
CL
GLOBAL
NETWORK
Innovation &
Access for All

International Conference on Compulsory Licensing : Innovation and Access for All

Editor: Vithaya Kulsomboon
Wanna Sriwiriyanupap
Kannikar Kijtiwatchakul

Documented: Alec Bamford
Bencharat Saechua

Printed: Health Consumer Protection Project
Faculty of Pharmaceutical Sciences
Phyathai Road, Patumwan, Bangkok, Thailand 10330
Tel : +662-218-8445
Fax : +662-251-3531
http://www.thaihealthconsumer.org, consumer_sss@yahoo.com

Organizers:

- Health Consumer Protection Program (HCP), Chulalongkorn University
- Faculty of Pharmaceutical Sciences, Chulalongkorn University
- Food and Drug Administration (FDA), Ministry of Public Health
- Health & Development Foundation (H&DF)
- Drug Study Group (DSG)
- AIDS Access Foundation
- Thai Network of People Living with HIV/AIDS (TNP+)
- Social Pharmacy Research Unit, Chulalongkorn University
- Pharmacy Network for Health Promotion (PNHP)
- Foundation for Consumer (FFC)

Supporting Organizations:

- National Health Security Office (NHSO)
- Thai Health Promotion Foundation (ThaiHealth)
- World Health Organization (WHO)
- Medecins Sans Frontieres (MSF)
- Oxfam

PREFACE

An international conference on “Compulsory Licensing, Innovation and Access to Medicines for All” was organized on 21-23 November 2007, and attended by more than 200 participants from four continents. This report is the result of that conference, which highlighted three important issues:

First, it was a global compilation of information about access to medicines, the problems, limitations, solutions and alternatives to these problems, international lessons learned by selected countries especially those that exercised the right under international trade rules to compulsory licensing to provide access to medicines. The compilation of this information is documented in this report as technical evidence.

Second, it was a forum for exchange among practitioners, academics, and networks of civil society organizations and patients, dealing with needs for medicines, efforts to produce medicines, and the struggle against monopolistic mechanisms and methods limiting access to medicines. This meeting of practitioners and their exchange of experience broadened the movement beyond any particular country into global community action underpinned by a firm conviction to promote equal access to medicines for all the world’s patients.

Third, the joint Bangkok Declaration of Compulsory licensing, Innovation, and Access to Medicines for All was announced. This Declaration is very important as it was written in the midst of a meeting attended by people from different sectors, as a commendation of the brave efforts of countries to use compulsory licensing, a call for the establishment of a network to promote access to medicines, recognition of the use of compulsory licensing as legitimate, refutation of allegations made by multinational drug companies against the use of compulsory licensing, and development of research and development mechanisms that are de-linked from the huge profits made from monopolies in medicines.

The essence of the information collected, propositions presented in discussion groups and the will of the declaration are all put together in this report of the conference. It is a significant international reference document that will gives governments, the public sector, the people’s sector and the academic community with better understanding of the issues so that the concept of access to medicines can be put into actual practice.

Assoc. Prof. Dr. Vithaya Kulsomboon
Manager, Health Consumer Protection Program

CONTENT

International Conference on Compulsory Licensing : Innovation and Access for All

21-23 November 2007
3rd Floor, Rachatawee Room, Asia Hotel
Bangkok, Thailand

Rationale:

In November 2001, all members of the World Trade Organization (WTO) signed the Doha Declaration, reaffirming that the intellectual property rules included in the TRIPs (Trade Related Aspects of Intellectual Property Rights) Agreement "does not and should not prevent members from taking measures to protect public health". They agreed that all countries can use a number of "public health safeguards" in WTO rules to promote access to affordable generic medicines.

International organizations, such as the World Health Organization (WHO) and the World Bank, explicitly support the use by developing countries of the flexibilities within the Doha Declaration and the TRIPs Agreement that ensures access to essential medicines. Under the TRIPs Agreement, the WTO's members are entitled to use flexibility measures, namely compulsory licensing, to override drug patents in order to prevent or solve their public health crises. Each country has the right to produce or import drugs from other countries for their own citizens, without the need for prior negotiation with the patent holder in the case of non-commercial or public use. However, governments have an obligation to pay royalty fees at a reasonable rate set by the government.

It can be observed that several developed countries, particularly Canada and the United States, have regularly applied compulsory licensing when needed, especially as a means to tackle monopoly distortions of the market. However in developing countries, few governments have dared to exercise the right of compulsory licensing in the face of considerable diplomatic and economic pressure from those representing the interests of the pharmaceutical industry giants. Developing countries that have issued compulsory licenses include but are not limited to Malaysia, Indonesia, Thailand, Brazil, and most recently Rwanda. In the majority of cases, compulsory licensing rights have been used by developing countries to secure access to anti-retroviral medicines to combat AIDS.

Nonetheless, multinational pharmaceutical companies have begun mounting protests, seeking to undermine the TRIPs safeguards and block the production of generic drugs that compete with their patented medicines. In India, government refuse to grant a patent for the leukemia drug Gleevec™ due to the fact that it is not truly innovated product, however, Novartis, the owner of Gleevec™, has filed a court case, seeking to obstruct the Indian generic drug industry from being a main supplier of cheap generic medicines to developing countries.

In Philippines, Pfizer filed a lawsuit against 2 government agencies involved in registration and approval process in order to block the government from approving the cheaper anti-hypertension - Novasc™ from India for immediately sale upon patent expiry which would delay cheaper drugs to enter market 18-60 months.

The latest high profile case emerged this year in Thailand. The Ministry of Public Health announced three compulsory licenses, including HIV/AIDS drugs and a medicine to treat non-communicable disease (in this case heart disease). This was the first case of its kind amongst developing countries. The international pharmaceutical companies involved reacted strongly, attacking the government decision through the media, and with the withdrawal of 7 applications for marketing its new drugs. Patients' health was held hostage while the company demanded the government to revoke the CL announcement.

Based on the Thai experience, it is clear that compulsory licensing can constitute an effective tool for developing country governments to wield real bargaining power against over-priced drugs, and facilitate generic competition which is the only proven method to reduce the price of medicines in a sustainable manner.

There is a need to organize a forum for sharing experiences and lessons learnt among those who have experiences and those who interested in using these safeguard measures on which would bring about a greater use of TRIPs flexibilities particular the compulsory licensing to ensure and sustain access to affordable medicines for all among developing countries.

Pharmaceutical companies repeatedly claim that compulsory licensing has impeded the industry's research and innovation which affects the ability to produce new medicinal products and raise these as a key rationale for retaliating against developing countries' efforts to enforce compulsory licenses. While it has become increasingly clear that monopolistic rights are not only the way to facilitate innovation but in many cases even lessen incentive to innovate. Though it is important to discuss how to manage or formulate intellectual property protection in such a way that it incorporates concern for public health, while promoting innovation, in a way which serves the public interest.

The balance between the need for inexpensive life-saving medicines for the poor and the continuity of creativity and innovation has become a worldwide controversy and a crucial challenge for the global community.

Objectives:

1. To share experiences and lessons learned on using compulsory licensing and other means under TRIPs flexibilities, with the purpose of enhancing the use of these means to ensure access to medicines for all.
2. To build cooperation and network in the international level among those who are interested in exercising TRIPs flexibilities.
3. To foster discussion on broader uses of compulsory licensing beyond AIDS drugs to other essential medicines for both communicable and non-communicable diseases.
4. To identify feasible alternative policies, which will effectively counter the obstacles and difficulties derived from the current intellectual property system, in order that developing countries can ensure access to medicines for the poor.

Organizers:

- Health Consumer Protection Program (HCP), Chulalongkorn University
- Faculty of Pharmaceutical Sciences, Chulalongkorn University
- Food and Drug Administration (FDA), Ministry of Public Health
- Health & Development Foundation (H&DF)
- Drug Study Group (DSG)
- AIDS Access Foundation
- Thai Network of People Living with HIV/AIDS (TNP+)
- Social Pharmacy Research Unit, Chulalongkorn University
- Pharmacy Network for Health Promotion (PNHP)
- Foundation for Consumer (FFC)

Supporting Organizations:

- National Health Security Office (NHSO)
- Thai Health Promotion Foundation (ThaiHealth)
- World Health Organization (WHO)
- Medecins Sans Frontieres (MSF)
- Oxfam

Day 1: Wednesday, 21 November 2007

8:15-9:00 **Registration**

9:00-9:30 **Opening Ceremony**
Opening Statement
Prof. Dr. Prawase Wasi,
The 1981 Ramon Magsaysay Award for Government Service
Chairman, National Health Foundation, Thailand

9:30-10:00 **Keynote Speech**
Intellectual Property : Rights and Wrongs
Medecins Sans Frontieres (MSF), The Nobel Peace Prize, 1999:
Dr. David Wilson, *Board of Directors, MSF Hong Kong*

10:00-10:15 Coffee Break

10:15-10:45 **International Trade and IP Rules (fact & myth)**
Dr. Brook Baker,
Professor of Law, Northeastern University, Boston, Massachusetts

10:45-12:00 **International Institutes' Role and its Support to Developing Countries on Using TRIPs Flexibilities**
- World Trade Organization : Ms. Jayashree Watal
- World Health Organization : Dr. William Aldis

Facilitator: Ms. Ellen F.M.'t Hoen LL.M.,
Access to Essential Medicines Campaign, MSF

12:00-13:15 Lunch Break

13:15-13:45 **Keynote Speech**
Health and Access to Medicine in Thailand
Dr. Mongkol Na Songkhla,
Minister of Public Health, Thailand

13:45-14:15 **Consequences of International Trade/IP rules (high cost medication/health services and sustainability)**
Dr. Sanguan Nittayarumphong,
Secretary-General, National Health Security Office, Thailand

14:15-14:30 Coffee Break

14:30-17.00 **IP Traps**

ddI: Ms. Achara Eksaengsri,
Government Pharmaceutical Organization, Thailand

Combid: Ms. Lawan Sarovat,
Health & Development Foundation, Thailand

Gleevec: India VS Novartis:
Ms. Julie George,
Lawyers Collective, India

Abbott: Mr. Nimit Tienudom,
AIDS Access Foundation, Thailand

Facilitator: Dr. Jakkrit Kuanpoth
University of Wollongong, Australia

19:00-21:00 Reception Dinner (Performance and Movie)

Day 2 : Thursday, 22 November 2007

9:00-12:30 **CL Implementation : Achievements and Challenges**

Indonesia: Prof. Samsuridjal Djauzi
Thailand: Dr. Vichai Chokevivat
Brazil: Ms. Gabriela Chaves
USA: Mr. Robert Weissman
Global: Mr. James Love
Facilitator: Dr. Vithaya Kulsomboon,
Faculty of Pharmaceutical Sciences, Chulalongkorn University

Coffee Break at 10:30

12:30-13:30 Lunch Break

13:30-17:00 **Improving Access to Quality Essential Medicines through Strengthening Local Production Capacities**

- Production of Life Saving Medicines in Africa:
  Dr. Krisana Kraisintu
- Thai Manufacturers
  Public Sector: Dr. Witit Artavatkun
  Private Sector: Mr. Rachod Thakolsri
- Indian Manufacturers: Mr. Atul Chabra
- Brazilian Manufacturers: Mr. Carlos Passarelli

Facilitator: Dr. Niyada Kiatying-Angsulee,
Faculty of Pharmaceutical Sciences, Chulalongkorn University

Coffee Break at 15:00

Day 3: Friday, 23 November 2007

9:00-12:30 **Innovation & Access for All**

- Thai Food and Drug Administration:
  Dr. Siriwat Tiptaradol, *Secretary-General*
- Health & Development Foundation:
  Dr. Krisana Kraisintu
- Medecins Sans Frontieres:
  Ms. Ellen F.M.'t Hoen LL.M.
- Oxfam:
  Ms. Corinna Heineke
- FTA Watch Thailand:
  Dr. Jakkrit Kuanpoth
- World Health Organization:
  Ms. Karin Timmermans
- Heath Action International:
  Ms. Miran Shiva
- Knowledge Ecology International:
  Dr. James Love

Facilitator: Dr. Jiraporn Limpananont,
Faculty of Pharmaceutical Science, Chulalongkorn University

Coffee Break at 10:30

12:30-13:30 Lunch Break

13:30-15:15 **Open Forum and Discussions**

- Sharing country strategy/plan on access to medicines
  (Thailand, Philippines, Indonesia, Brazil, India, and others)
- Networks and common plan of action
  - IGWG
  - TRIPs Council
  - Next ICCL
  - Others

Facilitators: Mr. Jon Ungphakorn
Consultant, Thai NGO Coalition on AIDS
Dr. Jakkrit Kuanpoth
FTA Watch Thailand


CL
GLOBAL
NETWORK
Innovation &
Access for All

Welcoming Speech

by
Assoc. Prof. Dr. Pornpen Pramyothin
Dean of the Faculty of Pharmaceutical Science,
Chulalongkorn University

Prof. Dr. Prawase Wasi, Ladies and Gentlemen,

It is a great honour to have with us as Chairman Dr. Prawase Wasi, winner of the 1981 Ramon Magsaysay Award for Government Service. I would like to express my profound gratitude for his kindness in presiding over the opening ceremony of the International Conference on Compulsory Licensing: Innovation and Access for All. This conference is being organized with the collaboration of the Health Consumer Protection Programme of Chulalongkorn University and its alliance networks with the support of the National Health Security Office and the Thai Health Promotion Foundation.

I am very proud to inform you that this conference includes more than 200 speakers and participants from 20 countries representing government agencies and NGOs, as well as international organizations.

The conference aims to share experience and to foster the increase of access to medicines, including the use of CL, and to enhance the use of these means to ensure access to medicines for all.

We are all aware that human rights include the right to health and human dignity, as declared in the 1948 Universal Declaration of Human Rights, Article 25.1. This article states: “Everyone has the right to a standard of living adequate for the health and well-being of himself and of his family, including food, clothing, housing, medical care and necessary social services, and the right to security in the event of unemployment, sickness, disability, widowhood, old age or other lack of livelihood in circumstances beyond his control.”

Access to medicine is a basic fundamental right of all human beings as it is involved in the right to life. Everyone has the right to have access to medicines directly and to promote self-reliance, regardless of their social and academic status.

Finally I would like to thank everyone for your kind support in making this conference possible. I would also like to wish all participants a successful and productive discussion as well as a pleasant stay in Thailand.

Ladies and gentlemen I would like to invite Dr. Prawase Wasi to open the International Conference on Compulsory Licensing : Innovation and Access for All.

Opening Statement

by
Dr. Prawase Wasi

I would like to invite all the participants to this very important conference. First of all I would like to invite you all to look at the first picture (PowerPoint slide of the earth as seen from the moon). The American astronaut by the name of Edgar Mitchell was standing on the moon and looked at the planet earth. When he looked at the entire earth in totality, his mind completely changed. He said, 'I came back to earth a totally changed man'. After being aware of the same oneness of the planet, his consciousness changed. He developed compassion to all mankind and all the environment and nature, because all belongs to this oneness.

Perhaps in this conference, we will face very complex and difficult issues and we will need a new consciousness to be able to cope with the difficulty of the issues. What we are dealing with is a very complex ethic of human values and policies. As all of us know, advancements in science and technology on the one hand have brought about wonderful diagnostic and therapeutic tools, the benefits of which no one can deny. But on other hand, advanced science and technology lead to products and methods which are very expensive, and this causes problems of inequity. As everybody knows, this outstanding problem has been with us for at least 4 or 5 decades because 30 years ago I participated in a Rockefeller meeting in Boston and talked about this issue of inadequate investment in research in diseases of the poor because they do not have the ability to pay. So research investment goes into diseases of rich.

So first of all, what can be done about this? Inadequate research on diseases of the poor, because when technology, such as vaccines or drugs, is developed, the poor cannot afford to pay. Therefore companies do not want to invest in research for the poor.

Secondly, when technology is available, it is expensive and not accessible to the poor. This happens not only in developing countries but even in the US. The US spends 12-14% of GDP on health, the highest proportion in the world, and much, much higher than other countries, both in terms of percentage and in real terms. Yet about 40 millions Americans are without health insurance of any kind, and they cannot afford to go to the hospital because it is too expensive. When Bill Clinton was running for the presidency the first time, he promised that if elected, he would reform health care in America. And he did try that, by appointing Hillary Clinton as chair, with the Minister of Public Health and other experts to try to reform it. But they failed. You can see how difficult it is. The proposed reform met with resistance and opposition from various sectors. Now Hillary Clinton is trying again, running for president and talking about health care reform, but in a modified form. She knows that she cannot use what is known as Hillarycare, the first Clinton health care reform plan.

So these are the outstanding problems; inadequate research for the poor and when technology is available it is not accessible to the poor. What can be done about this? It is very difficult. I think people are trying to find solutions to this. The Prince Mahidol Award Foundation early this year, together with the WHO in Geneva, organized a meeting in Bangkok, attended by the Director-General of the WHO, Margaret Chan. And the theme of the international conference here was this topic: How to make useful technology accessible to the poor. There was a lot of discussion and many recommendations from the conference.

To begin, I think we have to understand the complex drug system: the research on drug development, the manufacture and commercialization of drugs. It is a very complex system and no one understands it. What we know is what the drug companies tell us. They tell us that drugs have to be expensive, because drug companies invest so much in research. That's all we know and what can we do if we know only that, because in modern society there are many complex issues? If we are in darkness, we don't understand the elements of complexity. We don't know how to deal with it. It is very important to unfold complexity into its components so people can do something about it. Dr. Marcia Angel, the former editor of the *New England Journal of Medicine* wrote this book, 'The Truth about Drug Companies and How They Deceive Us'. Marcia Angel has found that what the drug companies tell us is not true.

1. The main research that leads to drug development is carried out in universities paid for by the taxpayer not drug companies - the drug companies come in only towards the end of the pipeline. But a lot of research, basic research, clinical research, epidemiological research, pathology research, molecular biology, and so on, which finally leads to drug development, is done in the universities, using taxpayers' money. So it's not true that drug companies invest so much in research for drug development.
2. Excessive profit. The figure I knew when Clinton was campaigning for health care reform in America was 27% of assets, which is far too high, higher than in other businesses. So why make so much profit from the blood, illness and death of people in America? The Clinton group called it blood money - why so much profit?
3. The CEOs of drug companies have incomes that are too high. The book cites one CEO who earned $150m per year. Why so much? When the poor cannot pay, why does the CEO have to earn $150m per year?
4. Drug companies lobby politicians to issue laws that favour the companies at the expense of the consumer to keep the price high.
5. Drug companies lobby for the appointment of the Secretary-General of the FDA.
6. The American people, because drugs in America are so expensive and the same drugs just across the border in Canada are much cheaper, want to buy drugs from Canada. And drug companies lobby politicians to issue laws or regulations to prohibit Americans from buying cheaper drugs from Canada.

This kind of truth I think we have to know. It is a function of the academics in the universities. I would like to urge them to understand the drug system. In Thailand we have a lot of PhDs in various faculties of pharmacy. But they have technical knowledge; most of them do not understand the drug system. So I think that there is a need to promote the interest of these academics to do research on the drug system, so that they understand the complexity and the components of the complexity so that the public can deal with it. Otherwise we only know from the drug companies that drugs have to be expensive, because they have to invest a lot in research. This is a strong message to the academics that we have to do more.

Now in this conference, we will be dealing with CL or compulsory licensing. On the one hand compulsory licensing brings about lower prices of drugs and can save millions of lives in the developing countries. But on the other hand, it will lead to a reduction in the profits of shareholders in drug companies. And it is very difficult to ask shareholders to reduce their profits when they live in a different world. The poor and the sick live in one world and the shareholders live in another world. They don't understand this. It is very difficult to ask them to reduce their profit so we can save more lives of the poor and sick. This is the issue that we will be dealing with, how to innovate and find ways and means to make drugs more accessible to the poor, how to deal with the funding of research, how to work with the government on policy. So there are technicalities to do with finance, policy and the many sectors involved here. Governments, drug companies, academics, civil society and the poor and the patients themselves are working on this.

The world economy is driven by greed. The present economic system is driven by greed. Maximum profit is the goal of economic development. So we should have to ask the critical question whether, for human development, maximum profit should be the goal of mankind or living together peacefully among mankind or between man and the environment. I believe that we have to change the goal of mankind from making maximum profit to living together. Living together should be the supreme goal of humanity or *summum bonum* of mankind. We cannot talk about maximum profit alone. But of course we don't expect drug companies to lose money or not make profits. That is not possible. But should maximum profit be the goal?

To deal with this difficult issue of cost we have to deal with technicalities of law, finance, policy, and so on. But it may not be adequate because the world crisis now is so great. (Ervin) Laszlo, (Stan) Grof and Peter Russell spent two days and two nights in California on the rim of the Pacific talking about world issues and they came to the conclusion that the present civilization will inevitably lead the world into a great crisis. They use the term 'consciousness revolution' that can bring man out of the present crisis. The Dalai Lama said that the present crisis is a spiritual crisis. There's a need for a spiritual revolution. Albert Einstein once said we shall need a radically new manner of thinking if mankind is to survive. If we continue with same worldview, the same thinking, mankind may not survive.

So when we deal with this issue, of course I know you prepare to seek a lot of ways and means how to find innovation in how to make drugs more accessible to the poor. But I believe that the world is too sick from the great divide between the haves and have-nots. The crisis is so great we have to work to heal the world. I would suggest that we use this opportunity for working toward making drugs accessible to the poor, to change our consciousness, change our manner of thinking to heal ourselves and heal the world.

SPEECH

Intellectual Property : Rights and Wrongs

by
Dr. David Wilson

Introduction

An international Member of the Board of Directors of Médecins Sans Frontières (MSF) from Hong Kong, Dr. Wilson received his doctoral degree in medicine from the London Hospital Medical School in the United Kingdom, and earned a Diploma in Tropical Medicine and Hygiene from the Liverpool School of Tropical Medicine. Dr. Wilson has been an AIDS activist since 1982 when the HIV epidemic first became apparent in the gay community in the north of England where he was a general practitioner. He has worked with Médecins Sans Frontières since 1991 and since 1994 he has been in the HIV Prevention and Treatment Programmes in Vietnam and Thailand. He was medical coordinator of the MSF in Thailand until August 2007 and was involved in treatment preparedness initiatives to support the Thai government's programme to roll out antiretroviral treatment nationwide. He has assisted WHO and MSF training programmes on working together towards treatment preparedness in 5 other Asian countries and has contributed to articles published in AIDS, The Lancet, the British Medical Journal and the International Journal of HIV and AIDS on care and treatment and the role of civil society on the access to treatment. He has participated in several international AIDS conferences, and presented and been invited as a speaker in several international meetings, such as the 2nd Singapore AIDS Conference in the year 2000 on the strategies to increase access to HIV treatment in resource-poor countries. In June 1999, in Washington DC, USA, he has joined Access to Medicine in Thailand: A Humanitarian Viewpoint, testimony to the International Subcommittee of the Presidential Advisory Council on HIV/AIDS.

Actually I was amazed when the conference organizers asked me to give a talk on this particular topic to this particular audience, because actually I knew nothing about intellectual property before I came to Thailand. So everything I'm going to tell you, you've told me already, many times in the past, so thank you very much for that.

While I've been in Thailand learning from many of the people I see in front of me, I've learned that if we want to understand patents, we have to go back a bit in time and we have to think: why do patents exist? what are they meant to do?

And in fact the first patents date from the 17th century in Europe. And there are 2 main objectives of patents. They are meant to benefit the inventors to provide an incentive to innovation through the prospect of monopoly pricing. That would encourage innovation. But also patents are meant to benefit the public. So to benefit the public, it is necessary to disclose the invention in a patent document. And we see in this early example of a tricycle lawnmower (refer to PowerPoint slide), there are 78 different points about this particular

invention which are described in detail in the patent. So the point about a patent is that it is to prevent trade secrets so as to benefit the public. And the patent is granted by a public authority, some branch of the government, and it confers a temporary monopoly in exchange for disclosure of the invention.

Can anything be patentable? For a long time, countries considered that there were some things that should not be subject to patent: food should not be, seeds should not be. They are examples of things which it is undesirable to have patented from the point of view of society.

So the idea of a patent was first proposed in the 17th century. But in case of pharmaceuticals and, in some countries, agro-chemicals, many, many countries have only introduced patents very recently. In this part of the world, China did not introduce process patents until 1984 or product patents until 1992. Thailand, very similar dates. And India only introduced product patents in 2005. So we see a wide difference in timing of the introduction of patents in different parts of world.

Thinking again about why and something that Dr. Prawase said, there is a common belief that patents are necessary to stimulate innovation, to stimulate research and development, and it is commonly said that there is something called the innovation cycle, which is the process of discovery, research, development and delivery. And one can start anywhere in this cycle. But thinking about discovery, as Dr. Prawase said, basic research is often done in universities by academics with government funding. Then other people, and this is commonly where pharmaceutical companies come in, develop the basic product (as in the case of a pharmaceutical) so that it's possible for patients to take the drug and for the drug to work in practice. Then there's a process of market approval and manufacturing the drugs before they can be delivered to the patients. Then there's found to be some small problem or other so there's a demand for something new and better and that leads back to discovery. So in this innovation cycle, actually I don't see the word patent and I don't see the word monopoly. So quite how the innovation cycle leads to the need for patents is for me difficult to see.

And also, if we think about the cost of patents, monopoly leads to higher prices. And again, if a patent is granted by the government for the advancement of the public good, it is obvious that the patent grant comes with obligations to the patent-holder. And also I think it is obvious if these obligations are not fulfilled, government should intervene.

So what are these obligations of the patent-holder? These were first described a long time ago and examples of the obligations can be found in the documents from a patent authority in Great Britain from nearly 400 years ago. And the obligations of the patent-holder include:

1. The continuous production of the patented article in sufficient quantity;
2. The maintenance of sufficient stock of the patented product on hand;
3. The keeping of its quality up to prescribed standards;
4. And the selling of the product at an easy and reasonable price with reference to a standard price.

If the patent-holder does not fulfil these obligations, then how should the government intervene? And compulsory licensing is one important way for the government to intervene. And the first mention of compulsory licensing anywhere, where the idea came from, was in the US. In 1790,

when the US passed its first patent bill, and there was a proposed amendment to patent law, made by the US Senate, to include the idea of a compulsory licence, but at that time, the House refused the amendment. Then there was much talk about this issue. How should the government intervene in the case of non-fulfilment of the obligations of a patent-holder? And about a hundred years later in 1873, this was discussed again at a Patent Congress in Vienna. And many countries supported the idea of compulsory licensing, which was seen as a compromise, really, between two groups, the pro-patent lobby and the free trade group. The free trade group considered that patents themselves were a threat to freedom. So compulsory licensing was maybe a way to allow patents to proceed, but for there to be some checks and balance, some flexibilities in the system.

And then in 1883 the Paris Convention, which was a group of nearly 100 hundred nations discussing patent issues, decided to leave the matter of whether compulsory licensing should be in the law of a country to the individual member country to decide. That was in 1883.

40 or so years later, that Paris Convention was revised. And at that time, the principle of compulsory licensing was included in the international convention. Most member countries revised their patent laws to include compulsory licensing.

So how does compulsory licensing relate to the issue of medicines, to pharmaceuticals? Well actually, early on in the 20th century it was of limited significance, and that's because half of the member states of the Paris Convention excluded pharmaceutical products from patent protection; France and West Germany until the 1960s, Switzerland, Italy and Sweden until the 1970s, Spain until the 1990s.

So compulsory licensing wasn't really discussed very much early in the 20th century in many countries. When it was discussed, there was support for compulsory licensing from the pharmaceutical sector. For example, Lord Trent, chairman of Boots Pure Drug Company, which is a big UK pharmaceutical firm (and patents existed on pharmaceuticals in the UK), believed that the license to manufacture any pharmaceutical should be granted to any firm which has the competence to do so up to a satisfactory standard. And he also proposed that if international agreements were introduced along those lines, that any competent firm could manufacture a drug, it would lead to a freer exchange of ideas, and wider availability of products, instead of unnecessary and uneconomic dependence by some parts of the world on others.

And then if we look at the situation in Canada, which Dr. Prawase mentioned, Canada did have patents on pharmaceutical products from early on in the 20th century but it had special provisions for compulsory licensing in relation to food and to medicines. But for the first 40 years or so of these legal provisions, the legislation required generic medicines to be produced locally within Canada. But at that time, the market in Canada was quite small and not really big enough for local production to be viable. So only 22 compulsory licences were issued, because of the smallness of the market. I say *only* 22, because that's a very small number, contrary to some more recent views. But in 1969, the law was amended to allow importation of generics under compulsory licence. And then in the 23 years following that, 613 compulsory licences were issued in Canada, with 2 results, really. One was that prices of medicines in Canada were among the lowest anywhere in the developed world.

But also a report in 1983, the Eastman Report, found that growth of the pharmaceutical industry in Canada was more buoyant than it was in the US. So again here we have some doubts seen about whether of not patents and monopolies actually do encourage growth of the pharmaceutical sector.

So to summarize compulsory licensing in relation to medicines, I think we can say that most countries for most of the 20th century didn't have patents on pharmaceuticals and where they did there were many exceptions. So really we begin to see some doubts shed on the common concept that monopoly really is necessary as an incentive for innovation. Then if we come up to 1986, more recently, and the launch of the Uruguay Round of the General Agreement on Tariffs and Trade, the Intellectual Property Committee of GATT lobbied more strongly to include intellectual property for pharmaceuticals. And the Uruguay Round was completed in 1995 and one conclusion of the end of the Uruguay Round was TRIPS, the World Trade Organization's Agreement on Trade-Related Aspects of Intellectual Property Rights. And this, among other things, made it necessary to have a minimum standard of protection for intellectual property rights, and in relation to pharmaceutical products, a 20-year patent. And then there was no differentiation in TRIPS between life-saving medicines and more trivial goods. And all member countries of the WTO had a deadline of up to 2005 to implement TRIPS in full. So that takes us to 1995.

And then in the next year, 1996, intellectual property concerns were raised for the first time at the WHO Annual Assembly, because until that time the WHO had had nothing to do with intellectual property or patents. The WHO resolution in 1996 stated this: The Director-General of the WHO should report on the impact of the work of the Wold Trade Organization with respect to national drug policies and essential drugs and make recommendations for collaboration between the WTO and the WHO.

And then some more things have happened since. In 1999 there was a stronger resolution, not just that the WHO D-G should report, but the WHO should provide support on patent issues and update the WHO's revised drug strategy to reflect concerns regarding new trade rules. And again in 1999 in Seattle, in the World Trade Organization meeting, the issue of access to medicines came onto the agenda. The EC, for example, proposed that compulsory licensing for drugs should be standard for the drugs on the WHO's Essential Drugs list.

Then eventually in 2001, there came out, in the Doha round of international trade discussions, the Doha Declaration on TRIPS and Public Health, which is a very important declaration. And the WTO Ministerial Declaration, known as the Doha Declaration, states: "We affirm that the TRIPS 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." So this is a very key event, very significant. This declaration marks a sea change really in thinking about patents on medicines. Or maybe I should say a reversion to the state that had existed for a few centuries before, up until the Uruguay round whereby pharmaceuticals were generally exempt from patents. And it was followed by a whole series, a cascade of activities that aimed perhaps to go back to this original formulation of intellectual property protection, in that it should be of benefit to society as a whole. And it also gave backing to countries to use the flexibilities that were inherent in the TRIPS agreement.

Here are some examples of the use of these TRIPS or Doha flexibilities.

- It has helped increase access to 1st line antiretroviral drugs which could still be produced as generics in countries such as India because they were invented, discovered before TRIPS.
- There is also a paragraph in the Doha Declaration about non-enforcement of patents, and this is quite widespread now in Least Developed Countries, and actively encouraged by UNICEF and IDA. Often these drugs are bought with Global Fund financing.
- Compulsory licensing is being applied by Thailand and Brazil to increase access to 2nd line antiretroviral drugs, and in the case of Thailand for cardiovascular disease.

Apart from the technical or governmental aspects of the implications of the Doha Declaration, I think we've also moved forward quite significantly, because other things have happened at the same time. There's been a big change really since about the time of the Doha Declaration in civil society action with respect to intellectual property and this is because of other considerations. For example, there are legal opportunities in many countries for civil society to challenge patents.

These are some examples from Thailand in 1999. The story there, which I think is an interesting story because it marks this change in the participation by civil society in intellectual property issues. In August 1998, quite a small group of people with HIV demonstrated outside the US Embassy in Bangkok. And this happened at the suggestion of the Thai Consumers Foundation, because there was an amendment to the Thai patent law being debated.

Another hot issue at the time amongst people with HIV in Thailand was the price of ddI (Didanosine), an antiretroviral drug. Why was it so expensive? Anyway, there was no answer at the time. But nevertheless, people with HIV and NGOs such as AIDS Access Foundation and MSF spent time learning more about this issue, with the result that in the next year, when the Thai Government Pharmaceutical Organization asked the Thai government to issue a compulsory licence on ddI, PHA understood enough about the issue to demonstrate publicly to support the GPO request. And I would say all those hundred people with HIV that took part in the demonstration, understood clearly why they were doing it and what the implications were. And that was a major change from the situation of a few years before. Anyway the Thai government at that time did not issue a compulsory licence. So three people with HIV together with the AIDS Access Foundation challenged the patent held by Bristol Myers Squibb on ddI in the intellectual property court in Thailand. This will be discussed by a speaker later in the course of this conference. Just one point to make is that the intellectual property court in Thailand asserted the primacy of human life was what mattered in trade agreements, and this was recognized internationally at Doha where it was insisted that TRIPS be implemented so as to promote the rights of members to protect public health. This is quite a piece of history because it was the first time that the Doha Declaration was quoted in a legal case.

Apart from the technical and legal and governmental aspects of this process, I think it was interesting that this particular example was part of process of empowerment of an important civil society group, because before this case, the activities of people with HIV in Thailand were

geared to income generation, moral support, sharing information about alternative medicines, massage, and meditation. But this particular ddI case led to an increased profile of people with HIV within civil society's support for access to treatment. It also led to increased political challenges facing people with HIV. I think this is a very important issue. It also led to recognition by leaders of people with HIV that community engagement is a crucial way to empower yourself.

On the other hand, this was one drug in one country and it was a lot of work by a lot of people. So there is still a place for changing the system, changing the legal context, because working one drug at a time, one country at a time you get somewhere, but quite slowly.

Following Doha there's been a backlash by the pharmaceutical industry and from some western governments, with the pursuit of increasingly high levels of intellectual property protection that were never even envisaged in TRIPS. And because of this TRIPS-plus approach, there have been studies done to try and go back to look at the evidence as to whether intellectual property really does encourage increased innovation, increased research and development and certainly whether or not it leads to accessibility of the new products.

In 2003, international NGOs organized an international meeting on looking at a global framework supporting research in health issues in areas where the market and the existing policy had failed. And partly because of this lobbying by NGOs, there was a further WHO resolution in May 2003 to establish a Commission on Intellectual Property, Innovation and Public Health. And this led to further strengthening of the World Health Organization's mandate to promote policies that increase the availability of generic medicines. And the report made by CIPIH was one of the more significant of the studies I mentioned in the precious slide.

As a result of this commission by the World Health Assembly, there was a wide variety of views and there were evidence-based conclusions and a lot of recommendations. And for the first time it adds an A to the three Ds of the innovation cycle. In this innovation cycle we need access to this innovation, otherwise it's meaningless. And another conclusion of the CIPIH report was that actually patents are ineffective in boosting research and development on the diseases of the poor. And the main conclusion of this report is that innovation should be driven not by market monopoly but by health needs, because as long as research and development depends on patent monopolies for financing, the core of the problem will not be solved.

So in fact, that's why we're all here. How can we move away from this situation of patent monopolies as the main mode of financing innovation? Actually, it's a well-known fact that competition, not monopoly, is what is needed to ensure access to anything. This by the way (see PowerPoint slide) is a picture in Angola of a Chinese company, one of many health care clinics in Africa using Chinese generic medicine.

The problem is that if most medicines may be patentable almost anywhere, then the competition will depend on the success of a drug by drug, country by country approach to patent grant opposition, compulsory licensing, voluntary licensing, some way of managing the intellectual property situation. But in a drug by drug, country by country approach, progress

is very slow. If we want a different way forward we have to divorce the price of a drug from the research and development. The WHO seems to have taken this on board and established the Intergovernmental Working Group on Public Health, Innovation and Intellectual Property (IGWG) in 2006. Earlier this year at the World Health Assembly a resolution was taken to encourage the development of health-needs driven research and development including addressing the linkage between the cost of research and development and the price of medicines and how can we have a method for tailoring the best mix of incentives to a particular condition or product, with the objective of addressing diseases that disproportionately affect developing countries.

The 2nd round of IGWG talks was completed a couple of weeks ago. Actually the delegates ran out of time so the discussions will resume in early 2008. Out of this 2nd round will come a revised text of the global strategy and plan of action, but as far as I know it is not yet available from the WHO. It should be available by the end of this month. At some points in this new text is discussion around the issue of finding new financing mechanisms to pay for research and development. Also the WHO has a mandate to take the lead in identifying R&D gaps, but with priorities to be set so as to address public health needs.

So I think this conference comes at a very suitable time, because the 2nd round of IGWG talks will resume in January. There is some time for advocacy with the key players. Some of the outstanding issues on which advocacy is needed are:

- Should this strategy and global plan of action be restricted to some types of disease or should it cover any disease affecting poorer countries?
- There is also the issue of technology transfer, which has not really been addressed yet.
- How can we make the policy role or leadership role of the WHO actually happen in practice, in ensuring access to medicines?
- Perhaps most of all, the challenge of finding ways to make it happen. There is discussion around the issue of paying for innovation and moving away from price monopolies, but how is it going to happen? In other words, how can we encourage innovation and access for all, which is why we are here?

