

## EFTA – Thailand FTA

### I. Executive summary:

Thailand has been hard hit by the HIV/AIDS pandemic, and faces with severe challenges in responding to the need for treatment, care and prevention for its population. Thailand has taken several important steps to tackle the spread of HIV/AIDS. It is a positive example of a developing country that has begun to develop effective programmes that are already bringing benefits to the Thai population, for example, setting up a wide prevention programme, and promoting the use of condoms, especially among groups at high risk. Prevention of HIV transmission from mother to child has commenced. Recently, Thailand succeeded in manufacturing a fixed dose combination (FDC) of anti-retroviral drugs (ARVs), which raised hopes that access to necessary medicines for all those that could benefit from treatment is an achievable goal.

Current developments on intellectual property rights (IPRs) especially Free Trade Agreement (FTA) negotiation are central to Thailand's ability to take necessary action to control the HIV/AIDS epidemic. The government's commitment to a national treatment program presently rests on domestic production of GPO-vir, a fixed dose combination of three separate drugs that are not patented in Thai IP law, and are therefore legal. GPO-vir is made by the Government Pharmaceutical Organisation, and is the therapeutic drug of choice (first line drug) for the treatment of HIV/AIDS patients in Thailand. There are concerns that second and third line drugs - those that will need to be substituted when adverse drug reactions occur, or when drug resistance develops - will not be affordable. These follow-on drugs are likely to be patented and priced beyond the ability of the government to pay.

Thailand signed the TRIPS agreement before it was required to do so, in 1992, and is now in negotiations with the EFTA on the terms of a bilateral Free Trade Agreement that will – if precedents set elsewhere are followed – include stringent new IPRs standards. The obligation to comply with even stronger intellectual property protection than TRIPS will directly threaten Thailand's ability to meet its health needs in the future.

The Thai NGOs coalition working on FTA was formed as "FTA watch". This coalition worked on it and published the study of the impact of U.S.-Thailand FTA in several areas: such as agriculture, investment, and intellectual property rights under the name of "Sovereignty not for Sale"<sup>1</sup>. Follow by the negotiation with US, Royal Thai Government started to negotiate with EFTA countries. The high level of Intellectual Property Rights (IPR) Protection is also the aim in the EFTA-Thailand FTA.

### EFTA-Thailand FTA:

#### A. The extension of patent term is not accepted

The patent term in Thai Patent Act is 20 years from filing date, therefore the delay in the process of patent granting do not affect the right of patentee. There is no obligation in the drug registration to wait for the granting of patent and the patentee has the full right for the invention even though the application is still in the granting process. In contrary, there is no regulation in the Thai drug registration process to enforce the patentee to elaborate the patent status of registered drug. In consequence, it delays the introduction of generic product into the market about 5 years after the patent expiry date of those drugs. In fact, Thailand must request the EFTA to shorten the patent term for the essential drugs, since it is the burden for Thailand to solve her health problems.

The EFTA countries request for the patent term extension 5 years to compensate the delay in the process of drug registration. In fact, the delay on drug registration process is not the real problem in Thailand, since new drug registration in Thailand takes for 1-2 years. The purpose of drug registration is the screen process to allow only safe and efficacy drugs available in country. Therefore, it is unfair to accelerate the drug registration process by using penalty mechanism as per EFTA's request to extent the patent term, since these two systems are unrelated with different goal. Instead, the EFTA countries should offer the technical

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<sup>1</sup> Jiraporn Limpananont, Sovereignty not for Sale: FTA Thailand-U.S., Chapter 5 FTA Public Health and access to medicines, ISBN 974-91935-7-1, 2004, 77 – 86.

assistance to Thai FDA for the efficient and fast drug registration process to benefit for the drug company as well as the people's health.

B. The patent rights should not threaten the protection of public health

According to Thai Patent Act, it protects against imports of pharmaceutical products without patent-holder's consent, and there are the measures like CL, government use and parallel importing to protect the public health. These provisions comply with TRIPs. In addition the TRIPs and Public Health declaration paragraph 4, 5, and 6 allow the country to protect public health 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.

C. Test data and trade secrets must not be used for market monopoly

To protect the undisclosed information of the NCEs on drug registration process, the provision in TRIPs 39.3 is adequate and effective protection<sup>2</sup>. The request of data exclusivity on the test data is "TRIPs Plus". Therefore, the text as in the TRIPs 39.3 should be in the FTA text.

