Thailand National Technical Consultation on

Free Trade Agreements and Intellectual Property Rights:

Implications for Access to Medicines

Bangkok, Thailand
8-9 December 2005

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United Nations Development Programme
12th floor, UN Building
Rajdamnern Nok Avenue
Bangkok 10200 Thailand
Tel: (66-2) 288 1828
Fax: (66-2) 280 0556
Email: registry.th@undp.org
Web site: www.undp.or.th

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Co-organizers:

Food and Drug Administration, Ministry of Public Health, Thailand

Department of Disease Control, Ministry of Public Health, Thailand

Chulalongkorn University

Joint United Nations Programme on HIV/AIDS

United Nations Development Programme

World Health Organization

Sponsor:

United Nations Development Programme

Participating organizations:

AIDS Access Foundation
Chulalongkorn University
- *Centre for Law and Policy*
- *Social Pharmacy Research Unit*
- *Faculty of Pharmaceutical Science*
- *Faculty of Political Science*

Consumer Foundation
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- *Bureau of AIDS, TB and STIs, Department of Disease Control*
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Soratham Law Office
Thai Action on Globalization
Thai AIDS Treatment Action
Thai Network of People Living with HIV & AIDS
Thai NGO Coalition on AIDS
Thai Pharmaceutical Manufacturers Association

International experts:

Carlos Correa, University of Buenos Aires, Argentina
Cecilia Oh, WHO Geneva
David Vivas-Eugui, International Centre for Trade and Sustainable Development, Geneva
Dr. Jakkrit Kuanpoth, University of Wollongong, Australia
Julian Fleet, UNAIDS Geneva
Karin Timmermans, WHO, SEARO/WPRO
Manuel Montes, Regional Centre in Colombo, UNDP
Muhammad Farid Wong, Ministry of Health, Malaysia
Bhanu Pratap Sharma, Ministry of Health, India
Pascale Boulet, Médecins Sans Frontières, Geneva

Organizing team:

Dr. William Aldis (WHO)
Håkan Björkman (UNDP)
Patrick Brenny (UNAIDS)
Lekha Chaturabatara (UNDP)
Mac Glovinsky (UNDP)
Thidaporn Jirawattanapisal (Bureau of AIDS TB & STI, Department of Disease Control, MOPH)
Dr. Suchart Jongprasert (Food & Drug Administration, MOPH)
Dr. Jiraporn Limpananont (Chulalongkorn University)
Cecilia Oh (WHO)
Ferdinand Strobel (UNDP)
Saranya Tanvanaratskul (UNAIDS)

Contents

Acronyms

ARV	Antiretroviral
CL	Compulsory licence
FDA	Food and Drug Administration
FTA	Free trade agreement
GPO	Government Pharmaceutical Organization
HIV/AIDS	Human immunodeficiency virus/acquired immunodeficiency syndrome
IP	Intellectual property
IPRs	Intellectual property rights
MoPH	Ministry of Public Health
MSF	Médecins Sans Frontiérs
NCE	New chemical entity
NGO	Non-governmental organization
PI	Parallel import
RTA	Regional trade agreement
STI	Sexually transmitted infection
TB	Tuberculosis
TRIPS	Trade-related aspects of intellectual property rights
UNAIDS	Joint United Nations Programme on HIV/AIDS
UNDP	United Nations Development Programme
WHO	World Health Organization
WTO	World Trade Organization

Introduction

Introduction

I

Background

The right of countries to protect public health is recognized by the World Trade Organization (WTO) patent rules – known as Trade-Related Aspects of Intellectual Property Rights (TRIPS) – and was further reinforced at the 4th Ministerial Meeting in Doha in November 2001 when the WTO members agreed to a Ministerial Declaration on TRIPS and Public Health, which became known as the "Doha Declaration":

> *"We agree that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health, and in particular, to promote access to medicines for all". (Paragraph 4, Doha Declaration, 2001)*

This declaration was an important victory for developing countries and for poor people around the world in need of affordable life-saving medicines. It further reinforced the recognition that WTO patent rules may lead to higher drug prices, placing medicines out of reach of those who need them, and undermining public health in developing countries. The WTO members thus renewed their commitment to allow necessary flexibilities in the implementation of the TRIPS agreement so as to ensure access to medicines at an affordable cost by permitting countries, when necessary, to produce or import less expensive generic versions of essential drugs.

However, the ability to use the flexibilities agreed in the Doha Declaration is now being compromised by provisions in regional and bilateral free trade agreements (FTAs) that oblige developing countries to implement much stricter intellectual property rights, going well beyond the provisions of the TRIPS Agreement, and without the flexibilities needed to ensure access to life-saving medicines. These so-called 'TRIPS-Plus' provisions include:

- "Data exclusivity provisions" that create new obstacles related to pharmaceutical test data, which delay the registration and availability of generic medicines;
- Rules which turn national drug regulatory authorities into "enforcers" of patents on medicines, creating additional obstacles and delays in market approval of cheap generic drugs;

- Extension of the life span of patents, beyond the 20-year minimum required by the TRIPS Agreement which will further delay generic competition;

- Measures which require known substances to be patented all over again for each "new use" that is later discovered;

- Restrictions that limit the ability to use "compulsory licenses" as legal tools to ensure access to low-cost medicines, as appropriate and when necessary.

Some or all of these provisions appear in concluded bilateral FTAs between the United States and Viet Nam, Lao PDR, Chile, Singapore, Australia, Morocco, Bahrain, as well as the regional Central American Free Trade Agreement (CAFTA).

The incorporation of these TRIPS-plus obligations in bilateral and regional FTAs have raised concerns about their impact on public health and access to medicines. In light of this, the World Health Assembly in Resolution WHA57.14 (22 May 2004) has urged WHO Members States "to encourage that bilateral trade agreements take into account the flexibilities contained in the TRIPS Agreement and recognized by the Doha Declaration".

Thailand and the United States are now engaged in a series of negotiation rounds in an effort to agree on a bilateral FTA between the two counties, and on the table are proposals for restrictive TRIPS-Plus provisions that many experts and activists believe will undermine access to essential medicines in Thailand.

The stakes are indeed high for Thailand, especially for the more than 600,000 Thais that are living with HIV/AIDS and whose survival will depend on availability of affordable antiretroviral drugs. As of today, over 80,000 people have access to these life-prolonging treatments, thanks to the supply of cheap, locally produced generic drugs, and the target is 150,000 by 2008. As a result, AIDS deaths in Thailand have already plunged by 79 percent since 2001.

The recent decision of the Thai Government to include HIV treatment in the '30 baht'universal health care scheme is being praised the world over. It is also a tribute to Thailand's firm commitment to the human right to health care as enshrined in the Thai Constitution. But this also means there is no turning back. As HIV-positive people inevitably develop resistance to first-generation drugs, the public health services will be morally and legally obliged to find ways to ensure access to second- and third-generation treatments to keep these people alive and healthy, whatever the cost.

This is why so many public health officials, experts and activists are concerned about the US-Thai Free Trade Agreement. Restrictive intellectual property rights will prevent Thailand from using locally produced affordable generic drugs and the price of second- and third-generation HIV drugs will remain exorbitantly expensive. Depending on the rate at which patients become resistant to first-generation HIV treatment and the rate of expansion of the programme, the cost of the Government's HIV treatment programme may increase from a current USD 38 million to more than USD 500 million per year within 10 years, according to Ministry of Public Health projections. Add to this the cost of other diseases requiring long-term treatment and the accumulated financial strain on the national health budget would be untenable.