Thank you all very much for listening. I would particularly like to thank Ellen ‘t Hoen, who has helped me a lot and given me permission to cite work in progress in this presentation. And as I said at the beginning all the other mentors, all the other people who have taught me what little I know about patent law, and to the other members of the audience, thank you very much.

SPEECH

International Trade and IP Rules (Fact and Myth)

by **Dr. Brook Baker**
Professor of Law, Northeastern University,
Boston, Massachusetts, USA

Introduction

Prof. Baker received his BA from Harvard University in 1969 and obtained his Juris Doctor from Northeastern University in 1976. Prof. Baker joined the Northeastern School of Law faculty part-time in 1979 and full-time in 1984. He directs the Legal Practice Programme and teaches negotiation. Prof. Baker has taught and consulted extensively in South African law schools and law school clinics since 1997, particularly on issues of multi-culturalism, human rights, and HIV/AIDS. Prof. Baker has written extensively for activists about the global AIDS pandemic. He is co-founder of Boston Global Action Network, African AIDS Project and a core member of the Health Gap, an HIV/AIDS global treatment access organization. His work with Health Gap has focussed on patent barriers to affordable medicines, globalization and the AIDS pandemic, the complicity of multinational corporations in the AIDS pandemic, and the under-funding of the Global Fund to Treat AIDS, TB and Malaria.

I'd like to start by saying I feel honoured to be here with fellow activists and with representatives of a government who have stuck their neck out so far under threat of trade sanctions and product removals by one of the world's most powerful industries and by the government that wields the most power internationally. You are heroes to us around the world. I turn frequently to the Thai press to follow up on your action and I also follow closely the concerted campaign by the drug industry and by the US government to discredit what you have done, to lie, to dissemble, to make false arguments. My purpose here today is to try to reveal those false arguments and to reassure us all that the path that you have taken is the correct path. It's the legal path, it's the moral path and it's the path that we hope you will continue to pursue.

I have catalogued a baker's dozen of what I call dirty lies by the drug industry and by the US government. For those of you who may not be familiar with the term 'baker's dozen' it means 13. So 13 lies by the drug industry and the US Trade Representative in particular.

Myth 1. *Thai compulsory licences are illegal.*

This is the biggest falsehood of all. A direct statement by a representative of Abbot, Melissa Brotz, was 'We do not view the compulsory licences on Kaletra to be legal'. Now I know we are going to talk a lot about the Thai compulsory licence and its legality and the grounds on which it was issued, but I'd like to make a few introductory remarks in that respect.

First of all we should be clear that it's lawful under TRIPS law and also under Thai law, and in fact would be legal under US law as well. And even though the US, and US drug companies continue to challenge its legality, you should rest assured that it is fully TRIPS compliant. Your licences were issued through proper procedures on valid public health grounds for public, non-commercial use, which required no advance negotiation with the patent holders. Your licences were fully compliant with Section 51 of the Thai Patent Act. Moreover you set a reasonable royalty and gave the drug companies an opportunity to negotiate or to appeal if they were dissatisfied with your licence. Dr. Wilson already talked about the Doha Declaration, and one of its key provisions, paragraph 5b, states 'Each member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted.' We have to keep that phrase in our minds. It is the unequivocal legal support for the action you took. You are an autonomous sovereign nation that gets to decide when and if you want to issue compulsory licences. As long as you do so through correct procedures, you have nothing to fear under international or Thai law.

Your licence was issued for public, non-commercial use and I'd like to walk our way through that phrase a little bit if you don't mind. The basic premise is that Thailand has issued these licences for use within your public health system, for individuals who access these medicines through your social insurance system and also for government employees. As such, this use is a public use. Provision of medicines by the government, for the use of its citizens, using public funds to procure the medicines, is in fact a permissible use under international law. Now members of the USTR, big pharma and right-wing think tanks would like us to think otherwise. One of them, Ron Cass, has said 'This phrase comprehends uses such as public research programmes, not monopoly provision by a government for-profit agency. Only the most cynical distortion of the text could conceivably cover Thailand's conduct here.' That's by the former Dean of Boston University Law School, right across town from where I teach. It's a total distortion of TRIPS law. As I said, the provision by government of medicines for its people is a government use. Even the UK Patent Act expressly provides that service of the crown, otherwise known as government use, or public non-commercial use, includes the production and supply of specified drugs and medicines. Now if it's in the UK law, why isn't it similarly permissible under Thai law? And of course, it is.

The pundits would like us to believe that non-commercial means that there's no sale for a profit, that everything has to be done on a non-profit basis. And of course there's no sustainable way for any drug company, generic, innovator, or otherwise, to manufacture drugs on a sustainable basis without making some profit in doing so. The fact that the goods are manufactured, the fact that they're sold and distributed, the fact that they're purchased by the government and given to its people, does not suddenly render that commercial use under this provision. The use is commercial to make a profit in the private sector, but when then provision is in the public sector, it's not an impermissible use. And of course we all know that Thailand has continued to permit sale by the drug companies in your private sector which comprises about 20% of your market, and also for the very extensive medical tourist industry that you have in Thailand.

Because this was a public, non-commercial use, Thailand was not obligated to negotiate with the patent owners before issuing a compulsory licence, either on price, or more specifically for a voluntary licence. Article 31 of the TRIPS agreement makes it very clear that prior

negotiations are simply not required. All that's required is notification and in fact notification can be after the fact. The USTR has said 'we have indicated with the appropriate Thai authorities to respond to any request to request discussions by concerned stakeholders, including patent holders' and the Wall Street Journal in an editorial called 'Theft in Thailand' claimed that the failure of consultation clearly breached the spirit if not the letter of Article 31. Nothing could be more contrary to the truth. It is simply not required in the very express language of the act, for you to have negotiated with the drug companies. Moreover, not negotiating with the drug companies would be completely lawful under US law as well. 28 USC Section 1498 expressly provides that any government official and any government contractor can take and use a patented process or product for government use in the United States. No special authorization from government, no special negotiation or notification to the drug company or any other patent holder. Instead you can simply take it, notify and pay after the fact.

Now of course we know that Thailand did in fact negotiate. Thailand negotiated for over 2-3 years with the drug companies to try to reduce prices and your White Paper noted the lack of progress in those negotiations.

Finally, Thailand offered a 0.5% royalty. Some may say that that royalty was low. Even though it was perhaps low, Thailand clearly indicated a willingness to open negotiations on the amount of the royalty and there is an express provision for appeal right within your Act. Although some of the pharmaceutical companies did negotiate, none of them actually negotiated to increase the royalty rate and none of them appealed within the statutory time period.

So in conclusion, there is no doubt whatsoever that your licences were in fact legal.

Myth 2. *Compulsory licenses are only for emergencies.*

Roger Bates of the American Enterprise Institute in April 2007 said "It is generally understood that compulsory licences should be confined to 'public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics,' which represent a 'national emergency or other circumstances of extreme urgency'." The president of your Pharmaceutical Research and Manufacturers Association took the alleged emergency rule and raised it one degree higher. He said "The law allows such actions with pharmaceutical products only in cases of extreme national emergencies, or during wartime." Given this continuing exaggeration and escalation of the standard, we can expect big pharma's next claim to be that compulsory licences can only be issued in the case of intergalactic warfare. The next time that trans-formers land in Thailand, that's when you'll be able to use a compulsory licence.

Of course the truth is that compulsory licences are not limited to emergencies. The international press consistently misrepresents the law in this respect. Virtually every article in the Wall Street Journal, the New York Times, the Financial Times, and other international press consistently refers to emergencies as if that's a requirement. I read to you before the provision that says that countries have the freedom to determine the grounds on which licences can be granted. By no means are those grounds limited to emergencies. Emergencies give you rights of expedited processes, as do public, non-commercial use licences, as do competition licences.

But compulsory licences are in fact not limited to such emergencies. So they would like us to believe that the only emergencies for which licences should be granted are AIDS in Africa and avian flu, if it eventually strikes. They are trying to restrict very closely the circumstances in which countries might respond. Fortunately, Thailand has broken out of the falsehood and has issued licences not only for AIDS medicines because of your very serious problem here, but also for Plavix, a heart disease medicine, drawing attention to the fact that licences can be granted in non-emergency situations for chronic diseases.

Myth 3. *Compulsory licenses are or should be rare.*

Of course this is partially true because the US government 'beats up' anyone who tries to issue a compulsory licence. It is also true because many countries have not enacted legislation to use the flexibilities they have. And there are forces within countries that sometimes resist the demands for access to medicines for all.

Despite the fact that licences are relatively rare, they are not rare historically. As Dr. Wilson previously clarified in his presentation, over 50% of the members of the WTO well into the 20th century did not provide patents on pharmaceutical products. Canada, in the time period 1969-1992, issued over 600 compulsory licences. It's odd for the pundits to claim that the licences are rare when pharmaceutical products were rarely patented worldwide before TRIPS and where even a North American country had so bravely and consistently issued compulsory licences in the face of pharmaceutical company opposition.

One additional point to make in this regard is that there is no artificial limit on the number of TRIPS-compliant compulsory licences that may be issued. Now we know that Thailand has issued 3 licences already, two ARVs and one heart medicine. We know that it is currently considering licences on four cancer drugs. In addition, it is considering licences on what are estimated to be 20 other drugs for other chronic disease problems. It is important again to emphasize, as was true in Canada, that there is no artificial limit, and that you can continue to pursue this approach to accessing medicines for all. The only thing that you are really are prohibited from doing is acting so uniformly to issue licences that you would be considered to be discriminating against the field of technology. TRIPS would restrict you to some extent from issuing a compulsory licence on every pharmaceutical product or process. However, it does allow you to differentiate, to decide that you are going to issue more compulsory licences for medicines than you might for bicycles. Differentiation is possible; discrimination against a field of technology might not be.

And of course Thailand has been very clear that there are limited grounds upon which licences will be granted. You've listed 5 grounds in your White Paper, all of which make perfect sense: listed on the national essential drug list; necessary to solve important public health problems; necessary in emergencies; necessary to prevent outbreaks of epidemics or pandemics; or necessary to save lives. These are all perfectly sensible criteria and are expected to apply to no more than 5-15% of patented medicines. One of the reasons it is going to be so few is that not many patented products are worth issuing compulsory licences for. Pharma hates to hear that. But it reveals how many of the patented medicines are me-too drugs with minor therapeutic advantage, if any. They are simply version B of product A. You

don't need compulsory licences on those. Nor do you need compulsory licences on medicines for which there are therapeutic generic equivalents.

Myth 4. *Compulsory licences are not OK for middle income countries.*

So we have the false claim that they are only for emergencies. We have the false claim that they must be limited. We have now the false claim that only certain countries can use them. Ronald Cass again in the Wall Street Journal argued "Thailand is an especially bad fit for compulsory licensing... is comfortably in the top half of all nations ranked by per capital GDP, with an average income 15 times that of the world's poorest countries".

Nothing is false in that statement about where Thailand ranks but there are two very clear falsehoods in this statement. First of all, TRIPS imposes no limits whatsoever on which countries can use compulsory licences. The US under TRIPS could issue compulsory licences tomorrow with no problem. Every member country has the unrestricted right to issue compulsory licences, no exceptions.

Some countries did improvidently decide to opt out, on a total or partial basis, to the Paragraph 6 system (related to the import of medicines when there is a lack of pharmaceutical capacity). That opt-out may in fact not be binding and is a derogation of the rights they had under the TRIPS agreement. It is also a lie to suggest that a country like Thailand is rich enough to pay the prices that pharma wants you to pay. Thailand's GDP is a small fraction of that of the US: $2,751 per year compared to almost $42,000 in the US. The Abbott discount price of $10,000 would still be 3.5 times more expensive per person in Thailand than in the US. In a country with a higher prevalence of HIV it is 10 times more expensive on a GDP basis for Thailand, even at the current discounted price.

Myth 5. *Compulsory licences are limited to just a few diseases.*

(I should have used 'lie' instead of 'myth' but I started with 'myth' so I will continue. But please read 'lie' for 'myth'.)

Countries have the right to issue licences on grounds they determine appropriate, including diseases for which they think they are appropriate. Pharma would like us to think that medicines for chronic diseases, which drug companies make the most money on, medicines for life-style diseases, which they make the most money on, should be off limit. They should be able to target the middle class in developing countries and extract every cent of profit they can from them. Nothing could be more false.

This is a topic that strikes particularly close to me. I have a younger son who is a survivor of paediatric cancer. My son Chad had cancer when he was 2 and a half years old and he is alive 22 years later. I cannot imagine the nerve of drug companies to make arguments to people who are sick and the parents and family members of children who are sick, as say, "Your child dies, because your child has the wrong disease. But that child lives because we have decided that one small category of cases is entitled to protection."

Drug companies complain particularly about the licence on Plavix, which is a blood thinner. There is simply no limitation.

Myth 6. *Compulsory licences may not be granted on price grounds alone.*

What the drug companies try to argue is, "Just because we charge high prices, why in the world would you want a compulsory licence?" In fact it is exactly because they charge super-competitive monopoly prices, a hundred times the cost of production, that countries need to issue compulsory licences. You have a World Bank study which indicated that Thailand would save $3.2 billion over 20 years on ARVs alone by using the TRIPS-compliant flexibilities that you are currently using.

I think it is important to emphasize that compulsory licences are not needed for price alone. There are other compelling reasons for issuing them. One is to prevent stock-outs and there is an instance in South Africa where one of the grounds for a new licence application before the Competition Commission is that the proprietary drug company has permitted stock-outs. You can issue licences to help promote technology transfer. Technology transfer is an empty promise in the TRIPS agreement. There are no teeth whatever in the obligation for technology transfer. In fact the opposite has occurred. Drug companies have disinvested in developing countries since TRIPS. So you have a right to try to build an industrial capacity and to pursue an industrial policy to have local and regional capacity. One of the reasons why Thailand is a hero to us all is that Thailand has helped to make the market for other developing countries and by setting an example, you are actually encouraging other developing countries, including middle-income countries, to issue compulsory licences. We will not have the lowest prices that we need for the chronic and neglected diseases of the poor, unless we have robust generic markets with multiple competitors. We have to do that by aggregating demand from multiple countries.

A final reason to issue compulsory licences is to permit the production of fixed dose combinations of medicines that are owned by different patent-holders, who will not make those medicines together. An example in Thailand might be to seek a separate compulsory licence on Ritonavir, so that as a protease inhibitor it can be combined with other protease inhibitors to be a competitor to, or even cheaper than, the current Kaletra formulation. This is an example of the importance of the need for fixed dose combinations.

Myth 7. *Compulsory licences are theft.*

The Wall Street Journal had an editorial entitled "Theft in Thailand". "By seizing patents for HIV/AIDS treatments and heart disease, Thailand has asserted that governments have the right to take intellectual property whenever they please." Governments don't take intellectual property. Governments use a pre-existing right that they had, even when those patent applications were filed. No one pulled the wool over Abbott's eyes. The compulsory licence laws were on the books when the application was filed for Kaletra. The government simply allowed another company to compete. Abbott's right to sell its medicines has not been removed. It still has a right to produce. It just can't do so on a monopoly basis any longer.

Myth 8. *Drug companies are always willing to negotiate.*

Since when? Maybe at the speed of glaciers, they will negotiate incremental decreases in price. But basically what they want to negotiate is price, on a very narrow spectrum of diseases. They will not negotiate on chronic disease medicines. Nor will they typically give voluntary licences. So they negotiate on everything except those things that are most important-deep, sustaining, predictable, long-lasting price discounts on all medicines and voluntary licences so that drugs can be produced even more cheaply.

Myth 9. *The Government Pharmaceutical Organization licence equals commercial abuse, and licences to generic companies inevitably lead to poor quality products.*

This is such a deep irony for the pharmaceutical monopolies to claim that there is commercial abuse by making drugs cheaper. The claim of a monopolist that someone else is cheating is pretty hard to swallow.

Compulsory licences are permitted to make a profit, that's the only way they stay in business. Countries can promote their own generic industries for local and regional production.

The slander in terms of quality is very consistent. Drug companies have questioned the quality of generics since generics began, and they will continue to do so. The response is very simple. When a generic manufacturer produces evidence of the bio-equivalence of a product, when the generic manufacturer meets good manufacturing practice standards, then the medicines are to all intents and purposes identical, and safe, and efficacious, and of good quality.

Myth 11. *Compulsory licences threaten R&D incentives.*

Dr. Wilson gave some information on research and development. I want to make two key points about market share.

Developing countries together represent about 12% of global pharmaceutical sales. The industry's audited total sales for 2006 was $608 billion (the unaudited figure is $643 billion), which includes only retail sales, not certain informal sales or hospital sales. When you take this astronomical global figure, the whole of Asia, Africa and Latin America comprise about 12% of the global market. How is it possible that this relatively small percentage of the global market is what energizes research and development? If you disaggregate even further and talk about Southern Asia and Southeast Asia, how can that fraction of the market be the determining factor about whether there is going to be research and development? The argument is simply preposterous. The press consistently makes the misrepresentation that the issuance of a compulsory licence here somehow threatens profits somewhere else. It claims that if you issue a compulsory licence in Thailand, Abbott stops making money in the US.

Transcriber's note. The speaker seems to have omitted Myth 10.

The companies will experience no effect on their profits in the rich country markets where they make 88% of their sales, and probably 95% of their profits. These are the questions that journalists could continuously ask the drug companies about research and development. How can South and Southeast Asia's infinitesimally small share of the global market affect research and development incentives? If Southern markets were so important, why have drug companies invested only 1% of their research and development on neglected diseases over the past 3 decades? If the current patent system is well-designed to provide incentives for research and development in therapeutically important areas, why do its incremental innovation outputs deform research towards lifestyle diseases, me-too drugs, and ever-greening strategies? These are the questions that should be asked whenever the R&D defence is raised.

Myth 12. *Because of the issuance of compulsory licences drug companies and the US government are justified in retaliating.*

I am here and I am mad because of what a drug company from my country has done and because of what my government has done. It is hard to express then outrage that I am sure you felt and that other people around the world felt when on March 10th Abbott unilaterally removed heat-stable Kaletra from the registration process. The idea that poor people living with HIV/AIDS in Thailand, who have to carry ice in lunch-boxes to keep their Kaletra cold, cannot have access to the newest heat-stable formulation, because Abbott had the nerve to take this medicine off the market is truly unbelievable. No drug company should be able to retaliate in that way. It is monstrous that it has done so. I am proud that consumers and activists in your country have taken the case to the Competition Tribunal in Thailand, challenging that decision. It is illegal, we would argue, to withhold those products from the market without justifiable reason, and to offer them abroad, but not here in Thailand and we hope that the Competition Tribunal will decide that matter promptly. Drug companies simply have to learn that this is not an acceptable tactic. The fact that they can deny access to delayed registrations is already problematic, but to withdraw a medicine is truly outrageous.

In the same way, it is an outrage that the US government has placed Thailand on the Special 301 Priority Watch List. It is simply unconscionable and probably contrary to US law. A provision of the US Trade Authority Act, which unfortunately has been honoured in the breach, directly says that the US Trade Representative is supposed to honour the Doha Declaration. How does it honour the Doha Declaration to put Thailand on the list because it issued compulsory licences? Of course the US government didn't stop at compulsory licences. It withdrew a billion dollars of no-tariff products under its generalized system of preferences. It is hard to measure the economic costs to the 3 Thai industries affected, but it is not insignificant. Again, I think it is incredibly important that Thailand has stood up to this trade pressure, and, even after this pressure was applied, to continue to consider compulsory licences. You are standing up and you are providing an example to other developing countries, who can now act in solidarity with you and follow your lead.

Myth 13. *A free trade agreement with the US will be beneficial to Thailand, with respect to access to medicines.*

I know there's been a suspension of the FTA negotiations here, in large part because of the heroic activism of people living with HIV/AIDS, who swam across rivers to try to interrupt those negotiations. There is great danger in what the US is seeking, even with some of the minor modifications that the Democratic Congress is taking up for new trade measures. We don't have time to go through all these now. I hope there will be time later in the conference to look forward to the danger that may exist in the trade agreement. There will be efforts to expand the scope of patentability, to restrict pre-grant opposition, to limit compulsory licences, to impose data exclusivity, to extend patent terms, and on and on. Also this will include the right of drug companies to sue countries directly under investor protection provisions. All of these provisions would be a total disaster for Thailand.

In conclusion, the crisis for access to medicines is already here. Since 2005, India has a product patent regime and although you can import from India the medicines that pre-existed the patent regime without a problem, importing the newest medicines will be much more complicated unless we find a way out of the TRIPS stranglehold that we all face. The new integrase inhibitor that's just coming onto the market in the US as a 4th line of attack on HIV will simply be much harder to access and much less affordable because of the complications imposed by the TRIPS agreement and its broader application to all countries except the least developed.

When we fight for access to medicines, when we fight for access to life itself, we are confronted consistently with lies and distortions, and we should call them lies. They are not just myths, these are lies that actually kill. We need to expose them and educate ourselves about them. We need to be able to stand up and refute them whenever they are made. We should continue this effort to identify and challenge each and every time pharma states a lie, or the USTR states a lie. We should stand up and say no.

Our final act of solidarity as activists and government officials and all the other people who are here today is one of international solidarity, which is access to medicines for all diseases, for all patients in all countries.

Role of the International Institute and its Support to Developing Countries on Using TRIPS Flexibilities

Facilitator: **Ellen F M 't Hoen**
Médecins Sans Frontières

Introduction

Ms. 't Hoen has been Director of Policy and Advocacy of the Campaign for Access to Essential Medicines of Médecins Sans Frontières since 1999. She is currently a research fellow at the University of Amsterdam, conducting research on the implementation of the Doha Declaration on TRIPS and Public Health. In 1981, she co-founded DES Action in the Netherlands. In 1990 she joined Health Action International to head the Policy and Campaigns Unit. 1996-9 she was the International Coordinator of the independent medicines journal La Revue Prescrire and Prescrire International and the International Society of Drug Bulletins. She is an expert in medicines policy and intellectual property law, and has been a consultant to a number of countries and internationals organizations. In 2005-6, she was listed as one of the 50 most influential people in intellectual property in the world by the journal Managing Intellectual Property. She has a Master's Degree in Law from the University of Amsterdam.

I invite the panellists Mrs. Jayashree Watal, World Trade Organization, and Dr. William Aldis, World Health Organization

Unfortunately, the European Commission will not participate in this panel which I regret very much because when in 2001, 6 years and 6 days ago, the Doha Declaration was adopted, the European Commission claimed to have played a very important role. But when countries actually start to use the Doha Declaration on TRIPS and Public Health, the European Commission today here in Thailand seems to be singing a different song, and has voiced criticism of the Thai compulsory licences. I think that the European Commission has a responsibility, if not a duty, to take part in this meeting. The European Parliament has recently adopted a number of resolutions asking the European Commission to change its policy to one that is more pro-health. The absence of the Commission here today is reason for deep concern, and as a European, I will make sure to take that concern back to our part of the world. They will hear from us.

We still have a fantastic panel. The first speaker, Mrs. Jayashree Watal is the Counsellor in the Intellectual Property Division of the World Trade Organization and for more than 2 decades has been part of the Indian government and has been very close to negotiations in the WTO and I think many of us have on our bookshelves the classic textbook Intellectual Property Rights in the WTO and Developing Countries, either legitimately bought or illegally copied, because it's a very expensive book. But if you practice parallel importation, you can get cheaper versions from South Asia.

Support to Developing Countries on Using TRIPS Flexibilities : WHO's Role

Mrs. Jayashree Watal
World Trade Organization

I wish to thank the organizers for inviting the WTO to this meeting and I am very grateful that my organization chose me to attend.

TRIPS Provisions of Direct Relevance to Public Health

What are the TRIPS provisions of direct relevance to public health? I want to stress here that these provisions are there, not because like manna they fell from from heaven, but because they were negotiated. They became part of the TRIPS Agreement with a lot of difficulty.

It would take a whole session to explain this properly. I will just note the Articles which are of direct relevance, which you can look up. There are others which have something to do with public health, but these are the most important.

Articles 7 and 8 were put into the TRIPS text by developing countries and subsequently watered down in the subsequent negotiations. Article 8 in particular mentions the words 'public health', the only Article of the TRIPS Agreement to do so.

Article 6 is about parallel imports and basically it does not put any restrictions on members adopting any particular regime of parallel imports that suits them. Whether a country does or does not allow parallel imports, or restricts them to the region, is up to the member. This was reiterated in the Doha Declaration. This is an important Article which was quite tough to negotiate. It was not so much because of the Indias and Brazils of the world that this Article was introduced, but because of very small countries in this region, members of the WTO, such as Singapore and Hong Kong, who thought that their economies depended on parallel imports, not of medicines, but of other products.

The entire Section 5 is on patents and is of direct relevance to public health for obvious reasons, particularly Article 31, which again was a very difficult negotiation. Originally there were 2 Articles, one on compulsory licences and another on government use, which were then merged into one Article similar to the current text. On compulsory licences there was a US draft proposal which said there should be only 2 grounds for compulsory licences: as a remedy for adjudicated anti-trust cases; and in the case of declared national emergencies. These are sometimes found in post-TRIPS FTAs. On government use there were no such restrictions because of Section 1498 in the US law. In the negotiations, and I can now say this openly because it is part of the record, India combined the text on government use and that on compulsory licences as both being use without authorization of the patent-holder and therefore should be treated in the same way and subject to the same conditions. This combination was backed by 3 of the 4 most influential members in the negotiations at that time: the EC, Canada, and Japan (which, with the US, make up the 'Quad'). The US basically fell in line. This merger of the two articles removed all restrictions on the grounds for compulsory licences and government use. The conditions were then diluted by

US negotiators to accommodate public non-commercial use and weaken the anti-trust, anti-competitive practices measures.

That is the history of how Article 31 came about. There will soon be an Article 31 bis in the text, once it is accepted by 2/3 of the members.

Article 39 was also important. The supporters were clearly looking for strengthened protection in an area which developing countries at that time were saying is not even intellectual property. Trade secrets are not part of intellectual property because by definition there is no disclosure involved. But trade secrets got in as did test data. This was not merely a North-South negotiation. It included countries like Canada, which at that time was not yet a member of the still-to-be-created NAFTA, which was responsible for much of the negotiated text. Argentina, Brazil and India were also involved. That text is really quite unclear. All it says is that there are 2 obligations, to protect test data against unfair commercial use, and to keep it secret except in certain circumstances.

The transitional arrangements were directly linked to what some developing countries had in mind, such as patents on pharmaceuticals, so there is a special provision allowing an extension of time for product patents in countries where these were not covered. Some countries did take advantage of these transitional arrangements, including India, but this was linked to Article 70, which obliged provisions such as exclusive marketing rights during the transitional period. This detracted somewhat from the benefits of the 5-year transitional period.

Article 40 deals with control of anti-competitive practices and IP licences. It is an important article and came about because of something that developing countries had been seeking for several decades before the TRIPS negotiations in UNCTAD and some of that language has now come into the text of a WTO agreement. I have included the issue of enforcement because avoiding or eliminating counterfeit medicines and ensuring that counterfeiters are punished are also measures that are of direct relevance to public health. In the section, Article 44 says that use by governments or by third parties authorized by governments cannot then be served injunctions by a court of law.

The transitional arrangements for LDCs (for which the WTO has no definition other than the UN definition) in TRIPS were to expire on 1 January 2006 and have been extended to 1 July 2013 for all provisions of the TRIPS Agreement except for National Treatment and MFN. For pharmaceutical products, patents and undisclosed information, these provisions would apply up to 1 January 2016, as well as the enforcement of these provisions.

There was a special waiver of exclusive marketing rights, which LDC members would otherwise have been obliged to put into place during this interim period, postponing this to 1 January 2016. But the mailbox still remains, under Article 70.8.

Doha Declaration on the TRIPS Agreement and Public Health

Let me just explain why the members WTO decided to do something. Note that the Secretariat of the WTO has no powers to take any initiatives, although it did do something quite unusual in taking the initiative of organizing a meeting with the WHO Secretariat in Norway in April 2001, to look at differential pricing. Differential pricing by patent holders would mean lower prices in lower income countries. The organization of the meeting was extremely difficult. The stakeholders were called to this meeting. When the report was put to the TRIPS Council, the members asked why the WTO Secretariat should be doing anything of this kind when it has no mandate to do anything on these matters. But at the same meeting the African group said they would like to have a special discussion on TRIPS and public health. So one day was set aside in June 2001 to discuss access to medicines, with no objections from anyone. That was the start of negotiations on the Doha Declaration, which finally came in November 2001.

The purpose was to respond about concerns about the relationship between strengthened intellectual property protection and access to medicines. There were different views on flexibilities in the TRIPS Agreement. Were there flexibilities? What was the nature and scope of these? Even now there are differences on this; at that time, the differences were much greater. Even if it was agreed that there was flexibility, would it be interpreted by members in a public health way and would it be challenged? To what extent would governments feel free to use these without fear of pressure from trading partners or from the research-based pharmaceutical industry?

There were general statements, some of which have already been referred to in this conference. But the first paragraph of this Doha Declaration is extremely important and was heavily negotiated. The text is 'Ministers recognize the gravity of the public health problems..., especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics'. This became the basis of a very lengthy discussion in the negotiations that led to the August 2003 decision. Then there is the statement that Ministers 'recognize that intellectual property protection is important for the development of new medicines and recognize concerns about its effects on prices'. Both these ideas were put into the same sentence for balance. Again, it was heavily negotiated. There was an agreement that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health and a reaffirmation that TRIPS can and should be interpreted and implemented in a manner supportive of members' right to protect public health and in particular to promote access to medicines for all.

What did the Doha Declaration really do? Did it change anything? It gives guidance for disputes by reference to objectives and principles. Developing countries wanted a reference to Articles 7 and 8; instead they got this, which comprises the titles of Articles 7 and 8, and somehow it falls in with the Vienna Convention on the interpretation of treaties. It contains a clarification on compulsory licences, which was very important. Each member has the right to grant compulsory licences and the freedom to determine the grounds. This was in plain simple language. The term 'compulsory licence' does not actually exist in the TRIPS Agreement as it stands today (it will once the amendment comes into force). The Doha Declaration uses the term 'compulsory licence'. On emergencies, it was clearly said that

the right to determine what constitutes a national emergency or other circumstances of extreme urgency is left to members. This clarification was not in the original proposal by the developing countries because they didn't think it was necessary, they thought it was self-evident. But Switzerland said in the discussion that every country has the right to determine what constitutes a national emergency and developing countries said that they would like that in the text. On parallel imports or exhaustion, there is clarification of the freedom for each member to establish its own regime.

There were instructions given for further work. For countries with no manufacturing capacity, an issue that was raised even before the Doha Declaration, some NGOs, including MSF, were extremely interested in seeing how, in a post-TRIPS world, such countries could make effective use of compulsory licensing. But the time before Doha was not enough to complete the work. Ministers were instructed to complete this in an expeditious manner, by December 2002, but it was not done until 8 months later as a result of a specific difficulty for some delegations, especially the US, on the scope of diseases and products that this decision would cover. This was the only difficulty that the US had. There was also an instruction to give effective extension for LDCs, as I have already explained.

August 2003 Decision: Implementation of Paragraph 6 of the Doha Declaration on TRIPS and Public Health

Why was there a need for a revision of the Paragraph 6 system? Take the case where there is a member with insufficient manufacturing capacity in pharmaceuticals and another member with such capacity, which has issued a compulsory licence to its generic manufacturer, who then gets a demand from the first country and wants to export to them. Can such exports take place? Today, under Article 31 (f) of TRIPS 1995, no such exports could take place except of the non-predominant part of the production. Small amounts, constituting a non-predominant part of production could be exported, otherwise no. This has been waived under the August 2003 decision and even 100% of production can be exported if certain conditions are met, including notification and special marking and labelling. Some other waivers are included, such as avoidance of double remuneration, if there is a compulsory licence in both countries. The notification requirement has been waived in the case of regional trade agreements where at least 50% of members are LDCs.

The Decision is really about the health problem in the importing member. The importing member could have imported earlier, if the drug was a 'pre-TRIPS' drug. But in a post-TRIPS world, a generic version would be produced only under a compulsory licence during the term of the patent. The legal problem is with the exporting member, and the decision is about solving that legal problem.

The entire text was ready by December 2002, but the US is on record as saying they could not agree on the definition of pharmaceutical products. The whole thing came together with the General Council Chairman's final statement with no change in the text. The Decision has been effect since August 2003 and remains in effect until it is replaced by the Amendment. The Amendment is technically equivalent to the August 2003 Decision, so the replacement of the Decision by the Amendment is only a technicality.

The Paragraph 6 system may need to be used even if there is no patent in the importing member. Some think that if there's no patent, what's the problem? The legal problem is in the exporting country. Suppose there is a public health problem in a WTO member requiring a generic pharmaceutical product, which is patented elsewhere and produced under a compulsory licence. If the product is patented there is an agreement with the originator company to supply it at reasonable prices and quantities. If the product can be produced domestically, or if it can be imported from non-patented sources, in the case of pre-TRIPS products, for example, or from a non-WTO member, there is no problem. But if there is a patent and a compulsory licence in the exporting country, and the amount that is needed by the WTO member with the health problem is more than the non-predominant share, then the Paragraph 6 system needs to be used. A separate compulsory licence must be issued for 100% exports.

The elements of the Chairman's statement are that the system should be used in good faith, and not to pursue industrial or commercial policies; that all reasonable measures should be used to prevent diversion; that information should be given on how countries determine that they do not having manufacturing capacity; that if expeditious reviews are required, the good offices of the WTO D-G or Chair of the TRIPS Council would be used to solve any problems of implementation; and a listing of the partial opt-out countries who wished to opt out only in case of national emergencies. The full opt-out countries were listed in a footnote to the Decision itself.

The timeline for using the Paragraph 6 system begins with the notification to the TRIPS Council by the importing member of intention to use the system. LDCs do not need to make a specific notification, only a general notification that they intend to use the system as importer. This may be done at the same time as the second notification of the details of the products that are needed, the name of the medicine, the expected quantities needed, a self-declaration as to whether or not there is manufacturing capacity, and, if there is a patent, whether it has granted, or intends to grant a compulsory licence. LDCs do not have to assess manufacturing capacity; they are deemed to have none. If there are 2 compulsory licences, the importing country's compulsory licence would not include remuneration on condition that it is paid by the exporting member. In every case under the Paragraph 6 system, there will be a compulsory licence in the exporting country and remuneration will be paid there. In the 3rd step, the TRIPS Council is informed by the exporting member of the grant of the compulsory licence and its conditions. Before shipment, the licensee would post on a website, either of the company or the WTO, information on the quantities to be shipped, the destinations, and the distinguishing features of marking and labelling adopted, possibly including colouring and shaping. The 5th step is the import/export and at this point the importing country would have to take reasonable measures to prevent re-exportation. These measures have to be within the means of the importing country, within its administrative capacity, and proportionate to the risk of trade diversion. This was heavily negotiated and will be in the text of the TRIPS Amendment. It is difficult to see how a case could be taken to dispute settlement.

The Chairman's statement was read a second time, for technical reasons. We know that 11 members have accepted the Protocol, and the first notification has been made by Rwanda, which will import from Canada, whose notification has also arrived at the WTO.

Why has there been only one notification? Why has the Paragraph 6 system not been used so far? In our view, the reasons are these. The non-predominant limit has not proved to be restrictive. Pre-TRIPS generic medicines are still available outside the patent system; these will eventually be replaced by improved patented drugs and drugs will become available for diseases for which there are at present no drugs. The needed medicines are often financed by donors, who have their own way of dealing with these issues: LDCs are being urged not to enforce patents; donors may negotiate better prices from patent-holders, where there are reductions of prices, either under threat of compulsory licences or voluntary licences. Legislative changes in exporting countries have been quite recent or have not yet been completed.

Some NGOs, including MSF, have raised the issue that the Paragraph 6 system is too complex, and that members lack the capacity to understand and use the system. Whether or not this is true, the WTO Secretariat holds dedicated national, regional and Geneva-based workshops to explain the Paragraph 6 system.

3-day regional and national TRIPS workshops run by the IP Division, include 1 day on public health. There is now an e-training course for government officials, which includes a separate module on public health. We invite to dedicated workshops representatives from the WHO, WIPO, civil society representatives from NGOs, and representatives from the generic research and production industry.

I will end with the observations that all these flexibilities are useless if countries do not take steps to avail themselves of them, and that intellectual property issues, including compulsory licensing, are only part of the bigger picture of access to medicines, which includes infrastructure, national health systems, procurement regimes, import tariffs, etc.

Ellen 't Hoen: Our thanks for explaining a complex issue so clearly, and for demonstrating the efforts made by the WTO to encourage countries to make use of the flexibilities. It is strange that the WTO makes more efforts in this direction than the WHO.

We will now hear from Dr. William Aldis, the Coordinator of Health Policy and Research at the WHO Regional Office for Southeast Asia. I know that he is very well known here. In Thailand he was the WHO representative from 2004 to 2006 and was the very loud and clear voice of the WHO in Thailand. He will speak on WHO's work in this area and will move us from talk of access issues to looking to a future where both access and innovation become reality.

Dr. William Aldis
World Health Organization

I would like to start by giving a justification about why and how the WHO is involved in this area. I do this because we hear from some quarters that there is no mandate for the WHO on these issues.