**Recommendations:**

- HIV-AIDS is not only the health problem in Thailand but it spreads rapidly all over the world. The control of this disease should be done worldwide; any obstacle for the accessibility to the medication must be eliminated. One big obstacle is the pharmaceutical product patent, so the essential drugs, especially ARVs and OI treated drugs must be exempted from the patent protection system.
- The IPRs and pharmaceuticals must take out from EFTA-Thailand FTA, since the impact of it lead to the problem of accessibility to medicines, which is the human's right and the right to health.
- In the issue of IPRs, since Thailand's legislations comply to the international standard of TRIPs, so there should be not any TRIPs Plus in FTA as the statement of RTG to the UN High Commission on Human Rights<sup>3</sup>.
- Royal Thai Government (RTG) should let all stakeholders have the opportunity to share their concerns and decisions when the negotiations could affect people health.
- The extension of patent life to compensate for the delay of drug registration process is not accepted. Since the goal of drug registration is the technical screening process for safety and efficacy, the strategy to accelerate this process by extension of patent life is very dangerous for public health aspect.
- TRIPs Article 39.3 is adequate and effective protection for the undisclosed information for the drug registration process.

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<sup>2</sup> Professor Carlos Correa in [://www.southcentre.org/publications/protection/protection.pdf](http://www.southcentre.org/publications/protection/protection.pdf): "Once data on a new drug have been submitted, their use by a national health authority to study and approve a subsequent application on the basis of similarity, does not entail a violation of the confidentiality"

<sup>3</sup> [http://www.omct.org/pdf/procedures/2005/84thhr\\_commission/written\\_replies/wr\\_thailand\\_07\\_05.pdf](http://www.omct.org/pdf/procedures/2005/84thhr_commission/written_replies/wr_thailand_07_05.pdf)

## II. HIV and ARVs treatment:

For the year 2005, it was reported that 1,070,000 adults have been infected with HIV in Thailand since the start of the epidemic<sup>4</sup>. Of these HIV positive people, 510,000 have subsequently died and 560,000 adults are currently living with HIV and AIDS. It is estimated that 17,000 new infections will occur this year and 37,000 adults currently living with AIDS illness. The Thai government is now offering free ARVs regimen to HIV-positive patients and the GPO-vir was currently used as the government program's standard first line for the ARVs treatment regimen. The government policy is to provide the ARVs for all needed patients and the target for the fiscal year 2005 is 80,000 cases. Roughly estimation based on the monthly expense of GPO-vir of 1,200 baht or 31.5 dollars, the government annual ARV drug expense for these 80,000 HIV patients will be 1,152 million baht or 30.24 million dollars per year. From the estimated data of ARVs treatment is increasing sharply (Figure 1) especially the second line drug as shown in Figure 2.

Figure 1 The estimated number of HIV+ people on ARVs treatment upto 2025<sup>5</sup>.

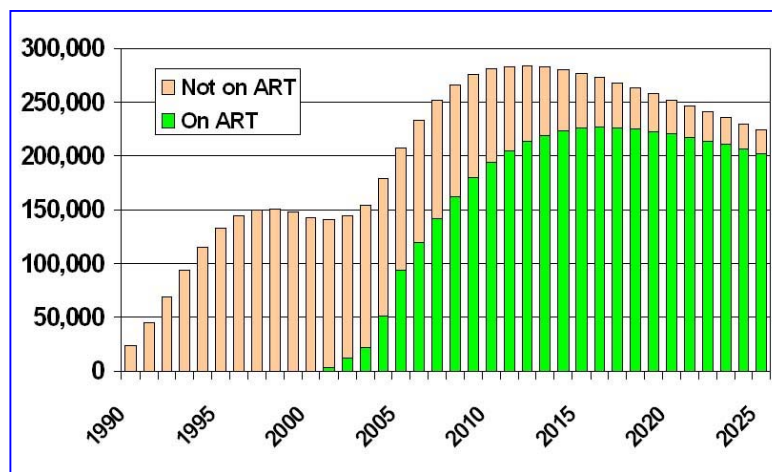
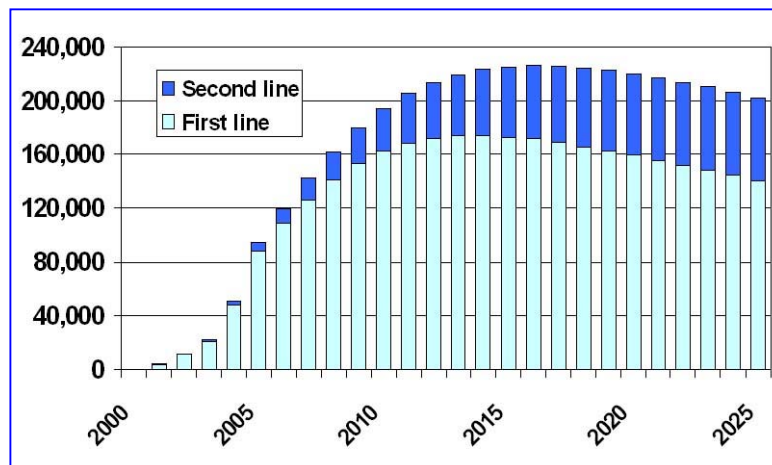