Giving up internationally agreed flexibilities in the implementation of intellectual property rights would put at risk the survival of hundreds of thousands of Thai citizens and would likely bankrupt the 30 baht scheme in the process.

From this scenario, many questions arise:

- How can Thailand, when faced with emerging diseases and long-lasting epidemics such as AIDS, accommodate increased intellectual property protection while meeting the demand for affordable and life-saving medicines?

- What are the public health implications of bilateral trade agreements that include intellectual property restrictions (including more market exclusivity mechanisms) that go beyond the internationally agreed TRIPS provisions of the WTO?

- What would be the financial viability and sustainability of Thailand's 30 baht universal health coverage scheme if Thailand's ability to produce affordable generic drugs is curtailed by stringent bilateral FTAs?

- What are the options and strategies available to Thailand to safeguard the human right to health care, as enshrined in the 1997 Constitution, and to guarantee affordable essential medicine to all its citizens?

To address these questions, the Food and Drug Administration (FDA), Thailand; the Department of Disease Control (Ministry of Public Health), Thailand; Chulalongkorn University; the United Nations Development Programme (UNDP); Joint United Nations Programme on HIV/AIDS (UNAIDS); and the World Health Organization (WHO) jointly organized this workshop entitled 'National Technical Consultation on TRIPS and Free Trade Agreements: Implication for Access to Medicines'.

Objectives of the workshop

The specific objectives of the workshop were:

- To share knowledge and experiences in the technical and legal aspects of intellectual property rights within the context of public health, particularly access to medicines.
- To build technical expertise on TRIPS, compulsory licensing, data exclusivity, and the role of drug regulatory authorities.
- To review possible strategies available to Thailand for the flexible implementation of TRIPS agreements necessary to meet the goal of 'Medicines for All' in Thailand.

Structure of the workshop

The workshop format included panel presentations, discussions and informal brainstorming sessions, which were facilitated by international experts and senior Thai officials. The workshop agenda was as follows:

Opening:

- Dr. Naransan Pleerakit (Deputy Secretary General, FDA Thailand)
- Prof. Charas Suwanwela (Chairman of Chulalongkorn University Council)
- Dr. William Aldis (WHO Representative, Thailand)
- Håkan Björkman (Deputy Resident Representative, UNDP Thailand)

Panel 1 - Pharmaceutical patents: Current trends and threats

- Julian Fleet (UNAIDS Geneva)
- Dr. Jakkrit Kuanpoth (University of Wollongong, Australia)
- Carlos Correa (University of Buenos Aires, Argentina)

Panel 2 - TRIPS and the Doha Declaration: Experiences on the use of TRIPS flexibilities

- Muhammad Farid Wong (Ministry of Health, Malaysia)
- Bhanu Pratap Sharma (Ministry of Health and Family Welfare, India)
- Cecilia Oh (WHO Geneva)

Panel 3 - Regional and bilateral FTAs: TRIPS-plus and implications for public health

- David Vivas-Eugui (International Centre for Trade and Sustainable Development, Geneva)
- Karin Timmermans (WHO)
- Pascale Boulet (Médecins Sans Frontières)

Panel 4 - Bilateral FTA negotiations: Lessons learnt and strategies

- Carlos Correa (University of Buenos Aires, Argentina)
- Manuel F. Montes (UNDP Regional Centre, Colombo, Sri Lanka)
- Dr. Jiraporn Limpananont (Chulalongkorn University)

Final Plenary: Thailand and TRIPS flexibilities: strategies and options

- Dr. Pakdi Pothisiri (Secretary-General, Food and Drug Administration, Ministry of Public Health)
- Dr. Sombat Thanprasertsuk (Director, Bureau of AIDS, TB and STIs, Department of Disease Control, Ministry of Public Health)
- Wiboonluk Ruamruk (Deputy Director General, Department of Intellectual Property, Ministry of Commerce)
- Dr. Pongpisut Jongudomsuk (Director, Policy & Planning Division, National Health Security Office)

II Summary of discussions

Summary of discussions

Panel 1:
Pharmaceutical patents: Current trends and threats

The first panel discussion provided a general overview of the current situation and trends with regard to intellectual property rights and their impact on access to essential medicines.

Julian Fleet (UNAIDS Geneva)

Mr. Fleet opened the panel discussion by giving an overview of global trade and intellectual property rules, in particular the TRIPS Agreement and access to HIV medicines. Emphasizing the need for scaling up treatment to address the AIDS pandemic, Mr. Fleet underlined the importance of TRIPS flexibilities as crucial means to help make medicines available and affordable. He encouraged Thailand to be aware of its rights under the global rules and to take advantage of them in order to preserve and improve its capacity to ensure access to medicines for its people.

He noted that the price of medicines affects the government and people of a nation as a whole. Mr. Fleet also discussed concrete strategies which Thailand could enact in order to provide powerful support to its people while at the same time maximizing affordability. These strategies include:

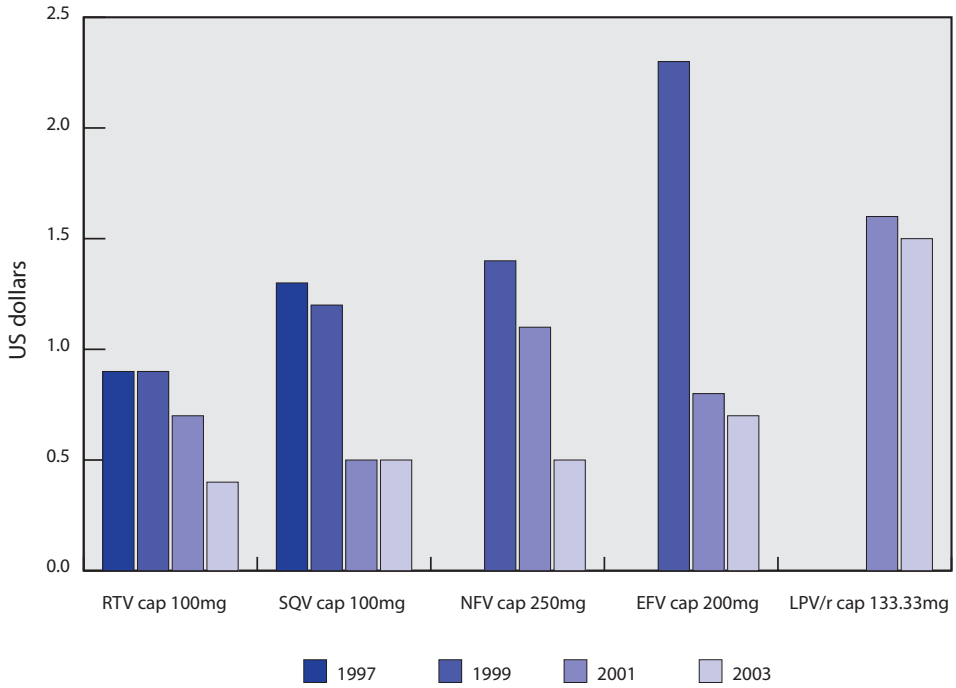
- differential pricing,
- generic competition,
- voluntary and compulsory licensing,
- high-volume purchasing,
- elimination of tariffs and taxes,
- local production, and
- flexibility in TRIPS.