I think it is first important to understand what the WHO is as an organization. I find that even with some of my UN colleagues, I need to explain patiently who we are and how we are governed. Understanding that is a necessary pre-condition for understanding how we operate in the area of trade and health. Some people incorrectly think that the Headquarters in Geneva, the regional offices and the country offices is the World Health Organization. But these constitute a Secretariat, hired by the WHO, which is 193 countries, each with their national interests. The process by which the WHO is governed by the World Health Assembly is fundamentally a political process by which a Director-General and Regional Directors are elected, and by which resolutions are passed. The Secretariat then assumes a valid and effective technical role in carrying out these resolutions. Essentially we have a political process leading ultimately to technical action. We have an Executive Board with 36 countries and it is quite democratic, unlike the United Nations. This Board is a rotating Board; every country, from small to large, will in turn be presented on the Board. Resolutions from the Board become the directives by which the WHO operates. Perhaps a better picture of the WHO would be a map of the world. We differ from the WTO in many ways. Apart from our governance arrangements, another difference is that we have 193 members, as opposed to 152. And those members of our organization that are not in the WTO tend to be what I refer to as the loser countries in international trade agreements. The different composition of our members should be (but is not always) an advantage in terms of global participation in trade and health issues.

One of many problems that we face as an organization is that the world looks north-dominated by some and south-dominated to others. If you go to Chile or South Africa, you may see a map of the world with the South at the top. To Northerners, it seems upside down. This reflects Dr.Prawase's comment that we live in different worlds. It took me 10 years to really appreciate in my heart how different the positions and understandings are between people from different countries and different segments of society. But it is a reality that we face in the WHO every day.

At the risk of boring some of you, I want to go back to our Constitution. We cannot operate in contradiction to our Constitution. I suggest to my younger colleagues that every Monday morning before they go to work, they re-read the WHO Constitution, because it is extra-ordinarily precise and specific, and even though it was written in 1946, it is absolutely current on the moral issues that should direct our thinking. One statement is that all people should enjoy a high standard of health, which is stated as a fundamental right. This is a powerful statement which, needless to say, is not always reflected in our daily work. Equity was already in the Constitution: 'Unequal development in different countries in the promotion of heath and the control of disease, especially communicable disease, is a common danger.' So inequity was recognized in 1946 before the word was in current use. Technology transfer

was also anticipated in 1946. 'The extension to all peoples of the benefits of medical, psychological and related knowledge is essential to the fullest attainment of health.' This is very specific. It says that everyone should have access and I would assume this includes methods of production, technologies, and intellectual property to assure the right to health that they have.

Since our governing body consists of member states and their governments, one could question whether the needs of individuals as represented by civil society, for example, are addressed. We have a statement "Governments have a responsibility for the health of their peoples which can be fulfilled only by the provision of adequate health and social measures." That locks us in to fulfilling and responding to the needs of individual people with problems.

I think you can see now why I recommend that my colleagues read this regularly, because in the absence of this type of moral guidance, everything that we do is at risk of becoming corrupted and weakened.

The first function of the World Health Organization is "to act as the directing and co-ordinating authority on international health work." I do not interpret this as some type of dictatorial power but rather as a responsibility. If you take this with everything else that I have presented, I think the argument from some quarters that the World Health Organization does not have a mandate in dealing with trade and health can be seen as completely ludicrous and untrue. I would comment further that we do see the need for collaboration with experts on trade in the WTO and WIPO, which is very positive and synergistic, because the issues that come up, for example in the Doha Declaration, clearly reflect sensitivity to the health consequences of trade, where we feel we do have something to say.

Because governments are mandated and required by our constitution to serve the health needs of their populations, it then becomes true that sick people should be recipients of our work and we are obligated by our constitution in a very specific way to see that their needs are met. We have situations where this requires statements and positions to be taken which can sometimes be somewhat difficult. But it is absolutely compelling that these principles are there.

On the Doha Declaration, I wish only to say that the language is something that even I, as a public health person, can understand. "Every member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted." That's good English.

So where did the WHO jump in? Let me go back to Resolution 56.27, where the WHO became aware of the need to educate itself on trade issues and their impact on health and, in order to achieve that, to set up a commission which would specifically, objectively, and rigorously look at the evidence and point a way forward in the form of recommendations. This was the Commission on Intellectual Property Rights, Innovation and Public Health. The Commission's report gives you a lot of source information if you are not familiar with that field. It is difficult to read since one sentence may be directly contradicted by the subsequent sentence. For example, one sentence may say that the patent system has failed

miserably to deliver products for so-called neglected diseases, while a later sentence may say that the patent system protects innovation and ensures the production and delivery of products. This reflects the contradictory national interest of our membership. This is why clear and unambiguous agreement is a great accomplishment. In the convening power of 193 countries, with virtually the entire world population, taking into account the constitutional background under which this happens, there is a tremendous amount of under-utilized power that resides in these resolutions when they are finally produced.

The Commission submitted a report which was "welcomed". Some pharmaceutical company representatives argue that, since it was "welcomed" and not adopted, it doesn't mean anything to the WHO. This view is demolished by Resolution 59.24, which established an Intergovernmental Working Group, which was to take forward the recommendations of the Commission.

The Intergovernmental Working Group is fraught with difficulty. They have met twice, in December 2006 and November 2007, and have drafted a Global Strategy and Plan of Action. They have held 2 web-based public hearings, with some concerns about the submissions to these hearings published recently in The Lancet in terms of which organizations were sponsoring these submissions. There have been regional consultations. This is important since conflicting interests can be reconciled at the regional level to achieve a regional consensus that can speed up the work of the Intergovernmental Working Group. The Trade and Health Working Group in our region has had 3 regional consultations, the most recent in the Maldives immediately preceding the 2nd IGWG. These regional consultations have resulted in a higher quality in the IGWG and in some cases have made it possible for better informed countries to be more confident. I don't think it would have been possible for Bhutan or Timor Leste or other small countries to stand up and say anything if we had not held these regional consultations. So like the training sessions of the WTO Intellectual Property Group, this process of informing people of the issues is absolutely crucial. It is very hard work and it takes a long time.

Another consequence of the regional consultations is that some countries were able to take a conciliatory role that was effective in negotiations, for example Thailand and India in the last IGWG. They were able to position themselves somewhere between Brazil and the US in order to move the process forward. Many submissions, including regional submissions have been brought into the IGWG process. Everyone knew that if the work was to be undertaken seriously, it could not be finished between 5 and 10 November. I think the "suspension" was quite realistic and not a bad thing. It reminds me that in the first round of submissions a year ago, Bangladesh noted that the material was too complex and there was insufficient time. Now the other countries understand what they were talking about.

My Regional Director, Dr. Samlee Plianbangchang, explained something to me the other day that I did not understand. He went back to the Framework Convention on Tobacco Control where initial positions were completely irreconcilable. They started from positional bargaining and got nowhere and instead returned to process, setting up a mechanism by which things could be decided. At the time, people who felt strongly about these issues thought this was a retreat, but by going back to process, it was possible then to move forward into

substantive issues and deal with them better. When things seem to be moving slowly or inefficiently, this may be a necessary phase of consensus building. We may be seeing that to some extent in the IGWG process.

What proposals are on the table in the IGWG? Let me make the point that we are here at a conference on compulsory licensing but I am sure that all agree that even if we solve every problem to do with compulsory licensing, we have not solved every problem related to the necessary technology, treatment, drugs and so forth reaching the poor people of the world, especially for neglected diseases. What is left out is the whole innovation process, how new discoveries will be funded and come forward. The IGWG sets a necessarily very broad agenda.

- Prioritizing research and development needs. We need to identify the critical failures so far of drugs and treatment for neglected diseases, such as tuberculosis, multi-drug-resistant TB, multi-drug-resistant malaria, and diseases for which there are virtually no treatments, such as dengue.
- Promoting research and development. This needs to be put in place by new actors using new funding mechanisms.
- Building and improving innovative capacity. This means creating new times and places and conditions under which new products, new understandings, and new inventions will be developed.
- Transfer of technology. A more level playing field must be created of capacity both to discover new inventions and to produce new products. It has been mentioned that some countries have been heavily compromised by the fact that they can't produce anything. Could that be improved?
- Management of intellectual property. Many people do not like the term "management" of intellectual property. Prof. Carlos Correa of the University of Buenos Aires has commented vigorously on this point. It sounds passive. The question is to change what intellectual property provisions there are, not simply accepting and adapting to those that exist.
- Ensuring sustainable financing mechanisms. We need mechanisms that are not linked exclusively to recovery of profit for having sold something. We must break free of that and find other arrangements such as research and development treaties or prize funds or government or non-commercial grant-funding. The profit motive doesn't seem to work at all well. The CIPIH report said that the patenting system fails completely. Only 13 of approximately 1,400 new drug molecules brought onto the market in the last 25 years of the 20th century were for neglected diseases. This is a horrifying failure that suggests a profound dysfunction of the present product innovation system.

It is useful to remind oneself of the 3 steps of discovery, development and delivery. Compulsory licensing will be useful in delivery. But unless there is some real transformation of the discovery and development process - what's done; where it's done; who does it; how it's funded - the delivery side will get us only a few out-of-date second-line drugs and the 3rd and 4th -line drugs, which, as with any infectious disease, will become the 1st and 2nd -line drugs, will not be available. Products for filariasis, leishmaniasis, dengue and so forth will not even be thought of. So we need to expand our thinking to these other issues.

Someone this morning should say something good about the private sector so I will volunteer. I worked in the private sector for 15 years. The energy, imagination, and obligation to produce results distinguish the private sector from the public sector in some cases and international agencies in others, where I can get paid at the end of the day, even if I've done nothing. I would suggest that our problem is not to eliminate the private sector from these processes but to discipline and transform the incentives of the private sector so that some of that energy will be appropriately directed, which it is not now. It is not a problem with the private sector *per se*, it is a problem of the grotesque distortions of what they do and why they do it. I think particularly at the discovery level there is tremendous potential in the private sector. It is a question of incentives. One reason they keep on producing life-style drugs and adding useless components to drugs and selling them as new products is that no one is asking them or requiring them to do anything different. In development, who is now doing clinical trials? It is the private sector. There is the question of how they do it. Most of my work has been in Africa and it is no real exaggeration to say that a human subject in Africa is less protected than animals in labs in the UK or US. Laboratory rats have be well fed, and not treated in a way that is painful. Human subjects in trials in Africa do not get those protections. The private sector's role in clinical trials should be disciplined.

Even when it comes to delivery, the private sector has a role. When we were trying to develop stock piles for the Mekhong for avian flu, with colleagues from the World Food Programme and Centre for Disease Control in Atlanta, we investigated every country and the only functioning drug warehouses with standard conditions of temperature and humidity control, with a logistician who knew all the principles of warehousing logistics, were in the private sector. They quite openly and willingly suggested giving 20% of their warehouse space. If we were to say unconditionally that the private sector is the enemy, I think that on the ground we would regret having said that.

I have said that the WHO is either blessed or fatally compromised by our deviant and diverse membership. The other problem is the question of interfacing between our respective organizations' resolutions, regulations, declarations, and so forth. That type of interfacing probably requires a lawyer rather than a doctor. But let's take an example of the isolation of the H5N1 avian flu virus in Indonesia. International health regulations state that it should be immediate and unconditional and samples should be immediately sent because it is a global requirement and those regulations are in effect. But the Convention on Biodiversity says a country has the right of intellectual ownership of biological products and life-forms from that country and the virus should be respected as intellectual property. The WHO, in Resolution 60.28, says there should be benefit-sharing, so if Indonesia sends its specimens, it should be assured a supply of vaccines. So these three sources of guidance are not in direct conflict with each other, but reconciliation is required. I think that going forward, reconciliation between private industry's needs and expectations and public needs, reconciliation between the industrialized and the so-called developing countries, and reconciliation between the expectations and requirements of different organizations, are all necessary.

Ellen 't Hoen: Thank you for a clear and inspiring presentation. When you were talking of the energy, imagination and need to produce in the private sector, I saw a similarity with the HIV/AIDS treatment movement, which has a lot in common. We like the private sector when they produce essential medicines that we all want. That is something that drives many of us in the work we are doing. We do not like a private sector that thinks it is OK to sell essential medicines to only 10% of the world population. As the WTO has declared, we want to have access to medicines for all and not just for the happy few. I will say another positive thing about the private sector. Discussions for the Doha Declaration unleashed the debate on intellectual property, the role and the problems it causes for access, and the lack of role in innovation. Those two debates are now coming together in the Intergovernmental Working Group. We have also seen in those discussions that the pharmaceutical industry is changing slightly the way it talks about its role. They are moving away from the mantra of needing higher levels of intellectual property protection; give us that and the wonderful new drugs will come automatically. I think there is an area of consensus that there are huge gaps in the system and that alternatives and new mechanisms are necessary to fill those gaps. I think that is a beginning.

I have also been informed that representatives of the European Commission are attending this conference.

SPEECH

Health and Access to Medicine in Thailand

by
Dr. Mongkol Na Songkhla
Minister of Public Health, Thailand

Introduction

Dr. Mongkol received his medical degree from Mahidol University in 1971 and a Masters in Public Health from the Institute of Tropical Medicine, University of Amsterdam in the Netherlands. He is a key player in the current government, who bravely and successfully implemented compulsory licensing in Thailand. This was the first case of its kind among developing countries. He had seen and been involved with at first hand the need for adequate health care in rural areas, where he practised medicine earlier in his career.

I really appreciate the kind and committed support of our foreign participants.

Very few people really believed that a country like Thailand would implement the TRIPS flexibilities, especially compulsory licensing. How can a developing country whose economy depends mainly on exports withstand foreseeable huge trade retaliation and diplomatic and political pressure from its trade partners who own the patents on novel molecules? Some guess that we would like to make a profit for our Government Pharmaceutical Organization. Others thought that this interim government had shifted the health budget to the military so we have to implement compulsory licensing to compensate for the loss of our drugs budget. Others even imagined that I want to gain popularity for the next general election. Ladies and gentlemen, I have never had any motivation to get into politics. I was made a minister by accident. So I don't behave like a political minister and I am sorry for those who expect me to be have like a politician.

Thailand is like other developing countries. We have pressing problems both of lack of research and development into essential new technology to treat neglected diseases which are rampant on our part of the world, and of limited access to available essential new technology for health due to the limitations of intellectual property management.

The problem of inadequate R&D on neglected diseases may be solved soon as many more people from the developed world come to live in tropical areas and are also at risk of neglected diseases. Global warming also brings many tropical diseases to the western world. This will soon create an effective market to motivate more R&D on neglected diseases.

However, the issue of access to available essential health technology will not be solved by globalization and global warming. In Thailand, we started universal coverage of the health insurance system in 2001. Furthermore, the Thai government committed itself in 2003 to a policy of universal access to antiretroviral drugs for all patients infected with HIV, which at that time was a death sentence. In addition, from January next year, the government will expand coverage to include renal replacement therapy. This may be seen by some as a populist policy. But these policies help millions of people with catastrophic illnesses. Several decades ago, when we did not have high-priced technologies, people died without financial burden. But nowadays, high-priced technology which can lengthen people's lives has put a really heavy burden, even to the level of financial bankruptcy, on the poor or even the middle-class. This is why we need to move to a universal access policy.

Last month, I went to Ubon Ratchathani province to visit renal failure cases in many districts. More than 60% were already bankrupt, because they had to spend a lot of money for renal replacement therapy, which cost them at least 15,000 baht a month. They start by selling their buffalo and after that their land and house, and then the property of their close relatives as well. The greatest pity was that their children had to leave school because they no longer had a house. That is the real bankruptcy of a cluster of families caused by renal failure. So in the last 2 weeks I decided to take this issue to the Universal Coverage Office and our committee fully agreed. The decision was sent from the National Health Insurance Office to the Cabinet for approval. We used the budget that was left over after buying HIV drugs. This year we were able to save about 900 million baht to treat renal failure patients. Starting next year, we can have a budget for renal replacement therapy, to prevent poor families from going bankrupt.

We have to take care of our poor people step by step. Through our commitment to universal coverage and our mandate to achieve universal access to essential medicines for all Thais under the National Health Security Act 2002, the Thai government has increased the health budget from 4% of the national budget in 1980 to more than 12% in 2007. This has clearly helped us to provide effective essential health care to all Thais, and also to more than 100,000 people living with AIDS. AIDS is no longer a death sentence in our country. The same will soon be true of people with end-stage renal disease and many cancers. However, the excessively high price of many patented essential medicines, not only ARVs, has obstructed us from achieving true universal access. We have established a system based on a national essential drugs list to make sure that we do not use drugs irrationally and these are the priority drugs that we need. We have also tried our best to mobilize more funding. For example, we have increased our budget for ARVs tenfold in the past 5 years. More than 90% of ARVs are now funded from government budget, less than 10% from the Global Fund. We tried to negotiate with the pharmaceutical industry to get lower priced drugs, but unsuccessfully. So finally we had to implement the TRIPS flexibility of compulsory licensing for public non-commercial use.

I would say that Thailand's main motive for using compulsory licensing is our commitment to universal access to essential health care for all Thai citizens. We want to achieve greater access with the same amount of money or even a little more. We do not want to save money, even though the interim government increased the budget by 20% and the budget

for the Universal Access Health Programme by another 20% over the last two years. Tens of thousands of Thais who require essential patented drugs, like some anti-retroviral and cancer drugs and drugs for coronary heart disease, cannot access these because of the high price. Some have the view that a middle-income country like Thailand should pay for the R&D costs of patented drugs and should not use the TRIPS flexibilities. But at the same time, we see many compulsory licences being implemented in rich developed countries for antibiotics and even drugs for prostatic disease, which can be used for treating male baldness. Indeed, we are a lower middle-income country, but we still have a big gap between the rich and the poor. Most Thais, and the government, will not be able to afford the high prices of patented essential drugs.

I would like to tell you the story of a middle-class engineer who happened to be sick with a cancer called GIST (gastrointestinal stromal tumour). He needed an anti-cancer drug called Imatinib. It costs 1.4 million baht per year. Some of you may already have heard about this on television about 4 months ago. This is 14 times the average per capital GDP of Thailand and 4 times his annual income. The Indian generic cost 20 times less. His health insurance refused to pay, as it was not listed on the Essential Drugs List, because the list was not updated sufficiently often. He ended up paying out of his pocket for the drug. But he could afford to do this for only 8 months. He finally decided to stop taking the medicine to protect his family from financial catastrophe. There was a television programme about this case which showed his mother crying, while trying to persuade him to take some bitter medicine which she had prepared, and which was almost too bitter to take. I finally intervened in this case and he later got the drug free of charge from Novartis. However, it was too late and he had to take 4 times the normal dose to survive. Imagine the level of toxicity he had to face. At the same time it was impossible for a minister to intervene into a case like this with no guarantee of success. This is a story of an educated middle-class man with 4 times the average income in a middle-income country like Thailand. There are millions of cases like this around the country and billions around the world, which suffer from their inability to access new essential medicines. What can we do to help them?

My experience of more than 20 years in rural areas, working with our poor rural people, has taught me that unless the government does more, there is no one to protect them from this kind of catastrophic illness. They have to sell their crops, their land, their assets, even their kids to get the money to save their lives.

I am convinced that many of our partners, particularly in the pharmaceutical industry, can help. Indeed, some of them are moving in the right direction with innovative and bold ideas. A company like Merck has provided unlimited free Ivermectin for the treatment of river blindness in Africa since the late 1990's. This won them the Prince Mahidol Award. Some companies have started a policy of moderately-priced patented drugs. Many companies have agreed to differential pricing mechanisms with moderately higher prices in middle- income countries and lower prices in low-income countries. Novartis, who owns the patent for the anti-cancer drug Imatinib that I just mentioned, recently came to us to propose unlimited free access for all patients under the Universal Free Access programme. We are in the final phase of discussion and hope to reach an agreement soon. Some are proposing differential pricing among different groups of people within the same country, in addition to the existing mechanism which is

applied to different countries. However, the majority still behave as hard-liners and continue the old way of doing business for maximum profit and neglecting the majority of their human friends on earth.

I am convinced that the owners and managers of the industry are also human beings with human hearts. They are our important partners in delivering essential health care to all with all possible innovative and sincere news ways of thinking. I am certain that the industry will help us not to have to move to more compulsory licensing.

Implementing compulsory licensing is not an easy undertaking. Strong political will and social support are needed but there are many difficult technical hurdles. First you need to have adequate information on the need for increased access to these essential patented medicines. This is to justify the action. Then you need to make sure that what you are trying to do is legally correct. The first time that we tried, we got information from Dr.Sanguan, who is here today, that helped our team make a good decision. Our team tried to contact many people, including legal counsel. According to the local and international legal framework, first you have to find good quality generic drugs, and register them. For some medicines you must register the generic even before the patented form, because the patent-holder refuses to patent the drug due to compulsory licensing. Many medicines are not included in the pre-qualification system of the WHO. Then you have to find companies who dare to face the possibility of legal challenge from the patent-holder, to import or produce the drug without profit. This is important when implementing compulsory licensing for public non-commercial use. Who would want to face litigation without profit? This is why we had to use the Government Pharmaceutical Organization and I would like to thank its board and management for their commitment and hard work. After all these hurdles, you will have to make sure that the medicines are of good quality and equivalent to the original products. Finally you have to make sure that you have sufficient sustained political and social support to survive the retaliation and pressure.

We have been very lucky so far. We received a green light from our leaders. Never before has a health policy received such strong public support locally and internationally. We also have a committed and able team of technocrats who have many years familiarity with the IP system. But most of all, we have good friends from all over the world. Many civil society organizations, particularly the Knowledge Ecology Institute of Dr. James Love, Médecins sans Frontières, Third World Network, Oxfam, the Clinton Foundation and others, including the network of Thai NGOs, who are here today, with many international scholars like Dr. Carlos Correa, and Dr. Gerald Richman, all provided strong social and information support. Some of you here also mobilized other strong support and even risked law suits from the industry. Some of you mobilized support from politicians in developed countries, like more than 30 US Congressmen, and European Parliamentarians. International organizations, like the Director-General of the WHO and UNAIDS Executive Director, also sent letters of support. I have heard also that the head of the WTO also spoke in public in support of our government. The UNCTAD Executive Director also came to Thailand and spoke in support of our movement, as did some Nobel laureates.

In summary, I would say that strong political will and commitment to universal access to essential medicines supported by social support from local and international partners, with

well-managed coordination, makes the impossible become possible. I do not want to say that we will do it again or not. I only want to say that I would like our good partners and the pharmaceutical industry to support our goals of universal access by trying to come up with some sincere and innovative ways of thinking about doing business, so that they can an appropriate profit from the rich and at the same time help to protect the poor from devastating catastrophe. I am sure that as human beings with human hearts, the leaders of industry will be able to give more love and compassion to all underserved people around the world. It is only them and their new way of doing business that will be able to help us not to have to implement the TRIPS flexibilities.

Legal threats, political lobbying, divide-and-rule tactics and diplomatic pressure may only delay the decisions to use the TRIPS flexibilities in developing countries, and will not be able to stop this unless the issue of access has been solved. The negative measures that have been used against Thailand and some other developing countries in spite of the fact that we are doing everything according to the international legal framework only contributes to a negative reputation and image for the industry. No matter how much money you gain, it will not be able to compensate for the loss of your social credibility and the pledge that you once were committed to, that is to find the best technology to save mankind. Let us all be united, be friends, be good partners. Let us all think differently with new ideas of ways of doing business for both profit and well-being for all. Let us all create a more friendly and kind and peaceful world where the rich and poor can live in harmony. This is my wish that I am sure all the partners will listen to carefully and will be able to commit to for the sustained survival of mankind.

Finally, no matter how much I appreciate the organization of this conference, I would not like it to be just a CL forum. I wish that this could also be a forum for establishing effective future cooperative social networks, both nationally and internationally, and social movements among all partners, public or private, to increase innovation and equal access to medicine, not only in Thailand but in other developing countries. I believe this forum will provide us with a very good opportunity to share our experience and to discuss openly about how to create a sustainable public health system that could ensure equal access among people to medicines and efficient public health services of good quality and safety. May I once again thank all conference organizers and supporting organizations for their efforts in making this international conference a success.

SPEECH

The Consequences of International Trade, IP Rules, the High Cost of Medication and Health Services and Sustainability

by
Dr. Sanguan Nittayarumphong
Secretary-General, National Health Security Office

Introduction

Dr.Sanguan received his medical degree from Ramathibodi Medical School, Mahidol University and earned a Masters Degree in Public Health from the Institute of Tropical Medicine, Antwerp, Belgium. He has received many honours and awards, one of which is Outstanding Rural Doctor of the Year for 1984. Dr.Sanguan is another key person who is actively involved in the success on implementing CL in Thailand.

After listening to the Minister, you may not need any more information from me, but I would like to expand on the rationale behind the CL initiative in Thailand, so that this can be understood by the pharmaceutical companies so that we can live together in harmony in a peaceful way.

First, I will talk on the background situation in Thailand before we started compulsory licensing; second, the consequences of the international threats and intellectual property rules and access to essential medicines for Thai people. Then I will talk about how compulsory licensing in Thailand came about and its impact on access. I think this is a very important part. When we implemented compulsory licensing, did we really increase access?

First here are the ten leading causes of death in Thailand (see PowerPoint slide). The Minister touched on the issue of cancer drugs. We have not yet implemented compulsory licensing for cancer drugs. This is under negotiation. We were heavily criticized for implementing compulsory licensing without proper consultation with the pharmaceutical companies. In fact, under TRIPS, this is not necessary. But to show our sincerity, we are trying to negotiate on the price of 4 cancer drugs. The leading cause of death is cancer. You can also see that hypertension and cardio-vascular disease in ranked third and heart disease fourth. Cancer and heart disease are among the top three causes of death in any year.

We can also consider the burden of disease. The two statistics that we use are the cost of treatment and the total significance of disease for society beyond the immediate cost of treatment. This is measured in years of life lost to ill health as the difference between and total life expectancy and disability-adjusted life expectancy (DALY). DALY is the sum of years of life lost to premature mortality and the years lost to disability. When we consider this, we can see the ten leading diseases in terms of DALY loss in Thailand (see PowerPoint slide). The first is HIV/AIDS (first for males and second for females). Stroke, or cardio-vascular disease, ranks 4th for males. So although this is not the same as the leading causes of death, there is a correlation.

HIV/AIDS is the leading disease in terms of DALY loss in Thailand. In 2005, anti-retroviral drugs were included in the benefits package for members of the Universal Coverage Scheme. I am responsible for implementing this scheme. The problem for me was how to provide effective and efficient access to drugs for patients. A combination of 3 anti-retroviral drugs is needed to control AIDS symptoms.

Vascular diseases occupy a significant portion of DALY loss in Thailand. Clopidogrel is a potent oral anti-platelet agent often used in the treatment of coronary artery disease, peripheral vascular disease and cerebro-vascular disease. Ischemic heart disease and stroke are a leading cause of death and burden of disease. So we want to do something to help the efficiency of the Universal Coverage scheme.

In 2005 it was reported that Plavix was the world's second highest selling pharmaceutical with sales of US$5.9 billion. So when we consider how to implement Universal Coverage efficiently, the Doha Declaration on the TRIPS Agreement and Public Health "emphasises that the TRIPS Agreement does not and should not prevent member governments from acting to protect public health. It affirms governments' right to use the agreement's flexibilities in order to avoid any reticence the governments may feel." So in fact the government has the right and responsibility to protect their citizens by providing access to essential drugs.

When we consider HIV/AIDS drugs, there is no real problem the first line regimen drugs Stavudine+Lamivudine+Nevirapine and Zidovudine+Lamivudine+Nevirapine, because the cost per month is not too high. If Efavirenz is included, the cost is higher at 3,200 baht per month. When we came to implement CL, we calculated that only 23,000 patients were able to access Efavirenz, while 50,000 needed it. In other words, we didn't have enough budget.

The second-line ARV drugs Lopinavir and Ritonavir cost more than 12,000 baht per month. Only 4,000 patients can access this kind of drug, whereas 10,000 need it. Although we have a Universal Coverage scheme, we do not have the budget to cover those patients.

When we looked at the generic drugs, we found that the original price of Lopinavir+Ritonavir was US$100, compared to a generic price of US$62, which would be lower after negotiation. The original price of Efavirenz is US$40 but the generic price is only US$17. The situation with other drugs is similar. Clopidogrel is amazing. The original price is US$2 but the generic price is only US$0.06. The price difference is 35 times. Clearly, if we can access generic drugs, we really can provide coverage for our people. For other kind of drugs, for example Antineoplastics, the original price of Imatinib is US$26 but the generic price is only US$1.4, a difference of 18 times. Letrosole is similar selling at an original price of US$6.6 and a generic price of US$0.2.

So we felt that if we were to provide Universal Coverage, we had to consider compulsory licensing. The criteria for compulsory licensing are first, the medicine should be essential, safe and efficacious; the price of the original product is too high to be affordable; there should be a generic version available with good quality, which we emphasize and we flew to India to see the production process to ensure quality; and the drug should be used only for public use in non-commercial Public Health facilities, in other words we respect the commercial rights of the patent-holder in the private market.

Then first announcement of compulsory licensing on 29 November 2006 covered Efavirenz and the second round was on 24-5 January 2007 involving Kaletra and Plavix.

The impact on access is easy to see. The original price of Efavirenz was reduced by the manufacturers from 1,400 baht per bottle to 777 baht, compared with 650 baht for the generic drug (before negotiation), because they knew that the Thai government was ready to take action, not just threaten. The original price of Lopinavir+Ritonavir was reduced from 5,900 baht to 3,488 baht per bottle, still higher the price of generics at 2,200 baht. The price of Clopidogrel was reduced immediately from 73 to 22 baht per tablet, but this is still much higher than the generic drugs at 1.1 baht per tablet.

The impact was not only in Thailand. Internationally the pharmaceutical companies announced reductions in the price of Stocrin, from 1,400 baht to 777 baht and the reduction in price of Kaletra was available worldwide.

These details show that as soon as we announced compulsory licensing, prices were reduced immediately. There was an impact internationally as well. This is thanks to our friends in many countries but it shows that if we unite we can really reduce the price of drugs.

You can also see an increase in the access to essential medicines for Thai people. Before we could buy enough Efavirenz only for 23,000 patients, but after compulsory licensing we could provide access to 46,000 patients. The increase in access for Lopinavir+Ritonavir and Clopidogrel was from 4,000 to 10,000 and from 10,000 to 350,000 respectively. This shows a great change in the access to medicines.

In terms of consequences, I want to mention international solidarity. I would like to thank many friends from around the world for their support. There was also support from Thai civil society. Very few public health policies are supported by the local newspapers. At first, when we first announced compulsory licensing, some columnists criticized us, but after the international reaction, almost all newspapers supported compulsory licensing. This became a social shield for the government agencies moving this issue. But we were sensitive to the word ‘pirate’. We were criticized for being pirates. We tried to seek an innovative solution to solve this problem permanently. I spoke to James Love. How can the country benefiting from demonopolization give a just reward for innovation? It is only fair that innovators are rewarded. But the innovation should not be used to increase the price of the drug.

Finally, although international trade represents a significant share of GDP in most countries, it also has negative consequences, especially for health services in developing countries. Any country has the right to use the safeguard measures in the Doha Declaration to reduce the negative impacts of free trade on public health.

We were very aware that after we announced compulsory licensing, Brazil also did so. And we would like to see many other countries in the future announce CL and create more friends. If the developing countries unite, then I think we have something to bargain with.

IP Traps

Facilitator:
Dr. Jakkrit Kuanpoth

Speaker

1. Experience of Thailand with ddI
   Achara Eksaengsri
   Government Pharmaceutical Organization
2. Combid is another case of the repercussions of the patent system
   Lawan Sarowat
   Health and Development Foundation
3. Market Strategies of Abbott
   Nimit Tienudom
   AIDS Access Foundation

Facilitator

Dr. Jakkrit Kuanpoth

Dr. Jakkrit

The term IP Traps is strategic. It means we are not talking about law or legislative provisions. We are talking about things surrounding the legislative provisions of patents, how patent law is translated into practice. We learn that countries with good experience in patent matters have had patents for hundreds of years. Countries which have recently introduced patent law will have little experience in its administration, Thailand being an example. The first Patent Act in Thailand was in 1979, which is comparatively recent. The 3 speakers will tell us the story of administering the patent system.

(Note: The following are English-language summary translations of presentations given in Thai)

Experience of Thailand with ddI

Achara Eksaengsri
Government Pharmaceutical Organization

This is an opportunity to review the history of ddI, which was the object of a civil society campaign for 5 years from 1999. In Thai law the granting of a patent requires 3 conditions: the invention is new; it involves an inventive step; and it is capable of industrial application.

ddI (didanosine) is an antiretroviral used in conjunction with other ARVs for the treatment of AIDS patients. In 1999 it was used with a second ARV AZT, but since then it has been used in a combination of at least 3 drugs, making it expensive. ddI was an invention of the US National Institute of Health, a government body, which licensed the rights to Bristol Myers Squibb (BMS). BMS developed a tablet formulation, adding an antacid buffer to prevent ddI being destroyed by gastric juices. Previously ddI had to be administered along with an antacid to achieve the same effect. BMS combined the two medicines into one tablet.

An application for a US patent by BMS was rejected in 1992 on the grounds that the addition of an antacid to the formulation was not a sufficiently inventive step to warrant the granting of a patent. A second application in May the next year was rejected on the same grounds. Attempts by BMS to gain a patent did not end there. A third application was made with additional information. But this information was very minor. A patent was granted in March 1999. It therefore took 7 years before a patent was granted. This is slightly faster than patent approval in Thailand. The first application for a patent for the combined ddI-antacid formulation was made in Thailand in 1992 and granted in January 1998.

An examination of the patent claims in the Thai application shows that a patent could not be filed for the ddI molecule since the inventor was the US NIH, so the patent was filed for the formulation that combined in one tablet a dose of 5 to 100 mg of ddI plus a water-insoluble antacid. The specification of 5 to 100 mg is important. The patent application process in Thailand is somewhat different from other countries. And patents granted in each country are applicable to that country only. A patent application fled with the Department of Intellectual Property will be published to allow challenges to the patent application to be submitted within 90 days. If there are no challenges within the specified period, the company can request the Department of Intellectual Property to review the application against the three criteria mentioned earlier. The review must occur within 5 years of the filing of the application.

When the patent application was published, the Drug Research and Development Institute at the GPO had begun development of ddI formulations and knew of the BMS patent application in Thailand. While this research was going on, the BMS patent application was made public and the range of 5 to 100 mg was noted. The R&D Institute was also developing formulations outside this range, including 150 mg. When the GPO looked at the patent application, it was noticed that the application was filed in January 1992. At that time, Thai intellectual property law did not allow product patents. It was assumed that the Department of Intellectual Property would have to reject the application. So the research continued. When the research was completed in 1997, the Government Pharmaceutical Organization ordered

raw materials ready for the production of ddI with a water-insoluble antacid. But on 22 January 1998 BMS was granted a patent on its ddI formulation. On 24 April 1998 lawyers acting for BMS sent a letter to the GPO informing them of the ddI patent and requesting that GPO production be stopped. No production had in fact started, only preparations. So nothing was produced after the raw materials were bought.

On 19 September 1999, AIDS NGOs, representing patients who needed ddI, which was then a basic drug, submitted a letter to the Ministry of Public Health asking the government to use compulsory licensing to enable the GPO to produce ddI tablets. When no reply was received from the Ministry, on 10 November 1999, a letter was sent to the Law Society of Thailand asking for legal assistance.

On 12 November 1999, a representative of the GPO met the Director-General and Deputy Director-General of the Department of Intellectual Property asking for a compulsory licence under Section 51 of the Patent Act. However, Section 51 specifies that the agency requesting a compulsory licence must be a government ministry, bureau or department. The GPO, as a state enterprise, was outside this act. On 17 January 2000, the Ministry of Public Health decided not to use compulsory licensing but gave permission to the GPO to produce ddI in powder form. The patent covered tablet forms but the GPO had developed both tablet and powder forms. There was a preference for a tablet form, since the powder form had a higher risk of causing diarrhoea. When the drug was distributed in powder form, some patients were unable to take it because of side effects.

A group of AIDS patients and AIDS Access filed suit against BMS on 9 May 2001 to demand reinstatement of dosing per unit which had disappeared from the patent claim. This would allow the GPO to produce tablets at other dosages. The court also named the Department of Intellectual Property as co-defendant, since it was responsible for granting the patent. On 1 October 2002 the court found for the plaintiffs and required BMS and the Department of Intellectual Property to revise the patent to include the dosing per unit. The court reaches its verdict in unusually quick time. Nevertheless, while the case was being heard, 2 of the 13 plaintiffs died for lack of medicine.

The verdict also accepted a new definition of ‘interested parties’. In intellectual property cases, the plaintiff must be a party which has been injured by the patent. The status of the AIDS patients was legally uncertain. Previously the only injured parties were those injured commercially. In this case, the defendants attempted to have the case thrown out because the plaintiffs were not injured parties. However, the judge in this case, having regard to the Doha Declaration, decided that the plaintiffs did constitute injured parties, opening the opportunity for consumers to file suit in future.

Disappointingly, the Department of Intellectual Property appealed the verdict on 27 December 2002, asking for the dosage not to be restored to the patent application. On 2 January 2003, BMS also appealed.

On 9 October 2002, the Foundation for Consumers and 3 more PHA filed suit in the Court of Second Instance calling for the patent to be revoked. Before this could come to court and after a year of negotiation between the plaintiffs and defendants, on 24 December 2003, BMS

announced they would terminate the ddI patent and withdraw their appeal. On 17 January 2004, BMS formally declared in court that they were withdrawing the patent in Thailand.

In the 5 years of litigation, use of ddI as a second-line regimen after GPOvir, had been very low.

The case has been a good opportunity to build string teamwork, using the expertise from many sources: people with HIV/AIDS, NGOs, academics, the Lawyers Council and foreign organizations. There was a high level of mutual assistance in the exchange of information and in relying on the specific expertise of each party. For example, the solidarity of the people with HIV/AIDS, the understanding of intellectual property law of the lawyers, the detailed scientific knowledge of the academics, and up-to-date information from foreign organizations like MSF on the patent history of ddI in the US, for example the reasons why the patent application was rejected in the US. This kind of information was very difficult to access in Thailand.