Figure 2 The estimated number of people need first and second line ARVs<sup>6</sup>.



<sup>4</sup> Wiwat Peerapatanapokin, presented "Thailand Projection 2005-2025: An Application of The Asian Epidemic Model", UN Theme Group Meeting, May 23, 2006, Bangkok, Thailand

<sup>5</sup> Wiwat Peerapatanapokin, presented "Thailand Projection 2005-2025: An Application of The Asian Epidemic Model", UN Theme Group Meeting, May 23, 2006, Bangkok, Thailand.

<sup>6</sup> Wiwat Peerapatanapokin, presented "Thailand Projection 2005-2025: An Application of The Asian Epidemic Model", UN Theme Group Meeting, May 23, 2006, Bangkok, Thailand.

The development of the ARVs has been aiming to obtain the cost-effective therapy. The desirable characteristics of the drug are better efficacy than the previous one, higher genetic resistant barrier, less pill burden, and once a day dosing. The main outcomes are to improve the adherence and the long-term effectiveness of the ARVs. Evidence from randomized controlled trials supports the use of triple ARV regimen; however, more research results are needed on the effectiveness of quadruple therapies and the relative effectiveness of specific combinations of drug<sup>7</sup>. Most of the ARV drugs are now available in Thailand. All ARV drugs in Nucleoside reverse transcriptase inhibitors (NRTIs) group are already available. These drugs are (a) Thymidine analogues including Zidovudine (ZDV or AZT) and Stavudine (d4T), and (b) Non-thymidine analogues including Didanosine (ddl), dideoxycytosine (ddC), Lamivudine (3TC), and Abacavir (ABC). For Nevirapine (NPV), efavirenz (EFV), and delavirdine (DLV) which are in Non-nucleoside reverse transcriptase inhibitors (NNRTIs) group, only delavirdine are not licensed in Thailand. Most of the Protease inhibitors (PIs) that are available include Saquinavir (SQV), ritonavir (RTV), indinavir (IDV), and nelfinavir (NLV). Others including amprenavir (APV), lopinavir+rtv (LPV) will be available soon.

To obtain the affordable triple ARV, the two NRTI's and one NNRTI are combined. The treatment outcome of the combination of two NRTI's (stavudine and lamivudine) and NNRTI (nevirapine) which is rather cheaper than other combinations though do not meet all of the characteristics' criteria but the locally produced medication, GPO-vir, made HIV patient be affordable for drugs. Its limitation came from the severe adverse reaction from nevirapine including hepatotoxicity and renal failure. Although the cost of ARV has been dramatically declining, a number of HIV patients could not afford the medication and the government has to play a major role to accelerate the access of the ARV. When drug price reduces, the number of HIV patients who are able to receive the ARV dramatically increases.

New drugs have relatively high cost and most of the ARV drugs are new and patented. The new ARV drug can substitute the first line drug, when HIV patients have the ADR or drug resistance. Although, in Thailand at present the GPO-vir can alleviate the situation of lacking the affordable first line medication, the patients who have ADR or drug resistance have to use other drugs under patent.