He remarked that even though prices of some generic medicines may be high in relation to local purchasing power, on the whole generics are significantly less expensive: the price of the least expensive generic first-line ARV regimen recommended by WHO is considerably lower than the least expensive first-line regimen on offer from the research-based pharmaceutical industry.

Mr. Fleet reminded the gathering of the UNAIDS position and advocacy for the elimination of tariffs and taxes on ARVs, as well as the use of TRIPS flexibilities, highlighting examples taken from Brazil. Brazil has demonstrated how a country can achieve substantial price reduction in many medicines through local

production of generic medicines, as well as by the threat of possible use of compulsory licensing mechanisms in price negotiations with pharmaceutical companies.

Imported medicines, Brazil, 1996-2003: Evolution of ARV prices for adult use (in US dollars)



Source: Julian Fleet, Workshop PowerPoint presentation, 8 December 2005.

Concluding, Mr. Fleet acknowledged action to protect public health was needed, specifically in the fields of patents, and reiterated the need for countries, especially Thailand, not to trade away public health interests in the name of potentially better trade conditions. With less than 2 in 10 people having access to the HIV treatment they need, the global community is compelled to do better.

ARV coverage by region, 2005

Geographical region	Number of people receiving ARV therapy (low estimate - high estimate)	Estimated need	Coverage
Sub-Saharan Africa	500,000 (425,000 - 575,000)	4,700,000	11%
Latin America and the Caribbean	290,000 (270,000 - 310,000)	465,000	62%
East, South and South-east Asia	155,000 (125,000 - 185,000)	1,100,000	14%
Europe and Central Asia	20,000 (2,000 - 6,000)	160,000	13%
North Africa and the Middle East	4,000 (2,000 - 6,000)	75,000	5%

Source: http://www.who.int/3by5/en; accessed 5 September 2005 in Julian Fleet, Workshop PowerPoint presentation, 8 December 2005

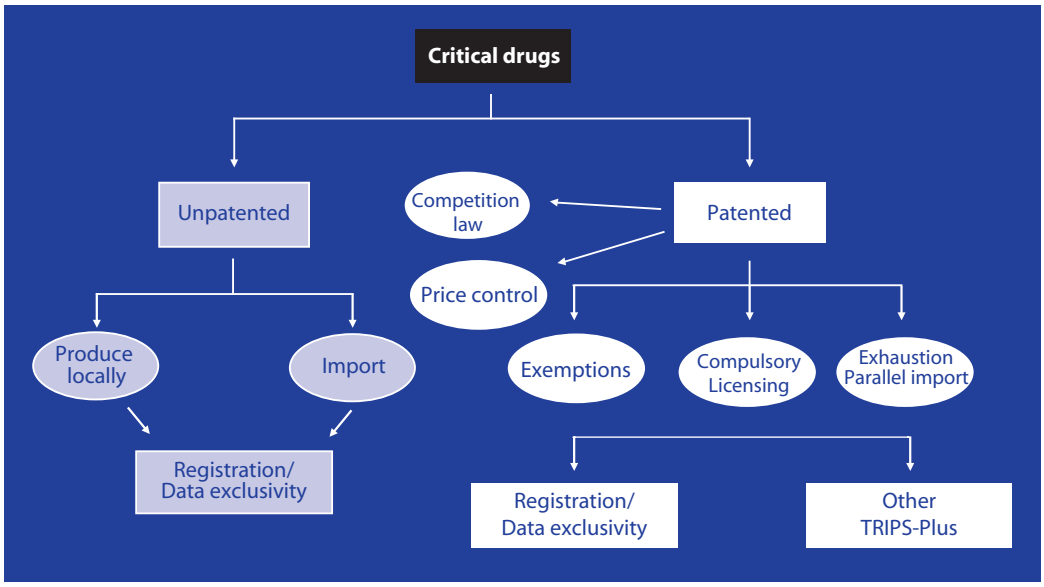
Dr. Jakkrit Kuanpoth (University of Wollongong)

Dr. Jakkrit provided a detailed assessment of the options available to Thailand for ensuring access to medicines. He noted that Thailand was facing external pressures to tighten intellectual property rights beyond what is reasonable. He emphasized the importance, at this juncture, for Thailand to take the necessary step of issuing compulsory licenses, as required, to ensure access to certain essential drugs. He recommended that Thailand issue a notification to the TRIPS Council of intention to issue compulsory licenses, as per Paragraph 6 of the WTO Doha Declaration.

He emphasized, however, that Thailand urgently needs to revise/adjust its laws with regards to patents and drug registrations in order to facilitate the issuance of compulsory licences. In this process, close collaboration between the Ministry of Public Health and the Ministry of Commerce is absolutely essential.

Regional pooled procurement to reduce prices and eliminate possible bottlenecks in the procurement process, and subsidies to firms that allow for faster production of generic drugs were also suggested as other options to be considered.

How to ensure the continuing supply of critical drugs



Source: Dr. Jakkrit Kuanpoth, Workshop PowerPoint presentation, 8 December 2005.

Dr. Jakkrit provided an overview of TRIPS-Plus provisions included in other bilateral FTAs and explained the different scenarios facing Thailand in its current negotiations with the United States.

Dr. Jakkrit recommended that Thailand:

- reaffirm the right of people to affordable healthcare;
- demand from the United States a political statement supporting compulsory licenses and parallel imports (PI);
- improve collaboration among government agencies to ensure that healthcare takes precedent over trade;
- insist that compulsory licensing is subject to conditions under TRIPS Article 31 only;
- share information with the United States regarding invalid patents and revocation of patents; and
- support parallel import into and out of the country.

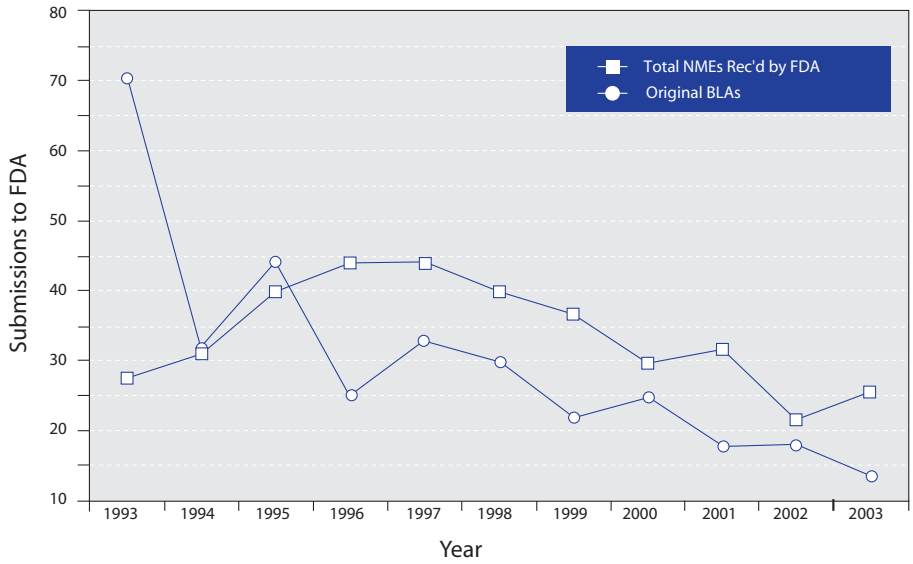
Dr. Jakkrit then recommended that UNDP, WHO or UNAIDS:

- establish a 'hotline' to help countries ascertain patent status;
- provide technical assistance on the use of compulsory licenses, PI, price control, competition law, etc.;
- issue drug guidelines for generic procurement;
- provide pricing information;
- negotiate with pharmaceutical companies not to insist on patents in Least Developed Countries (LDCs); and
- establish a South-South collaboration network (South Africa, India, Brazil, China (PRC) and Thailand).