This experience has taught us the lesson of strong networks and we would like to seem the same thing happening at the world level in protecting the right of access to medicines. We also learned the scientific and technical complexities are difficult to explain to other parties such as the lawyers and PHA. There can also be differences in the strictness with which patents are granted. The interpretation of the Patent Act in court seemed to be different from the interpretation that most people would have just from reading the Act. For example, it was difficult to understand why people with HIV/AIDS who were effectively denied access to life-saving medicine were not considered to be injured parties. Also the important content of a patent cannot be amended after the patent is published so it was hard to understand why the removal of the dosage range did not constitute a significant amendment. We also learnt that in matters of bilateral trade it is necessary for civil society to be strong enough to challenge other forces working on the government.

Dr. Jakkrit

Let me emphasize out some important points in that presentation.

First, it is claimed that patents encourage research and development. In the ddI case the research and development was not the result of the patent system. It was funded by government. But the commercialization of the results of publicly funded research under patent causes problems with access to medicines. So there is a question as to whether patents do encourage research and development.

The second issue concerns adoption of intellectual property law and its implementation. Many countries are encouraged or even forced to adopt patent law. But implementation is left to government agencies. In many cases the government agencies implementing the law are closely linked to international agencies promoting the protection of intellectual property, which shall remain nameless but you might think of an organization in Geneva. This raises the legal issue as to whether the criteria of patent law must be the same all over the world. For example, why is a novel inventive step or industrial application a basic criterion? In the case of ddI we see a lack of efficiency in the government agency, here the Department of Intellectual Property, leads to a market monopoly blocking access to medicines. You see that civil society and the public have to pool resources to fight to have the patent revoked.

From the legal perspective, judicial interpretation of the law is very important. The ddI case shows that Thai judicial interpretation is different from other countries. In the developed countries, the interested parties who have the right to challenge a patent must be competitors. The Thai judicial interpretation viewed pharmaceuticals as unique in the sense that not only are competitors affected but also the consumers, in the case, the patients who cannot access the medicines. The court ignored international agreements like TRIPS and looked at how Thai law could be interpreted. This could be a crucial example for other countries to follow.

Combid is another case of the repercussions of the patent system

Lawan Sarowat
Health and Development Foundation

The time frame for patent applications in Thailand is as follows. It takes 1 to 1.5 years from the filing of an application until the date of publication. Examination of the application takes another 4-5 years and after this is completed there is another 1.5 to 2 years before the patent is issued. The whole process therefore takes about 7-8 tears, which is similar to other countries. The Combid application followed this pattern.

The patent history of Combid started with the filing for a US patent by Glaxo Smith Klein (GSK) on 22 February 1996. An application was filed in the UK on 31 October 1996. On 26 September 1997, the US FDA approved Combid. A patent was applied for in Thailand on 27 October 1997, which was approximately 20 months after the application in the US. On 30 December 1997, the UK application was refused. But on 15 January 1998, GSK in Thailand claimed a priority date based on the date of application in the UK, or approximately 14.5 months earlier, even though the UK application had been refused.

When the Thai application was published, the Health and Development Foundation submitted a challenge on 11 May 2000. The reasons for the challenge were that the application was for a combination of AZT 300 mg and 3TC 150 mg, although both AZT and 3TC were out of patent in Thailand, and that there was no innovative step. The opinion of pharmaceutical scientists was that a patent was improper. At the same time the GPO was researching the same drug.

The filing date in Thailand was 27 October 1997, as already mentioned. On 15 January 1998, a priority date was claimed. It was assumed at the time that the priority date claimed would be the US filing date of 20 months earlier, which would have exceeded the limit allowed by Thai law. On 14 February 2000, the Department of Intellectual Property published the patent application. The GPO and Health and Development Foundation took advice and assumed that the period for challenge was in the 90 days following the date of publication. So the Health and Development Foundation filed its challenge on 11 May 2000. This challenge was eventually rejected by the Department of Intellectual Property on 11 October 2005. In the intervening 5 and a half years, the Foundation sent 3 letters to the Department of Intellectual Property, asking for the response to the Foundation's challenge.

The Foundation found the rejection of their challenge incomprehensible. The formulation was not novel and the ingredients were out of patent. What had happened was that a subcommittee had been formed to consider the challenge, and the chair of this sub-committee was connected to GSK. Another member of the subcommittee had conducted research for GSK.

We realized that if the patent was approved, the GPO would be vulnerable to a legal suit since it had been selling its version of the drug since 2001. The GPOvir medicine, containing AZT and 3TC would also be open to legal challenge. The repercussions would be immense and this was something we could not accept. We mobilized the networks of PHA and AIDS Access Foundation to send letters to the Ministry of Commerce after October 2005.

We had to file an appeal within 60 days. The appeal was filed on 13 December 2005, just within the deadline. We had to find supplementary data, specifically on the use of the UK filing date as a priority date when that patent had already been rejected.

The alliance working on this, PHA, academics and NGOs, decided to submit letters to the relevant Ministries to consider the conflict of interest in the subcommittee rejecting the challenge. A letter was sent to the Ministry of Public Health explaining that a patent for this medicine would have no meaning. The Ministry supported this position and was very helpful.

We had asked that the subcommittee seek information from Dr. Jiraporn Limpananon as to whether a patent should be granted in this case. Dr. Jiraporn was eventually called to educate the subcommittee on the pharmaceutical evidence, pointing out that the patent claim was scientifically meaningless. Dr. Jiraporn represented no vested interest but only the interest of the public.

On 8 August 2006, GSK abandoned the patent application. But this was not the end of the story. On 30 August 2006, the Patent Office issued a letter to the Health and Development Foundation saying that the company had withdrawn its application in Thailand completely. The Foundation received this letter on 3 October 2006.

Again the process of getting this patent application stopped took 5-6 years.

On 7 August 2006, the networks of PHA and consumers, and NGOs working on HIV/AIDS demonstrated in front of the GSK office in Bangkok, with placards saying that Combid was not a novel drug and should not be granted a patent. Eventually a company representative came to accept a letter calling for the patent application to be withdrawn. On the next day, it was withdrawn.

On the same day, 7 August 2006, there was a demonstration on the same issue in India and the next day the application for an Indian patent was also withdrawn.

The Combid case highlighted the weaknesses of the patenting process in the Department of Intellectual Property. It was quite incredible that the Director-General of the Department should reject the challenge to the patent when this challenge was supported by scientific

advice of the Ministry of Public Health that the drug was not a novel product and did not involve any inventive step. The DIP also ignored the fact that the same drug was refused a patent in the UK.

In conclusion, the patent-granting process should act as a mechanism allowing the opportunity for the Thai people to participate fully in the examination of patent applications and to protect themselves against fraudulent patents at the beginning of the process. The DIP can also reject applications quickly.

The next step is to amend the Thai patent law for the benefit of the people. The DIP and Ministry of Commerce is in the process of amending the law and they want to remove the opportunity to challenge patents in the examination stage, and allow only post-patent challenges. We do not think this is appropriate and are drafting a people's law so that the public can see which version protects the public interest. At present there is also no price-capping mechanism for pharmaceuticals, so producers with monopoly patents can charge any price. Dr. Sanguan's talk earlier gave examples of the difference in prices between patented and generic versions. We want the amended Patent Act to be looked at by the rest of the world to see how people's rights can be protected.

We should not have to protest in the heat and sun to gain access to essential medicines. But it is a long and hard struggle to secure one's rights. And it is a struggle that transcends national boundaries.

Dr. Jakkrit

The two speakers have demonstrated the inefficiency of he patent-granting process in middle-income developing countries like Thailand. Thailand is fortunate in one sense in that it has a civil society which can look after the interest of the public. But I am concerned about countries that lack a strong civil society. Can government agencies be relied on the run the patent system? Do they have a strong and efficient Patent Office which can guarantee to the public that the patents granted will be valid?

I have a question for the WTO representative. Under TRIPS, are developing countries required to protect second medical use? Are they required to provide criminal sanctions such as in the case of the GPO where those producing generic medicines receive letters threatening criminal prosecution? Why do developed countries provide only civil sanctions under patent law while developing countries like Thailand have to provide criminal sanction?

Market Strategies of Abbott

Nimit Tienudom
AIDS Access Foundation

Before I speak on my prepared topic, I want to say that in the discussion of prices and numbers of patients, if our work saves the life of one person, then it is worth it. Our objective is not to impose CL, or to challenge patents. Our goal is to save lives by giving access to medicines. And I want to thank everyone here for the help they give us in reaching this objective.

My assigned topic is Abbott and my first point is the Abbott is truly evil. I am able to talk to all sorts of companies, but when I look at what Abbott has done to Thailand, I have to say they are selfish.

Before there was a compulsory licence on an Abbott drug in Thailand, the things we heard from international forums was that Abbott never reduces prices. In all the negotiations that we have had in Thailand on sourcing medicines, we have never seen Abbott reduce prices. That may look like they are merely protecting the company's interests but after Thailand issued a CL on Kaletra, it became clear that Abbott is a villain.

When we fought to include ARV in the health security system, we found that we needed to upgrade the drugs and Kaletra is very important because 140,000 people were receiving drugs but 10% were expected to become resistant and so about 10,000 a year will need new drugs.

Dr. Jakkrit

From the 3 speakers we have learned how the companies manage to get a patent, and how civil society finds it difficult to fight in the courts and in the Patent Office to get a patent revoked or amended. Civil society also tries to challenge the dominant position of the companies in society, sometimes successfully, sometimes not. What we can learn from these presentations is how a developing country can live with a patent system, how a patent system can be designed and changed to suit their needs, not only to encourage innovation, but also to ensure access to medicines.

Additonal Comment

Mrs. Jayashree Watal

In answer to your question as to whether the WTO requires criminal sanctions against patent infringement, the answer is no. But TRIPS is a minimum standards agreement, so countries which go beyond TRIPS are allowed to do so.

The question of second medical use is more difficult. The issue is controversial and there are opinions on both sides. It was brought up in the TRIPS negotiation in the context of test data for products that use new chemical entities. At that time there were countries granting patents for new medical uses.

I have been asked to speak briefly on the situation with respect to Gleevec in India, which was to be presented by a speaker who cannot attend. This case will have repercussions for Thailand and other countries. It is similar to that of ddI in Thailand. In 1997, Novartis filed for a patent in India for the anti-cancer drug in a β-crystal form, used to treat chronic leukaemia. I understand that the drug is not an entirely new form but is an improvement on existing drugs. In 1997, India did not yet have patent protection for pharmaceutical products, but were required by WTO regulations to operate a mailbox system, under which Novartis filed an application.

As a result of a dispute between the US and India at the WTO, India was obliged to grant Exclusive Marketing Rights (EMR), similar to exclusive patent rights for a shorter period. In 2003, Novartis was granted EMR by the Indian government, which they enforced very comprehensively and rigorously against the local generic producers. The courts granted several injunctions to Novartis, asking local companies to stop producing the drug. This significantly increased the price.

The Indian Cancer Patients Aid Association challenged the Gleevec EMR. In January 2006, the patent examiners decided to reject the Gleevec patent on 3 grounds. First, the invention was not novel; secondly, it lacked an inventive step; and it was not an invention as required by the Indian Patent Act. The rejection took the form of an administrative order. Novartis challenged the order in the court on 3 grounds. First, the Indian Patent Act has a specific provision which is not TRIPS-compliant; second the law is unconstitutional; and third that the law is vague and not enforceable in a court of law. The court passed judgement overruling all the grounds for the Novartis challenge. The court noted that a domestic court was not an appropriate forum to decide issues of TRIPS compliance. If Novartis wished to challenge Indian law, it should do so in its home country with a view to taking the issue to the WTO dispute settlement process. The court, similar to the ddI case, interpreted the case in line with the country's international obligations and declined to protect the patent-holders.

CL Implementation: Achievements and Challenges

Facilitator: **Assoc.Prof.Dr. Vithaya Kulsomboon**

Speaker

1. Dr. Robert Wiessman
   Essential Action, USA
2. Dr. Samsuridjal Djauzi
   University of Indonesia
3. Dr. Vichai Chokewiwat
   Chair of CL Implementation Committee,
   Chair of the Board of Government Pharmaceutical Organization Board, Thailand
4. Gabriela Costa Chaves
   Pharmaceutical Researcher, Brazilian Interdisciplinary AIDS Association
5. Dr. James Love
   Knowledge Ecology International

Facilitator

Assoc.Prof.Dr. Vithaya Kulsomboon
Faculty of Pharmaceutical Science, Chulalongkorn University

Dr. Robert Wiessman
Essential Action, USA

The action of Thailand by civil society and the government in the area of CL has had an impact not only on Thailand but globally.

In 1999 a conference on compulsory licensing launched the global movement on essential medicines. Hopefully this conference will move the process forward. There are many ways to go forward in promoting generic competition but it will be important for other countries to follow Thailand's example and issue more compulsory licences.

The US has been by far the leading user of compulsory licences in the world since it urged Canada to stop issuing them in 1990. The US routinely issues compulsory licences, a fact which is not generally realized. But the US protests against other countries doing the same thing. It is worth looking at actual US practice.

There are two main areas where the US uses compulsory licences.

- Government use
- To remedy anti-competitive practices

There are a number of areas where the US government uses compulsory licences. These include special statutes for clean air technology and nuclear power technology, special rules for pesticide data registration, and so on.

The government use statute is a very aggressive, broad and powerful compulsory licensing statute and is used routinely in a way that is even more aggressive.

The statute states "Whenever an invention described in and covered by a patent of the United States is used or manufactured by or for the United States without license of the owner thereof or lawful right to use or manufacture the same, the owner's remedy shall be by action against the United States Court of Federal Claims for the recovery of his reasonable and entire compensation for such use and manufacture." (28 USC 1498 (a)).

This means that the United States or its contractors can use any patent, without any prior negotiation with patent holders, and offer it to any government contractor. This is routine practice in the US government. Patent holders' only remedy, if they are unhappy, is to seek compensation.

Note that the argument in Thailand as to whether the GPO is a government agency would be irrelevant in the US, where even private companies, if they are producing for the government, are covered by the government use statute.

Every patent ever filed in US is covered by the government use statute. There is no need to assess its importance for public health purposes, or whether it is the only way to deal with the problem. No discussion with the patent holder in advance is necessary. The US government complained that Thailand failed to enter into negotiation with the patent holders, but its own law does not require this. No prior negotiation is ever required. The government has the automatic right to use a patent; there is no need to specify the patent or why it is being subject to a compulsory licence. The government can authorize contractors to use any patent; they get same rights as the government. Contractors can use any patent to do the job the government has assigned to them.

Patent holders' only remedy is to seek compensation. No injunctions or delay. It is irrelevant if the government could have avoided infringement. All compensation cases are heard in a specialized court called the Court of Federal Claims. They have higher compensation levels than in Thailand related to market conditions in an area of law that is evolving.

The idea behind this government use provision is that since the government gave the patent, it can use it in any way it wants to avoid price gouging by patent monopolists. The goal is to get the best priced contract, irrespective of patent issues. Federal Acquisition Policy guidelines state 'Generally, the government will not refuse to award a contract on the grounds that the prospective contractor will infringe a patent.'

The government routinely includes in contracts an authorized consent clause which grants contractors the same rights as the government. The objective is to promote competition.

Examples of Government Use

Sevenson vs. Shaw (2007) is a high profile case from early this year about toxic waste cleanup. Shaw, a government contractor, used Sevenson's special patented technology to clean up the site without authorization. The court ruled in favour of Shaw saying it was for government use, hence there was no need for specific authorization. Shaw had shown its plans to the government which had raised no objection to the patent infringement. Even if there was another way to do the cleanup without Sevenson's technology, it doesn't matter.

A university doing research for the federal government is covered by government use rights. An equipment supplier providing equipment to a government contractor is also covered.

Much litigation comes down to how much compensation is owed to the patent holder. This is a complex evolving area of US law. The basic principle is that compensation should be the same as it would be if a market-based deal had been made. The patent holder is entitled to reasonable royalty, based on the value of the invention, not the value to the government. There are moves to push royalty rates down, but the current range is normally 1-10%.

US Competition Policy (Anti-trust policy) is another area where the US uses compulsory licensing very aggressively, as a remedy for anti-competitive practices. The Thai authorities in considering the Abbott case should be aware of how aggressive the US is in this kind of case. There are 2 main areas:

- As a condition for merger approval
- Abuses of a patent

If any two large companies in the world want to merge, but want to do substantial business in the US, they must get approval from the US government. For example, if two Thai firms wanted to merge, but they intend to sell things in the US, then they need US government approval.

The government looks to see if the merger will reduce competition overall or in certain markets. Sometimes the government will issue compulsory licences to increase competition where otherwise it would be reduced.

Examples cover pharmaceutical companies, frequently in the US. In 2000 when Pfizer acquired Warner Lambert, both had drugs for solid tumours in the US. To create a competitor, the US not only issued a compulsory licence on the Pfizer product, but ordered Pfizer to pay OSI, a Pfizer competitor, the costs of completing clinical trials. Otherwise, Pfizer would be too competitive.

Approval of the Wesley-Jessen merger related to contact lenses contained some important language which ordered a 'non-transferable, irrevocable, non-exclusive, royalty-free licence'.

Cases of abuse of patent may involve collusion of brand name pharmaceutical companies and generic companies, where the brand name companies bribe the generic companies not to enter the market or to stop or delay the entry of products to market. The remedy has been to make the generic company enter the market or allow other companies to do so, by compulsory licensing.

In cases of standard setting, if an industry is trying to agree on a standard, then each party must declare any patents they have. If companies don't disclose their patent on a product, then by law, the government can issue a compulsory licence to remedy the monopoly. The general principle is that if you don't disclose you have a patent then you will lose your patent rights through compulsory licensing.

In most developing countries, brand name companies do not disclose their patents, and the local Patent Office does not have the capacity to determine who holds patents. This principle says that if a patent is not disclosed, then it will be cancelled through compulsory licensing.

There have been some changes in US patent policy. In e-Bay v. Mercexchange (2006), the US Supreme Court ruled that injunctions will be much harder to obtain in patent infringement cases. The expectation is that the injured party will simply infringe the patent and pay compensation. This is equivalent to compulsory licensing.

This is related to patent reform legislation in Congress. It would change the way compensation is given in patents. It puts the compensation levels much lower than they are now. Compensation would be based on the value of the invention, not the invention in which it is incorporated. For example, compensation for infringement of a patent on a steering wheel should be based on the value of the steering wheel, not the car in which it is incorporated.

The e-Bay decision allowing infringement of patents and the move to lower compensation together lead to pretty robust system of CL as a matter of course in general patent law.

The situation the US is completely different from the way the US thinks the rest of the world should behave.

Things are getting better; there is more flexibility and freedom available for other countries to issue compulsory licences in the future.

The US placed extreme pressure on the Thailand government as the compulsory licensing process was unfolding and afterwards, in retaliation for the compulsory licences, the USTR put Thailand on the Priority Watch List which is very harmful. But Thailand has refused to bend to the US, which is good.

The USTR action led to a considerable reaction in Congress. Thirty-five members of the House of Representatives, including important members, publicly objected to the USTR actions against Thailand. This may make it harder for the USTR to pressure other countries in this way. But Pharma is still very strong in Congress; it is strong with Democrats as well as Republicans.

There is more interest among the Democrats in the House and less so in the Senate in a gentler stance on compulsory licences. But there is still discomfort on compulsory licences in middle-income countries on drugs that are not AIDS drugs. It will get easier as more countries issue compulsory licences and on more kinds of drugs.

In formal trade policy, things are in flux. The Democrats in the House are requiring the government to renegotiate terms on access to medicines in FTAs with Panama and Peru (also Colombia and Korea).

Changes to patent extension

- Patent extension is now voluntary
- Linkage eliminated
- Data exclusivity requirements weakened

Countries now recognize that they will have to do more than has been agreed with the Bush administration, which is the friendliest administration ever to Pharma. We should be able to improve these terms if we have new set of free trade agreements in the future.

All Democratic presidential candidates have accepted a global AIDS platform that supports "trade agreements that protect access to generic competition".

Dr. Vithaya

This presentation shows compulsory licensing is a simple thing. When in Thailand we decided to use it, we thought it was difficult and when we talked to the lawyers, it was difficult to understand. One difficulty was knowing who is the designated agency. This presentation makes clear that government use is very broad and perhaps we can speak of people's use. As a pharmacist, we think of the most common drugs as 'over-the-counter' drugs. Now it appears that compulsory licensing is like 'over-the-counter'.

You may know that in Asia, the first use of compulsory licences was by Malaysia, but unfortunately the representative of Third World Network could not attend. The second country was Indonesia, with issued a compulsory licence on the ARV Neviraprine. The second Indonesian compulsory licence on Efavirenz did not make as much news as in Thailand.

Compulsory Licensing in Indonesia : Achievements and Challenges

Dr. Samsuridjal Djauzi
University of Indonesia

For people in developing countries, antiretroviral treatment is a dream. Fortunately the dream has (almost) come true.

History of ARVs in Indonesia

In 1999, a working group on AIDS was set up at the University of Indonesia to improve diagnosis and access to treatment. In June 2001 there was a visit to India where generic ARVs were being produced and in November 2001 we visited the GPO of Thailand. In 2002 our National Movement for Access was started with imports of generic ARVs from Indofarma.

In 2003 there was the Yogya roundtable meeting of NGOs in ASEAN countries. In December 2003 the WHO started its 3x5 programme and the local pharmaceutical industry began ARV production. In 2004, 25 hospitals distributed ARVs but by 2007, 237 hospitals were using locally-produced ARVs.

Before the 3x5 programme there were limited services mostly in big cities. CD4 and viral load tests were available and we knew about the pattern of opportunistic infection. At the time, 95% of people paid out of pocket for their AIDS-related care. Triple therapy cost about Rp 380,000/month (US$40).

Some of the issues of ARV in developing countries:

- Health infrastructure
- Trained health workers
- Sustainability of ARVs
- Quality of ARVs
- Adherence

Indonesia learned about ARVs from other countries: Brazil, African countries, Cuba, India, and Thailand, and from roundtable meetings in Canberra in 2002 and Yogya in 2003.

Situation in 2003

- Increasing needs
- Some clinical experience
- Availability of generic ARVs
- Government commitment to provide free ARVs
- Local production (capacity 10,000)
- WHO guidelines in limited-resource countries

The first compulsory licences were issued in 2004 for Lamivudine and Nevirapine by presidential decree, which did not allow much time for negotiation. Because we are not a rich country, compensation or royalties was set at 0.5%.

The WHO 3x5 Programme was important support for developing countries with a global commitment to access for all

Challenges

- Lack of support from international donors
- Intellectual property rights issues
- Doha commitment is still not working
- Response from international pharmaceutical companies is negative

Training was done by WHO, government, health professionals, NGOs and hospitals.

Indonesian government policy

- Strong support for WHO 3x5 programme
- Provide national budget (mostly for 1st line ARVs)
- Increase number of ARV providers (hospitals)
- National ARV guidelines (based on WHO guidelines for limited-resource settings)
- Welcome foreign donations (mostly for 2nd line, etc.)

National Guidelines

- 1st line: AZT, 3TC, d4T, Nevirapine, Efavirenz (which in 2007 was still being imported but a compulsory licence for Efavirenz has been issued and local production is in process)
- 2nd line: Tenofovir, Videx, Aluvia

The compulsory licence for Efavirenz was issued by a renewal of the presidential decree in March 2007, adding Efavirenz.

Almost all 1st line ARVs are produced in Indonesia. Local pharmaceutical production capacity is 800,000 bottles/year. At present, 25% of this capacity is used.

The national pharmaceutical organization Kimia Farma, besides local production, also provides warehouse and distribution (41 branches in 33 provinces). It also supports imported drugs such as methadone for harm reduction programmes.

2nd line ARVs are provided by the Global Fund. We are considering issuing a compulsory license because we do not want to be dependent on international manufacturers. For example, last year we experienced a freezing of funds from the Global Fund.

Funding for the 1st line ARVs comes from the national budget with some support from the Global Fund while 2nd line ARV funding comes entirely from the Global Fund. Indonesia provides free ARVs for all those who need them.

Achievements

There are 237 ARV providers (hospitals) in Indonesia. They have put 10,000 people on ARVs but hope to achieve 30,000 by the end of 2008. More than 95% of those on ARVs are on first line drugs.

Challenges

- Freezing of Global Fund
- Interrupted supplies
- Significant increase in national budget for ARVs
- Low level of support from international donors for ARVs
- Quality control of local production (studies show high efficacy)
- Sustainability of local production (raw material sources and budget)
- Complexity of WHO pre-qualification process
- Pressure from international agencies against local production

Opportunities

- Collaboration among ASEAN countries (government and NGO) and among 8 developing Muslim countries (Bangladesh, Egypt, Indonesia, Iran, Malaysia, Nigeria, Pakistan and Turkey)
- Unused local production capacity

CL Implementation : Achievements and Challenges – Thai Experience

Dr. Vichai Chokevivat
Chair of CL Implementation Committee,
Chair of the Board of Government Pharmaceutical Organization Board, Thailand

CL in Thailand did not happen overnight. In 1995 the US tried to force Thailand to make amendments to its 1979 Patent Act with the objective of making the Patent Act cover product patents. The amendments also sought to extend exclusivity from 15 to 20 years. Thailand, led by Professor Samlee Jaidii ("kind heart"), at that time head of the Drug Policy Group, fought these changes.

In 1990 the US downgraded Thailand from the Priority Watch List to Priority Foreign Country. In 1992, after a military coup, Thailand amended its Patent Act as the US demanded. This was eight years before the changes would have been required by the WTO.

Some elements remained in the Patent Act even after the first amendment in 1992, largely as a result of the NGOs. There was still a Committee on Patented Drug Price Control and a technology transfer requirement. However, the committee never met and there was no technology transfer. And after a second amendment was forced on Thailand in 1999, the Committee on Patented Drug Price Control and the technology transfer requirement were eliminated. What remained was Article 51: the right of the Thai government to issue compulsory licenses for government or public non-commercial use. The first reason why this article remained in the Act was that the text of the article was in line with the flexibility principles of the TRIPS agreement so it was allowed to remain in the law. I also believe that the US government thought that the Thai government at that time was very submissive and obedient to them; they might be wrong.

On November 29, 2006, the Thai government issued its first CL on the ARV Efavirenz. On January 24, 2007, a CL was issued for the 2nd line combination drug Lopinavir/Ritonavir. The next day, on January 25, 2007, a CL was issued on the heart disease drug, Clopidogrel.

Historically January 25 is a very important day for the Thai people. On January 25, 1592, King Naresuan conquered the Burmese army which brought about the independence of the Ayutthaya Kingdom for the next 175 years. January 25 is also Thai Army Day.

Now Efavirenz is imported. The first batch was 66,000 bottles and the second batch was 100,000 bottles. The price was reduced from 1,400 baht per bottle to 650 baht and is now 615 baht per bottle as a result of currency changes. Maybe the price will be reduced even more for the third batch, because CL opened the opportunity for competitive generic prices.

The first batch of Lopinavir/Ritonavir from Abbott was for a six-month supply. The price was reduced from almost 9,000 baht per month to less than 2,000 baht per month. Abbott reduced the drug from US$2,200 to US$1,000 for developing countries and US$500 for least developed countries (LDCs). We tried to negotiate with Abbott a reduction to US$500 for Thailand but failed.

The first order of Clopidogrel was for 2 million tablets. We estimate our need at 20 million tablets per year. The price was reduced from 70 baht per tablet to 1.06 baht per tablet. This price reduction saved the Thai government 1,330 million baht.

The Thai government encountered many problems but also gained a lot of support. Twenty-two Members of Congress sent a letter to the US Trade Representative (USTR) demanding that it respect Thailand's CL actions. The response from the USTR admitted that "We have not suggested that Thailand has failed to comply with particular national or international rules". We prepared a white paper that includes this letter. The WHO Director-General also confirmed, in a letter to the Minister of Public Health, Thailand's right to issue CLs.

The following were key factors in our attempts. In 1999 NGOs and PHA groups first asked the MoPH to issue a CL. They organized a protest and stayed 3 nights in front of the MoPH asking for a CL on one product. However, there was no response from the MoPH at that time, for a number of reasons. But then, a number of key factors fell into place that facilitated the CL. Minister is very knowledgeable and experienced in working with the poor; he is also very decisive. The civil society network is also very strong and could rely on support from people outside the country such as Dr.James Love.

The Thai government has also prepared well by thoroughly studying national and international laws and experience, consulting with all concerned persons, including many lawyers, and creating international links. The MoPH made the decision on our own responsibility according to Article 51 of the Patent Act. We did not ask permission from the Cabinet as we believed we may not get a 'yes' because some government ministries, such as Commerce or Foreign Affairs, may not approve of CLs, since they would fear it would disturb trade or international relations. These people never saw poor patients. They normally attend cocktail parties and so don't know how much people suffer.

The key strategy used in our approach was learned from Professor Prawase Wasi, who is a very important strategist in Thailand. He is a medical doctor, but has been involved in political reform in Thailand. A long time ago he suggested this strategy to use when dealing with difficult problems. It's called the "Triangle that moves the Mountain."

There are three components to the triangle: knowledge and evidence; social support and political commitment.

All actions need to be based on knowledge and evidence; hence issues need to be clear and well understood. In Buddhism this is 'right understanding'. We need to know what we are going to do, the consequences of our actions and the challenges to be faced. Social support from the people is necessary. We need to inform people and learn from them. We cannot just go by ourselves; we needed support from the people. Then we have to push for political commitment. In this case, we could discuss with the Health Minister as he is the key person to make decisions. We followed this strategy.

The key concept in our approach was, "soft but firm." We should be gentle and humble. We don't need to have a loud voice but we need to make a strong and firm decision.

This approach is in line with the Thai identity which consists of: love of freedom, non-violence, and preference for coordination and cooperation.

Usually Thai people think they cannot work in teams, but in reality, they can coordinate very well because we are an extremely receptive people. So the concept of soft but firm is in line with our identity; we just have to follow the concept.

We have learned from our past experience. An example is the 40-year campaign on tobacco control. The first 20 years of the campaign was called the 'anti-smoking' campaign and met with little success, because the smoker was looked on as an enemy. Then the name of the campaign was changed to a 'no smoking' campaign which has had satisfactory success. The view of the smoker was changed from an enemy to a friend who needed help.

Now we are in a world of globalization and in the information age. Public relations are important. Therefore we must be proactive and not reactive. We anticipated a lot of problems after the first CL so we prepared the White Paper (first in Thai, then in English). If you start with writing, then you can make everything very clear. Many organizations came and asked many questions; we could answer them with reference to points made in White Paper.

Another form of proactive public relations was our visit to the World Health Assembly (WHA) where we met many kind people who asked many questions. We also made two trips to the United States. We went to many places and met with friends and others who did not agree with us. We met with the Clinton Foundation in their Harlem headquarters. Their offices are very humble and not expensively furnished. This was very impressive.

We went to the Office of the US Trade Representative. They asked many questions and after 30 minutes of discussion, the Deputy concluded that what the Thai government did was reasonable.

But when we met with the Secretary of the Department of Commerce, they had different views and were not as nice. We felt that they work only for the pharmaceutical companies and not for the people of the United States. Abraham Lincoln said the government should be of, for and by the people. But the Department of Commerce just works for the pharmaceutical industry.

The pharmaceutical industry condemned us for destroying R&D. But when we answered their questions, they apologized. I think that they told other organizations that we are soft but firm.

We briefly met with Democrats and Republicans from both the Senate and the House of Representatives. Because there was little time and no space, we sometimes had discussions in corridors, in front of Thomas Jefferson's picture. So we feel we have support from President Jefferson.

Before the CL, we tried hard to negotiate with the pharmaceutical companies but failed. When I was Deputy Director-General of the Communicable Disease Control Department, I chaired a committee to buy some patented drugs for opportunistic infections at a discounted price. But the pharmaceutical companies would not reduce their prices since they had a monopoly.

The price was 270 baht per tablet. After their monopoly was eliminated the price was reduced to 10 baht, a reduction of 27 times.

There are criteria for the selection of drugs for government use. We will not issue CLs for all products, only essential medicines. For example, we do not need a CL for erectile dysfunction or acne drugs. We have criteria which we follow. The medicine must be listed on the national drug list. It must be necessary to solve important public health problems, or necessary in situations of emergency, extreme urgency, for the prevention and control of outbreaks or epidemics and for saving lives. Low price generics must also be available. There must be significant benefits over existing drugs. Lifestyle or cosmetic drugs are excluded.

Quality Assurance of Government Use Drugs

- WHO-prequalified products
- Tested by Department of Medical Sciences
- Thai FDA approval/registration (which is difficult to get)
- Tested by GPO
- Post marketing surveillance

After negotiating for 1 and a half years, the CL announcement brought many pharmaceutical companies to the table, e.g. MSD, Abbott, Roche and BMS.

A patent is not a property. It is a right that a state or global community grants to a patent holder to promote invention for human good. Such a right must therefore be flexible, internationally called flexibility by the WTO.

We have to stand firm on our national dignity and lawful right to compulsory licensing to protect our citizens and ensure that they will have sustainable access to the health security for all.

We don't fight with the pharmaceutical companies. We don't think we are winning; we just think we are doing our duty to make essential medicines available to the people. When I was interviewed by Al-Jazeera, I was asked if we were winning. I said no, we just think we have done our duty.

Compulsory License Implementation in Brazil : Achievements and Challenges

Gabriela Costa Chaves
Pharmaceutical Researcher, Brazilian Interdisciplinary AIDS Association

The Brazilian Interdisciplinary AIDS Association was created in 1986 by professionals, PHA and those committed to face the epidemic. Its aim is to mobilize society to overcome HIV/AIDS and to monitor public policies on health, education, treatment, prevention and human rights. BIAA's mentor, Betinho, said, 'AIDS is not only a disease or a health problem, but also a cultural and political problem that demands a response from different sectors of society.' This reflects the views expressed by the Thai movement.

Patents became an issue in the AIDS movement in Brazil in 1999 due to the cost of medicines. In 2001, a case was filed by the US at the WTO against Brazilian patent legislation, specifically related to compulsory licences. Since then, civil society has been involved in pressing for implementation of the TRIPS flexibilities.

In 2001, the Brazilian Network for the Integration of Peoples (REBRIP) was created, a network composed of several NGOs and social movements which monitors FTAs for their impact on public policies and people's lives. It is organized in Working Groups on various issues including intellectual property.

ABIA coordinates the Working Group on Intellectual Property (WGIP), composed of several organizations in different regions in Brazil including a consumers rights NGO, a human rights NGO, the National Association of Pharmacists, Oxfam and MSF. It aims to monitor and minimize the negative impact of the patent system on access to medicines in Brazil.

The legal situation on access to medicines starts with the 1988 Federal Constitution which guarantees the 'right to health for all Brazilian citizens'. This was a hard-won right. This formed the basis of the Unified Health System in 1990 which guarantees access, universality, non-discrimination and community participation. With respect to HIV/AIDS, the Sarney Act (1996) guarantees treatment to all, including ARVs and treatment for opportunistic infections. In 1996 a TRIPS-compliant Patent Act was passed. A National Medicines Policy and Essential Drugs List came out in 1998. The Sarney Act was important in promoting local ARV production and, because of the lack of patents on pharmaceuticals at that time and the existence of local laboratories, generics could be produced at cheaper prices.

Some flexibilities were included in the 1996 Patent Act, including compulsory licences and

the prior consent of the Ministry of Health in granting patents for pharmaceuticals.

There were also some problems. One is a limited use of the transition period allowed by TRIPS to grant patents to pharmaceuticals. Pharmaceutical patents were granted from 1997 onward. This had the implication that we could not develop local capacity in generic production. Also, since the 1980's there had been pressure from the US and a pipeline mechanism was set up. This worked as follows. For 1 year (1996-97) patent claims were accepted for products which had been granted patents in other countries. These claims were not examined in Brazil. This led to patents with a lack of novelty. Pre-grant opposition exists in very limited way. Parallel imports were not fully implemented.

There were 3 phases of compulsory licences in Brazil. At first compulsory licences were used only as threat in government negotiations over price with pharmaceutical companies. ARVs were a significant burden on the government budget and local production capacity gave us the information on the real cost of production. Some important reductions were achieved. In 2003, the same tactic was used, since 3 ARVs accounted for 63% of the government ARV budget. Civil society did not consider the use of compulsory licences as a threat was sufficient.

Step two was in 2005 when the government declared a public interest over Lopinavir/Ritonavir. But there was a setback when the government signed an agreement with Abbott not to issue a compulsory licence, in return for a fixed price until 2011. This agreement was heavily criticized by civil society. The WGIP considered turning to the courts as a mechanism to protect collective rights. In 2005, the courts were asked by civil society organizations to rule against the government and Abbott and to require the government to issue a compulsory licence. The judiciary did not respond favourably to the claim, arguing that it would invite retaliation from the developed countries and pointing to the local lack of capacity to produce drugs. WGIP and MSF produced a technical study proving that the local capacity did exist. The findings were supported by later studies by the Clinton Foundation and UNDP.

The third phase from 2007 has seen full implementation of compulsory licences in order to procure cheaper medicines. By the end of 2007 there will be 75,000 patients being treated with Efavirenz at a price of US$580 per year since 2003. The precedent of the Thai government was important because they had been offered US$228 after the compulsory licence. Government negotiations with Merck were met with an offer to reduce prices by 2% only. Efavirenz was declared by the government to be of public interest, a move supported by civil society, and finally the first compulsory licence was issued in May 2007. Local capacity is being developed, while generics are being imported from India.