Actually, several medicines could be combined for triple ARV. Efavirenz is one example that, if it is cheaper or can be locally produced, may also be used in the combination of triple therapy as well as nevirapine. With the less severe ADR characteristic, but relatively expensive, efavirenz is spared for the substitution of nevirapine when a patient resists to the medication or has severe ADR. Because efavirenz is a patented drug, an HIV patient has to take this medicine separately from the other two NRTIs. The negative consequence will result in less compliance of the medication and will result in more failure of the clinical outcome. At present, since the ddl patent was withdrawn by the court's conclusion, it provides more treatment choice for a new combination or a substitution of any NRTI, when it is necessary. It should be noted and will be described later in the case of ddl about the great success of civic movement to bring the drug company into the court for their exploits of patent protection system. Based on the remaining patent duration of some existing ARVs, at least about ten years are needed for allowing locally generic production for these patented ARVs.

### III. IPRs protection in Thailand

Since 1985 the PhRMA (Pharmaceutical Research and Manufacturers of America) had claimed to lost US\$ 165 million export revenue for Thailand according to the weak patent protection in pharmaceuticals, so the USTR put trade pressure on Thailand to introduce high standard patent protection. In response to this pressure, in 1992 Thailand amended the Patent Act allowing drug product to be patented and extending the patent life from 15 to 20 years. It was amended before the conclusion of TRIPs in 1994 and even in TRIPs for the developing countries that were not obliged until the end of 2000.

To comply the TRIPs 39.3 in data protection provision, in July 2002 the Thai Trade Secrets Act was enacted. The authorized market approval agencies when requiring as a condition of

<sup>7</sup> Rachel Jordan, Lisa Gold, Carole Cummins, and Chris Hyde. Systematic review and Meta-Analysis of evidence for increasing numbers of drugs in antiretroviral combination therapy. *BMJ* 2002; 324: 1-16.

approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data shall protect such data against unfair disclosures.

Since the Thai Patent Act was urgently amended to grant a pharmaceutical product, where as the Department of Intellectual Property, (DIP) did not prepare well for this burden. One of the evidence for it is the lawsuit on ddl formula patent (Thai patent 7600) on May 1, 2001. The plaintiffs were the AIDS Access Foundation and HIV patients. They alleged that Bristol-Myers Squibb (BMS), the patentee intentionally delete the dose restriction of ddl written in the claims after the publication of the application. Consequently, it broadened the scope of claims to all drug strength. Finally on October 1, 2002, the court noticed that the removal of the dose range extended the patent protection beyond the scope of the initial application, and ruled out that BMS and DIP must correct the claims in the Thai patent 7600 by adding the range of ddl. This court case set the important precedent on the definition of “plaintiff” for the drug patent. The plaintiff is not limited to only the competitive pharmaceutical industry but it is including consumer too. The court considered this based on the concept of human right and the right to health and the Doha Declaration.

Then on October 28, 2002, the second IP court case was challenged by the Foundation for Consumers and AIDS patients. They claimed to revoke the BMS’s ddl patent on 3 reasons. First, BMS applied this product patent on July 7, 1991 before the new amended Patent Act was officially enacted on October 1, 1992. Second, there was no novelty in this invention. The information of this drug was disclosed and it was already on the market before it had been patented. Third, this invention was trivial and no inventive step. During the process in the court, the BMS decided to end the case by dedicate this patent to the Thai people in December 2003.

There are several pre-grant objections to the publicized patent applications, such as the Health and Development Foundation filed an objection to Glaxo Smith Kline on Combid patent application of the combined formula of Lamivudine and Zidovudine which all of these active ingredients are not patented in Thailand; GPO filed objection on the patent applications of ddl pellet, and the use of nevirapine hemihydrate in liquid dosage form (Table 1)

Table 1 The ARVs patent applications, which were objected to be granted

Drugs	Claims	Filing date	Remain patent life	Date filed objection
ddl pellet	Process and Product	17/05/99	15 years	14/02/2003
AZT + 3TC	<i>Formula AZT + 3TC + Glidants</i>	27/10/97	13 years	11/05/2000
Nevirapine	Use nevirapine hemihydrate in liquid dosage form	18/08/98	14 years	27/02/2001

The impact of pharmaceutical product patent on the accessibility to medicines is well recognized, for instance, the high price of patented drug<sup>8</sup> and the delay in the introduction of generic drugs into the market. The TRIPs and Public Health declaration also reflected the impact of TRIPs on high price in article 3. One of the obvious health problems in Thailand is HIV-Aids and the prices of ARVs are high. The daily ARVs cost is about 2 - 10 times the daily wage. Most of PLWA who need ARVs cannot afford the medication. So during 22 – 23 December 1999, at the grass yard in front of Ministry of Public Health building, there were several camps of about 100 PLWA and NGOs. They requested the government authorities to apply Compulsory License on ddl tablet for the production of cheap generic drugs. Since the argument of the government in refusing the use of CL was the fear of U.S. trade sanction, so they sent the letter to the U.S. President asking about this argument. Even the reply letter from the White House confirmed the country’s right to implement CL compliant to TRIPs, but the Minister still refused to issue CL on this patented ddl. The difficulties in using CL to solve health problems are usually found in most developing and least developed countries.