Carlos Correa (University of Buenos Aires)

Mr. Correa provided an overview of current trends and issues related to intellectual property rights. He presented evidence demonstrating the stark contrast between the decline of innovation and development of new drugs with the sharp rise in patenting of minor developments around old drugs.

Decline in pharmaceutical innovation: 10-year trends in major drug and biological product submissions to FDA



Source: Carlos Correa, Workshop PowerPoint presentation, 8 December 2005.

Mr. Correa explained the proliferation of 'low-quality' (frivolous) patents and various strategies used by pharmaceutical companies to maximize their benefits from intellectual property rights, including:

- *blanketing*: a jungle or minefield of patents;
- *flooding*: multiple patents, major as well as minor;
- *fencing*: blocking certain lines or direction of research and development;
- *surrounding*: an important central patent is surrounded by other less important patents that block the use of the central patent, even after its expiration; and
- *networking*: building of a patent portfolio to strengthen overall protection and bargaining power.

Mr. Correa next provided an overview of the various TRIPS-plus provisions, including the possibility of patenting second uses, drug registration-patent linkages, extension of patent terms and data exclusivity, which are being proposed by the US Government, and their implications for countries such as Thailand.

He also pointed out that some of these TRIPS-plus provisions even go beyond US patent legislation, and that the industry is using the FTAs to further tighten US legislation outside the country's own system.

Mr. Correa concluded by saying that it is important to understand the context of this push for increased patent protection, the trends and changes in the pharmaceutical industry structure, and the close relationship between the pharmaceutical industry and the US Government. The aim of the industry is not to increase research and development through increased intellectual property protection, but to limit generic competition by delaying entry of generic products and thus maximizing profits from older drugs.

Panel 2:
TRIPS and the Doha Declaration: Experiences on the use of TRIPS flexibilities

The second panel discussion addressed specific experiences of countries that have used TRIPS and the Doha Declaration flexibilities to achieve the desired national outcomes.

Muhammad Farid Wong (Ministry of Health, Malaysia)

Mr. Wong explained the process that led up to Malaysia's issuance of a Government Use Compulsory Licence for import of HIV medications, specifically, zidovudine, combivir and didanosine.

He detailed the step-by-step approach of the Ministry of Public Health in submitting a proposal to the Cabinet for approval, negotiating with the Indian manufacturer CIPLA, and issuing the Compulsory Licence. He explained how pressures from trade officials and the pharmaceutical industry were trying to stop this process, and how strong leadership and solid policy analysis of available options on the part of the Ministry of Health prevailed in the end.

Mr. Wong then explained the ensuing sharp drop in the cost of these drugs, including a drop in prices of the brand-name versions, namely from GlaxoSmithKline (GSK). For example, monthly treatment cost per patient dropped from USD 261 to USD 45 for d4t+ddI+Nevirapine and, more significantly, from USD 362 to USD 115 for Combivir+Efavirenz.

Monthly cost of treatment per patient (in US dollars), Malaysia

Treatment	2001 patented price	2004 patented price	2004 generic price
d4t + ddl + Nevirapine	261.44	197.10	45.32
Combivir + Efavirenz	362.63	136.34	115.14

He ended by pointing out that once government support for compulsory licensing was shored up, there was very little or no opposition from the US Government or the pharmaceutical industry.

Bhanu Pratap Sharma (Indian Ministry of Health and Family Welfare)

Mr. Sharma outlined and discussed India's recent Patents Act as well as the past Indian Patent Acts, which were so successful in providing the means for India to supply many of the world's developing countries with inexpensive imports of generic drugs. Mr. Sharma provided a detailed account of the recent amendments to the Indian Patents Act, the drug policy of India as it relates to TRIPS, and flexibilities under TRIPS and their incorporation in to the Indian Patents Act.

Specifically, he explained the provisions related to the issuance of compulsory licenses, the required three-year delay between date of patent and the possibility of issuing a compulsory license. He also outlined the conditions that apply to compulsory licensing, what qualifies as reasonable requirements, and available 'fast mechanisms'.

He emphasized that the Indian Patents Act:

- reflects almost all the flexibilities allowed under the TRIPS Agreement and the Doha Declaration;
- is well-placed to meet the objective of the National Health Policy and Drug Policy;
- encourages technology and diffusion, thereby strengthening the indigenous manufacturing capacity, availability and affordability of safe and quality drugs; and
- avoids TRIP-Plus provisions.

Mr. Sharma concluded by suggesting points for future action, including:

- creating a mechanism in the Ministry of Health for monitoring the impact of new trade agreements;
- negotiating prices with patented drug manufacturers before granting market approval;
- developing an inter-country database on the price of drugs negotiated with patentees for bulk supplies;
- monitoring of prices of patented drugs; and
- increasing capacity within the Ministry of Health to trigger the implementation of safeguards under the Patents Act.

Cecilia Oh (WHO Geneva)

Ms. Oh used comparative experiences from other countries including Malaysia, Mozambique, Indonesia and Zimbabwe to explain the mechanics of the use of compulsory licences and government use provisions. She said that a range of flexibilities were available within the TRIPS Agreement that could be used as measures to protect public health and promote access to medicines. They include the following:

- Transition periods for the implementation of TRIPS provisions;
- Compulsory licensing;
- Government use of patents;
- Parallel Importation;
- Exceptions to patent rights;
- Exemptions from patentability; and
- Limits on data protection.

She also presented possible reasons behind the fact that only a few countries enacted the flexibilities allowed in TRIPS, which limit exclusive patent rights to allow access to affordable medicines. According to her, insufficient national capacity and lack of patent data were the main obstacles. Ms. Oh called attention to the fact that even though TRIPS flexibilities have been re-affirmed by the Doha Declaration, they need to be incorporated into national law. Addressing the issue of patent data, Ms. Oh included in her presentation the patent status of a number of key ARVs.

In addition to compulsory licensing and government use of patents, as options available to enable or facilitate access to affordable medicines, Ms. Oh also presented other options which should be incorporated into the national law. For example, parallel imports, which is the import and resale of a patented product in another country, without consent of the patent holder; and noted patent exceptions. Patent exceptions are the specified and limited use of patents in specified circumstances, which are automatically applicable if provided for in legislation without further conditions. An example of this is the Bolar Exception, which would permit the production of the generic version of a patented medicine prior to the expiry of the patent, so as to allow the generic version to be submitted for testing and approval, enabling

speedy introduction of the generic product once the patent expires. Other exceptions may be for research, experimentation or private use.

