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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ISBN: 974-93632-7-2

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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

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- *Social Pharmacy Research Unit*
- *Faculty of Pharmaceutical Science*
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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

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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