<sup>8</sup> Jiraporn Limpananont, “Thailand: The Impact of Pressure from the US”, page 41 – 43, Patent, Pills and Public Health: Can TRIPs Deliver?”, published by: The Panos Institute, UK, ISBN 1-870670-61-2, 2002.

#### IV. IPRs protection and Access to medicines

The impact of drug patent and the affordability to drug was analyzed on the data of patent status of the ARV drugs in Thailand and the comparison of the price of branded drug, generic drug, and minimum daily wage. The patent status of the ARVs, marketed in Thailand is shown in Table 2. The NRTI is categorized according to the patent status into 2 groups: (1) no patent such as ddC, d4T, 3TC, ddl tablet; (2) in the process of granting patent such as AZT, ddl pellet, AZT + 3TC, abacavir. Because the patent life starts from the filing date, even if the ARVs have not yet been patented, none of the generic producers start research and development for generic production. The patented NNRTI is Efavirenz. Nevirapine is not patented but Nevirapine in liquid dosage form is in patent granting process. Most of PIs are patented or in the process of granting patent except Nefinavir and Ritonavir.

Table 2 The patent status of ARV drugs in Thailand. (May 2004)

ARVs Group	Drugs	Claims	Filing date	Remain Patent Life (years)	Patent status in Thailand
NRTI	ddl pellet	Process and Product	17/05/99	15	Publicized *
	Abacavir	New combination abacavir+NNRTI	13/05/98	14	Publicized
	AZT + 3TC	Formula of AZT + 3TC + Glidants	27/10/97	13	Publicized *
	Zidovudine (AZT)	Process of formulation	14/03/86	2	Pending
NNRTI	Nevirapine	Use nevirapine hemihydrate in liquid dosage form	18/08/98	14	Publicized *
	Efavirenz	Structure	30/07/93	9	Patended
PI	Lopinavir (+Ritonavir)	Structure	04/12/96	12	Publicized
	Indinavir	New combination of Indinavir + efavirenz	30/03/94	10	Patended
	Indinavir	Structure	03/05/94	10	Abandon
	Saquinavir	Process	19/11/90	6	Publicized

\*See Table 1

In order to compare the price of branded drug and generic drug, the group of NRTI is chosen on the criteria that there are both off-patent (branded and generic drug available in the market) and on-patent drug (ddl pellet). The result in Figure 3 showed that the price of branded drug (B) is about 5.6 - 25.8 times higher than the generic drug (G). The price of the only patented drug of ddl pellet 400 mg in 2004 is 194 Baht/capsule.

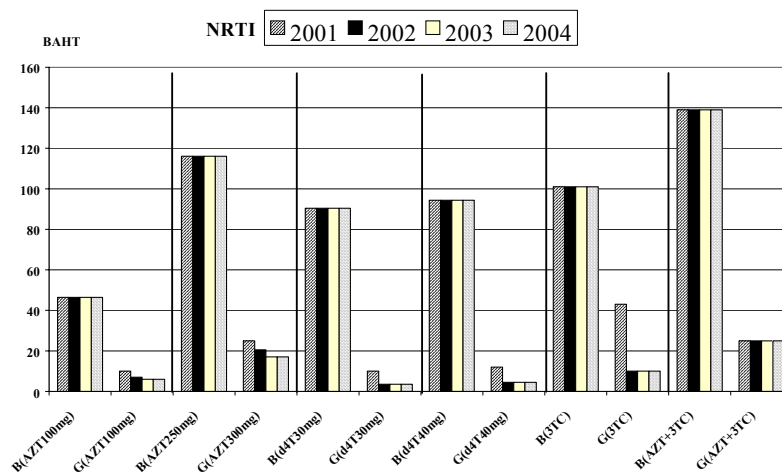


Figure 3  
Comparison of ARVs price in Thailand (unit price)