In conclusion, Ms. Oh called for greater collaboration between the Ministry of Health and the Patent Offices. She stressed the importance of public health as the primary concern in all trade negotiations and suggested the need of an intellectual property rights checklist for the use of governments in trade consultations. Such a 'tool' could perhaps be made available through the work of WHO and UNDP.

An Intellectual Property Rights Checklist

National legislation
- ☐ TRIPS flexibilities incorporated

Administrative and decision-making system
- ☐ Inter-sectoral cooperation
- ☐ Accurate and reliable patent data
- ☐ Guidelines for compensation-setting

Integrating public health into intellectual property and trade
- ☐ Patentability criteria
- ☐ Public health protected in trade negotiations

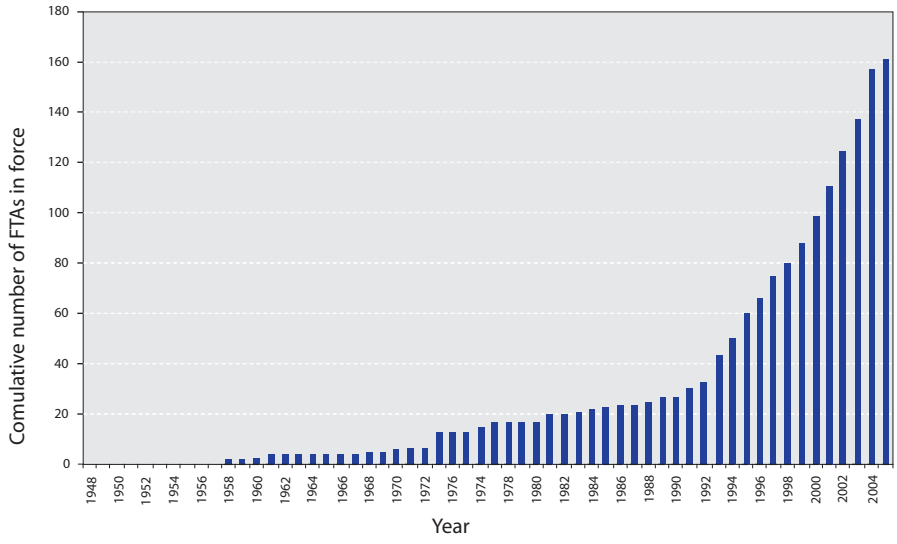
Panel 3: Regional and Bilateral FTAs: TRIPS-Plus and the implications for public health

Panel 3 focused on FTAs and the results of these agreements. The panel members shared practical experiences of past negotiations.

David Vivas-Eugui (International Centre for Trade and Sustainable Development, Geneva)

Mr. Vivas-Eugui began by presenting the growth in the number of FTAs since 1947.

Evolution of FTAs since 1947



Source: WTO in Carlos Correa, Workshop PowerPoint presentation, 8 December 2005.

He explained the dynamics of regional and bilateral trade agreements, outlining the interests of both developed countries and developing countries.

Mr. Vivas-Eugui presented the existing bilateral negotiations of both the United States and the European Union, and he further elaborated on the IP provisions and TRIPS-Plus general issues and patent-related issues.

Mr. Vivas-Eugui then examined the costs of IP provisions on healthcare, summarizing from two research studies that an adequate methodology for comparable results needs to be developed. He concluded his presentation by addressing the question of what opportunities, or 'policy space', were available for affordable medicines within the confines of patent laws after an FTA has been signed, as well as what options are available for policies outside the patent regime.

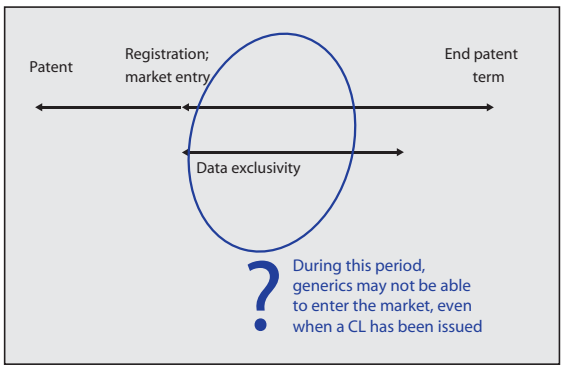
Why **developed** countries are interested in intellectual property rights in regional trade agreements:
- increased interest in protecting investments in new technologies;
- need to consolidate market access of products with high technological content;
- the logic of the minimum floor of the TRIPS Agreement;
- difficulties in moving issues forward at the multilateral and regional levels;
- the triangle of IP interest: Pharma/Bio, Hollywood and Silicon Valley;
- slow progress in patent law harmonization;
- lack of patent enforcement.

Why **developing** countries are interested in intellectual property right commitments in regional trade agreements:
- need for market access and consolidation of unilateral tafiff preferences;
- expectations about investment and improvement of countries' international economical image;
- lock in market reforms;
- competition with other trade partners;
- need to avoid isolation;
- security and aid concerns;
- perception that IP is not a problem, the problem is that we are poor;
- association with the leader as the decision comes from the highest political levels.

Karin Timmermans (WHO)

Ms. Timmermans focused on the provisions of data exclusivity and the limitations they imply. She showed how data exclusivity prohibits generic manufacturers from using bioequivalence data to register their products; it de facto disallows any recreating of the chemical formulas used in the concerned drugs. Hence generic companies have to wait until the end of the data exclusivity period, which is generally about five years, to launch their products.

New chemical entities (NCEs), standard situation



TRIPS Article 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.

In some cases, data exclusivity can even extend the originator's monopoly beyond the original patent period.

Key points that Ms. Timmermans made about data exclusivity were:

- data exclusivity creates additional barriers to access to medicines;
- TRIPS Article 39.3 (see box below) does NOT require data exclusivity; and
- national laws do not need to provide data exclusivity.

Another issue addressed in the presentation was 'linkage', which Ms. Timmermans referred to as another unnecessary barrier to access to medicines. 'Linkage' means that the Drug Regulatory Authority cannot register a generic version of a medicine that is still protected by a patent.

After these explanations, Ms. Timmermans presented a country-by-country comparison of the provisions on data exclusivity in recent FTAs with the United States, which shows a trend of an increasing number of TRIPS-Plus provisions.

Overview of recent US FTAs

Provisions	Viet Nam	Lao PDR	Chile	Singapore	Australia	Morocco	CAFTA	Bahrain
Exclusivity	V	V	V	V	V	V	V	V
New Indications	(V)	(V)		(V)	V	V		V
Including foreign registration				V	V		V	V
Including disclosed data				V			(V)	V
Can surpass patent term				V	V			V
"Local" definition NCE					V		V	V
"Waiting period"							V	
"Linkage"			V	V	V		V	V

Source: Karin Timmermans, Workshop PowerPoint presentation, 8 December 2005.