Lessons learned

- Important precedent of the Thai government both for using compulsory licences and facing pressure
- Strong support of civil society, domestic and international, and government officials, especially the new Minister of Health
- Pressure in the mass media against the compulsory licence, arguing a lack of local production capacity and poor quality of imported generics
- A Q&A publication copied the Thai white paper used to provide public information about the measure

The battle is only beginning and there are still several challenges in implementing TRIPS flexibilities. Civil society needs a continuous commitment to monitor ongoing problems related to patent issues and new medicines. Booklets and documents in easily understood language have to be produced.

Another ongoing challenge is the implementation of public health TRIPS flexibilities both on a product by product perspective and for the entire system. It is not easy to find the status of patents. Then we have to consider pre-grant challenges and public education in each case. If a decision to seek a compulsory licence is taken, then we need to build popular support and production or import capacity.

But there is a need to improve the system. At present there are 1,182 pharmaceutical patent claims in the pipeline system in Brazil, which are being extended by the courts because patents have been granted elsewhere, although they have not been evaluated. The major problem for the government is that patents were granted through the pipeline system. So a bad decision in the past is causing present problems.

Ministry of Health prior consent can analyze patent claims from a public health perspective and can therefore eliminate non-innovative claims. However if the Ministry of Health prior consent conflicts with the view of the Patent Office, this fact is not made public and no competitor product can be introduced, since the patent remains in a 'pending' state.

Therefore in 2006, the WGIP presented information for the Patent Office to use in denying a patent to Tenofovir for lack of inventiveness and in dividing the patent claim for Lopinavir/ Ritonavir since the first drug was a 'pipeline' drug. However, since patent applications are dealt with in a 'black box', there is no way of guaranteeing success.

The Patent Office is also reviewing its guidelines for pharmaceutical patents. There has been a non-transparent process reviewing second use of polymorphic forms. However, we know that the pharmaceutical companies are participating fully in these discussions. Civil society participation has been rejected. The review is also trying to weaken the role of prior consent by the Ministry of Health.

Another problem is a bill introduced last year to include a linkage between patent and medicine registration, a TRIPS-plus measure. This is being processed quietly in the legislature and we are trying to monitor this

Challenges

We need political will, social support and technical information. This will be helped by south-south cooperation, and a discussion of the most suitable alternatives in the context of developing countries.

Dr. James Love
Knowledge Ecology International

The TRIPS agreement itself does not use the term compulsory licence; it uses other phrases to describe the use of a patent without the permission of the patent owner. The Paris convention did use the term compulsory licensing. The term compulsory licensing was used in the 2001 Doha Declaration, and the 2003 WTO General Council decision regarding the Doha Declaration.

The language can be confusing. There are many ways you can use a patent without the authorization of the patent holder. There are many names for it in different national laws: ex officio licences, government use, crown use, public interest, etc. Compulsory licensing is used as a shorthand term to describe these various ways in which the government wants to override legal patent monopolies.

Within TRIPS itself, there are different provisions related to medicines.

In the section on patents, Article 30 is a general agreement that exceptions can be created to patent rights if there is some form of reasonable balancing test. That may or may not involve payment to the patent holder. Any CL regime could be implemented under this Article.

Article 31 sets special provisions relative to patents in the form of procedural rules, which, if followed, makes the action automatically legal under TRIPS. The certainty of the Article 31 remedy is therefore often preferred.

Important in pharmaceutical patents is disclosure of test data, which is dealt with in Article 39 which makes no reference to compulsory licensing. Some governments use the compulsory licensing of data in, for example, agricultural products.

Article 40 deals with control of anti-competitive practices in contractual licenses and gives very strong authority to governments, notwithstanding any other TRIPS provision, to control abuses of licences and patents. This is a very important provision often ignored because it is not in the patent section. It applies also to data, copyright and other rights of the TRIPS agreement.

Article 44 deals with injunctions and it is being recognized that these provisions are very important. Little attention was paid to this until a 2006 US Supreme Court decision requires US judges to consider compulsory licences as an alternative to the enforcement of an injunction in every form of patent. So there is now a defact to right of anyone who infringes a patent to request a compulsory licence as an alternative enforcement of the legal remedy. This has caused a review of this provision to understand how this was possible.

Some recent state practice for compulsory licensing

Italy

Since 2005 Italy has issued three compulsory licences on pharmaceutical products. In February 2005 the Italian competition commission (AGCM) began an investigation into refusals to license patents to an Italian company that manufactured active ingredients for antibiotics by two large companies (GlaxoSmithKline and Merck). The first case was resolved in 2005, with a compulsory licence on Merck patents on an antibiotic important for treating infections in hospitals. In the US we have 90,000 deaths per year as a result of infections in hospitals, about 5 times the number of deaths from AIDS, so the problem is serious.

In February 2006 AGCM issued a compulsory licence on the GSK patents on a product used for migraine headaches. In the press release they emphasized their efforts to reduce the delays in bringing generic drugs to market to pave the way for substantial price reductions.

All three compulsory licences were initially designed exclusively for the export market to France, Spain and other European countries. Patent protection for the Italian domestic market is longer than for other countries in Europe. The Italian government wanted its local manufacturers to be able to produce and sell to other countries even though it couldn't sell in its own domestic market. This was outside the framework of the August 30 WTO decision where the EU countries had opted out as an importer. So the exports were authorized under the much more liberal and easier rules as a remedy to anti-competitive practice. The Italian cases show how foolish the 30 August 2003 decisions were, by showing how easy it is to solve export problems without crazy procedures. It's as if there are 2 procedures. One for developing countries, which is quite supervisory and intrusive and requires notification to the TRIPS Council of licences and so on, which imposes a lot of costs on companies. And then there is a simple method that European and US companies use when it's convenient.

In another case, Merck was judged in March 2007 to have violated its patent rights for a drug used for prostate conditions and male pattern baldness. As this was the second violation by Merck in two years, the royalties paid were zero. This was a punitive measure, legal under TRIPS, against the abuse of patent rights and anti-competitive practices. Again this was for the export market.

This should be shown to the pharmaceutical companies who claim that compulsory licences can only be passed in emergencies.

Germany

In 2000 Chiron of California sued Roche of Switzerland for infringement of its patent on a blood screening HIV probe and lost. Roche filed for a compulsory licence in Germany. This occurs commonly in Germany where the public has no right to the court file. After settlement, the files are destroyed. If an infringement suit is successfully defended it is routine to file for a compulsory licence. In this case, the data was revealed by Chiron in its filing with the US SEC. In 2001 in return for a licensing agreement between the two companies, Roche agreed to discontinue its compulsory licensing attempts. Roche used a compulsory licence to get a licensing agreement from the patent holder.

France

The government amended the patent laws to make it easier for them to issue compulsory licences (ex officio use) on patents on BRAC 1 and BRAC 2 breast cancer tests and other diagnostic tests.

Belgium

Belgium modified its patent law in 2005 in a similar way.

Europe

Europe has mandatory compulsory licensing of patents on genetically modified plants in its 27 countries. The EU did this in order to extend patent protection on bio-tech agricultural inventions. Because Dupont and Monsanto were big holders of patents, the EU wanted to protect their plant breeders. Upon payment of a fee, governments must grant compulsory licences if plant breeders ask for them. The plant breeder has absolute rights under this law. If they ask for a compulsory licence, the government has no choice, it must be issued. The European Commission claims this is consistent with the TRIPS agreement including provisions against discrimination on fields of technology. They claimed this does not constitute discrimination, just differentiation.

Avian Flu Cases

Many countries declared compulsory licences on Tamiflu. In some countries there were no patents on Tamiflu, so no compulsory licences were issued. However, some countries did have patents. These countries, including Korea, China, Taiwan, Argentina, the US, Canada and Indonesia, issued or threatened to issue compulsory licences on patents related to generic Tamiflu production. The US threatened a compulsory licence unless Roche re-located production to the US because they feared that in a pandemic, no one would allow exports. So Roche agreed to do that. The US also insisted that much of the WHO stockpile be located in the US even after it was announced that these supplies would be seized in an emergency.

In 2006, the Centre for Disease Control threatened to use a compulsory licence on patents for reverse genetics for Immunex, which were largely government-funded inventions. The US insisted on zero royalties for its own stockpiles of the avian flu vaccines.

South Africa

In the 2003 Hazel Tau/TAC competition cases, Hazel Tau alleged excessive pricing of several AIDS drugs (3TC, AZT, 3TC+AZT and NVP) and the competition authority ordered a compulsory licence based on a refusal to license and denial of access to essential facilities. The case was settled with a 5% royalty, and licences to several companies and the right to export to the sub-Saharan African market. In the case of excessive pricing, there was a test which is whether or not the price is excessive in South Africa. The document was complicated but one essential was that if an item can be copied, like a drug, or software or other intellectual property, then there was a special standard of pricing. There should also be a difference between essential and non-essential goods. For goods that could be copied and were essential, the rule was

that the patent-holder had to licence it unless they could demonstrate that the price was affordable for most people in the country. In South Africa, the price was clearly non-affordable for most people, therefore it was illegal not to licence the patent. I think every country should have this rule. If a producer can put an item into the market at a price that most people can afford, that would be a defence.

There were 2 controversial cases in southern Africa. In May 2004 in Mozambique, the government declared a national emergency and paid 2% royalty fees after issuing a compulsory licence. It turned out that Cipla had a patent on a 3 in 1 version of an AIDS drug. This went awry since the company that was going to manufacture under the compulsory licence was the biggest supplier of raw materials to Cipla, and decided not to pursue the case.

What was useful about this case was the compulsory licence was short and easy to understand. When other countries saw how easy it was, they were more prepared to follow suit. The compulsory licensing process was demystified.

Dominican Republic

On the other hand, there are fewer compulsory licences in Latin America. The compulsory licence on Plavix in the Dominican Republic was aborted because of a letter written by the French government. There are many cases where compulsory licences were not used for fear of trade repercussions.

Article 44.2 : Injunctions

Article 44 of TRIPS deals with enforcement of IP rights for patents, copyrights and other intellectual property. TRIPS does not require even the possibility of injunctive relief to enforce the exclusive rights of a patent. Governments or third party users are required only to provide adequate remuneration for usage rights.

If a government follows Article 31 and issues a compulsory licence for governments or third parties authorized by governments or others, it can limit the remedy to just payment of compensation. The US goes beyond this. In the e-Bay decision, a judge, not the government, authorized the use of a patent, which is not covered in the first part of Article 44.2. We thought may be the US had violated the TRIPS agreement by allowing judges to issue compulsory licences independently of the provisions of Article 31 of TRIPS. But the last part of Article 44.2 says that in other cases where the remedies in the first part are inconsistent with the law, (remedies in the first part means having to give the possibility of injunctions, and an injunction means preventing patent holders from using a patent) declaratory judgements and adequate compensation should be available. The Article says that if your law says you do not have grant injunctions, then you don't, but have to pay compensation to the patent-holder, the plant-breeder, the copyright owner, etc. For plant breeders and copyright owners, there is no Article 31 provision. In such cases there is no injunctive relief in the US. Most people had never focussed on this provision. It says that if someone has a patent or copyright, and you let someone use it, you have to give them money, but it can still be used.

Recent US decisions under Article 44

In 2006 Microsoft was sued for patent infringement on Digital Rights Management, used to protect their software from piracy. So they had to pirate one piece of technology to protect their product from piracy. The courts agreed with Microsoft, which was granted a compulsory licence by the court to use two patents to protect their product from piracy.

Also in 2006, DirecTV, for US$1.60 per device, is allowed to use patents on the decoders by a compulsory licence.

In August 2006, the court granted Toyota a compulsory licence on three patents on hybrid transmissions on a car that costs US$20,000-30,000. The royalty is $25 per vehicle.

In September 2006, Johnson and Johnson were granted a compulsory licence to use patents on medical devices for angioplasty.

At about this time, Abbott asked for a compulsory licence in the US, but lost its case. So while Abbott was complaining about a Thai compulsory licence on their product, they were trying to get a compulsory licence in the US.

India

It is mandatory to grant compulsory licences to products manufactured before the change in the patent law. There will be many cases when the patent law is finalized and it will be interesting to see what the royalties are in those cases. It is interesting that they are mandatory. In Canada there is a very complicated system for using the export provision. In India it is simply mandatory. If you are trying to supply Thailand with a drug from India, the government has to give the generic manufacturer a licence to supply your market. This is a simple, short way of implementing Article 6 of TRIPS.

New thinking on compulsory licensing

- Think of grounds for compulsory licensing that focus on outcomes, such as:
  - Do patients have access to products?
  - Are prices reasonably affordable for most people?
  - Are patents necessary for a new product such as a fixed dose combination or a better delivery method?
- Consider mandatory licensing approaches
  - Move toward a patent system as a liability rule or a claim for remuneration, so patents would be valuable as a source of money, not complete control over the use of an invention
- Reform remuneration methods to reflect the value of an invention in improving health outcomes and budget constraints
- Use collective management of IPR
  - Patent pools for entire groups of patents rather than a case-by-case approach. This attacks a policy issue in a systematic way and becomes less political since individual patent holders are not singled out. A decision affecting an entire class of drugs would attract as much publicity as a compulsory licence on one drug
  - Prize-type rewards, instead of exclusive marketing rights

- New business model for licensing
  - Separate the market for innovation and the market for product (break the link between the R&D incentive and the price of a product)
  - Eliminate monopolies on products
  - Create funds for innovation rewards that are based on a fixed negotiated percentage of the drug purchase budget.

Question and Answer Session

Prof. Baker: Is it best to settle on price concessions alone or are there compelling reasons for collective action by developing countries to develop competitive generic markets, even when pharma offers price concessions? For example, Brazil got locked into a bad deal by negotiating solely on prices. The drug companies are interested in locking countries into long-term price agreements as a way of freezing out generic competition and keeping developing countries' markets fragmented.

Thai Ministry of Foreign Affairs representative: (For Mr.Weissman) Do the Democratic presidential candidates, especially Clinton, support medical access for all? What is the opinion of the American public on compulsory licensing and this campaign? If they support it, does that mean the public is against the Bush administration? *(For Dr.Vichai)* If there is pressure from the developed countries and the US decides to boycott Thailand in some way, could you assure the Thai public that the compulsory licence would not be lifted in the future?

Mr. Weissman: Thailand's compulsory licence is not a huge front-page controversy in US. Most Americans have no idea a compulsory licence was issued in Thailand. Members of Congress know. It is not trivial but it is not a broad public issue. The Wall Street Journal did a survey and found that by, I think, 2 to 1, Americans support Thailand's compulsory licence. There is a great deal of antipathy toward brand name drug companies in the US. There is a lot of support for innovation and new technology and a desire for new cures for diseases but there is also, based on experience, great anger at pharmaceutical companies for high drug prices. It is a front page issue in the US about parallel importation from Canada which has overwhelming support. People are in general very ready to be critical of the brand name companies, and there was quite substantial support for the Thai case. If Americans were aware of what was happening in Thailand there would be overwhelming support.

Mr. Love: We spend a lot of time talking to Members of Congress about trade policy. On the presidential side, if any of the Democrats get elected, it will be very good for Thailand. For the Republicans, McCain would be good for Thailand as he is good on pharmaceutical issues. It will be bad if Giuliani won because he was a lobbyist for Big Pharma. Congress is going to be more Democratic and the trade committees will be supportive of Thailand. What could be problematic are the remuneration royalty rates; they are very low and it is difficult to defend a rate of 0.5% of the generic rate. Plavix went from 70 to 1 baht. This makes it very easy for Big Pharma to criticize the Thai government.

Dr. Vithaya: We need to look from a civil society perspective. The US said that the Priority Watch List decision was not based on the compulsory licensing issue. It is hard to determine the reasons for US government reaction or decision.

Mr. Nimit: It is argued that compulsory licences discourage future R&D. In countries with high levels of compulsory licensing, such as the US, is this the case?

Mr. Love: When drug companies make R&D decisions, they don't think about the Thai market. High income countries (like Japan) are what drive the R&D. Collectively the sales of AIDS drugs in the developing countries are small but are becoming a more significant part of the overall Big Pharma market. Big Pharma is concerned about Thailand, China and India; a 5 billion people market moving in the direction of compulsory licensing. They are not thinking about 2007, they're thinking about 2027. In the short run, Thai compulsory licences have zero effect. In the long term, 5 billion people make a difference about the rules. As your income rises, there will be pressure on Thailand to pay. The question is what would be a good outcome in these negotiations in terms of low-income countries' contribution to R&D costs. A price that 80% of the population cannot afford is morally repugnant. That's why the IGWG discussion on new models of innovation and access is so important. We want to reject monopolies imposed in developing countries and come up with a different business model for paying for innovation that is consistent with universal access.

Mr. Weissman: Some companies said they wouldn't locate investment here or would change their R&D. Neither of these is true. Decisions on plant location and type of R&D have nothing to do with national rules on patent protection. If Thailand is an attractive place to do production and R&D for the global market, it is irrelevant if there is patent protection locally. Big Pharma is in a crisis from their own point of view; very few new products are in the pipeline. Rich country markets are expanding only slowly. There was recently an expansion in the US market for pharmaceutical coverage for senior citizens and that is the last big growth opportunity in the rich countries. Their new growth markets are in the middle income countries; that's where they see 15% returns on investment.

Prof. Baker: Other departments in the government are not as supportive of universal access as health agencies. How can we generate political pressure so that parliaments do not undo what public health agencies think is vital, or departments of trade do not get cabinets to reverse decisions? This is a problem in Brazil, the US and Thailand. How can we create a broader consensus on these issues with other departments?

Dr. Vithaya: In Thailand there is a plan to communicate with the Ministries of Foreign Affairs and Commerce, who are attending this meeting.

Mr. Love: Thailand was the first to issue a compulsory licence on a 2nd line ARV and the first in the developing countries to issue a compulsory licence on heart disease drugs. What Thailand did was very important. It is important to go beyond 1st line ARVs. This puts pressure on Brazil as well. It forced the issue about drugs outside ARVs. The global community is in debt to everyone in Thailand's social movement. They dismantled the monopoly on fluoconozole and the challenges to patents on ddI and Combid; this was due to the

contribution of Thai academics, legal experts, pharmacists, etc. Any request you make for cooperation will be granted because Thailand has been crucial for success.

Mr. Weissman: One of the ways to overcome political pressures from other government agencies or other forces in society is to force the issue by acting, to communicate directly with the people, opponents or presumptive opponents, and they can be moved, as even the USTR was moved through conversations with civil society. Thailand has created an opening for other countries. Other countries have a duty to push the agenda as much as possible so that Thailand is not just an outlier. The best way to show support would be for more compulsory licences to be issued, and to move to systems that make compulsory licences more routine and develop systemic ways to deal with access to medicines and the management of patents and intellectual property questions.

Dr. Vithaya: In the beginning we were afraid about whether what we did was good or bad. But the information that we have received from all over the world has confirmed what we have done so far. Compulsory licensing is a means, not a goal. Not a victory, but a duty. It's an effective tool not a panacea. Compulsory licensing is a magic drug that can treat the lack of access to medicines. Compulsory licensing balances in economic terms the externality which creates the negative consequence of drug patent monopolies, which delay or impede access to medicine of vulnerable people. This is not just about saving costs or saving lives but saving mankind.

Production of Life-Saving Medicines

Moderator: **Dr. Niyada Kiatying-Angsulee**

Speaker

1. Successes, Lessons Learned and Challenges in the Production of Life-Saving Medicines in Africa
   Dr. Krisana Kraisintu
2. Improving Access to Quality Essential Medicines through Strengthening Local Production Capacities
   Dr. Witit Artvatkun
   Former director of an autonomous hospital and now Director of the Government Pharmaceutical Organization
3. Improving Access to Quality Essential Medicines: Industry's View
   Mr. Rachod Thakolsi
   Thai Pharmaceutical Manufacturing Association
4. Improving Access to Quality ARVs in Developing and Least Developed Countries
   Mr. Atul Chabra
   Manager, Central Institute, Ranbaxy ARV Business
5. Brazilian Policies on ARV Universal Access: the Role of Local Production
   Dr. Carlos Passarelli
   Former Deputy Director, National STD and AIDS Programme, International Cooperation Advisory of NAP, Ministry of Health, Brazil

Moderator

Dr. Niyada Kiatying-Angsulee
Faculty of Pharmaceutical Science, Chulalongkorn University

The two objectives of this session are to explore the availability of generic medicines and to identify strategies of cooperation to develop the local generic industry

Successes, Lessons Learned and Challenges in the Production of Life-Saving Medicines in Africa

Dr. Krisana Kraisintu
Health and Development Foundation

(This is a summary translation of a Thai-language presentation)

Sub-Saharan Africa has 42 countries, mostly poor, with 900 million people. 50% are too poor to afford medicines. In the east, central; and west parts, the infrastructure is different. The east is better since they were formerly British colonies. Former Belgian colonies occupy much of the centre where the situation is not as good, but the countries in the west are worst. They produce 8 kinds of medical product, including raw materials for drugs, excipients, antibiotics, biotech products, blood products, herbal medicines, finished products and sterile products.

In Africa, apart from lack of finance, there is also a lack of Drug Regulatory Authorities, so a lot of substandard drugs can be expected, since there is no testing. So the important thing is to set up local production, which is a long term solution. Since 2002 we have been saying there must be local production. In east Africa there is some which needs to be improved. If there is no production it must be created.

The first country I went to is presented in the book *Gypsy Pharmacist* – the Congo. I started there in 2002 and finished the project in 2005. The reason it took that long was the constant fighting and conflict. We started from planning the factory, and supervised the construction. We taught production until they were self-reliant. I asked the owner of the factory where he wanted to build and he pointed to the top of a hill where there was nothing except one tree. I didn't know that we had to start with construction. I might have second thoughts, but I have no reverse gear and I had to go ahead. Finally it was finished. The lower part is a clinic and diagnostic centre. The upper part is the production facility.

You have to forget WHO pre-qualification standards. In Africa they are not relevant, because the only goal is to produce life-saving drugs. There was only one HPLC in the whole country, even though the country is 9 times bigger than Thailand. Usually qualifications were at the bachelors degree level.

The first pill we produced was Afri-vir, an antiretroviral cocktail drug. The opening ceremony was full of dignitaries, including the twin sister of the president, who was a target. This plant was operated by 10 staff, taking care of 30,000 patients in the eastern Congo. The villagers had to pay, but at very low rates of €14 a month.

My second country was Tanzania, where we worked to renovate a 40-year-old factory. It was quite difficult. I learned that it is easier and cheaper to build new than renovate. I also spent 3 years there. The company was Tanzania Pharmaceutical Industries. It started as a state enterprise that made losses for many years and was finally sold to the private sector with the government holding 40% of the shares. The project cost altogether US$1m. The drug produced was TT-vir (from Thai-Tanzania). Some of the equipment was bought from Thailand so apart from putting the Thai name on the product we were also able to sell Thai equipment. Other equipment was from India. We also installed a HPLC. This plant has 10 staff. Tanzania

has 2 million HIV-positive and 200,000 who need ARVs. We had to make sure that we were able to talk to the politicians since without their agreement, nothing could be done. Apart from the ARV, we also produced malaria drugs. In the WHO 2003 guidelines, the prescribed drug is artesunate. We produced Thaitanzunate. The cost of a 6-pill course of treatment using imported European drugs is €8, but the local production cost was 60 cents. I was popular among the drug companies, who wanted to kill me for undercutting them. The WHO guidelines cal for an artemisinin combined therapy, which is artesunate plus amodiaquine in a fixed dose combination. They also make a syrup form for children. This was launched in September 2003.

In west Africa, I have been to 6 countries, Gabon, Benin, Burkina Faso, Mali, the Gambia and Senegal of which 5 countries are part of a project of the Ministry of Foreign Affairs. West Africa has a very low level of infrastructure. In these 6 countries, only Mali had a government plant, built by the Chinese, which needed renovation. Senegal had factories belonging to Pfizer and Aventis, and said they did not need local production. I taught making suppositories at a local hospital. Gabon also has a plant but we had to clarify with the government if it was private or public, and if the later we would help. In Burkina Faso, there was a factory, but the government put a high tariff for raw material but a low tariff for finished products, so there was no incentive for local production and the factory was closed.

In Senegal we taught how to make artesunate suppositories, which are also in the WHO treatment guidelines. I made almost 10,000 suppositories altogether.

In Mali, we taught anti-malarial drug and suppository production in quite a modern plant. We saw that Mali had potential. At first sight, the factory was dirty, like a bakery. The project finished last June. People who work in this plant spoke French and I spoke English so communication was difficult, but practical demonstrations were successful. In Mali we produced Thamasunate in 100 and 50 mg. The HLPC was 15 years old and had never been used and it took 2 weeks to make it work. We also produced a fixed dose combination of artesunate and amodiaquine. There was no proper machinery, so we made do.

I was then sent to east Africa. In Tanzania, Ethiopia, Uganda and Zambia I was with private sector people, who were looking for 5 year sales contracts including technology transfer. This was not relevant in Ethiopia because the government had reduced the tariff on raw materials to zero and raised the tariff on finished products to stimulate local production.

The plant in Ethiopia, Bethlehem Pharmaceuticals, was modern but they ran out money. I had to work with the bank to get a loan. They got US$6m in investment.

In Zambia, one company was selected to produce for the Church Health Association of Zambia. Many hospitals in Africa are run by the church. If we get the churches to produce, they can distribute to the various hospitals. I am still trying to raise funds for Zambia to help produce anti-malarial drugs.

In Uganda no private sector company wants to invest. But in fact Uganda is the pearl of Africa, very green. Renee Industries is owned by a 5th – generation Indian and we tried to help in transfer technology, but there is no one in the private sector who wants to collaborate.

In east Africa the infrastructure is there and language is not a barrier. In west Africa, people are fast learners. The thing to do to make things work is to get your hands dirty and do the actual production. If you put money into the government it will never work, because the money will be in the politicians' pockets and will not reach the people.

Improving Access to Quality Essential Medicines through Strengthening Local Production Capacities

Dr. Witit Artavatkun
Former director of an autonomous hospital
and now Director of the Government Pharmaceutical Organization

(This is a summary translation of a Thai-language presentation)

There are 2 views towards the production of medicines for HIV/AIDS. The first view is capitalist; the other is based on a system of merit. These 2 lines of thinking are moving in different directions. Dr. Krisana's presentation was along the lines of a system of merit. I have never seen any TNC taking this line.

I hope no one uses the WHO GMP to arrest Dr. Krisana for producing substandard drugs in the Congo. In Thailand they say there is a lot of money. So the companies try to discredit this line of thinking. Many people have died because they had no access to drugs. I want to show appreciation for what Dr. Krisana has done as an example for younger professionals.

On access and standards, the GPO has not weakened its intention to achieve its goals. We are certified only for Thai GMP, but we do not think that this is in any way inferior. Before Dr. Krisana produced GPOvir, ARVs were very expensive and many people were denied access. Since then prices have dropped and this is her contribution. We have not weakened our commitment and effort despite having only Thai GMP. We have worked with HIV/AIDS patients and learned about their needs and constraints. We have to admit that our technology is not as advanced as in other countries but our moral values are not inferior. Personally I feel that health should not be a business with drugs companies listed on the stock exchange, which means that they have to seek high profits to please their shareholders. To me, this is against medical ethics and our own feelings, so I have resolved that if I have to leave my position, I will never go into business.

GPO is the only state enterprise that produces drugs and other medical products. It was established in 1966 and has sells 2-300 types of drugs and has 2,000 staff. Even though I was appointed as director only 4 months ago, I was involved in some of the CL work of the Ministry of Public Health. I feel that CL is a humanitarian issue.

The GPO is building a new factory in Thanyaburi to get WHO GMP qualification. An e-auction will be conducted in December this year after a long delay. I am committed to getting this plant built to international standards. This plant will produce Oseltamivir.

We are coming out with a new drug, GPO-L-ONE, Deferipone, for thalassemia, in which we have put a lot of effort. The situation in Thailand is that 100,000 thalassemia patients out of 500,000 need blood transfusions and medication.

We are also responsible for making sure orphan drugs are available in all the government hospitals. These are our main tasks, together with research and analysis into natural products. We work with other researchers to use these natural assets.

After I came to my position, we looked at the cost structure and the Ministry's policy is to reduce the prices of GPO drugs. We have started reducing prices, including ARVs. We cannot look only at the bottom line. We also need to guard against epidemics. The price of L-ONE from Europe is 60 baht per pill, from India, 30 baht and from GPO, 3.50 baht.

We also need to build a flu vaccine plant, costing over US$1 billion, to prepare for bird flu. A pilot plant is being set up at Silpakorn University, to be built in 2008, with help from WHO experts. Production will be 2 to 10 million doses per year.,

In the natural product manufacturing project, we are doing research on how to make use of our natural resources.

I believe that there are no safe drugs, since no one takes drugs for fun. We want the Thai people to take care of their health, so health education has to be accessible to all Thais. Prevention is the best policy. Relying on CLs for cancer drugs and ARVs will bring about conflicts. In Buddhism, good health is one's best fortune.

Improving Access to Quality Essential Medicines : Industry's View

Mr. Rachod Thakolsi
Thai Pharmaceutical Manufacturing Association

My presentation will deal with the obstacles to CL implementation, improving access, and strategies to improve access.

The industry view on obstacles to CL implementation is that even though we know that CL is legal, industry is still afraid of possible retaliation from the patent-holders. With respect to our government, we know that our team in government is educative and ready with all of the studies, but when we first heard of the announcement of CL, we were a little worried. The question within the industry was whether it was legal. There was so much on the news in Thailand that there was retaliation, not from the original company but from the US government. For the manufacturers, even though we don't play much role today in helping the country with CL, we are still questioning ourselves how far we can help the government. Even though the government has prepared themselves so well, the retaliation from the US has been so much, how can industry in Thailand cope with this situation? The preparation for the CL in Thailand is more or less government action, so is limited to a select group. Industry did not have much involvement. We don't have much knowledge on the legal side.

In industry's view, to help, we would require some longer-term government policy. We need much more information before we can know how we can help.

With respect to the level of improved access, perhaps it is time to step back and look at how successful we have been in Thailand in improving access. On the price perspective, it is known that most CL announcements have to do with price. The government has a limited budget, so it requires a low price. So the question to the patent-holder is whether they can reduce the price. It is expected that if the price is not consistent with government expectations, there will be a compulsory licence. The question to the government is what is a reasonable price. The answers may not be today. We need to know what the criteria are for setting the price, what is reasonable for everyone and especially what is the role of industry in this. From a product perspective, even though today in the developing countries, the CL announcement is to do with a communicable disease and requires a state of emergency. But as we learned this morning, in the developed countries, it goes beyond that. For most of the products that have patents there would be a reason to declare CL.

If we ask what the next step is in improving access, there are 3 parts to the strategy: long-term strategy; international strategy; and strengthening local production.

At the national level, as with countries around the world, policies change from government to government. We know that today, the government is very willing to deal with CL issues. But we don't know if the next government will be so daring. So it is very important for any country to know whether we have a long-term strategy, a continued approach in the same direction. Thailand last year had a lot of problems with the FTA which is already a high pressure on us, and the CL announcement increased the pressure. Today we have a national CL committee, but we do not know with a change of government whether this will be permanent or still active or whether we will have policy continuity in the future. Sometimes it is awkward that with things that are legal like CL, we are intimidated. We don't know how open and clear our CL policy should be. If possible in the future, it would be good if we can have a watch list of products where we are considering CL, and can share this list openly with anyone. We can declare the products where a CL may be considered in the near future if the success in level of access does not meet our requirements. We need to announce criteria on pricing. I know that the criteria vary from country to country based on the cost of living. But if we can share a price model, and can calculate an internationally acceptable price, CL announcements in the future will be more or less automatic. We will not need bargaining or negotiation, and everyone will know ahead of time when a CL will be announced. We know that CL announcements are legal, but we need to educate the Thai people and have everyone here and abroad learn that CL is normal, the right thing to do. Today, many people in Thai industry still have second thoughts on this issue about whether Thai industry had the support of the Thai government. We don't know the effect on our companies. Many of our companies sell not only locally here in Thailand, but also abroad, and there might be a serious effect on the countries we export to. We also need to prepare the alternative manufacture of substitute drugs. Many times when the government declares CL, they start looking for sources of alternative drugs. But we should prepare even before the CL announcement. If we have alternative sources ready, the original company may have second thoughts and reduce prices before the CL is announced.

In Thailand today, most innovation is done by the GPO who are equipped and qualified to do so. In Thai industry, very few are willing to share the task of innovation. So we need to have some discussion or strategy on this. We need collaboration among developing countries. It would be beneficial to develop a consensus on a wish list. Many of us share the same problems, so maybe the products on the list could be the same.

Internationally we have shared best practice. So far we have not heard much about voluntary licensing, which can sometimes make things easy. We can set common goals and practice, learn from best practice. We can also share price information, opportunities for alternative sources for drugs.

In Thailand, with the signing of the FTA last year, we are aiming to raise standards to PIC/S or WHO/GMP. In the near future many factories in Thailand will be certified, which we see as a gateway to opportunity. We know that to manufacture CL medicines, we need this certification. This helps in improving the acceptance of substitute drugs, improving quality and preparing local production of CL medicines.

To strengthen local production in Thailand, there are already government incentives like Board of Investment tax incentives and this is very helpful. We also have government budget for training programmes for capacity building.

Questions:

Dr. Jiraporn: Why are generic drugs not produced immediately in Thailand after the patent expires? For some drugs, we would expect a generic to be in the market, but there are none. Is this because of limitations in manufacturing capacity? What prevents local manufacturers from starting generic production as soon as the patent expires?

Dr. Witit: Thais react slowly. From my limited experience, I see there are obstacles and difficulties, we lack researchers and analysts. Relatively few people can develop formulae compared with other countries. The delay of trials can be 3 years. We are looking for ways to make this period shorter. We are hoping to get generics for drugs coming out of patent into the market faster. The capacity of production plants in Thailand is OK. The GPO has been carrying a large burden of 2-300 drugs.

Mr. Rachod: Thailand is known to have a very fast launch of a generic after the patent. This was true until the Patent Law was implemented in 1992. When the new Patent Law was introduced, we had a number of problems, especially on patent information. It was very difficult in Thailand to get access to correct information on a patent, even though patent information should be easily available on the internet. Nevertheless we have to follow the patents filed in Thailand and it was very difficult in the past. Today it is much better. This is one of the biggest issues for us in introducing generics quickly.

Dr. Krisana: There should be an agency with the responsibility of acting as an information centre on out-of-patent medicines where companies can seek information. Also a special task force should be set up to produce drugs that are coming out of patent. This is normally a slow process and these two agencies should be set up to accelerate things.

Mr. Weissman: Can you comment on the proposals to privatize GPO and what that would mean for the public health mission of the agency.

Dr. Witit: There is as yet no policy to privatize the GPO but in various fields of management we are trying to set up joint ventures for technology transfer and joint production. The joint venture companies are a model that GPO will use to reform the organization that is at present a state enterprise, to pass more of the burden to the private sector and strengthen it. So this is a form of corporatization or privatization, but it is clearly in the form a joint ventures. But the GPO itself will continue to be a state agency with a basic duty in ensuring sufficiency of medicines needed by Thais.

Dr. Krisana: Privatization is good for developed countries but for developing countries or LDCs, I don't agree with privatization. I don't speak as someone who used to be with the GPO, but there is a need. For example, in Africa there are 54 countries. We surveyed 46 countries and 37 had medicine factories of their own. In only one did the factory belong to the government. When there is a problem, there is no one to rely on. Everyone pins their hope on the private sector. Government facilities can help solve the problem. All countries are trying to privatize, Ghana completely, Tanzania 60%, Zambia completely. If you think in terms of competition, it's good, but in terms of essential drugs for the people, I disagree completely with privatization in developing countries or LDCs.

Dr. Witit: (In response to a question about the need for GPO to make a profit for the government.) Previously there was a requirement that all state enterprises be profit-seeking. However, the current policy of the Ministry of Finance is to recognize differences among state enterprises and the GPO is now considered to have a social welfare function. It is therefore not necessary for the GPO to raise medicine prices or do anything else that would increase profits at the expense of public health. However, the GPO does have to cover its costs. There is also a need for greater efficiency within the organization.

Improving Access to Quality ARVs in Developing and Least Developed Countries

Mr. Atul Chabra
Manager, Central Institute, Ranbaxy ARV Business

Presently more than 2 million people are receiving ARVs in developing and least developed countries, though 6.5 million should ideally be on treatment. In the next decade, at least 10-12 million will requires ARVs. There are motivational programmes like the WHO 10x10 or Pepfar 2x8 programmes. This requires all of us to implement our plans to bridge the gap. I will take Ranbaxy as an example.

Several years ago when Ranbaxy entered this domain, there were 100,000 patients receiving ARVs in developing countries. There were 2 sets of challenges which faced us.

Externally, several million patients needed to be started on 1st and 2nd line therapies and paediatrics. This meant a high volume of high quality drugs, when required and where required. Demand at that time was fragmented, but is now becoming consolidated. What was needed were drugs tailored for compliance and longevity of treatment. This meant fixed dose combinations and co-packs which the original research companies were not bringing to the market. At the same time there was limited funding.

Internally, our focus at the time was on Europe and US. To develop immediately high quality products for the developing world, there was limited set-up time. So we had to use the existing research and production facilities that had been set up for the US and Europe.

There was an opportunity for Ranbaxy to create a significant difference in the treatment landscape, especially in developing and least developed countries, and to establish the company as a responsible multi-national generic producer. We are a third world company, so we have to be there when here is a problem facing third world countries. So in 2001 we decided to use our facilities for ARV production and today there are over 400,000 patients on Ranbaxy ARVs. Ranbaxy is a leading supplier of ARVs to global NGOs, institutions and government programmes. We have a contract with the Clinton Foundation to provide affordable ARVs in more than 60 countries.

