilities would have significant impacts on accessibility to the vital medicines. The TRIPS-Plus rules are proposed by US pharmaceutical industries, who give no thought to HIV-infected patients in developing countries who need the medicines most direly. Those companies are pursuing the higher level of protection not to increase research and development, but to limit generic competition in order to increase their profits.

Thailand unquestionably possesses the manufacturing capacity to produce the generic ARVs. Such capacity will allow Thailand to take advantage of the TRIPS flexibilities to get affordable treatment for its growing HIV/AIDS population. However the constraints under the proposed US FTA threaten to restrict the measures the country can take to pursue affordable drugs, and will affect ability of Thailand to continue its ARV treatment and other healthcare programmes. Thailand must be aware that it has obligation to ensure the realization of the right to health, which means any increase in IP protection must be balanced by the right of access to healthcare and essential medicines. In order to make ARV treatment affordable for the most vulnerable groups in the country and comply with the right to health under the international human rights instruments that Thailand adheres, generic competition must be upheld and the Thai government must reject the TRIPS-Plus rules proposed by the US.

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<sup>1</sup> When the patented drug has been sold by the right holder or with his consent, the patent holder cannot prohibit the subsequent import or resale of the product because his rights to the product have been exhausted by the act of selling it. This is known as “the principle of exhaustion of rights”. Countries may implement this principle differently. Some may apply the principle when drugs are sold within the national border only (called national exhaustion), but other countries, notably the European Union, allow no restrictions on import when drugs are put on sale in members of the community (called regional exhaustion). Many countries currently adopt the principle of international exhaustion of rights, whereby the patent rights are exhausted after the first marketing of the patented article by the right holder or with his consent, regardless of the place of marketing.

<sup>2</sup> Thai patent law provides for examination of the patent applications as to substance. In practice, due to limited resources and facilities, the Department of Intellectual Property hardly conducts patent search and examination, but simply grants patents in pursuant to the examination result in a foreign country. In other words, the Thai patent office always accepts the search and examination results obtained by a foreign patent office, particularly those of the developed countries who are considered more capable of thoroughly examine applications.