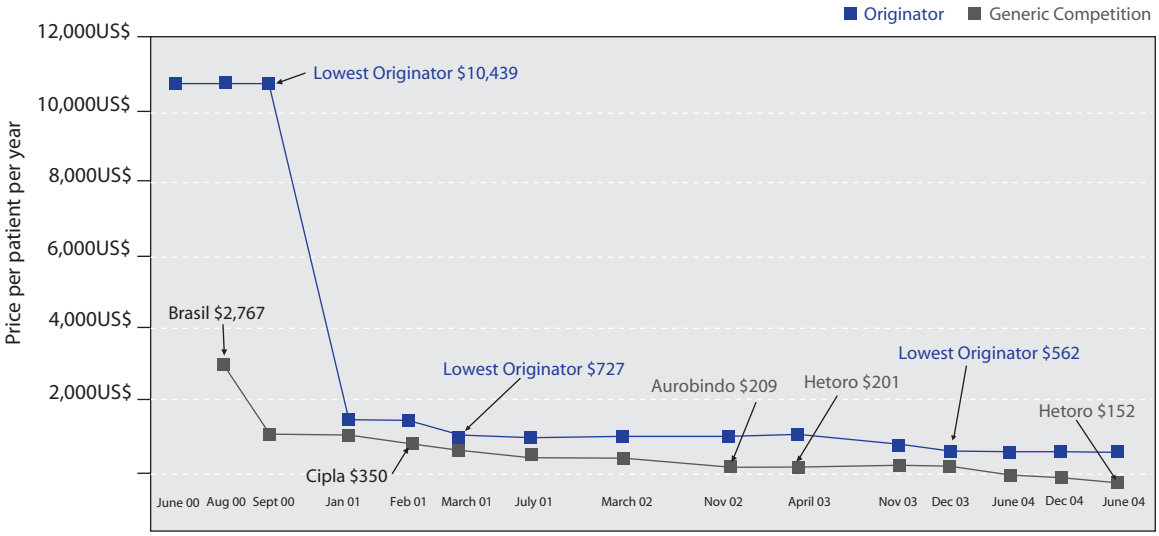
Her conclusion included recommendations on what countries could do about data exclusivity:

- no FTA;
- avoid data exclusivity in the FTA (stick to TRIPS wording);
- limit the duration of data exclusivity;
- limit the scope of exclusivity:
  - only for new chemical entities
  - only for undisclosed data
  - don't extend it to foreign registration; and
- create national exemption mechanisms.

Pascale Boulet (MSF Geneva)

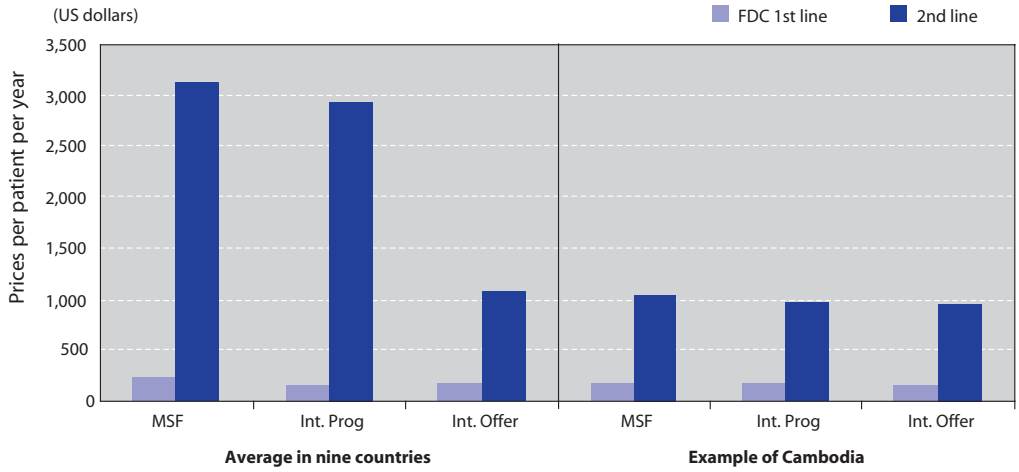
Ms. Boulet addressed the problem of access to newer medicines posed by TRIPS-Plus provisions. Using several examples, she showed how generic competition had been very successful in lowering the prices of essential medicines, particularly first-line treatments now being used in developing countries.

Generic competition and first-line ARV treatment, May 2000-June 2005



Source: Pascale Boulet, Workshop PowerPoint presentation, 8 December 2005.

However, Ms. Boulet then explained that AIDS is a chronic disease. Access to newer and adapted treatments, or second-line treatments, will be necessary, as has been clearly demonstrated in developed countries: 20 percent of patients need second-line treatment after just two years on first-line. But the costs are much higher.



Source: Pascale Boulet, Workshop PowerPoint presentation, 8 December 2005.

Comparison of prices of first- and second-line ARV treatments

Ms. Boulet noted that Thailand's ARV programme currently treats more than 80,000 people with first-line drugs and this has been possible because of generic production by the GPO. Her question was: How will this be possible with the current prices on second-line medicines? And her answer was only if generic competition remains possible through:

- routine use of compulsory licenses – Doha Declaration §4;
- no data exclusivity – TRIPS Art. 39.3;
- patents only for truly new and inventive products/processes – TRIPS Art. 27.1; and
- no linkage between patents and drug registration.

She then outlined the conditions that would be created if the US-Thai FTA contained the TRIPS-Plus provisions, including restrictions on compulsory licences, data exclusivity, the role of drug regulatory agencies in enforcing patents, and additional patents for new uses. Her conclusions were:

- second-line ARV treatment is only an illustration of the prices of all new medicines ;
- TRIPS-plus provisions included in many US FTAs will further limit generic competition and access to affordable medicines ; and
- use the Doha Declaration to take necessary measures to ensure access to essential drugs.

Panel 4: Bilateral FTA negotiations: Lessons learned and strategies

Panel 4 considered available options and strategies for Thailand with respect to FTA negotiations.

Carlos Correa (University of Buenos Aires)

To open this panel discussion, Mr. Correa addressed the risks of bilateral FTAs. He emphasized that those involved in FTA negotiations have a responsibility to the citizens of their respective countries to ensure that the outcome does not have a disastrous impact on public health and the provisions of health service. Mr. Correa called everyone's attention to the potentially huge loss of lives and financial cost of increased intellectual property protection, factors that must be weighed against any potential benefit from increased market access given by an FTA. He emphasized that while market accesses gained through FTAs are transient, restrictive intellectual property rights are impossible to undo and their impact will be long term.

Mr. Correa provided insights into the close relationship between the US Trade Representative and the pharmaceutical industry. According to Mr. Correa, the strategy of the United States in terms of intellectual property rights is to not negotiate on the key issues until the very last stage, after compromises on other issues have already been reached. At that point it is basically too late to re-negotiate, thus forcing agreements on terms favourable to the United States. He also reminded the audience that some of the TRIPS-Plus proposals are even beyond US legislation.

Mr. Correa made a strong plea for transparency in the FTA negotiating processes, including making available negotiating texts and facilitating consultations with all relevant government agencies, civil society, private sector firms, consumers and other stakeholders. When and if a draft text on intellectual property rights is tabled, it should be made public without delay. Mr. Correa gave the example of Colombia where the intellectual property section of the text was made public and openly debated.

In his closing remarks he advised Thailand to be very wary of 'side letters' that the United States may propose as a means to introduce safeguards to address public health concerns. The legal status of such 'side letters' and the safeguards they may allow for are doubtful, in contrast to the provisions in the FTA itself, which are clearly binding on the Parties.