On the innovation front, we were the first in the world to file a paediatric 3-in-1 ARV drug with the WHO. Today we have 15 ARVs pre-qualified by the WHO. We have more than 38 ARV approvals across 50 countries, with more than 300 in the pipeline, which also validates our stand that when you are taking a drug to country X, you should comply with local regulations. As a responsible manufacturer, we try to register our products in each and every country where we market.

How was Ranbaxy able to deliver this? In 2001-2, Ranbaxy had the R&D competence to deliver various ARV combinations and generics and we used that capacity to the hilt to deliver and make treatment more convenient. We decided to use one of our best manufacturing facilities for making ARVs and this facility is a modular facility. To give you an example, we can produce close to 2 billion capsules or tablets per month. We can produce close to 600 tons of API per month in this facility. This is only one of 20 facilities which Ranbaxy has across the globe. With the commitment we have in this area and the steps we are ready to take, plus to comply with regulations both at the international and local levels, we file our product wherever we supply our drugs. For example, we have more than 1,000 approvals in Africa, with an equal number on the pipeline for a variety of drugs. We have also sales and support officers in many countries to make sure that that if any customer has a query, they should be able to reach you. That is why we have offices in more than 50 countries and a ground presence with other distributors and networks in more than 125 countries. Ranbaxy ARVs have been exported to Africa, south and east Asia, central and south America and CIS countries.

Our objective is to meet the treatment gap across the globe in a cost-effective manner. The required capability, capacity and domain knowledge for access and delivery is available in Ranbaxy and various Indian generic manufacturers. There is room for improvement in cross-country harmonization of regulatory requirements.

Registration in each country takes 1 to 2 years. Harmonization would allow registration across countries in one go. This can change the treatment scenario in developing and least developed countries.

In any country you will find numerous organizations working, for example Global Fund, MSF, Clinton Foundation and each has a Ministry of Health. But each has their own plan. If these people come together on a board, and there is a harmonized plan, it can significantly change the treatment landscape, allowing economies of scale and ensuring efficiencies.

This would lead to consolidation of demand. The cost of treatment does not consist solely of the cost of the drug. There is also the cost of the infrastructure, the cost of transport to treatment centres. Consolidation will also reduce these costs.

Research and innovation is required. The original research companies do not work together to create drug combinations, which are required in the developing and least developed countries. Generic companies work on very limited margins. A fund for generic research and development of fixed dose combinations for adults and children can also take us a long way ahead in making treatment accessible.

Brazilian Policies on ARV Universal Access : the Role of Local Production

Dr. Carlos Passarelli
Former Deputy Director, National STD and AIDS Programme,
International Cooperation Advisory of NAP, Ministry of Health, Brazil

In my first visit to Asia I have discovered many similarities between Brazil and Thailand and other countries in the region. We were invited here to represent Brazilian manufacturers, but I am not a manufacturer. I work at the Ministry of Health. We have close connections especially with the public laboratories in Brazil. I will speak on the relation between local production and policy.

The first case in the AIDS epidemic in Brazil was reported in 1980 and since then we have accumulated around 433,000 people with AIDS (not HIV), with an estimate of people infected with HIV of 600,000. The prevalence rate for the general population aged 15 to 49 is 0.61% (0.80% for males and 0.42% for females). So Brazil is considered a low prevalence country. The cumulative number of AIDS deaths from 1980 to 2005 is 183,074. The mortality rate is 6.0 per 100,000 and the AIDS incidence rate is 19.7 per 100,000. Around 33,000 new cases are diagnosed each year. The geographical distribution of AIDS shows early prevalence in the south-west, the most developed and populous region. It later spread to more remote regions, but it remains predominantly an urban epidemic. Scholars have called the epidemic in Brazil a concentrated epidemic. Prevalence rates in the general public are below 1%. In the first years, prevalence rates among vulnerable groups, such as men who have sex with men, commercial sex workers and intravenous drug users were between 10 and 40 times higher than the general population. Those groups are still the ones most affected by AIDS in Brazil with prevalence rates of around 5% in each group.

We have seen a stabilization of prevalence rates in the past few years and a reduction in mortality rates in the past 10 years, one of the most important outcomes of the Brazilian response. There is increasing prevalence in the heterosexual exposure groups. The epidemic is growing in women through heterosexual transmission, and there are regional and internal differences in the trend of the epidemic. More poor people have been infected in later years.

The Brazilian response was early and showed high political will among the health authorities. In 1982, with only a handful of cases, a network of gay men was trying to provide information in the form of peer education and in 1983 an HIV/AIDS programme was set up in São Paolo State government. There was strong civil society participation from the start of the epidemic, not only directly with people affected but also at different levels of decision- and policy-making. We tried to establish a balanced approach between prevention and treatment, which was possible because we have a legal framework and, importantly local ARV production.

As a general principle now established in our constitution, it is the responsibility of the state to provide information for people to be able to make the healthiest choices. For the poor especially it is difficult to decide whether to access food or drugs or medical supplies, like condoms. The state has the obligation to help each citizen make this decision. The Brazilian experience with HIV/AIDS is an example of how the state can help in this.

In the 1980, treatment focussed on opportunistic infections, capacity and institutional building and training for health professionals. AZT was introduced into the Brazilian market in 1988 but it was imported from the US and people had to pay for it. In 1991 the Brazilian government started to deliver AZT free of charge to all in need of this drug. In 1993, some private laboratories started to produce AZT and ddI the following year. In 1995, there was private production of ARVs for distribution to the government. In 1996, the Sarney Act established the obligation of the government to provide ARVs to people who need them, and a new TRIPS-compliant Patent Act was passed. In 1999, a law on generics was passed, partly a response to the Patent Act, in order to accelerate the entry of generics into the market. In 2001, the US took Brazil to the WTO dispute resolution mechanism, and it was important in making the government and civil society aware of patent issues and the importance of the consequences of enforcing intellectual property rights.

After universal ARV treatment was started in 1996, mortality rates fell from a national figure close to 10 per 100,000 to approximately 6, where it has been stable for more than 5 years. Hospitalizations also decreased significantly. An estimate of hospitalizations avoided as a result of universal ARV treatment is calculated to have saved US$2.3 billion. Offering treatment may seem expensive, but from another perspective it represents significant savings. The effect on survival has also been significant. Without treatment in 1989, the average survival rate was 5 months. This had improved to 18 months by 1995. But after universal treatment, it had become 58 months by 1996. Of the ARVs approved for the universal treatment system, 8 are produced locally, 8 are imported and 1 has been withdrawn. The pattern of drug use has changed over the years. AZT-3TC combination has replaced AZT. An anticipated increase in use of Tenofovir, which is imported under patent, will replace AZT and AZT-3TC combination, which is locally produced. Similarly, use of imported Efavirenz is increasing at the expense of cheaper, locally-produced Nevirapine. Among protease inhibitors, the same pattern can be seen. The use of Kaletra is increasing in Brazil and other countries because

of its superior qualities, while use of locally-produced competitor drugs is decreasing. So the overall tendency is for imported drugs to replace nationally-produced drugs. This has an effect on government budget expenditures. In 1999, the first year that drugs were registered, budget was spent overwhelmingly on drugs from multinational companies rather than nationally-produced drugs. Over the next 3 years, expenditures were more balanced. But from 2003, from one-third to three-quarters of the budget each year was spent on drugs from multinational companies. In 2005, this translated into US$310 million spent on imported ARV drugs, mostly Efavirenz, Lopinavir and Tenofovir. A similar situation was found in 2006 and 2007. There is an interesting relationship between the number of patients receiving ARVs and expenditure of ARV procurement. While the number of patients has steadily increased, a rise in expenditures from 2002 to 2005 was reversed as a result of compulsory licensing and price negotiations.

Our experience shows that the transition from 1st line to 2nd line drugs can double budget needs in 2 years. Since the number of patients requiring 2nd line drugs is expected to increase in Latin American in 2007 by 50-60%, the proportion of budget spent on 2nd line drugs will increase to 60-80% and the overall budget will increase by 40%.

There is a clear link to patents. A large proportion of the budget for ARVs in recent years has been spent on just 3 patented drugs. This poses a risk to the viability, sustainability and universality of the ARV policy. There is also an effect on other health problems that are common in our country. We have evidence that some of the patents were granted without appropriate examination by the Brazilian Patent Office.

The Efavirenz patent will expire in 2012. It was a pipeline patent, meaning that the patent was granted by the national patent office without examination. We began in 1999 with 2,500 patients, and by the end of 2007, there will be 75,000 patients using this drug. The price has been stable since 2003 at US$1.59. The price dropped dramatically in 2001 as a result of a threat to issue a compulsory licence. The number of patients increased by 2,900%, where as the price was reduced by 77%. We suggested to the producer a price of US$0.65, the same price that was offered to Thailand after the compulsory licence here. This was refused. They offered a 2% reduction only. The last round of negotiations involved the Minister himself and their offer stayed at 2%. We could not afford the price that they were offering, so in April 2007, Efavirenz was declared a public interest drug in the Presidential Decree issuing the compulsory licence. We are now importing a generic version from 2 Indian manufacturers, both pre-qualified by the WHO.

There were legal problems in the granting of the patent to Liponavir/Ritonavir, stressing the problem of not having clear pre- and post-grant challenges. It is important to have mechanisms to allow civil society to raise objections to patents. There are 25,000 patients on this drug. It was declared a public interest drug in 2005 as the first step toward using a compulsory licence, but at that moment, we had no pre-qualified generic version (we do now). More than 27% of the national STD/AIDS budget is used in the procurement of Liponavir/Ritonavir, making it a very expensive burden for the government. We have a steady increase in the number of patients but the reduction in price has been relatively modest.

The patent claim for Tenofovir is still under investigation after 8 years, with concerns about

its innovative quality. We have clear evidence that it should not be granted a patent. Initially it was used as a 2nd line drug but more recently it was been included as a 1st line drug. This case shows the importance of protecting only the pharmaceutical products which effectively comply with the patentability criteria, since patents have a significant impact on price and access.

A calculation was done by one of the Brazilian laboratories comparing the projected cost of patented drugs from 2006-10 with the estimated costs of locally-produced generics. These 3 drugs cannot be produced locally only because of patent restrictions; there is potential local capacity to produce them. The savings would increase each year and total US$645.5 million.

In terms of future perspectives, it is important to foster national production capacity. There is a need for greater investment in production of raw materials and synthesis of API, production of new molecules and prevention technologies, laboratory supplies for diagnosis and, monitoring, improvement of existing ARV formulations such as ddI and paediatric formulations and new fixed-dose formulations, and a strengthened WHO pre-qualification process. Paediatric formulations are needed because children with HIV/AIDS are a developing country phenomenon. Price negotiations need to be improved; Brazil is paying more than other countries for the same drugs. We noticed an improvement in the price negotiation process after the compulsory licences. It is important to make effective use of compulsory licences and not only to threaten. We need to stress repeatedly that intellectual property impacts on price.

A comparison of prices of 4 drugs and drug combinations, calculated on cost per patient per year, among 6 Latin American countries shows that Mexico, a member of NAFTA, is paying by far the highest price for all drugs, between 3 and 20 times the lowest price paid. Regional negotiation yielded even lower prices.

Fostering south-south cooperation is an important factor in building local production. There are some important international initiatives like the Clinton Foundation, UNITAID, etc., but our capacity to work together is the most important tool we have to strengthen our capacity in supplying drugs and other health needs. The Technological Cooperation Network (Argentina, Brazil, China, Cuba, Nigeria, Russia, Thailand and Ukraine) deals with capacity building and technology transfer at the country level. It is devoted to the production of ARVs, condoms, and diagnostic supplies.

To guarantee local production it is important to stress IP-related issues. These include the establishment of legal provisions to enable countries to use the TRIPS flexibilities and to avoid frivolous patents and ever-greening; provisions for parallel imports and exports; easier compulsory licensing; Bolar exceptions; guidelines for patentability, such as those of the WTO which have not been disseminated as they should; prior consent of the health sector; and review of FTAs to prevent patent abuse.

In 1998, we held an HIV/AIDS conference about ‘bridging the gap’ and we are doing that in this conference. (Slide of a cartoon where a gap between patients and medicines is being filled with money.) Some see the problem as ‘filling the gap’ [with money]. And developing countries cannot afford this.

Questions, Answers and Comments

Dr. Baker: How can we have a productive discussion on the complicated issue of quality, price and local production vs importation from countries that already have quality and low price? Thailand is temporarily satisfying part of its need for lower-cost quality medicines by turning to India. Brazil also looked to India to source Efavirenz. We want to develop local capacity, but we don't want to lose quality or pay a premium price, unless there are sufficient benefits from local production. Among those benefits might be the existence of alternative sources of supply to prevent stock-outs and interruptions or to ensure a degree of competition. The difficult question is how to make the right balance. This should be discussed because decisions have to be made between a compulsory licence for local production, which may be more expensive and may not meet global quality standards, and a compulsory licence for medicines of assured quality and lower cost sourced from the international market.

Dr. Passarelli: I cannot answer the question but want to make comments based on the example of Brazil. In Brazil, local capacity is a question of potential. We are producing 1st line drugs but for 2nd line drugs we did not have the same development as in India because we did not make use of the period allowed by WTO before becoming TRIPS-compliant. Legislation was changed very quickly and there is a powerful pharmaceutical lobby which pushed for rapid approval of the law. A congressman has admitted that they did not know what they were approving at that time. We cannot sit and cry, we have to do something, including exchange of experience with other countries. We pay high prices even for the medicines we produce ourselves. For 1st line drugs it is sometimes cheaper to import. This is partly because until 6 months ago there was no policy for this sector. In order to prevent shortages, we need to accept a higher price. But over the long-term, cooperation among developing countries can improve the situation.

Mr. Chabra: Any patient in any part of the world has the right to the best quality. We must assure the highest quality in local production. In any life-long drug, any compromise in quality can lead to serious consequences.

Dr. Witit: From the point of view of patients, doctors, nurses and pharmacists, the highest quality is essential. Despite the pressure of budgets, the GPO is committed to the highest levels of quality.

Dr. Ellen't Hoen: The concept of essential quality standards is one that is important to discuss, rather than the highest possible standards where improvements are sought even though there is no additional advantages in terms of health. Such efforts would hamper production.

In Brazil's case, it seems that Brazil must start to issue compulsory licences on a much larger scale than now. Whether you issue 1 or 20 or a 100, the pain will be the same. So you cannot be criticized more than now when you have issued one compulsory licence. Perhaps we should change the way we talk about it. When we say that we're not producing a drug because there is a patent, we could instead say we're not producing a drug because we

haven't yet issued compulsory licence. This changes perceptions. It highlights the need for responsibility.

I feel that in the international area there is a need for a much larger voice from the generic pharmaceutical industry, whether local or internationally active. At discussions at the WTO, WHO or WIPO, the generic industry is not properly represented. Is there any discussion among generic manufacturers to get together at an international level to increase their voice in these fora?

Dr. Passarelli: I an only say what the President of Brazil said when he signed the compulsory licence for Efavirenz. He said if it was necessary to do it again, Brazil would not hesitate, and every time we have a public health problem that could be solved with a compulsory licence, we would do so. I don't think Brazil will issue compulsory licences once a week. But it is correct to look at the intellectual property restraints on access and to implement the measures necessary to overcome those restraints. Other compulsory licence cases are being studied. But we have one laboratory that does not deliver the drug as contracted. This is a clear justification for a compulsory licence because they are abusing their patent monopoly. But it is necessary to convince other sectors in the government. The decision has a huge impact on health but sometimes the decision comes from the Department of Foreign Trade. Brazil is living in an interesting political moment for the health sector.

Mr. Chabra: If there is a consolidation, it will help bring the cost down and make the therapy more accessible. For local production, a decision has to be made on the mark-up. For example, for the basic triple-regimen in an African developing country, Indian manufacturers would charge about US$100 per annum, or less than US$9 per month. This is a big reduction from the cost of 3-4 years ago of around US$50.

Dr. Krisana: At every meeting there is the aim of WHO pre-qualification. Medicines can be produced to the standards of Pharmacopoeia, which is the lowest acceptable standard. Countries that are non-producers, like francophone Africa, or those with limited production, like Ghana and Nigeria, want WHO pre-qualification standards. Why is it necessary to speak like that? They are not on the ladder because they haven't even started. In Europe there is 40-50 years experience, in Africa they have none, so how can they reach these standards?

This is a meeting about CL, which I totally agree with. This does not mean that we must always import medicines. We have to build our strength to produce whatever we license. And we must have a clear time frame for production. We should be ready to produce whatever medicines we license.

Another issue is voluntary licensing (VL). This is also beneficial, especially as a compromise. I had experience with VL in Tanzania. One large company entered the market offering a VL for one drug. They wanted the publicity as a company with good will to agree a VL with an African country. They sent a team of 10 people to check the factory. After 2 days they produced a 10-page report of things that Tanzania had to correct. Tanzania could not get a VL with this company. There is no way we can get a VL in Africa. In developing countries like Thailand it may be possible, but not in LDCs.

We must separate privatization from improving management. State enterprises in Africa became cumbersome and inefficient. It was said that the way to improve efficiency was to privatize. But do not mix these ideas. In Africa, countries had to privatize because they borrowed from the IMF and one of the conditionalities was the complete privatisation of state enterprises. They did not consider if these state enterprises were life and death to the people. If efficiency is not good, then improve efficiency. But do not involve this with privatization. LDCs and developing countries still require state-owned medicine production agencies.

There are definitely problems of access to drugs. Africa has the worst problems. How can we transfer the technology to both rich and poor? And how can the intellectual frontier be widened so that the poor can benefit. Tomorrow I will present a model that may bridge the gap in technology between rich and poor countries. We also need innovation. It's not that the rich prevent the poor countries from inventing new medicines. There needs to be a compromise. The benefits of innovation should come in part to the developing countries. The poor need access to medicines. It is not enough to think only of profits. We make medicines so that they have better lives.

Corrina Heineke, Oxfam Germany: Yesterday we spoke about the R&D of Big Pharma not catering to the needs of developing countries. A WHO report speaks of Indian generic manufacturers increasing their R&D in new drugs. The report says that generic companies put only 10% of their R&D budgets into Type 2 and 3 diseases that affect mainly developing countries. Could you please give a break-down of your R&D strategy? What conditions would be needed for generic companies to increase the portion of budget going to these diseases?

Mr. Chabra: In Ranbaxy, our researchers focus on 3 areas: generic research for alternatives to innovative products in developed and developing countries; new delivery systems for existing drugs; and new drug discovery. This last is becoming more important and the lead molecule in our new drug discovery is for the treatment of malaria. Right now, this is in phase II b, developing a combination product to prevent resistance. The WHO has given it the generic name of Arterolane. If everything is OK, phase III will start next year and the product will be launched in 2011. As a third world company, we are dealing with a third world disease. We are also developing medicines for other diseases of the third world. Also we have a presence in more than 40 countries in Africa, with offices in 10 and 2 manufacturing plants in South Africa and Nigeria. The Nigerian plant is making paediatric ARV syrups. There is a commitment at Ranbaxy to developing and least developed countries. Any product we develop for a developed country also goes to developing and least developed countries.

Representative from Thai Network of PHA: Is it possible for developing countries to cooperate in developing new medicines? I would also like to see cooperation among developing countries in using CLs to counter the drug companies, so that if one country issues a CL, other countries will support it. Is this possible?

Dr. Niyada: This is the main objective in this conference: to invite friends to join in one voice on the importance of compulsory licensing.

Mr. Weissman: I know that there is strong pressure on Thailand to privatize. I want to follow on the comments of Ellen't Hoen, first on the generic industry and its engagement. There

is an international generics trade association with a meeting in Miami, Florida, next week. Registration is US$4500, which effectively excludes many generic firms around the world. The US generic firms do not take their trade association seriously, nor does the biggest Israeli firm. Perhaps the Indian firms can push the US firms to be more engaged, because they view their markets as national and they are not engaged internationally as they are engaged in US politics. On the point that Brazil should issue more compulsory licences, I feel it is awkward for an American to suggest that developing countries should issue more compulsory licences when it is our government that is responsible for countries not doing it. But developing countries should issue more compulsory licences and as a practical suggestion on the price negotiation issue. This was the big issue in Thailand with claims that there was insufficient transparency and openness. In fact, under TRIPS., not only does the government not have to have prior negotiation for public use, but the prior negotiation that is supposed to take place is not about price, it is about getting a licence. If countries enter negotiations with the position that they want a licence because they think that generic competition is important, so there should be discussion on the terms of a licence. If there is no agreement on that, we will issue a compulsory licence. That will maybe change the dynamic about how the issue is resolved. This avoids the political question as to whether the country is willing to do this kind of thing. But some of these framing things might be helpful.

Also, where there is an opportunity to re-visit national law, if countries adopt the principle that if prices are too high for people to get access to medicines they need, then a compulsory licence will be issued, then the problem of proceeding case-by-case is taken care of. Most countries are not reviewing their compulsory licensing or patent laws at any one point, but some are, such as the Philippines at present.

I have a question for Mr Chhabra on your call for national or regional registration systems. Perhaps the panellists could comment on how that could be done practically, since the Indian firms can benefit from WHO pre-qualification in ways that other firms may not be able to. What kind of systems can we look for in registration that will speed up generic entry but also respect national sovereignty interests and the legitimate interest of countries in having their own reviews of drugs?

Mr. Chabra: Regarding harmonization, I think the WHO has started discussion with developing countries in harmonization at least for ARVs so that access can be improved. The background is that countries require different degrees of batch stability data, etc. The idea was that with harmonization, producers would not have to prepare a different dossier for each country, which incurs costs which ultimately will be passed on to the consumer. My point was how to dig out the inefficiencies which are in the system. If developing countries look at stringent regulatory requirements, such as US FDA or WHO pre-qualification, then if they harmonize, a producer can submit the same dossier to a number of countries. This will reduce filing time as well as costs. Also, filing costs in developing countries are around US$1,000 per product and are valid for only 2-3 years. So it must be paid again. Perhaps developing countries could waive registration costs for ARVs. Again, this will bring down the overall costs of bringing the product to market. These are small measures that can help in improving access.

Mrs. Watal: I would be interested to hear from the Chinese representatives present and also more about the African situation with regard to API. When we talk about local production

in Africa we are not talking about production from the basic stage; we are talking about imports of intermediates or formulations or so on. Who has the capacity to produce APIs for the essential drugs that we are talking about? And at what stage do you get to API production?
Representative of MSF in Beijing: The challenges facing China are not very different from what has been discussed in terms of universal access to ARVs. At present, the Chinese government is providing free access to a restricted set of ARVs. There are some locally-produced 1st line drugs, but there is no local production of many essential drugs, because of both patents and other regulatory protections. No 2nd line drugs are covered by the free ARV policy and the majority are not registered. So the access programmes in Brazil and Thailand would seem luxurious to Chinese patients.

Also, Chinese patent law has been under high pressure from China-US relations. The patent law was first amended in 1992, which introduced patents on pharmaceutical products. So there was no opportunity to use the transitional period when China entered the WTO. The patent system is very much influenced by EPO standards and we received a great deal of technical assistance from Germany and other European countries. So standards are those of developed countries and sometimes not pro-public health and this is now difficult to change.

In terms of production, China has full capacity, but is restricted in terms of intellectual property and quality. With regard to Chinese exports of APIs and intermediates, our contacts with a limited number of generic manufacturer show their concern about how to grow in the international market because more and more drugs are coming to market and some of the intermediates have been patented in China, the whole process has been patented, so it is very difficult for them to grow

Dr. Krisana: There are only 2 countries that can produce APIs in Africa, Egypt and South Africa, but production is limited to simple products, not ARVs. There are 3 factors in the manufacture of APIs. One is the petro-chemical industry, which exists in Egypt. The second is the labour cost. No one can compete with China on this, not even India. The third is the market. If the population is smaller than 100 million, it is better to import. In Africa, API production is plant-based, like artemisinin from artemisia annua. The plant source grows in China but can also be grown easily in Kenya and Tanzania where yields are much higher than China. The yield of artemisinin in Tanzania is 1.4%. In the past, they grew the plant and send dried leaves to the UK for extraction of artemisinin, which was then sent to Belgium for synthesis, and the medicine was then sent back to Tanzania at a high price. But now they are constructing a factory for extracting artemisinin and a plant to synthesize the derivatives of artemisinin. These are the only ways of manufacturing API in Africa.

Representative from the pharmaceutical industry in China: We produce API. On quality, I consider the WHO pre-qualification as a very good international standard for generics to ensure good quality medicine. I see no contradiction with price, if you achieve quality to this standard. As an API producer I am always fighting with customers who ask for price reductions. The challenge for Chinese manufacturers is General Manufacturing Practice (GMP). In China we have not been using GMP for very long. We are still learning how to achieve international standards. 2 Chinese companies have WHO pre-qualification and one company (my competitor) has FDA approval for ARV in API and formulation. But it takes time to achieve international standards. One of the key questions is investment in upgrading the facility or learning to make

English-language paper presentations to international authorities. It took my company 2 years to go from chemical manufacturing to production of API to international standards. The second challenge for generic formulation comes from my experience in marketing in Africa. We see African generic manufacturers trying to achieve WHO pre-qualification. The first question is the money to finance achievement of international standards, which is funded by the Global Fund or UNDP. The question is how long does the learning process take to get generic production to international standards. In some cases this has taken 10 years and is still unfinished.

The big challenge for global generics will be this. All the money for ARVs is from the global community. If you get FDA or EPO approval or WHO pre-qualification, then you can participate in public tenders. I understand that at the moment most African countries, for ARV business, is in disarray. More than 80-90% is propaganda. That means if you want to tender, you need one of the international standards. While you are learning to reach these standards, you not allowed to sell any ARVS in the region. In Ethiopia, they are stockpiling their production because they cannot yet get WHO pre-qualification. They have the costs of investment to reach standards, but meanwhile they cannot sell. If you are a private enterprise, how can you wait 2-3 years before you can get the entrance ticket to participate in tenders?

My experience is that in Africa they never talk about compulsory licences except in Mozambique and Zambia. But in South Africa, Kenya and other countries, they seem to have no difficulty in getting voluntary licences. As a Chinese manufacturer, I am jealous of the Indian manufacturers, especially with regard to 2nd line ARVs. A lot of voluntary licences have gone to Indian manufacturers. Because I am from the commercial side, I don't spend much time to find out the reason but we also try to contact the originator and they agree to talk but after some months it is still just talk. They do not seem to be interested in voluntary licences in China. I am also jealous of South Africa which has 5 or 6 voluntary licences from GSK. In fact there are only 2 production companies. The rest are marketing companies.

Prof. Samlee: Regarding the privatization of state enterprises, at present there is no policy to privatize. After the economic crisis in 1997, there was a policy and GPO was under threat of privatization. This is a political question and we do not know what the future policy will be. We proposed in the people's drugs bill that there should be control of drug prices. The Ministry of Commerce argued that price controls would violate the rights of the manufacturers. This is a real political issue. The people's movement must ensure that local industry is strong and self-reliant and develops its capacity, produces quality medicines for the poor. This argument against price controls clearly comes from the transnational business sector. Linking price to quality is a business concept. The people's movement wants quality medicines at an appropriate price. We don't want to beg. We are prepared to pay a fair price. This is an issue for Thailand that is subject to fluctuation and the same thing can happen elsewhere in the world, especially in the south. Mr. Weissman noted that privatization is a method of reducing self-reliance. So today we need to discuss how to upgrade and strengthen local industry. Industrialists have spoken about meeting standards. The poor need quality medicines but not at expensive prices. The political situation must be made clear. Thailand is in a state of flux and we do not know what is in the future but we believe there must be an industry in the hands of the state. We have lost this fight over whether the universities stay in the government system. Medicines are one of the four basic needs. This is an issue where the transnational companies have brain-washed the politicians and lie behind the opinions

of the Ministries of Foreign Affairs and Commerce. We must remain aware of the political situation and be careful. The people's sector must work together against the ugly, greedy and lying pharmaceutical companies.

Unidentified participant: It is very inspiring to hear of global solidarity on access to quality essential drugs. Is there any awareness among us of how difficult it is for people living with psychosis or psychiatric illness to access drugs? What measures have been used to solve this problem?

Closing Remarks

Dr. Witit: In the past 2-3 weeks, GPO personnel have protested a proposal by the Council of State on government procurement calling for free competition in all dimensions. We were concerned about the drugs industry, especially the state sector. In the past the GPO has not emphasized its social role very much. But later with the support of leaders from the Ministry of Public Health who take a greater social role, the GPO has changed its policy. Many parties were not happy and tried to push this decree. I do not think it is different from 1995-6 when the economic crisis was the result of financial liberalization. No one really knows the end result of liberalization. People who have studied in Harvard and elsewhere haven't studied the last chapter. I think that free competition among parties that are not equal is ineffective. I come from the hospital sector and in the past 10 years, government hospitals have been told by foreigners to get hospital accreditation. Many hospitals have pursued ISO certificates until they look more like factories than hospitals. But the essence is still the same. What was bad is still bad, what was good is still good. With respect to WHO GMP for medicines, I don't really accept this. Over the past two years, the GPO has closed several plants to the point where hospitals lack drugs. I'm not sure if quality is a big thing. I have come from the outside and in the past 4 months I have visited 6-7 pharmaceutical production plants in India with WHO GMP. I looked at the atmosphere and procedures and physically I wonder if they are excessive. When I visited at accredited hospitals in the US or UK, the operating theatres for brain and eye surgery were not as clean as the drugs plants in India. The drug production processes are maybe germ-free and dust-free, but in the end people put the pills in their mouths with their hands and they are full of bacteria. Is what they are saying just to fool us? I speak as someone who doesn't have any knowledge. But the policy of the government that we must follow globalization, I will follow as far as I understand how.

Mr. Chabra: I think the way forward would be to balance quality and the ability to increase access because access is very essential.

Mr. Rachod: I think the balance between quality and price varies from country to country and depends on the readiness of each country to implement their own level of quality and most of you understand what it mans. It doesn't matter which standard we use as long as we understand that the safety and efficacy of the drugs is assured.

Innovation & Access for All

Facilitator:
Dr. Jiraporn Limpananont
Faculty of Pharmaceutical Science,
Chulalongkorn University

Speaker

1. Dr. Krisana Kraisintu
   Health and Development Foundation
2. Dr. Mira Shiva
   Asia-Pacific Chair of Health Action International
3. Dr. Jakkrit Kuanpoth
   FTA Watch Thailand
4. Thoughts on regulatory and legal issues
   Karin Timmermans
   Technical Officer for IPR, Trade and Health, WHO Regional Office, NewDelhi
5. Challenges to Pharmaceutical Companies
   Corinna Heineke
   Oxfam Germany, Health Action International
6. Campaign for Innovation+Access
   Dr. James Love
   Knowledge Ecology International

Facilitator

Dr. Jiraporn Limpananont
Faculty of Pharmaceutical Science, Chulalongkorn University

Our conference must be very important. PReMA has bought full-page newspaper advertisements in the English-language newspapers and 3 Thai-language newspapers. How much money have they spent on for advertisements like this? If they put this money into R&D, we could benefit from innovation in new drugs and access to medicines.

In this final panel, we will discuss new models for R&D based on public health needs, rather than a market-driven R&D based on patents as we have now, when there are problems in access to medicines for the poor.

In the previous 2 days we have learned about the inefficiencies of the IP agencies in developing countries in dealing with the patent-granting process, leading to problems with ever-greening patents and invalid patents. We have looked at the alternative of CL. It is recognized that CL

for government use is merely the means towards the goal of affordable access to medicines for all. We have learned about the capacity of generic drug manufacturers and the obstacles related to the intellectual property regime. Today we look forward and the speakers will propose models, mechanisms, strategies and policies to promote public health-driven R&D, rather than market-driven R&D as we have now with the patent system. We also want to propose a mechanism to ensure accessibility of medicines for all.

Yesterday we heard about the transfer of technology from Dr. Krisana. TRIPS Article 66.2 reads: "Developed country members shall provide technology transfer to least developed countries." This is a TRIPS obligation dating from 1994. In almost 13 years we have not seen any real technology transfer from developed countries to less developed countries. They claim that they have instead given medicines to all these countries. This is like giving fish but not teaching them how to fish. Dr. Krisana has tried to prove what real technology transfer is in countries where living conditions are very difficult. She has risked her life to teach but has made her dream of technology transfer to the least developed countries like Africa come true. Here she will present a new model to bring access to innovation and medicines for the poor.

Dr. Krisana Kraisintu
Health and Development Foundation

I have been working in Africa for the past five years in 11 countries covering the Horn of Africa (Eritrea, Ethiopia), east Africa (Tanzania), southern Africa (Zambia), central Africa (Democratic Republic of Congo, Gabon) and west Africa (Benin, Burkina Faso, Mali, Senegal, the Gambia). In the next years I will be working in ECOWAS countries (Nigeria, Liberia), and 2 projects in Burundi on artificial limbs and local production, and maybe Somalia to build a factory in Somaliland.

An assessment of pharmaceutical industries in 46 African countries showed that 37 have pharmaceutical industries, and of these, 25 have only tertiary manufacturing, meaning packaging imported finished products in blisters or bottles. Only 12 have secondary manufacturing, meaning they import active pharmaceutical ingredients or APIs, from Abbott for example, and manufacture finished products. Nine countries have no pharmaceutical industry at all. Those 9 countries include Botswana, a rich country with a population of only 1.5 million with no need to manufacture anything. In central Africa, there are countries with no manufacturing at all, like Chad, São Tomé and Principe, and Equatorial Guinea. In west Africa, Guinea, Guinea-Bissau, Mauritania and the Gambia also have no manufacturing industries.

We have to answer some questions. How can we distribute the technologies that we have to the rich and the poor? How can we to make innovation out of all these troubles? How can we widen the intellectual frontiers? How can developing countries improve access to life-saving medicines? There are challenges that I can see. The WHO survey showed that less than 5% of countries have strong Drug Regulatory Authorities (DRA), 20% have moderately strong DRAs, 30% have weak DRAs and 35% have very limited DRAs, meaning they cannot control the quality of imported products.

Each year, 6 million people die from 3 diseases: HIV/AIDS, malaria and TB, with malaria being the #1 cause of death in Africa. Most international companies are not interested in LDC markets because of their low or zero purchasing power and government budget constraints. I don't know what some rich countries like Gabon are spending on, although the people are very poor. Maybe the President and his 75 wives and 80 children are rich. They also have weak domestic pharmaceutical industries in terms of a poor operating environment and deficient health and drug distribution systems.

There are numerous barriers to pharmaceutical production. Apart from the weak DRAs already mentioned, there is a lack of infrastructure in terms of manufacturing processes, lack of well-trained and skilled technicians, and a lack of industrial know-how in manufacturing, meaning they do not have dossiers for manufacturing any drug at all. They have no technology for analysis (countries may have modern equipment from developed countries but they don't know how to use it so it may be left unused for 15 years), no synthesis capacity (apart from in 2 countries, Egypt and South Africa), and no government incentives. Governments may impose a much higher tax on APIs than on finished products, which is a disincentive to manufacturing finished products. In Burkina Faso, a manufacturing facility had to be closed down because it could not compete with imported products. Also there is no access to donor markets.

I have been talking of technology transfer for years since I left Thailand in 2005. We also have to think of drug quality. I like the concept of essential quality at the standard of Pharmacopoeia. We are not lowering quality. Please stop talking for the moment about WHO pre-qualification. We are taking about access to life-saving drugs.

There are several advantages to international standard GMP production, but it takes time. Let us start at the beginning before we move to international GMP.

1. We can foster national scientific and technological capacity.
2. Local pharmaceutical manufacturing can be a focal point for a knowledge- and skill-oriented society, and for a transition into other products. Once the capacity for simple drug manufacturing is in place, more advanced products, like sustained release, can be developed.
3. Industry will increase employment.
4. Economic self-sufficiency is enhanced.
5. Most importantly, the risk of counterfeit drugs is diminished, a large-scale problem in Africa. For example, a large company from the east exports quinine tablets to DRC with a content of only 30%. I cannot understand how a company, which can achieve WHO GMP and exports around the world, exports to poor countries with no analytical capacity, drugs with 30% active ingredient. This is counterfeiting and it kills people.
6. It provides long-term sustainable conditions for research and development for drugs for other neglected diseases.

'Humanitarian research' is defined as 'use of licensed technology or licensee improvements for purposes of research relating to life-saving drugs'. It allows research to take place in any country, but it requires that the provisions of the license apply to all resulting end products in low and middle income countries.

To facilitate the development of life-saving drugs, consideration could be given to assembling a research team of independently minded scientists and academics all with a different type of training and attitude toward research for life-saving drugs. A humanitarian-minded, multi-disciplinary team with pharmacists, chemists and pharmacologists is needed.

The cost of the development cannot be recouped but there is no reason to think that this research will be done on a for-profit basis.

There are 13 sequences in product formulation. It is simple to develop a product; it is not as difficult or as expensive as the pharmaceutical industry claims.

1. Propose a product that the country needs
2. Pre-formulation studies
3. Active ingredients
4. Excipients or chemical properties of excipients
5. Packaging materials, which are important because they will affect the stability of the products
6. Analytical method development for active ingredients and excipients
7. Formulation
8. Analytical method development and validation, necessary for registration of the product dossier
9. Quality control tests on the finished products
10. Stability tests
11. Trial batch production
12. Bioequivalence study
13. Manufacturing

Quality control and stability tests take about six months. All 13 steps can take 6 to 12 months if have there is a special task force doing it. So it is not difficult to formulate one formula.