The accessibility to the ARVs could be considered by comparing the daily cost of the ARVs with the minimum daily wage. The daily drug costs of the regimen containing all brand drugs (B), and the regimen containing available generics (G) were presented in Table 3. Based on the standard treatment guideline, the regimens may contain 2 drugs from NRTI and 1 drug from either NNRTI or PI. The regimen may also contain 2 - 3 PIs. Since 2002, the cheapest and most effective ARV is GPO-vir (d4T+3TC+Nevirapine). It costs only 40 Baht daily. The patient compliance of GPO-vir is high since these 3 off-patent drugs are in one tablet. The result in Table 4 shows that even though most of the regimens comprised only one on-patent drug, the drug costs in branded drug group (B) are about 1.8 – 7.7 times higher than the regimen containing generic drugs (G). In 2004, the range of daily cost of branded ARVs (B) is 252 -791 Baht, while the regimen containing generic drugs (G) is only 40 – 448 Baht. When changing to use the regimen that contains only the patented drug without generic drug, the daily cost is around 200 Baht greater than the daily wage of 170 Baht.

Table 3 The daily cost for ARVs therapy in Thailand during 2001 – 2004.

REGIMEN \ YEAR	2001			2002			2003			2004		
	B	G	B/G	B	G	B/G	B	G	B/G	B	G	B/G
GPO-vir30				436	40	10.90	438	40	10.95	438	40	10.95
d4T+3TC+NVP	465	156	2.98	436	57	7.65	438	57	7.68	438	57	7.68
AZT+3TC+NVP	470	176	2.67	441	78	5.65	443	74	5.99	443	74	5.99
d4T+3TC+EFV	489	212.7	2.30	489	126.7	3.86	493	138	3.57	493	138	3.57
AZT+3TC+EFV	494	232.7	2.12	494	154.7	3.19	498	155	3.21	498	155	3.21
AZT+3TC+RTV+IDV	546	284.5	1.92	546	206.5	2.64	535	192	2.79	535	192	2.79
d4T+3TC+RTV+IDV	541	264.5	2.05	541	185.5	2.92	530	175	3.03	530	175	3.03
Combivir+NVP	361	136	2.65	332	50	6.64	333	50	6.66	333	50	6.66
d4T+ddI+NVP	375	128	2.93	345	85	4.06	347	85	4.08	347	85	4.08
Combivir+IDV	273	157.4	1.73	273	91.42	2.99	252	70	3.60	252	70	3.60
AZT+ddI+RTV+IDV	455	256.5	1.77	455	234.5	1.94	444	220	2.02	444	220	2.02
AZT+3TC+RTV+SQV	781	519.5	1.50	781	441.5	1.77	791	448	1.77	791	448	1.77

## V. EFTA-Thailand FTA and Access to Medicines

### A. The extension of patent term

The patent term in Thai Patent Act is 20 years from filing date, therefore the delay in the process of patent granting do not affect the right of patentee. There is no obligation in the drug registration to wait for the granting of patent and the patentee has the full right for the invention even though the application is still in the granting process. In contrary, there is no regulation in the drug registration process in Thailand to enforce the patentee to elaborate the patent status of registered drug. In consequence, it delays the introduction of generic product into the market about 5 years after the patent expiry date of those drugs. In fact, Thailand must request the EFTA to shorten the patent term for the essential drugs, since it is the burden for Thailand to solve her health problems.

The EFTA countries request for the patent term extension 5 years to compensate the delay in the process of drug registration. In fact, the delay on drug registration process is not the real problem in Thailand, since new drug registration in Thailand takes for 1-2 years. The purpose of drug registration is the screen process to allow only safe and efficacy drugs available in country. Therefore, it is unfair to accelerate the drug registration process by using penalty mechanism as per EFTA's request to extend the patent term, since these two systems are unrelated with different goal. Instead, the EFTA countries should offer the technical assistance to Thai FDA for the efficient and fast drug registration process.