Manuel Montes (UNDP Colombo Regional Centre)

Mr. Montes focused on the FTAs from a trade policy perspective. Mr. Montes explained that the world trading system is managed by lawyers. Their starting point is that intellectual property rights exist to protect private investment, while often ignoring the possible economic and public health impact that they may have. Economists have long realized, however, that the health industry requires government intervention to correct market failures, provide effective incentives for research and development, and ensure and sustain access to life-saving drugs.

To Mr. Montes, the biggest difficulty in trade agreements is the lack of discussion and internal negotiation between national sectoral interests. Consequently, Thailand needs to look at its interests across all sectors affected by an FTA, including the health sector. His recommendations for the Thai Government are to

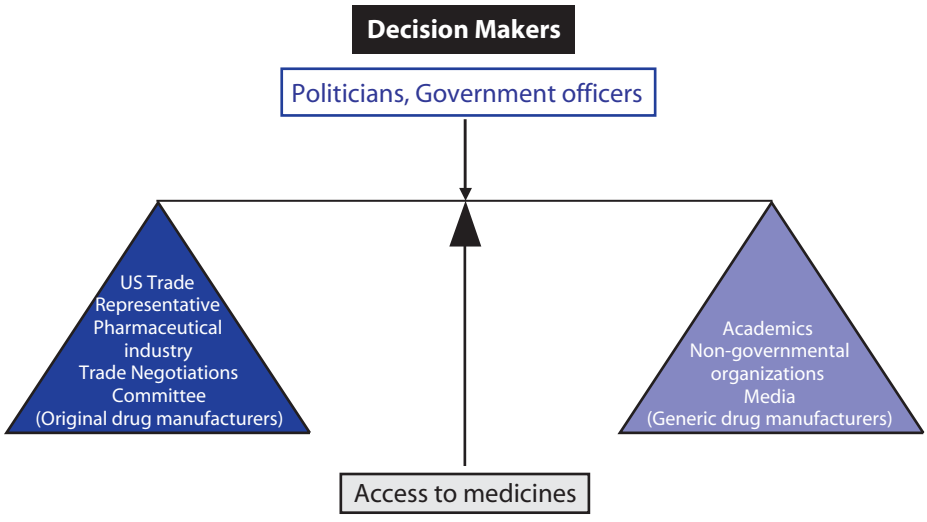
- improve quality of IP for health;
- work on IP exemptions;
- maintain a distinction between patenting and market regulation by passing relevant laws, and resist reverting to a 'primitive system';
- implement IPR work into administrative procedures, which is even in the interest of the industry; and
- invest in the modernization of industry.

He agreed with other speakers that Thailand is now in a very dangerous position in their negotiations and that the stakeholders involved need to realize this.

Dr. Jiraporn Limpananont (Chulalongkorn University)

Dr. Jiraporn explained the past and present of intellectual property rights in Thailand, emphasizing that Thailand is already compliant with TRIPS standards. She elaborated on the possible impacts of measures such as data exclusivity on public health in Thailand, including the huge financial impact of a possible US FTA with TRIPS-Plus provisions on the Thai health budget. Dr. Jiraporn pointed out that the trade negotiations on the issue of pharmaceuticals is imbalanced by the vested interests of multinational drug corporations and their powerful lobbying in the negotiation. Although Thailand has strong academia and civil society, in the end the public interest is still dependant on a top-level political decision. To change this, Thailand needs to empower its people and shift the emphasis of the trade negotiations towards their effect on the Thai population as a whole.

People's empowerment: Balanced decision



Thailand needs to do its best to make sure the FTA provisions in the current negotiations do not go beyond what has already been agreed internationally by the TRIPS agreement and subsequent WTO declarations. The country should refuse to accept any TRIPS-Plus provisions, and fully adopt and implement safeguard measures to protect public health. Involving all stakeholders and applying political pressure can be very instrumental towards this end.

In her conclusion Dr. Jiraporn emphasized that Thailand, lacking substantial IP structure and experience, needs to look to other countries with more experience for advice. She also advocated for transparency in the negotiation process with the Thai people.

Final Plenary: Thailand and TRIPS flexibilities: Strategies and options

The final plenary provided an opportunity to discuss the options and strategies available for Thailand in maximizing the use of TRIPS flexibilities to ensure sustainable access to affordable and life-saving drugs in Thailand.

Dr. Pakdi Pothisiri (Secretary General of the Thai Food and Drug Administration)

Dr. Pakdi reviewed Thai legislation related to intellectual property rights, analysed the reasons why such flexibilities have not yet been used, and made suggestions for the way forward.

He assured the audience that Thailand intends to make optimal use of TRIPS flexibilities and explained that Thai legislation already incorporates most of the TRIPS flexibilities with regards to the Bolar provision, parallel importing and compulsory licensing. He noted, however, that the WTO 30 August (2003) Decision had not yet been incorporated into Thai legislation.

Legal availability of the flexibilities in the Thai Patent Act (as amended BE 2535)

- Section 36, Paragraph 2, 4th bracket
  - Bolar provision
  - ensure prompt introduction of generic drug products upon the expiration of patent
- Section 36, Paragraph 2, 7th bracket
  - international exhaustion of rights
  - parallel import allowed
- Sections 46-50
  - compulsory licensing for any party requesting to use patented invention
- Sections 51-52
  - government use options
  - war-time emergency use by the Government Cabinet
- No Section yet amended to accommodate the Decision on Para. 6 of the Doha Declaration (in process of amendment)

The problem, Dr. Pakdi explained, is that despite the available legal options for the protection of public health, in particular access to medicines, no flexibilities have ever been utilized (except the Bolar provision) by the Government. He cited some of the reasons for this, including:

- lack of confidence due to insufficient intellectual property literacy and management, which leads to a fear of consequences if intellectual property laws are used incorrectly;
- lack of experiences among relevant government agencies;

- lack of interdepartmental coordination and cooperation;
- public health situation appears stable without utilizing these flexibilities.

In order to implement these flexibilities effectively, Dr. Pakdi called for an improvement in communication, cooperation and coordination between Thai governmental agencies on this issue. Key agencies include the Food and Drug Administration, the Department of Disease Control, the Department of Intellectual Property and the National Health Security Office. He also stressed the need to for government cooperation and coordination with potential capable manufacturers and/or importers of medicines, both government pharmaceutical organizations and private local pharmaceutical manufacturers. He noted the need for improvement in the capacity of local manufactures to produce the necessary drugs.
His strategies for implementation also called for a concerted effort to strengthen Thailand's capacity in intellectual property and knowledge of intellectual property laws and to fully understand the issues involved to utilize the right flexibilities and exceptions.

Dr. Sombat Thanprasertsuk (Director, Bureau of AIDS, TB and STIs, Department of Disease Control, Thai MoPH)

Dr. Sombat provided an overview of Thailand's HIV treatment programme. Over 80,000 patients are now being treated with ARVs by the Government programme, and the target is 100,000 by the end of 2006 and 150,000 by the end of 2008. He explained that the first generation treatment provided to these patients cost USD 470 per patient per year. As patients develop resistance to this treatment, it will be necessary to move to a second-generation treatment which will cost the Government approximately USD 7,000 per patient per year. Dr. Sombat therefore estimates that within 10 years the programme will reach around USD 500 million, a huge burden for the national health budget, unless of course Thailand secures access to affordable generic second-generation drugs through the use of TRIPS flexibilities and/or other means.