I propose a model of technology and research skills transfer between the US and African nations. I am working with Louisiana State University (LSU) to develop an exchange program between US graduate pharmacy students and African researchers, where the students spend 6-12 months in Africa to do research or teach and where African students and researchers spend time in the US. If the model at LSU works, it can be extended to other places.

Laboratory space and a US grant have been secured. The long-range goal is to establish a formulations laboratory in LSU. Any formula from LSU will be given free to any LDC. The focus will be on three diseases starting with malaria. The project will also work on 2nd line ARVs and tuberculosis.

To improve access to essential medicines, the stimulation of local manufacturing of non-patented essential drugs provides a win-win solution to all involved parties. Most importantly it presents a viable and sustainable means of tackling the problem at its source.

Dr. Mira Shiva
Asia-Pacific Chair of Health Action International

I have been working for 25 years in the area of rational drug policy.

Even the medicines of yesterday are not available to our people. We all know that there about 300 essential drugs, many have the technology to produce them, and millions have no access to them. About 13 million die each year from malaria, HIV/AIDS, TB and other diseases of the poor that could be prevented. Mental health problems are also increasing and chronic diseases like diabetes are appearing among the poor. This is a result of the absence of distributive justice. Increasingly trade has taken over policy-making to the neglect of human life and human health. This devaluation of humans is pathology #1. The poor, the vulnerable, the disabled are devalued even further. The Human Development Report and others show that inequities in the world are increasing and the reaction that should have occurred has not. Inequities are accepted because the economy has grown. People in India are told to be happy when the GPD increases by 9% and the suicide of 150,000 farmers becomes a non-issue, as does the increasing costs of medical care and medicines.

To improve access involves improving the health service infrastructure, cheap effective medicines, use of the patent system with public health objectives in mind and compulsory or voluntary licensing.

The World Bank may consistently advocate privatization; if 80% of health care services are in private hands where profit maximization is the mantra, then questions of equity and responding to the needs of the people do not arise. Public health takes a back seat and curative health care, with costly diagnostic tests and treatments becomes most important be cause that is where money can be made. It is important that the health care system, drug production, medical services and curative care institutions be in the public sector.

Cheaper medicines must be available and the patent system should protect public health. The flexibilities must be used. Today there is great concern over HIV/AIDS where patient groups have been very active. The disease elicits heartfelt empathy and the feeling that something should be done. But this level of concern is not shared with other diseases. Any action that is thought appropriate for ARVs should be extended to other medicines that are relatively neglected.

When it is said that voluntary or compulsory licensing is piracy or cheating, this is not true. Many medical professionals accept the gifts of the pharmaceutical companies, and they forget the poor of their own country and speak the language of the companies. India had process patents, not product patents. Doctors began to say that India was a pirate. We asked 'Who told you? We have a Patent Act. It is not piracy.' So a lot of education is needed for medical professionals who do not believe in public health.

The pharmaceutical industry is doing so much innovation that we should be happy. But if the innovation is linked to increasing profits, and not therapeutic benefits, then that innovation is good for the pharmaceutical companies but is not good for the larger public.

Of about 2800 'new' drugs between 1984 and 2004, only about 10% had an obvious therapeutic advantage, less than 20% had a possible advantage and the rest contributed nothing new. Between 1975 and 2004, approximately 1556 new active ingredients were developed, of which only 18 treated tropical diseases which affect the majority in the world. Only 3 dealt with TB; the last TB drug to be developed was 24 years ago. The question is: how far is this innovation responding to the needs of the majority and their public health problems?

It is clear that that commercial R&D has failed on many fronts. It has not provided the drugs that we need for the diseases that are our major problem. Innovations are very costly. If the people do not have the purchasing power to access these new medicines, the drugs sit uselessly in warehouses.

The pharmaceutical industry says that it takes 10 years to develop a new drug, that it costs US$1-200 million per drug. But much research funding is 50% public and 50% private.

What are the incentives for research? Some researchers respond to a need; some want to make money; some want fame; for some it is a competition. Should the cost of R&D be funded beforehand by different agencies?

Apart from compulsory or voluntary licensing, funding can be provided for research into drugs for essential medicines. Under 'equitable' licensing, there would be an exclusive licence for high-income countries and open, non-exclusive licences for poor and middle-income countries with an unlimited number of licences to allow generic competition, because where the population is large, you need large-scale production. Another model is the patent buy-out where the WHO totally buys out the patent and uses it as it sees fit.

A new drug requires a 'push' mechanism with a large sales force to create a market by saying how good it is, that it has no side effects, etc. If direct funding is given for R&D into needed products, then product development partnerships are worked out. This has occurred with 63 products, in HIV/AIDS, malaria and TB, since 2000, with funding from the Gates Foundation, Rockefeller Foundation and Wellcome Trust.

Increased demand creates a 'pull' mechanism. A market is guaranteed, such as for pneumo-coccals by GSK where US$1.5 billion worth of doses at US$5-7 per dose will be bought by the Global Alliance Vaccine Initiative (GAVI) from 2010 on, and R&D and production is funded on that basis. This is an innovation+access platform, involving many of the organizations represented here.

The AIDS drug d4T, Stavudine, was synthesized in the 1960s by the Michigan Cancer Centre. In the 1980s, Yale University found that it was effective against HIV and took out a patent on use. In the 1990s this was licensed to Bristol Myers Squibb and registered as Stavudine. When the South African government wanted this drug for its people, Yale reported that they could do nothing since the licence had been given to BMS. The students disagreed, arguing that the product of research by a university or publicly-funded institution could not become the exclusive property of a pharmaceutical company. This led to the creation of

Universities Allied for Essential Medicines (UAEM) a very important initiative. An equitable licence was granted in South Africa.

Production can be separated from R&D. Development can be public or private, research can be done under contract or by free competition, there has to be encouragement of non-profit research as opposed to the trend of funding university and public-sector research from private sector sources, and there must be sustainable public funding for clinical trials.

Today 50% of R&D spending is public money from taxes. Complete financing by public funding is cheaper than refinancing by patents. New sources for money have to be found such as health insurance or airline taxes. Public health-oriented, meaningful R&D is a public responsibility.

Production by competing generic producers will lower prices. Local production must be given priority over imports, possibly by state companies.

Non-profit R&D is possible, as shown by the Drugs for Neglected Diseases Initiative (DNDI) has shown. The model produces medicines that are needed, on a non-profit basis, responding to public health needs, using public sector research institutes and sometimes private sector.

The prize fund model uses public funding for all necessary drugs. Industry makes an advance payment for R&D and if there is successful innovation, they receive guaranteed payment for a limited period (like tax holidays, for about 10 years). There is no monopoly and generic production is allowed. The incentive is the prize, not a patent. The amount of payment depends on various factors including the number of treated patients, the therapeutic value (treatment of symptoms or eradication of illness), and the significance for global health (such as communicable diseases). This mechanism connects industrial activities to real health needs.

The concept of drugs as a public good is that access should be for everybody, with no exclusion for social status. It has been calculated that complete public financing of R&D and generic production is cheaper than a patent system with exclusive production and refinancing through high prices.

Innovation only makes sense if people get access, especially the poor majority, not the few covered by private insurance, or government insurance. In India, 80% of medical care is in private hands.

Many people innovate for a higher purpose than making money. Jonas Salk, inventor of the polio vaccine in the 1950s, was asked who owned the patent. His answer was ‘Well, mankind, I’d say. There is no patent on the sun. Could you patent the sun?’ There has been no patent on penicillin, X-rays and many other medical innovations. The reward has been fulfilment, a sense of having contributed to society in a way that, apart from the material and intellectual, has a spiritual dimension.

Dr. Jakkrit Kuanpoth
FTA Watch Thailand

I want first to look at how well the current system has worked in encouraging R&D and innovation in the pharmaceutical sector. Only 10% of the total global investment in pharmaceutical research is directed towards neglected diseases affecting 90% of the world population. In other words R&D is geared towards to developing drugs that have a market. The question is how to bridge this research gap.

Big multinational pharmaceutical companies will say the patent system is working well in terms of allowing the company to recoup R&D costs and to use part of the profits for developing new pharmaceuticals.

But many people in the third world know that this is not really true is the sense that the patent system allows companies to monopolize the market and do whatever they want. And the money used for research in fact solves the problems of the developed countries rather than the developing countries.

The patent system has been heavily criticized in recent years and has been the subject of studies since WW2. Compulsory licensing has emerged as a tool to help bridge the gap in terms of solving research inadequacy. However, the experiences of many countries has shown that compulsory licences are only a short term and unsustainable solution, because a lot of political will and government involvement is needed

The British government has successfully allowed private competitors to seek compulsory licences in order to create competition to balance the monopolistic power of the pharmaceutical companies. But this may cause more problems than solutions in developing countries in the future.

International players have tried to come up with solutions such as the R&D Treaty where each country contributes to R&D based on its GDP. Government buy-out schemes have also been proposed. But the Inventors Certificates used by the eastern bloc countries did not work very well and have been abolished. The question remains. How can we solve the problem of R&D for neglected diseases?

Studies since WW2 have shown that the patent system is not significant for all industries. Only some really benefit from the patent system as such. The pharmaceutical industry is one where patent protection had been demanded.

Pharmaceutical R&D comes from profits earned mainly from OECD countries, mostly the US because there are no price control mechanisms. The US has therefore contributed most to pharmaceutical R&D.

R&D is conducted by 3 types of organization. Private corporations' profits provide approximately 50% of R&D. 30% comes from national government agencies, such as the US National Institute of Health. 10-15% comes from non-profit organizations.

The way research is carried out depends on the objectives of the organization. Companies cannot justify their actions to shareholders if they use their profits to solve the problems of the poor in developing countries without earning profit. The US cannot justify using tax revenues to solve health problems in, for example, Vietnam. NGOs may have humanitarian motives, but many question if they can be relied on to carry out R&D on neglected diseases. These bodies are not required to solve the research problems of developing countries. But developing countries are obliged to provide patent protection to encourage R&D although the R&D does no solve their health problems. The problem is that third world countries need to protect patents but do not get anything in return.

The problem would still not be solved by saying that governments should carry out non-profitable research while private companies do profitable research as now. The question is why the US government, for example, should fund research into African health problems. They have no moral obligation to do so, let alone a legal obligation. The other alternative is philanthropic organizations who come to the third world with the attitude that these countries cannot rely on themselves, and who, like gods, will donate what they no longer want. This will not solve the problem. Do people in the developed world have the moral obligation to do this? The answer is no, they don't. This is not sustainable, since legally and morally they can stop at any time.

So then what should poor countries do? Do they have any legal capacity to bargain for a system that will provide a sustainable solution to their problems?

There is one possibility. If you look at how the current IP protection system is working, developing countries are required to protect IP if they are WTO members. Why then do developing countries want to be WTO members? Because they want to get access to export markets. They then accept the economic and social burden of protecting IP, but not to access R&D for their own benefit. But the benefits are uncertain. Currently most developing countries provide more IP protection than they are obliged to under TRIPS. Examples include protection of second medical uses, which is not required by TRIPS or any other international treaty. They also protect copyright distributed on the internet, again without any obligation under TRIPS or other treaties. They vigorously enforce IP rights and establish special units dealing with IP infringements; for example Thailand spends tax money to establish an IP court, an IP prosecution unit and an IP police in order to suppress IP infringements in Thailand.

But Thailand enforces IP laws more than they are obliged to under TRIPS, in order to gain market access. Who benefits from this? If you look at Geographical Indications (GI) protection, the beneficiaries are the exporters of wines and spirits in Europe. If you ask who benefits from the enforcement of copyright, the answer would be the entertainment industry in Hollywood, the US music industry, Microsoft and a few businesses in Europe. What do these people contribute to the Thai economy? Nothing at all.

Look at Microsoft as an example. The Business Software Alliance (BSA) tried to pressure Thailand to enforce copyright law against piracy. They came up with a figure that IP infringements cost copyright owners US$100m per year. After Thailand vigorously enforced

copyright law, BSA kept quiet. How much did BSA and Microsoft gain from this enforcement? Should they contribute to this? The effort that Thailand and other countries put into the fight against piracy should come back to them in the form of tax credits that can be used for R&D. There would be a lot of incentive for Thailand to combat piracy if the savings could be used for medical research by Thai research institutions or collaboration with the north or south. Other industries should contribute something from what they gain from Thailand. Whoever gains from the enforcement of IPR in the third world, Microsoft, BSA, book publishers, etc., should contribute something in return.

The strengths of this proposal include the fact that it is based on economic incentives rather than philanthropy, such as the programmes of the Gates Foundation or Clinton Foundation. The developing countries should stand on their own feet and get what they deserve from their efforts in suppressing piracy. This concept will create economic incentives for small countries to wipe out IP infringements. The amount of money required to support depends on the work of the third world in dealing with piracy rather than a financial burden on tax-payers in developed.

There are some weaknesses. First, how can one assess the losses caused by piracy? People would look at the figures given by BSA as an exaggeration, which I believe is true. If it has been calculated, for example, that the cost of piracy on Microsoft programmes in Thailand has been 100 million, after the suppression of piracy, the reduction should be calculated and converted into a tax credit or R&D credit for Thailand. I will leave this for the economists to calculate. But not the BSA.

How could this financial commitment be enforced internationally? You can do it nationally if you have no international obligations. The weakness here is similar to that of the proposed R&D treaty. How can countries like the US and other OECD countries be forced to join? Asking them to join the Kyoto Protocol would be much easier.

This proposal can only apply to countries with relatively large markets with high levels of piracy activities like Thailand, China, Indonesia, Vietnam, etc., all the countries that the US put on the Priority Watch List. But for small LDC countries in Africa or Asia, I doubt whether this can work. This is just one proposal where there is still a lot of work to do.

Thoughts on regulatory and legal issues

Karin Timmermans
Technical Officer for IPR, Trade and Health, WHO Regional Office, New Delhi

Before starting my presentation, I want to make a small comment on compulsory licensing. There is not much that is left to be said, except for one thing, which is a personal comment rather than a WHO position. It has already been said in this conference that compulsory licence is not only for cases of an emergency. An emergency is just one of the situations in which one may have to use a compulsory licence. TRIPS only says that the procedures to be used in emergencies are easier and some requirements can be waived. Also, emergencies can occur at any time, anywhere, and you may need a compulsory licence. I know from Malaysia and from the first compulsory licence in Indonesia that it took about 1 year from the moment when the Ministry of Health decided that it wanted to go for a compulsory licence to the moment when the licence was actually issued. We also heard yesterday, from Brazil and Thailand, that they did not manage to issue a compulsory licence overnight. It takes time. It makes sense to me for countries to issue a CL once or twice to get the experience and learn how to do it. I think this is plain common sense. This should be part of emergency preparedness plans.

Innovation without access does not make sense. And having access to innovations that don't happen is also pointless. We very clearly need both. The system that has been put in place to achieve both is the patent system. Dr. Wilson explained very clearly that patents are meant both to promote invention as well to disclose inventions to make them available. The system is meant to be kind of balance and how the balance works depends on the details of your patent laws and regulations and how they are implemented.

We also know that there are problems with system. Too many people don't have access to medicines. Whilst the majority of those people live in developing countries, it is not exclusively such people that have problems with access and the best known example in the developed world is elderly people in the US who do not have insurance coverage and who have to try to buy their medicines from Canada or Mexico or the internet.

Data also shows that innovation does not work particularly well developing countries. Only 13 of 1,400 new drugs developed between 1975 and 1999 were for tropical diseases or for neglected diseases.

On the innovation side, the problems are also not exclusively in the developing countries. Data on the number of new medicines that have been developed in the US show a declining trend. This is not new information to companies. Due to long development pipelines, companies see these trends well in advance and obviously take action to try to protect their bottom line. These actions take many different forms. Over the past 10 years or so, we have seen a significant increase in mergers as companies try to buy pipelines. We have seen increasingly aggressive marketing techniques being used. We have seen patents for minor inventions, some would say trivial inventions, which some refer to as ever-greening.

One example is levofloxacin. The first patent was on ofloxacin, which is a racemic mixture with 2 different three dimensional shapes. The first patent protected the combination of both shapes. It was found that one shape was more effective than the other so the second patent applied only to this shape. Now there are some questions for patent law here, since the first patent already discloses the 2 shapes so how can it be argued that one of these shapes is then new? There are also questions about inventiveness, since it is well known that one isomer will be more effective than others.

We also see examples of double patenting, for example of salts, where a patent is granted for a substance, including its pharmaceutical properties, and a later patent is granted for the same substance is a particular salt form.

You could say that companies are 'guilty' in applying for such patents. But companies are not the only ones to blame since someone is granting these patents and perhaps should not have done so. Patent offices and their examiners share at least part of the blame, because by granting these patents, access is being hampered.

I would argue that this is hampering not only access. If a company can make money by getting this kind of patent, why would they bother to make a serious effort doing real innovation and taking big risks if the research isn't successful? So one might wonder if, by granting this kind of patent, we are ultimately hampering innovation. I am sometimes surprised that this question is not asked often enough or loudly enough.

A final strategy that has been used is the demand for TRIPS-plus requirements. Although the demands differ, what they have in common is extension of patent monopoly rights on existing products or to create new or different monopolies. They include extension of patent terms beyond 20 years, limits to the grounds for issuing compulsory licences, patenting of new use or second indications, data exclusivity (disallowing use by the regulating authority of the originator's data to register generic versions) and linkage (forcing the regulating authority to refrain from registering generic versions of drugs under patent).

Data exclusivity and linkage, to someone like me from a medical background, appear particularly worrisome, because they have to be implemented by the drug regulatory authorities, who are not usually consulted in any of these discussions, who often do not have the capacity to implement these provisions. In fact, with regard to linkage, even the European drug regulators complain about a lack of capacity. And if Europe cannot do it, countries like Cambodia or Malaysia or Thailand will be even worse placed. Regulatory authorities should focus on ensuring quality, safety and efficacy, which is their expertise and mandate. There are also serious questions about policy coherence. The ministries of health are on the one hand trying to make medicines and public health care affordable and available to the public and on the other hand are keeping needed products off the market.

Here are some thoughts on way forward.

1. Avoid TRIPS-plus provisions
2. Implement the patent system correctly
    - Apply stricter criteria for patentability
    - Use pre-grant oppositions to assist patent offices

- Have an alert system to share information on revocations in other countries
- Provide comprehensive research exemptions in legislation

3. Develop and test complementary or alternative incentives for innovation
   - Public-private partnerships; e,g, Medicines For Malaria Venture
   - 'Sensible' patenting and licensing strategies
   - Patent pools
   - Advanced purchase commitments
   - Prize fund
   - R&D treaty

   This list of alternatives is not comprehensive and others, such as open source, have been mentioned in the conference. 2-3 years ago when alternatives were mentioned, there were relatively few ideas. There has been progress but the discussion must be continued in the IGWG and other fora. There must also be a move to action to try out some of these ideas.
4. We must also tackle outstanding challenges for drugs of the future. This includes developing appropriate regulatory standards for biogenerics, which is being considered in the US and Europe but not much in the developing countries, where it is important even though some countries do not have the capacity. Unless developing countries become actively involved, then when such medicines become more common, we find we are policy-takers rather than policy-makers.

Challenges to Pharmaceutical Companies

Corinna Heineke
Oxfam Germany, Health Action International

Obstacles to access for the poor include high prices through monopoly rights on patent medicines, probably the major obstacle, and through mark ups in the supply chain (taxes, surcharges, retail fees, etc.). There is also political pressure from donor countries and from the pharmaceutical industry. Thailand knows what this feels like after having been put on the USTR Priority Watch List, and received letters from the US Ambassador and the EU Trade Commissioner Peter Mendelson. Economic partnership agreements negotiated by the EU tie development aid to negotiating certain chapters to new FTAs. Legal challenges from the pharmaceutical industry have recently been seen in India, where Novartis sued the Indian government on the cancer drug Glivec.

Karin (Timmermans) has just mentioned additional rules outside the patent system-data exclusivity and linkage. The protection of test data can delay generic competition for many years.

Apart from campaigning for access to medicines, Oxfam is also asking donor countries to support the strengthening of infrastructure and health systems in developing countries. We need about 4.25 million new health workers in developing countries to provide health services. Without the infrastructure, some people may not be able to access services or follow a regular regimen because of the distance to the nearest clinic.

A lack of medicines goes beyond high prices and many speakers have mentioned the lack of R&D that addresses diseases predominantly prevalent in developing countries. Only 3 new drugs for neglected diseases were developed between 1999 and 2004 out of 163 new chemical entities.

Even if new medicines are being developed, they often do not come in presentations appropriate for developing countries such as heat stable products or child formulations.

With respect to potential effects of data exclusivity, Oxfam has done some interesting research on the US-Jordan FTA. This could be relevant since the EU has asked South Korea for 10 year data exclusivity in bilateral trade negotiations and the draft of a mandate for negotiations with ASEAN, which are about to start, is very similar.

Jordan signed a Free Trade Agreement with the US in 2001 only one year after they acceded to the WTO. Since 2001 prices of medicines have increased by 20%, partly as a result of data exclusivity. The study shows that out of 103 new medicines, constituting just over half the new medicines registered in the Jordan market, 79% are not available in generic form, solely due to data exclusivity. Many companies didn't even bother to register a patent because they had data exclusivity. Clopidrogel or Plavix was not affordable in Jordan because they could not import or produce a generic version. The price of medicines to treat cardio-vascular diseases or diabetes was often 2 to 6 times higher because compulsory licences were denied due to data exclusivity.

On the responsibilities of the pharmaceutical companies in improving access to medicines, while governments obviously have the responsibility to do everything to improve access for the populations, including the use of the TRIPS flexibilities and improvements in their health infrastructure, and donors also need to support them in that, the pharmaceutical industry needs to change its business model in order to take account of the 2 billion people that lack access to life-saving medicines.

In 2002 Oxfam, together with VSO and Save the Children, asked in a report called Beyond Philanthropy whether companies do enough to assure poor people's access to affordable medicines. The situation then, and to a large extent today, looked rather disconcerting. Oxfam will be bringing out an evaluation of the progress since that report

The big pharmaceutical companies are offering lower prices mostly when under pressure, with Brazil and Thailand being good cases in point. When companies do act in the best interests of poor people, it is mostly done to manage their reputational risks, not because the company actually believes that they have a responsibility to take action. There is very little transparency in the make up of prices. When companies say they are providing medicines at cost, it is not known, or very rarely known, what goes into the calculation of the price. Most companies do not have a systematic tiered pricing policy that takes into account the purchasing power of every developing country or differentiates both within those countries, and between low-, middle- and high-income countries.

There may have been a small improvement, but there is a lot of focus on high profile diseases such as HIV, TB and malaria, and often limited to the poorest LDCs in sub-Saharan Africa.

Middle-income countries like Thailand are not viewed by the industry as countries where there is a need to provide cheaper medicines.

There is also a perception in the industry that non-communicable diseases do not warrant the use of the TRIPS flexibilities and are not seen as a public health problem. Yesterday a new report came out on the rise in non-communicable diseases which says that non-communicable diseases such as cardiovascular diseases, diabetes and asthma now account for about 60% of deaths worldwide, and 44% of premature deaths, and 8 out of 10 of these deaths occur in middle- or lower-income countries. So this is a huge problem that needs to be addressed by the pharmaceutical companies.

So how has the industry addressed some of these challenges? They have basically used donations as reputational patchwork. Let me give 2 examples.

Novartis has offered to give Thailand its cancer drug Glivec free to pressure them not to issue a compulsory licence. Glivec is 10 times more expensive than the generic version. As a response to the high profile law suit in India, the company reiterated that they provide free Glivec to 99% of all patients in India who need it, amounting to 6,600 patients. But 24,000 leukaemia patients are newly diagnosed each year in India, Novartis cannot claim they provide lifelong treatment for all these people.

A second example is Merck's cervical cancer vaccine Gardasil. Merck announced it will donate vaccinations to one million women in some of the world's poorest countries. There are nearly 500,000 new cases each year and 250,000 deaths from cervical cancer, 80% of which occur in the developing world, because women don't get tested for cervical cancer sufficiently early. The company says that the vaccine has been approved in the US for all 9-26-year-old women. If we treat only 1 million women, the PR looks good, but many poor women will not benefit.

Oxfam believes that donations are not a sustainable way of bringing down prices and that generic competition is a more effective and long-term sustainable way of bringing down prices. There are problems with donations not reaching people in the right volume, at the right time, when necessary. We have seen donations of products that have expired, and where people may not know how to administer the product.

At the moment, R&D incentives for Big Pharma are based on intellectual property. Among incentives replicating the market model which could provide incentives to big pharmaceutical companies are advance market commitments. The Global Alliance for Vaccines and Immunization is currently preparing a pilot advance market commitment for pneumococcal vaccines to stimulate private sector R&D and sales of vaccines and 6 governments have already provided funding for this for up to $1.5 billion. Some of the original creators have withdrawn support for this mechanism because it is viewed as an excessively generous subsidy to the pharmaceutical industry. The vaccine already exists in the north and only needs to be applied to different strains in tropical countries. There are concerns that the final producers would be paid a huge amount of money without a clear and guaranteed increase in funding from them, and there are no guarantees in the contract on the affordability of the final vaccine.

Another instrument is the malaria subsidies, supported by the European or UK government. The assumption is that artemisinin-based combination therapy for malaria is provided through the private sector and for people to get access they should be able to go to their normal providers and access these therapies at a lower price. I believe some research has been done in Tanzania that shows that the lowest quartile of the population doesn't go to the private sector to receive those therapies. A problem with these subsidies is that the success is calculated on the number of patients receiving treatment but does not account for cost of training, dispensing, or the shopkeepers and health workers that deliver the medicines, or for who will look at the registration of these medicines. None of this is included in the cost of the subsidy.

What can the pharmaceutical industry do and what must they do? We need a systematic tiered pricing policy that addresses the real purchasing power for each country, that goes across their medicines portfolio and is not limited to high profile diseases, and that addresses all developing countries not just some LDCs.

More R&D is needed for diseases that primarily affect poor people and for presentations suitable for developing country conditions.

Companies must respect the TRIPS safeguards, stop lobbying developing country governments not to use the TRIPS flexibilities and stop lobbying their own governments to seek Free Trade Agreements that restrict the use of these flexibilities. They should consider foregoing patent rights, for example if they enter joint public-private partnership initiatives that have largely been funded by public funding mechanisms. For example the German company Boehringer Ingelheim has signed a non-assert declaration with generic producers on their AIDS medicine Nevirapine, which means that they won't enforce their patent rights against generic production for LDCs, low-income countries and African countries. But this is only one medicine for one disease.

The industry must recognize that there is no 'one size fits all' approach to developing countries and diseases, not only for their moral obligation to provide access for the poor because in the end they will lose out in their markets, which some investors have already pointed out to them.

Campaign for Innovation+Access

Dr. James Love
Knowledge Ecology International

The challenge

Innovation and access are both important. The current trade framework focuses only on measures to promote monopolies and high drug prices as the reward for innovation. High drug prices are poor incentives for innovation that primarily concerns poor people. Monopolies lead to excessive, irrational and harmful investments in marketing products and monopolies and high drug prices create access barriers.

In order to change or replace the current global R&D framework it is important to address both innovation and access. Innovations should address health needs for everyone and R&D incentives should not present access barriers

The reason we have policies to promote high drug prices is directly linked to the belief that people have that these are necessary to promote innovation. It's not as if policy makers hate poor people. They actually believe that it's a necessary evil to have high drug prices for 20 years and that if you don't do that, you won't have innovation. So you really have to tackle that issue. If you want low drug prices, you have to show how you can have low drug prices and still have innovation.

There is a campaign for innovation+access or i+a. It's a very flexible campaign. You don't have to do it this way. You can make up your own platform. It's a high level idea that you try to do both innovation and access at the same time. What brings people together is the idea that both are important. The details as to how you do it, are sometimes controversial and not everyone agrees on the details of how you get there. But what we want people to agree on is the high level idea, that you want to have policies that do both innovation+access. Evidence, policies should determine how you get there. Some countries may choose different paths for cultural, political or economic reasons but still everyone should insist that policies do both.

Idea 1
De-link R&D financing from drug prices

As long as the only way to finance new drug development is through high drug prices, you're pitting innovation and access against each other. You can't have a system that relies on high drug prices to finance R&D and then be shocked when that system produces high drug prices. You have to come up with a new system that doesn't rely on high drug prices. That's the hard thing to make people understand. But it's important to get people focused on this.

One way to think about this is the availability of 'push' financing, like government grants or other subsidies for drug development. Not all drug development comes from private corporations; a lot comes from governments and donors. It's important globally that there

is public sector research, open source research, grants to study science to find, for example, the causes of avian flu, public databases, etc. So part of what needs to be done is to create a global mechanism for public sector research.

The TRIPS agreement doesn't do this. There is no benefit under TRIPS agreement if you fund a billion dollars of public sector research. But if you raise the price of a heart disease drug, it is rewarded by TRIPS. It's a very unbalanced regime. So the global regime should reflect the value and importance of public sector research. In the US, $30 billion is spent on the National Institutes of Health on public research and $8.5 billion on the Centre for Disease Control and additional money in other parts of the government that do health-related research. This is valued very highly. So in a global regime, you should not ignore these activities that are important for progress.

There can also be 'pull' incentives that reward private investors, both profit and non-profit, who are successful. But these do not have to be linked to monopolies or high drug prices. So we are looking at prizes as the pull mechanism. We are not saying that prizes should replace government grants or other public sector financing. But it should replace monopolies and high drug prices as the incentive system. Do you want to grant someone a monopoly on a drug as an incentive for investment, or do you want to give them a cash prize? People in the public health community are not familiar with the literature on prizes and think of the Nobel Prize or other reputational rewards. We will need to invent our own way of thinking about prizes. The basic point is that it is a way of giving money to an R&D investor that is not linked to the price of the product. It is a separation of the market for innovation from the market of the product itself. It allows you to de-monopolize the products but still give rewards to successful developers.

The most concrete proposal is Bill S. 2210 (US Senate bill proposed by Bernie Sanders), which would eliminate all monopolies in the US market. It substitutes $80 billion a year, increased in line with GDP, in prizes for successful drug developers. The rewards are linked to the impact of the inventions on health care outcomes. Some money is set aside to reward products that deal with global health problems, including global neglected diseases and new treatments for tuberculosis and AIDS.

The Sanders Bill is important because it attacks the biggest pharmaceutical market in the world, the US, which is also the most important to the Big Pharma companies and it suggests that it is possible to transform radically the US pharmaceutical market. If that was to happen, the rest of the world would be forced switch from high prices to low prices. Otherwise it would be unsustainable to have generic competition across the board on the US and not have it in Canada or Europe. It's a most subversive proposal in that at one stroke it would change the global market for the next 100 years.

It would have enormous benefits to the US market in terms of insurance companies, government, tax-payers, and employers. It would immediately save over $200 billion per year in the US market. The Sanders Bill could be financed out of the savings to government in the US. The federal government is now paying over a $100 billion for drugs in the US market, with the states paying even more.

The Sanders Bill is a serious proposal and has been endorsed by the Consumers Union, the Consumer Federation of America, PIRG and a number of NGOs. A number of academic economists have commented seriously on the proposal. We are very committed to a campaign to change the US market.

There is also a proliferation of proposals by academics, NGOs and health professionals to start something smaller than transforming the US market, which is half the global pharmaceutical market. Some drug companies have endorsed the idea of prizes to reward TB drug development. Most patients infected with TB are con-infected with HIV and live in developing countries, and to have high prices for TB drugs is not a good thing for the treatment of TB. So Novartis and other companies endorsed the idea of an R&D treaty and prizes to reward successful developers of drugs for TB and other similar diseases, basically Type 2 and Type 3 (neglected) diseases.

This is a sensitive area because drug companies know that the goal is to change the pricing of all drugs, not just TB drugs. They are torn between the idea that this mechanism is very attractive for diseases like river-blindness and their desire to maintain monopolies on drugs for cancer and heart disease. They think if we fail to use prizes for Type 1 drugs, they will support prizes for Type 2 and Type 3 diseases. But if they think we are going to transform the system totally, there's panic in Big Pharma.

But there is support for prizes among Small Pharma. There was a meeting in San Francisco of venture capitalists, where a proposal was made for prize-type mechanisms to reward biotech companies working on neglected diseases, targeted at meeting certain benchmarks in research, which is not very different from the way venture capitalists reward biotech today.

There is now a discussion about the best way to pay innovators and the idea of breaking the link between the price of a product and the reward is very important, because it means poor people can get access to products for the cost of making a copy.

This is a proposal that has been made for the Global Fund or similarly supported funds. Donors from the US and Europe are funding a lot of treatment for AIDS in places like Africa. They only do it because the cost per patient is considered reasonable to the donor compared with what they can spend on other investments like road development or other health care services. Unfortunately some companies have become very aggressive in patenting and pricing AIDS drugs, even in Africa. As the cost goes from $100 per patient to $2000 per patient for second generation drugs, it becomes impossible to sustain millions of people on donor-supported drugs. So the US and Europe need to have cheap drugs, just like Thailand needs cheap drugs, to meet their long-term commitments to provide treatment.

So rather than have one AIDS drug cost $2000 and another cost $25, the idea is to switch the business model for the donor market, and have a fixed fraction of perhaps 10% the Global Fund or similar funds go to paying rewards to innovators, linked to health care outcomes in the countries where the drugs are used. A voluntary patent pool is created and prize payments are restricted to companies that license patents to patent pool. If patents not licensed to patent pool, then countries are encouraged to issue compulsory licences,

because this is a humanitarian programme and it is our money that is at stake. This system is an offer they can't refuse.

Some think this can be done in Thailand. The Health Security Office could set aside part of the budget for the purchase of drugs for AIDS, cancer and other diseases, to de-monopolize completely the manufacturing and sale of products, and then give prize rewards to inventions that improve health outcomes in Thailand. You have a discussion about how much of the budget should go to innovators and how much to drug purchasing. But the most important thing is that on the margin, the products would be very cheap. The heart drug went from 70 baht to 1 baht when it was de-monopolized. That's a big change. It means access can be significantly expanded.

Implementation under current TRIPS framework and within current Thai patent law is possible, without changes to TRIPS or Thai patent laws. You can say that the patent pool is created, reward those that licence innovations to the patent pool, and issue compulsory licences for those companies that won't do it. Thailand already has all the tools needed to do this. Then you have a discussion with the Europeans and the Americans to explain that you are trying to balance innovation and access. I think this can be explained in the US Congress and the European Commission and it can also be explained why it would be a good idea on the US and Europe.

Idea 2
Global Treaty on Medical R&D

The objectives of the treaty still need to be debated. Public health NGOs should consider different purposes and benefits from a possible R&D treaty, because there are countless different ways you could think about doing this.

At the WHO IGWG on Nov 7, 2007, there was tentative consensus reached on public health innovation and intellectual property:

"Encourage further exploratory discussion on the utility of possible instruments or mechanisms for essential health and biomedical R&D including inter alia an essential health and biomedical R&D treaty."

It was the #1 priority of the big pharmaceutical companies to stop agreement on this language. We were told by the German delegation that it was red-lined by the European Commission and would never happen. There would be no language on an R&D treaty. We were then told by the Brazilian delegation that we should give it up as a lost cause. But to everyone's surprise it was agreed. The language was supported by the US and Canada, led by the diplomacy of Kenya supported by Brazil, Thailand, Switzerland and other countries. The US had issued a warning the previous week to its FTA partners not to support an R&D treaty. Some calls were made to the US Congress and in a week the US position changed.

This is a big victory for the social movement. It was difficult because the R&D treaty has been advertised to Big Pharma as an alternative to tough IPR agreements. It has not been a stealth campaign. It has been a direct challenge about how to transform the global system.

The possible elements of a treaty on medical R&D include first of all a mechanism to determine priorities. There also have to be norms for sustainable funding of medical R&D, including priority projects. This can be thought about in different ways. It could be voluntary like the Global Fund, where promises are made to pay, or the international financing facility where bond agreements are signed for a 20 year period. It could be funded from transactions like taxes on air tickets or currency transactions or the sale of bullets. It could be a progressive share of GDP. It could also be some other way. But if you want to challenge the IPR way of thinking about drug development and the monopoly system, you have to explain where the money comes from. The R&D treaty would probably also deal with access to knowledge and other issues.

Issues of access to knowledge include access to government-funded R&D through a requirement to publish results on the internet. The US now requires this for NIH-funded research, but it is not required in Europe. If this were part of the treaty then developing countries would have access to information and could be suppliers of research services. There would also be faster scientific progress.

There is also discussion on the creation and management of open libraries of compounds so the drug developers would not have to go to big pharmaceutical companies to access such information.

The free movement of researchers, primarily from developing countries, could also be a component. This would get around visa problems and so on so that they could attend conferences where R&D is discussed.

There could also be incentives and obligations to invest in public goods, such as open source databases, the human genome project, etc

Some countries such as Australia have suggested subsidies for the cost of clinical trials, since they are a public good, and a protocol on the funding of comparative clinical trials so that there will be unbiased information about which drugs work the best in different settings, which is also a public good. There may be global norms for transparency of data so companies do not suppress scientific information about drugs that harm people. Global ethical standards could be set to protect subjects of clinical trials so that developing countries are not just providing human guinea pigs for private corporations without any commitment to provide access to products when they are available or to sustain treatment for life, and to ensure proper informed consent.

Many other issues can be discussed, including

- transparency of investment flows;
- payment for research on the causes of health problems, such as environment, diet, lifestyle, irrational use of medicines, poor diagnostic capacity, etc. where there is a social global interest;
- research on with health systems are most effective;
- technology transfer, where some creative ideas from the EU before it expanded to include eastern European countries;
- obligations under the Convention on Biodiversity;
- traditional medical knowledge, etc.