According to the Chutima's study<sup>9</sup>, in 2003, generic drug substitution of the original products, which share the first 50 percent of imported drugs, have saved \$US 264.3 million. Without

<sup>9</sup> Chutima Akaleephan et al, "Possible Impact of Market Exclusivity Extension on Pharmaceuticals in Thailand" 2005.

generics, Thailand would have to pay \$US 517.0 millions, instead of \$US 252.6 millions on the same drugs. One year market exclusivity extension affects an increase of \$US 0.1 to 1.1 million per drug item, which increases to \$US 13.9 to \$US 90.2 millions for ten year extension. With the average of 60 annually registered new drugs, the estimated annual cost increase would be from \$US 6.4 to 65.9 million for one year extension and \$US 836.7 to \$US 5,411.4 million for ten year extension. If the mark up is 40%, the additional drug expense in retail price will be approx. 7,000 millions, which is equal to the current total Thailand health expenditure. The wide range between the minimum and the maximum figures is due to the wide range of the price of generics and the different growth rate of the generics and the patented drugs.

#### B. The limitation for the use of TRIPs flexibility: Compulsory License, Government Use, and Parallel Importation

According to Thai Patent Act, it protects against imports of pharmaceutical products without patent-holder's consent, and there are the measures like CL, government use and parallel importing to protect the public health. These provisions comply with TRIPs. In addition the TRIPs and Public Health declaration paragraph 4, 5, and 6 allow the country to protect public health 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. Therefore the FTA will not contain any limitation for these flexibilities.

#### C. The protection of undisclosed information

To protect the undisclosed information of the NCEs on drug registration process, the provision in TRIPs 39.3 is adequate and effective protection.

*“TRIPs 39.3: Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which 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.”*

Consequently, Article 39.3 cannot prevent a regulatory authority from using/relying on the data of a registered product in order to assess and register other "similar" products so long as this information is not disclosed<sup>10</sup>.

## VI. FTA and Right to Health

Civil society groups have responded locally and internationally with the concern of TRIPs-plus in FTAs and their impact on the right to health. FTA-Watch, a coalition of Thai groups, submitted a request to the 84th Session of the UN High Commission on Human Rights urging their consideration of the report of Thailand to raise concerns about the effect of TRIPs-plus rules in FTAs on the right to life<sup>11</sup>. Furthermore, In June 2005 a coalition of seventeen NGOs from EFTA countries and a coalition of sixteen NGOs from Thailand submitted the letters of request to the UN Special Rapporteur on the Right to Health, urging him to intervene in Thailand's FTA negotiations with the US and EFTA<sup>12</sup>. In July 2005, Thailand's Supplementary Clarifications<sup>13</sup> to the Human Rights Committee as part of Thailand's Presentation of its Initial

<sup>10</sup> Professor Carlos Correa in ://www.southcentre.org/publications/protection/protection.pdf:

*“Once data on a new drug have been submitted, their use by a national health authority to study and approve a subsequent application on the basis of similarity, does not entail a violation of the confidentiality”*

<sup>11</sup> FTA Watch, Thailand's Free Trade Agreements and Human Rights Obligations, Submission to the 84th Session of the UN Human Rights Committee, March 2005, [http://www.ftawatch.org/autopage1/show\\_page.php?t=22&s\\_id=3&d\\_id=3](http://www.ftawatch.org/autopage1/show_page.php?t=22&s_id=3&d_id=3) and also see [http://www.ftawatch.org/autopage1/show\\_page.php?t=22&s\\_id=2&d\\_id=2&page=1](http://www.ftawatch.org/autopage1/show_page.php?t=22&s_id=2&d_id=2&page=1)

<sup>12</sup> Déclaration de Berne, Request for an urgent appeal to stop EFTA Member States (Switzerland, Norway, Iceland and Liechtenstein, from imposing TRIPs-plus rules in a free trade agreement (FTA) with Thailand, Lausanne 20 June 2005, <http://www.evb.ch/fr/p3647.html>

<sup>13</sup> [http://www.omct.org/pdf/procedures/2005/84thcommission/written\\_replies/wr\\_thailand\\_07\\_05.pdf](http://www.omct.org/pdf/procedures/2005/84thcommission/written_replies/wr_thailand_07_05.pdf)



Report under the International Covenant on Civil and Political Rights reported as following quote:

*“...outcomes of FTA agreements should not contradict with or undermine the benefits Thailand receive from other agreements, especially from the WTO’s TRIPS agreement (Doha Ministerial Declaration on TRIPS – Public Health).”*

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Drug Study Group  
Thai NGO working in the issue of pharmaceuticals and health

FTA watch  
Thai NGOs coalition working on FTA

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