Dr. Sombat proposed a shift in the way patents are defined. Patents on pharmaceutical products that are life-saving and necessary should not be viewed in the same way as patents on music or movies. There needs to be a balance between the interests of the producers and public health. He stated that beyond TRIPS flexibilities, patents should be redefined in terms of public health.

He also called for better collaboration and communication between agencies to facilitate the strategic and appropriate use of TRIPS flexibilities. Using such flexibilities needs to reduce the price of drugs as intended. Thailand also needs to further develop its capacity to produce generic drugs and explore possibilities of importation. He concluded by saying that Thailand needs to find ways of ensuring an affordable supply of drugs, because otherwise most of the available limited resources will be spent on treatment and not prevention and the HIV epidemic will continue to spread. Further investment in prevention is urgently needed.

Wiboonluk Ruamruk (Deputy General Director, Department of Intellectual Property, Ministry of Commerce)

Ms. Wiboonluk expressed her appreciation for this opportunity to share views and expertise on these important issues. She said that this meeting is definitely of benefit to Thailand and is especially timely as her Department prepares for the next round of US-Thai FTA negotiations.

Ms. Wiboonluk said that IPRs are an integral part of innovation and development, but that it is necessary to strike a balance between protection and innovation. She announced that her Department is in the process of implementing the Doha Declaration with the hope of presenting it to the Parliament in 2006. She reminded the audience, however, that most of the TRIPS flexibilities are already incorporated in Thai law, but have yet to be used.

Ms. Wiboonluk emphasized the importance of fully amending the law to take into account the Doha agreement. She concluded by saying that the time has come for Thailand to make use of the existing legal flexibilities, as per requirements of the public health sector, and to determine if they work in practice, or if further legislation is necessary.

Carlos Correa (University of Buenos Aires)

On behalf of the gathered international experts, Mr. Correa provided some final words and recommendations for the consideration of the Thai government, civil society and the private sector. He highlighted the importance of the existing TRIPS flexibilities in Thai law, and encouraged the Thai Government to make better use of these flexibilities. Mr. Correa advised that the United States will urge Thailand to forego these flexibilities in the FTA negotiations, and that communication among the Thai negotiators and key stakeholders in civil society and the private sector will help strengthen Thailand's ability to resist these pressures. The strategic definition of public health requirements is missing in the current Thai government negotiation strategy, and this needs to be urgently addressed.

Closing discussion and concluding remarks

In the final discussion, many participants raised pertinent questions and provided helpful suggestions and additional information. Many pressed for greater transparency and consultation in the FTA negotiation process, involving a broad range of interested stakeholders. Many expressed serious concern about the potential inclusion of restrictive TRIPS-Plus provisions in the FTA.

In conclusion, Mr. Bjorkman, UNDP, read out the list of recommendations that had been tabled by the resource persons that morning (please see Section III of this report), then closed the consultation by thanking everyone for their extremely valuable contributions to the meeting and their unwavering commitment to the health and well-being of people in Thailand.

III Summary of recommendations

The following is a summary of the recommendations developed by the participating Thai and international experts. The recommendations, made in the spirit of partnership and open dialogue, reflect their opinions on what is in the best interest for Thailand and its citizens.

1. **Thailand should endeavour to preserve its sovereign right to use, to the fullest extent, all available flexibilities** contained in the Trade-Related Intellectual Property Rights (TRIPS) Agreement – and affirmed by the Doha Declaration on the TRIPS Agreement and Public Health – in order to safeguard public health and the well-being of its citizens. In this regard, Thailand should review and further strengthen existing national legislation allowing for the following modalities in ensuring access to medicine for all:
   - Compulsory Licensing and Government Use provisions
   - Parallel importing
   - Exceptions to exclusive patent rights
   - Patentability criteria (definitions of invention, etc.)
   - Flexible data protection provisions
   - Competition policy
   - Preventing incorporation into national law of non-violation provisions

   In this context, Thailand could study the intent and letter of the Indian Patent (Amendment) Act 2005, among others, as guidance towards ensuring that Thai national legislation allows for the full use of available TRIPS flexibilities.

2. **Thailand should consider issuing Compulsory Licences for second-generation HIV-drugs**, as appropriate and as per the needs of the public health sector, in order to ensure an affordable supply of HIV treatment for those patients that may be developing resistance to the first-generation treatment already available at affordable prices in Thailand. In this context, Thailand should take into consideration Malaysia's recent government use authorization for the import of generic medicines as an example of the use of TRIPS flexibilities as allowed by the World Trade Organization.

3. **Thailand should not be obliged to accept any TRIPS-plus provisions that may be proposed in the context of regional or bilateral free trade agreements (FTAs)**. No FTA negotiating text is a *fait accompli* and there should instead be consideration of a pro-active approach by Thailand in proposing its own negotiating text safeguarding Thailand's right to use TRIPS flexibilities as per WTO agreements. Thailand's proposal could provide for a general safeguard provision on health to be included in the negotiating text.

4. **Every effort is needed to ensure transparency of the FTA negotiating processes**, including making available negotiating texts and facilitating consultations with all relevant government agencies, the civil society, private sector firms, consumers and other stakeholders. When and if a draft text on intellectual property rights is tabled, it should be made public without delay.

5. **Thailand should build on existing studies to assess the impact of TRIPS-Plus provisions on the financial viability and sustainability of the immensely popular 30-baht universal health care scheme.** More research is needed on the social and economic costs of possible TRIPS-Plus provisions in FTAs and the ensuing increased IP protection standards. Such studies need to be made public and effectively communicated to policy makers, parliamentarians, and the public at large. The studies should include but are not limited to the following:

   - Financial implications of increased drug prices due to a tightening of patent protection for the viability and sustainability of the 30-baht health scheme;
   - Cost of gradually switching patients requiring treatment to WHO-recommended second-line ARV treatment as they develop resistance to first-generation ARV treatment, using TRIPS-Plus and no TRIPS-Plus scenarios;
   - Cost of granting exclusive rights on test data and second use patents.

6. **Thailand should consider developing, where necessary, transparent and clear guidelines on the patentability of pharmaceutical products;** and clear mechanisms and processes for effective use of compulsory licensing (including guidelines for compensation- or royalty-setting).

7. There should also be efforts to **examine and re-assess the validity of frivolous or low quality patents on pharmaceuticals**, and where necessary, to challenge such patents.

8. **Thailand should explore and ensure that obligations in other chapters of the potential FTA do not undermine the national public health objectives and policies**, including obligations in investment, services, government procurement and dispute settlement.

9. **Thailand may consider requesting technical cooperation from relevant international organizations**, such as the UNDP, WHO and UNAIDS, for the implementation of the TRIPS flexibilities as well as the effective use of such public health safeguards to protect public health and promote access to medicines.

10. **The relevant UN agencies could be requested to provide appropriate fora for all relevant agencies and actors in Thailand** to debate issues related to the FTA negotiations and to create appropriate mechanisms to monitor the impact of new trade agreements.

United Nations Development Programme
12th floor, UN Building
Rajdamnern Nok Avenue
Bangkok 10200 Thailand
Tel: (66-2) 288 1828
Fax: (66-2) 280 0556
E-mail: registry.th@undp.org
Web site: www.undp.or.th