There are also questions about the relationship between R&D treaties and IPR agreements. The treaties are in fact less of a problem than the treaty-plus norms that people follow because of political pressure. The worst treaty that the US has signed would allow you to protect consumers fairly well if you could get away with it politically. There is a need to change social ideas about what's appropriate, which might obviate the need to change existing treaties. How far you can change formal or informal obligations under IPR monopoly agreements depends on the level of commitment to an R&D treaty. The fewer the commitments under a medical R&D treaty, the fewer benefits from a reduction in the norms of global IPR treaties and agreements. It is therefore important that any proposal for an R&D treaty be serious.

Next steps

WHO has agreed to discuss "an essential health and biomedical R&D treaty". So NGOs need to develop constructive and informed positions on key issues in such a negotiation. There are not enough NGOs working on this topic. There needs to be a real social movement behind this. It takes a lot of support from social movements in north and south for this to happen. There is also a need to make people in the US and Europe see why it's in their interest to have a better model to control diseases, improve cures and advance science. If you think, rightly, that the system is working badly in your country, don't assume that it works well in the US. Europe now has countries with incomes lower than some African countries in the same political organization as countries like Denmark and Sweden and they therefore need new ways of thinking about solving these problems.

The innovation+access campaign is Version 2 of the earlier campaign which was focussed on access and unethical marketing issues. We are now attempting a hostile takeover of the R&D issue. We are no longer going to outsource thinking about R&D to Big Pharma, we're going to do it ourselves and develop a system that serves people, not the other way around.

Questions and Comments

Prof. Baker: It was argued, as part of the idea that developing countries should take greater responsibility for their own health needs and R&D, that developed countries do not have responsibilities to people in the rest of then world. I strongly resist the idea that people in developed countries do not have obligations to people elsewhere. This comes from many reasons and I think they are enforceable reasons.

The first is that we created the neoliberal economic and political global order that increases people's vulnerability to disease and prevents their access to life-saving medicines. This is the system we have created. We are complicit in its consequences. If its consequences are ill health, it is our responsibility to recreate the system so that it responds to those health needs. It is simply a question of fairness and equity and even reparation.

Secondly, many of us would like to think of ourselves as global citizens not just citizens of

a nation. I would urge people in developing countries to urge us to be global citizens. Nation states are an unfortunate feature of current global order.

But I think everyone agrees that the human rights framework does have some relevance. Even if it does not have many enforcement mechanisms, it creates obligations. There is a human right of access to essential medicines. Nothing could be clearer in the current human rights literature than that this right exists. Concurrent with that right is the obligation of governments to ensure access to medicines in both developing and developed countries. Developed countries like the US have an obligation not to interfere with the realization of the right to health of developing countries. They have an obligation to regulate their drug companies so as not to interfere. I think we should use the language and understanding available to us about global citizenship, about the consequences of globalization and about human rights to make the moral arguments to first world countries that this system has to be changed.

Robert Weissman: One small comment on a slight on (Dr.) Mira (Shiva)'s presentation which had a reference to a website for *www.essentialinnovations.org.* This is incorrect. The correct website is *www.essentialinventions.org.* Essential Innovations is front group for Big Pharma funded by a group of organizations including the International Policy Network and the Intellectual Property Institute in Texas, which pretends to be the website for Essential Innovations and tries to confuse people. Obviously effectively. It is another version of USA for Innovations that you are familiar with. But it is again a sign of the duplicity of the industry which we see at every turn.

The big question has been a theme in a number of presentations. If we are going to speak about the innovation side, there has to be discussion about funding mechanisms. I am wondering if the panellists could think about how that seems both from a northern perspective and more interestingly from a developing country perspective. Outside of the LDC context, there is the idea that there is some obligation to pay for R&D. There are different proposed mechanisms but ultimately there is this obligation to pay. People are already paying through high drug prices. How do people feel about that? A possible implication is that if there are going to be compulsory licences issued, then royalty rates may have to be higher, or compensation systems may have to offer greater payments than half a percent of the generic price. This is a real issue hat must be decided if we are to move beyond rhetorical endorsement of these proposals.

Jon Ungpakorn: I always wonder why we don't talk about some sort of global fund for research and innovation to which every country in the world pays according to its economic situation. In that sense it would seem to be a system in which developing countries could not be accused of not participating in the funding. In conjunction with that, why is the concept of a global universal health insurance not being talked about very much? If many developed countries feel that it is the right of their citizens to be protected with guarantees on health, and if we consider ourselves as members of a global community of human beings, why can we not talk about moving toward a global health insurance? I would like to see more opening up of concepts. If we can get more global cooperation on funding of research and development of essential drugs, maybe we can have global cooperation in developing some form of universal health insurance.

Responses

James Love: The concept of global citizenship reminds us that we all have obligations that extend beyond our borders. The Sanders Bill has enormous set-asides of billions of dollars a year as rewards for developing treatments for tropical or neglected diseases, precisely because it is felt that country that benefits so much from globalization has obligations. Within the idea of an R&D treaty, the bulk of funding will come from high-income countries. Denmark has 4 million people and a GDP equal to the sum GPD of all LCDs, which comprise 700 million people.

I think it is a mistake to think about the developing countries' obligations as zero. It's a trap. You lose political power. In the case of UNITAID the growth of participation is now in developing countries. Kenya, Chile and many developing countries are participants. It gives them a stronger voice in priority setting, and management of the fund. What you want to avoid is Bill Gates and the G8 determining global policy for everyone without a voice from the rest of the people in the world and without any transparency. The amounts don't have to be huge, but they can't be zero and they have to meet a threshold.

There is an issue between global and local. We have been very much in favour of the money for R&D being spent locally. There is an obligation for Thailand and Thailand can satisfy this obligation by investments in Thailand's universities or businesses. Others prefer to see a globalization approach. The Germans, Swedes and Kenyans have proposed a global fund for neglected disease research. I foresee some combination of the two. I don't think you want all the management to be done in Geneva. I think it's a good idea to have a component that is domestic and one that is international. You also want to have incentives where developing countries collaborate among themselves.

Karin Timmermans: On the need for more global collaboration and coordination, I think things are happening but perhaps not fast enough. There are 2 levels of collaboration. There is the formal government-level cooperation, where the most important progress is in the IGWG process and is a positive example, which indicates that we are moving in the right direction. Governments and international organizations always move slowly, but at least they are moving and in the right direction. The second level of collaboration is informal among NGOs and civil society, which are needed to push the policy makers like WHO.

Corinna Heineke: Many governments are still failing to meet their obligation to spend 0.7% of GDP on development aid. If they do, then there is a lot of money, some of which can be directed to essential health services and some of the ideas being discussed at IGWG.

Dr. Krisana Kraisintu: With respect to funding, why don't we tap some of the funding from Arab countries? The countries of the Gulf Cooperation Council apply Islamic law whereby rich people have to donate 3% of their income to the poor and each year they spend a lot on foreign workers. The OPEC Fund and Kuwait Fund support lots of projects, especially in Africa. As the price of oil rises, a surplus will be there.

My presentation was not about a model but an actual working project. It may be small but it is a starting point.

Dr. Jakkrit Kuanpoth: On global citizenship and moral obligations, personally I don't like the humanitarian approach and I don't think it really exists in the real world. People in the developing world should rely on themselves. There should be capacity building in every country, so that people do not have to wait and beg. Many people in the third world are contributing something for free. The petroleum industry is a good example. In the pharmaceutical and biotech industry, traditional knowledge and genetic resources are contributed for free. How can the money be taken back? Amend the unjust system and allow the people to earn what they deserve, not wait to see what comes out of the research in Europe the US that can benefit them. This is not sustainable. If the third world is confident that they have something to contribute, they should set up a system to deduct money to put back into their own economy to benefit in a sustainable way. There should be south-south collaboration in R&D that involves medical researchers in the third world, which would be real technology transfer so people can do things for themselves and rely on their own biological resources and traditional knowledge. Any philanthropic or humanitarian approach will be useless and in the long term will not work.

Mira Shiva: 2 days after the Novartis judgment came from Chennai High Court, which threw out the case because they said it was not in their jurisdiction, there were same kind of full-page newspaper advertisements in the Indian press, using a misleadingly positive name. The people behind it were from the US and the content was an attack on Cipra for selling ARVs in Africa at lower prices than in India. We need a list of the big-time and small-time crooks.

Gandhi believed there should be a voluntary austerity, not the austerity forced by the IMF that denies your basic needs and rights. International agencies continue to pauperize you and force you to change your policies in ways that are not in the interests of public health. Then you get trapped in a situation where resources are scarce. The legal system further squeezes your neck. Gandhi advocated civil disobedience against unjust laws or Satyagraha. He said that unjust laws are meant to be broken such as in the Salt March to Dandi. Civil society has to resist unjust laws.

Turmeric has been newly found to have anti-oxidant, anti-cancer and antibiotic properties but has been used for thousands of years. The patenting of turmeric was resisted. Neem has bio-pesticidal properties with the active ingredient of azadirachtun, which means 'free tree of India'; pharmaceutical companies attempted to patent it but were again resisted.

Profiteering from medicines has to change, like the slave trade had to change, land mines had to change, apartheid had to change

Dr. Jiraporn Limpananont: Everyone has human dignity and many things in the world are unjust. Dr. Prawase Wasi asked how to move the mountain. We need knowledge, and strong social movements and we have to identify the key change agents. If these three things come together we can move the mountain. In the afternoon, we will try to move the mountain together. We will hear about strategies from many countries and try to form a common plan of action.

Press Conference

Facilitator:
Assoc. Prof. Dr. Vithaya Kulsomboon

Speaker

1. Dr. Brook Baker
   Professor of Law, Northeastern University, Boston, Massachusetts, USA
2. Dr. Carlos Passarelli
   HIV/AIDS Programme, Ministry of Health of Brazil
3. Dr. Robert Weissman
   Essential Action, USA
4. Dr. James Love
   Knowledge Ecology International
5. Nimit Tienudom
   AIDS Access Foundation

Facilitator

Assoc.Prof.Dr. Vithaya Kulsomboon

Dr. Brook Baker
Professor of Law, Northeastern University, Boston, Massachusetts, USA

I would like to congratulate the social movement in Thailand and the Ministry of Public Health for its forward-looking decision to issue compulsory licences. It is essential to emphasize that what Thailand has done is totally legal under national and international law. It is possible for a country to issue a compulsory licence on any grounds that it determines to be appropriate. It is a lawful flexibility for any country, including middle-income countries like Thailand. It is a flexibility that can be applied to any disease, certainly HIV/AIDS, which is a significant problem in Thailand, but also for heart disease, or for any other disease which the government identifies. Under international law, the TRIPS agreement and the Doha Declaration, it is completely lawful for Thailand to have done what it has done.

There are strong arguments that the retaliation by Abbott Laboratories in withdrawing 7 products, in particular a heat-stable form of Retonivir, and the pressure put on Thailand by the US government through the Office of the US Trade Representative, are both illegal. The withdrawal of products from the Thai market may well be illegal under Thai competition

law, and is being challenged by consumer groups, where we hope for a favourable decision, clarifying that this kind of action is intolerable and illegal. Under US law, there are requirements that the US Trade Representative respect the Doha Declaration on the TRIPS Agreement and Public Health. The action of the US in putting Thailand on the 301 Priority Watch List and withdrawing Generalized System of Preferences trade advantages in retaliation may well offend the obligations that the US has under international law.

The action of Thailand has set an international example that other developing countries have followed and will continue to follow. Thailand's decision to issue further compulsory licences on medicines for cancer and other chronic diseases is entirely appropriate. These are positive developments for the international community and for poor people in developing countries. There should be widespread support not only among proud Thai citizens for the action taken by their government and activists but also among citizens in other developing countries.

Dr. Carlos Passarelli
HIV/AIDS Programme, Ministry of Health of Brazil

The Brazilian government issued a compulsory licence in May 2007 for an antiretroviral drug. Brazil has had since 1996 a very active programme of HIV/AIDS treatment, offering universal access to all patients needing treatment, care and support. Since the beginning of the programme we faced difficulty with the prices of medicines. In the past 5-6 years the sums spent on buying imported medicines were a burden on the national budget. Brazil produces some medicines and others are imported from multinational companies. The need for a compulsory licence on one of these medicines was economic. The experience of Thailand was an inspiration for Brazil. If Thailand had not taken the lead in this process it would be very difficult for Brazil to take the same measure. It is important to be here to exchange experience and determine a common future for developing countries.

Dr. Robert Weissman
Essential Action, USA

The health advocates attending this conference have celebrated what Thailand has done in issuing compulsory licences and we all look to Thailand as a beacon that has shown us the way forward to a sustainable way to make medicines available and affordable. We look to Thailand to continue to show leadership with more compulsory licences to come. One of the lessons we were able to draw from the conference is that what Thailand did is uniquely important as a middle-income country issuing multiple compulsory licences on 2nd generation AIDS drugs and non-AIDS drugs. We also noted how many other developing countries have issued compulsory licences. These include Brazil, Indonesia, Malaysia, Malawi, Zambia, Zimbabwe, Eritrea, South Africa and Ghana among many others. A consensus view emerging from the conference was that it will be much more important for countries to do compulsory licensing not just on an episodic basis for individual products, but regularly and routinely to introduce and use compulsory licensing to lower the cost of

medicines and make essential therapies available to people who need them. One other conclusion that we were able to recognize is that although compulsory licensing is something new for many developing countries, it in fact regularly and routinely used in rich countries such my own, the US. The US is by far the most aggressive user of compulsory licensing in the world. The US routinely issues government-use compulsory licences of the sort that Thailand issued, not just for important products but for any product. There is no special review process to issue government-use compulsory licences. They are automatically available to any government officer in the US. This right is given not just to the government, but to contractors and even sub-contractors. The right may be explicitly authorized or may merely be implicit in the fact the government hired someone to do a job for them. This is one of many examples that we saw of how the US and the European countries make regular use of compulsory licensing. We are hoping that developing countries will follow this model, and choose to do more of what the rich countries do and less of what they say the developing countries should do.

Dr. James Love
Knowledge Ecology International

One idea discussed at the conference is that the problem of access is linked to the problem of paying for innovation. One idea of paying for innovation is to give monopolies for new medicines. The granting of monopolies creates too many problems: high prices for drugs; barriers to access; ineffectiveness in stimulating investment in basic research or treatments for tropical diseases. There is now a focus on new thinking about ways to finance innovation, in particular ways of financing innovation consistent with universal access to products. One idea that has been discussed is the idea of giving rewards, such as cash prizes, for new inventions on the basis of the impact of the invention on health care outcomes. To do that, the products are demonopolized so that they can be freely copied, with the benefit of cheaper prices from generic competition. But there would also exist a reward system for companies that invest in R&D that is rationally related to the benefit gained from the innovation. There is also the idea of a global treaty on biomedical research and development. We support discussions on such a treaty in the hope that such a treaty would compete with and possibly replace treaties that deal only with monopolies.

Nimit Tienudom
AIDS Access Foundation

We activists working on HIV/AIDS and issues of access believe that compulsory licences are not the only way to secure access to health care and medicines. Access is our goal and at the moment compulsory licensing is just the most effective mechanism to secure universal access to medicines and to tackle monopolies.

The health care system in Thailand is currently providing 1st line antiretroviral treatment for 140,000 patients, allowing them to lead a better life. These patients are aware that 2nd line

antiretroviral drugs are on the market and are living in desperate hope of having access to these drugs. Currently there are about 10,000 patients who need to be placed on 2nd line antiretroviral drugs, which were not affordable because they are under patent. The government issued a compulsory licence to lower the price and increase access.

The networks of people living with HIV/AIDS have created awareness among patients of other chronic diseases such as renal failure, heart disease, psychiatric illness and cancer. Treatment of these diseases involves costly medicines. They now see compulsory licensing as a way to bring prices down and provide them with access to treatment. From now on, we all will struggle together to realize our dreams.

Thai people are now covered by health insurance. There is the FDA and the national essential drugs list to guarantee the quality of drugs provided under the universal access programme.

Dr. Brook Baker

I want to comment briefly on the large advertisements that the big drug companies are paying for in the Thai press. Thailand, in addition to suffering retaliation from Abbott and the US, is also suffering from a misinformation and disinformation campaign, where the very rich pharmaceutical companies make false claims in support of their pursuit of higher profits. They claim that Thailand does not have the right to do what it did, either because of its status as a middle-income country, or because of the diseases for which it has issued compulsory licences. They claim that research and development will be undermined if Thailand doesn't pay. They suggest that they are reasonable and negotiate in good faith. All of these claims turn out to be false. As I said before, Thailand is within its rights. Thailand represents 0.05% of the global market. The large drug companies make 88% of their sales in rich country markets which are not affected at all by Thailand's decision. I think the press and the Thai people would be wise to be aware and resist the misrepresentations that are essentially being paid for out of your drug dollars.

Assoc. Prof. Dr. Vithaya Kulsomboon

To achieve our ultimate goal of access to medicines, at the conference we have created a new global network compulsory licensing, Innovation and Access for All, or I + a4a. This will link together networks of patients, NGOs, academics, public health experts, government officials and generic drug manufacturers to find a way to ensure that patients have access to medicines with acceptable quality. I would like to ask all of you to stand to welcome this network and to work together to improve access to medicines for all.

Open Forum
Challenges and Ways Forward : Country Reports

Facilitators:
Mr. Jon Ungphakorn & **Dr. Jakkrit Kuanpoth**

Speaker

1. Dr. Niyada Kiatying-Angsulee
   Thailand
2. Elmira Bacatan
   Philippines
3. Gabriela Chavez
   Brazil
4. Dr. Samsuridjal Djauzi
   Indonesia
5. Dr. Mira Shiva
   India
6. Dr. Robert Wiessman
   USA

Facilitator

Mr. Jon Ungphakorn & Dr. Jakkrit Kuanpoth

Dr. Niyada Kiatying-Angsulee
Thailand

I am merely presenting the work of many organizations.

A meeting on 1 October 2007 to develop a strategy for access to medicines was attended by 40 participants from 9 organizations, comprising the Health Consumer Protection Programme, the Pharmacy Network for Health Promotion Programme, the Social Pharmacy Research Unit, the Faculty of Pharmaceutical Sciences (all of Chulalongkorn University), the Health and Development Foundation, AIDS Access Foundation, the Foundation for Consumers, the Drug Study Group, and the Thai Network of People Living with HIV/AIDS.

The objectives are:
'Medicines are ethical and moral goods. It is necessary to have essential medicines available for public use on an equitable basis and in a timely manner. Additionally the country should be self-reliant in medicines at a certain level, in case of war and emergency and in the public interest.

'People maintain good health and can be self-reliant in health care with particular emphasis on health promotion and utilization of health-related local know-how, Thai traditional medicine, local medicine and other alternative medicine.'

The policy is 'Health before trade interests'.

The 7 strategies are:

1. Development of networking for access to health care
   - Rational drug use
   - Effective drug system management
   - Legislation

2. Coalitions of patients with he same diseases
   - Thai Network of People Living with HIV/AIDS (TNP+)
   - Cancer patient network
   - Network of patients requiring long-term kidney treatment
   - Other networks to be formed

3. Matching the price of medicines to the cost of living of people in the country
   - Drug price control mechanisms
   - TRIPS flexibilities

4. Capacity building of domestic drug manufacturers
   - Essential Drug List
   - Bolar provision
   - Ethical clinical research centre
   - Timely and effective registration system
   - New drug registration
   - Regional cooperation

5. Patent-related strategy
   - No TRIPS-plus provisions in FTAs
   - WHO patentability criteria
   - Patent database
   - Patent Act (New Patent Act can be tabled before parliament by a provision allowing citizen-initiated legislation)
     - Patentability criteria
     - Compulsory licensing
     - Pre-grant opposition
     - Pharmaceutical patent committee (abolished in the previous Patent Act)

6. Promotion of rational drug use
   - Update of National List of Essential Medicines (NLEM)
   - Adoption of NLEM for all sectors
   - Promote International Non-Proprietary Name (INN)
   - Mandate implementation of INN

- Enforce use of INN in all schemes
- Role of health professionals in rational drug use

7. New drug research and development
   - Feasibility study of alternative approaches to R&D such as:
     - Research prize funds
     - Medical research and development treaty
     - Advanced market commitments
     - Patent pool
     - Drug researcher pool

Elmira Bacatan
Philippines

In 1999 only 50-79% of Filipinos had sustainable access to affordable essential drugs. Under the best case scenario, 16 million Filipinos have no access to essential drugs and under the worst case scenario, one in two have no access. In 2006, the WHO, together with HAI and Institute of Philippine Culture, surveyed drug prices and discovered that innovators' branded drugs from the private sector cost up to 184 times more than the international reference price and that generic medicines cost up to 26 times higher.

PITC, a government agency involved in parallel importation of off-patent medicines, compared trade prices of branded medicines in India, Pakistan and the Philippines and found that prices in India and Pakistan were much cheaper than in the Philippines. For example, Pfizer's Norvasc costs in India 5.93 pesos, and in the Philippines, 39 pesos. This large price differential forced the Philippines government to implement parallel importation.

The Philippines pharmaceutical market in 2006 was about 97 billion and is very price-driven, growing by 7.4% in value but declining by 3% in volume. As of March 2007, there were 258 drug manufacturers, 70% of which are foreign multinationals. 80% of toll manufacturing for multinational companies is done by one company; a sister company handles about 65-70% of wholesale distribution. More than 60% of retail sales are handled by one company, Mercury Drug. Drug prices in the Philippines are one of the highest in Asia in terms of per capita income. Access to medicines in the Philippines is being tackled on 3 fronts.

TRIPS flexibilities have not yet been incorporated in the current IP Code which has broad patentability criteria. Parallel importation is not permitted outside of the country. Restrictions on compulsory licensing for government use are too limiting. A bill supported by civil society 2 years ago failed to pass in the face of industry lobbying. A second attempt underway has been met by more discreet industry lobbying which is harder to counter.

Government agencies conducting parallel importation of off-patent medicines have been sued. In one case, importation for testing and registration before patent expiry was challenged by Pfizer in court. Intervention by patients was initially denied since they were judged to have no 'economic interest', and this is under appeal.

Patents are being challenged. When it was known that the Norvasc patent has been denied in the US, this information was passed to the government agency being sued for importing it. They filed a petition with the Intellectual Property Office to cancel the relevant patent; the petition is expected to be resolved by the end of the year.

Efforts are also being made to increase awareness of issues like TRIPS flexibilities among the public and legislators and to gather support from the executive and legislative branches of the government. There is an ongoing search for legislative champions for reform of the IP Code and other issues. Counter-offensives are also launched against pharmaceutical associations and other groups lobbying against the reform.

Among the ways forward is the prompt sharing of information and expertise over the internet. When attempts were made to introduce the TRIPS flexibilities into Philippines legislation, there were questions about how this was done in neighbouring countries, which we could not readily answer, since our examples were all drawn from rich country practice. We also need increased access to IP expertise supportive of TRIPS flexibilities. Most IP experts in the Philippines are either on the payroll of pharmaceutical companies or are in institutions overloaded with other cases. It would also be useful to share campaign materials that have been used to educate the public and legislators, especially in countering myths propagated by the industry.

A country needs assessment is also required to inform decisions on compulsory licensing and other measures. The structure and procedures for an alliance of countries implementing TRIPS flexibilities should also be considered. Local capacity should be strengthened in the production of generics, patent examination and IP expertise.

Gabriela Chavez
Brazil

The Intellectual Property Working Group has ongoing strategies. The first is public awareness and advocacy capacity-building in order to protect public health and to monitor the negative impact of Free Trade Agreements and IP on access to medicines.

The other challenge is to incorporate into the Brazilian health movement the positive achievements at the international level.

There is a need to monitor patent status and the possibilities of pre-and post-patent opposition within a strong network of developing countries.

We also consider the courts as a means to achieve collective rights on public health for 3 reasons. First, it is a way to raise awareness of the negative implications of IP on health policies, because courts cases attract media attention. The struggle of the social movement becomes a struggle of the general public. It is also a way to find alternatives to the current system. We also want to stimulate the judiciary to pressure the executive branch into taking measures to protect public health.

Dr. Samsuridjal Djauzi
Indonesia

Indonesia is very happy to participate in this conference because the issue discussed, compulsory licensing, is very relevant to our public health care problems. Millions of Indonesians are unable to access essential medicines. Civil society has tried to fight this situation, but social structures and international pressure have not benefited our struggle. Compulsory licensing is one part of the relationship between developing and developed countries. In theory, they have equal status, but in reality, developing countries have to struggle for their rights. Equal status for developing countries is not given voluntarily by developed countries. Fortunately we also have friends in developed countries, who have empathy for our rights and support our struggle. Compulsory licensing is legitimate; it is not a criminal action; it is not piracy. We should disseminate this understanding among developing countries and also to countries, parties and companies who object to compulsory licensing.

In Indonesia there is still misunderstanding about compulsory licensing due to misinformation. That is why we need a strong message to disseminate understanding of compulsory licensing. We propose that compulsory licensing should be discussed among regional organizations like ASEAN, and should be one of the topics for regional collaboration.

We also hope and expect a positive position from the WHO because compulsory licensing will help and support the WHO programme of access for all. We have in Indonesia implemented compulsory licences for 3 drugs and will continue to use compulsory licensing for the benefit of our people. We hope that this important momentum will continue and that networking will have a positive role in increasing our capacity to implement compulsory licensing.

Dr. Mira Shiva
India

The Novartis case is a focus of attention. It has three components. One is the High Court case. The second is a submission to the Indian Patent Appellate Board. The third is the boycott of Novartis.

India's National Pharmaceutical Policy should have been formulated in 2002. Because of pressure from consumer and health groups on the proposed removal of drug price controls, it has been delayed. A second objective is to have a sensible National Pharmaceutical Policy.

Public interest litigation has gone before the Supreme Court on drug price controls and access to essential drugs

The Drugs and Cosmetics Act is to be amended. There was an attempt to include data exclusivity. This is under the Health Ministry; drug pricing is under the Chemical Ministry, and patents are under the Commerce Ministry, all of which have to be lobbied.

A new drug regulatory authority is to be formed. It is not clear how much will be in the public interest and how much is being pushed by international harmonization. Civil society is making submissions and monitoring developments.

A report on patentability was withdrawn but is to be resubmitted. It proposed that patenting only a new medical entity or chemical entity is a violation of TRIPS, which civil society challenges. Work is being done on pre-grant opposition, and competition law.

Information for the public is needed on counterfeit drugs. We are nervous about the implications of the Indo-US Knowledge Initiative, the proposed training of patent officers by the US, the impact of GATS on health services, in particular human clinical trials and drug retail services.

Support is also being given to other social movements working on, for example, Special Economic Zones, farmer suicides as a result of agricultural policy, and the Indian People's Tribunal Against the World Bank, which discussed many issues including health.

Dr. Robert Wiessman
USA

There are efforts to support the IGWG process. Domestically, in addition to the Sanders Bill, an important issue will be a process for creating generic versions of biologics drugs. It is unlikely that there will be access to biogenerics in developing countries until there is a process in the US.

On overall trade policy, more space will be available under a Democratic Congress and possibly a Democratic President. Under a Republican President there is unlikely to be any new trade agreements, but bilateral pressure will be very intense.

There will be work on pro-industry front organizations with a website soon that tracks these groups. Also the US and European countries are proposing a new treaty on copying, which they call counterfeiting and piracy. It is important to have a public health and public interest perspective. There is also interest in disclosure of patent status as a small but significant piece of information to be gained from networking with other countries to obtain the information or to campaign for systems to require companies to disclose patent status.

The most important thing to come out of this conference is that the best way to support Thailand is to do more compulsory licensing and we are eager to work with anyone to advance compulsory licensing by providing technical and research support. A priority drug will be the HPV vaccine.

Open Forum

Dr. Jakkrit Kuanpoth: The full-page advertisements in the Thai English-language press cost about 200,000 baht. The message is 'stop taxing medicines'. It implies that the expensive price of pharmaceuticals is the result of government regulation, such as taxes, and that if there were no taxes, the price would come down. The information is misleading in that it does not disclose how much the companies charge, or how much they pay for advertisements like this, or invest in R&D, or how much profit the companies make in each year in each country.

This perhaps is a good example of how we can move forward. They are placing these advertisements in Thailand because Thailand is jeopardizing their interests. If Indonesia and Vietnam do the same thing, you will see this kind of advertisement. If civil society in each country is not strong enough to give the other point of view, the public will easily be misled. I would like to propose to the meeting the question of how we can provide accurate information to the public. In Thailand, this is already being done, but in other countries this may be a bigger problem.

Dr. Samsuridjal Djauzi: In Indonesia it is important to develop friends in the media with an understanding of compulsory licensing, who can present correct information so that we do not have the cost of advertising.

Jon Ungphakorn: In Thailand, when USA for Innovation placed advertisements attacking compulsory licensing, there was a lot of criticism of the 2 newspapers, the Bangkok Post and The Nation, which carried the ads. Both then agreed to give the same space to civil society for free. It may be possible therefore to ask for the right to reply.

Dr. Jakkrit Kuanpoth: I was asked by a reporter why pharmaceutical companies were not invited to attend this meeting. The conference has therefore been reported as one-sided. I told them that last year I was invited to attend a conference in Singapore by pharmaceutical companies to which no civil society representatives were invited. Each side has the right to organize a conference, set the agenda and invite the participants that they choose.

Prof. Baker: One of the things I have discovered at this conference is how polite people from Thailand are, and I know Americans are often not very polite. But in responding to misinformation, it is important to be very direct and quick. Anything that is not refuted develops a life of its own. Every time it is repeated without refutation, it gets stronger. It is therefore necessary to respond to such advertisements and right-wing think-tank pieces that get placed in the press and interviews with industry-supported academics.

Dr. James Love: I have been working on issues to do with pharmaceutical drugs for 18 years and I have never been invited to a meeting of Pharma. We have invited people from pharmaceutical companies to dozens of conferences, and hundreds have attended, but not once have I been invited to their meetings.

Dr. Jakkrit Kuanpoth: Misleading information will be spread from time to time by the industry. The point is how to provide the public with accurate information. One way is to organize conferences like this. But can it be done very often and in every country?

Negotiations are going on at the WHO TRIPS Council and other international NGOs working on access to medicines and research and development issues. How can the work of NGOs be supported?

Virat Purahong, Chairman of Thai Network of people living with HIV/AIDs: Thailand has been criticized for implementing compulsory licences by the media and transnational companies. In the past 3 days, I have learned that compulsory licences are not illegal. The fact that activists, lawyers and fellow campaigners have met here is a good sign that we can challenge transnational companies, challenge patents that deny the poor access to drugs. I want to make clear that the patients' network has come together and looks forward to joining with networks of psychiatric patients, cancer patients and diabetic patients, so that we can join forces to push for access to medicines. This is the power of the people's sector. The academics can lead, but our strength is in the people's movement. We will fight to the end.

Khrueawan Thiangtham, Psychiatric Patients Network: With regard to treatment and ensuring a voice for psychiatric patients, we should not neglect that fact that one psychiatric patient in a family can affect the lives of 5 or 6 others. Psychiatric cases in Thailand are invisible. Many people think that severe cases involve violence. But in fact, most psychiatric patients have great difficulties and there is a deep stigma attached to this illness, so that patients are cut off from society. They may be excluded from education because of the behaviour changes caused by their illness. The students themselves may not understand and neither do the teachers. In employment they can work if under treatment, but they are not covered by social insurance so they suffer discrimination. Psychiatric illnesses are not covered and when we ask, no reason is given. It seems that people think that nothing useful can be done for people who are 'crazy'. There are sufficient drugs for depression, but for anti-psychotics, consider that a person with a bachelors degree and a salary of about 8,000 baht cannot access effective drugs, whether as a result of patents or not. Older generations of drugs have side-effects that prevent the patient from participating in society or being employed. This is also a sizable group of people, affecting about 1% of the population. Depression affects 4-5%, bipolar 1.2%. In this conference mention has been made of deaths and disability. 1 out of 10 deaths results from suicide and many suicides are the result of psychiatric illness. Psychiatric illness is not taken care of in Thai society at all, but it is something which, if not dealt with, is a social and economic burden causing loss. I am disappointed that I am the only person who has been allowed to attend this meeting as a representative of many others for whom access is an important issue. I will report the discussion in this conference to them and I invite those here who have information to tell us how to develop a network.

Jon Ungphakorn: As you will understand, although Thailand has universal health coverage it by no means inclusive of all diseases and we are gradually trying to fill in the gaps. For example, this year the National Health Security Office has agreed to cover chronic kidney disease. Treatment of psychiatric illness is still not yet covered.

I also cannot stress too much the importance of patient networks in the movement for access to medicines. In Thailand, without the Network of People Living with HIV/AIDS, over 1,000 organizations, and a growing network of people with kidney disease and hopefully of people with psychiatric illness, our campaigns would not be even half as effective. When, as last year, we can have 10,000 people in the streets of Chiang Mai, opposing the negotiations

on intellectual property right in the Thai-US FTA, then the newspapers write about it. Then it becomes news and important to society. This is something that we all need to develop in our countries.

Dr. Jakkrit Kuanpoth: There are some key players outside the health sector, such as people in the patent and intellectual property offices and there is a question about how to work with such people. I was told that in Thailand recently, the Ministry of Public Health proposed a bill to control drug prices. This was vigorously opposed by the Ministry of Commerce. One argument raised by the Ministry of Commerce was that control of prices was not the role of the Ministry of Public Health, and it should be left to the Ministry of Commerce, even though they had done nothing on this. The Ministries of Commerce of all countries give more sympathy and support to the pharmaceutical companies and try to ensure that these companies face no barrier to doing business in the market. It would be very useful if anyone has any ideas about how to work with such organizations, so that, for example, health agencies and the Patent Office could work in national unity on this issue. What is the situation in the US? Is there any conflict between the drug regulatory authorities and the USTR?

Dr. Robert Weissman: I don't think the US is a good example. There is not much conflict, because the drug regulatory authority, like the USTR, is very friendly to Big Pharma, is not an advocate for health and is certainly not eager to cross the interests of Big Pharma.

More generally, if you assess what's happened to the access to medicines movement, there is a remarkable set of middle-income countries' delegates in Geneva, which have changed over time since they have been forced out by the US, who educated themselves about access to medicines, and have been very effective at the WTO and elsewhere. That came about because people talked to them. Even though they were hostile at first, they were educated and many, but not all, were converted. Even at the WIPO, which just a few years ago was the home terrain of Big Pharma, the same process took place and people were turned. There are institutional conflicts but there is also a lack of knowledge and they have to be engaged in conversation and I think they can be moved.

On an unrelated point, I would like the thank the organizers for the initiative to put this conference together to draw us all together to carry forward the conversation, to be not just a leader by example, but also a leader by forcing the conversation and pushing everything forward on compulsory licensing and access. On behalf of all the participants I want to thank the secretariat for their efficiency, generosity, hospitality and warmth.

Jon Ungphakorn: Thank you for those remarks which are a suitable way to end this conference and we look forward to working together towards the next conference which we understand will be in Indonesia.

Dr. Vithaya Kulsomboon: I would like to invite the representatives of 3 patients' organizations in Thailand, Khun Virat of the Network of People Living with HIV/AIDS, and representatives of the networks of kidney patients and psychiatric patients, and Gabriela Chavez of Brazil, to read the conference statement.

Conference Statement
Bangkok Declaration on Compulsory Licensing, Innovation and Access to Medicines for All

From November 21 to 23, 2007, 200 experts, social activists and patient network representatives from all over the world have gathered in Bangkok, Thailand, to discuss compulsory licensing, innovation, and access to medicines for all.

1. We recognized and applauded Thailand's leadership in the use of compulsory licensing to overcome legal monopolies as well as decisions by Brazil and Indonesia. Thailand's continued leadership on compulsory licensing is important, but so too will be the actions of other countries. Because of economies of scale, it is important that the potential market in developing countries for generic products is large enough market to collectively justify entry by generic suppliers.

2. To achieve our optimal goal on innovation and access to medicines for all, we have created a new global network on compulsory licensing, innovation and access for all (I+a4a). This network will link together patients, NGOs, academic/public health experts, government officials, and generic drug manufactures to find ways to ensure that patients have access to medicines with acceptable quality.

3. We confirm that compulsory licensing of patents is a legitimate, important and effective tool to protect consumer and public interests. Thus every country should have the right to systematically and routinely use compulsory licensing and other means under TRIPS flexibility similarly to wealthy countries. Governments all over the world use compulsory licensing in a variety of contexts and in many different fields. The right to use compulsory licensing is incorporated in international law and precedent, including the WTO TRIPS agreement and Doha Declaration.

4. Objections to the use of compulsory licensing in developing countries to ensure access to medicines for all patients are often based upon untruthful, misleading, unproven assertions and assumptions, and are designed to appeal to prejudices regarding the developing world. This should stop.

5. It is feasible to permit generic competition for products, dramatically expanding access to medicines, while ensuring sustainable sources of financing for needs driven research. Because we can promote both innovation and access, we must reject policies that force choices between the two, and accept the marginalization of low income and uninsured persons. We applaud the May 2007 World Health Assembly resolution WHA 60.30 which calls upon the WHO to consider new mechanisms that de-link R&D incentives and financing systems from the prices of drugs. We support the calls for a new global treaty on medical R&D, that does not force countries to embrace monopolies and

high drug prices to finance medical innovation, and which boosts investments in needs driven essential R&D, including R&D needed to address the special health problems of developing countries.

Our cause is important for everyone. We are seeking global norms that ensure innovation and access for all. This is an achievable goal, if we collaborate and work together.

Bangkok,
November 23, 2007

Thai Statement

We in the name of the Patients' Networks of in Thailand, we affirm that the declaration and principles of this conference are important and necessary for all people in the world. The task of fighting for the right of access to medicines is the responsibility of us all. We will cooperate at the global, national and patient network levels to attain our goal of universal access to medicines.