

**IMPROVING ACCESS TO MEDICINES IN
THAILAND:**

The use of TRIPS flexibilities

Report of a WHO Mission

Bangkok, 31 January to 6 February 2008

In accordance with the terms of reference of the mission, this report provides technical information and policy options on the general rules and mechanisms available to countries for use of the flexibilities contained in the WTO TRIPS Agreement and other international agreements, in order to promote greater access to pharmaceutical products.

The report of the mission is not intended to make any evaluation or assessment of the use of TRIPS flexibilities in Thailand.

Although the mission met with the various stakeholders during its visit to Bangkok, the discussions were aimed at facilitating an understanding of the context and circumstances related to the granting of compulsory licences in Thailand, and identifying the appropriate technical and policy support required on the use of TRIPS flexibilities.

This report has been prepared under the responsibility of WHO. In the context of resolution WHA60.30, resource persons from UNCTAD, UNDP and WTO participated in the mission to provide technical and factual information with regard to the TRIPS Agreement.

Members of the mission:

Germán Velásquez, WHO/HQ (Team Leader)

Bill Aldis, WHO/SEARO

Karin Timmermans, WHO/SEARO

Cecilia Oh, UNDP

Kiyoshi Adachi, UNCTAD

Roger Kampf, WTO

Xavier Seuba, WHO temporary adviser, Pompeu Fabra University, Barcelona

Contents

Terms of reference

Introduction

- I. Cost-containment mechanisms for pharmaceutical products
- II. Non-voluntary licences for government use: practical aspects and procedures
- III. Other important TRIPS flexibilities to promote access to medicines
- IV. Information on country experiences with the use of TRIPS flexibilities to protect public health and access to medicines
- V. Guidelines and tools on the use of TRIPS flexibilities to promote access to medicines
- VI. Final remarks

Terms of Reference
WHO Mission on the use of TRIPS flexibilities
Bangkok, 31 January to 6 February 2008

In the context of resolution WHA60.30, WHO headquarters and the Regional Office for South-East Asia, in collaboration with other relevant competent international organizations, will provide technical and policy support on the general rules and mechanisms available to countries for use of the flexibilities contained in the TRIPS and other international agreements in order to promote access to pharmaceutical products.

The mission will provide relevant materials and guidelines for the implementation of TRIPS flexibilities and suggest possible indicators¹ for future assessment by the Thai authorities of the measures. It will also advise on the practical aspects and procedures for the use of TRIPS flexibilities: compulsory licensing and government use in particular.

The mission will provide factual information on other country experiences on the use of TRIPS flexibilities to protect public health.

As requested by the Thai authorities, the mission will include visits (or a technical workshop) to: the National Health Security Office, the Food and Drug Administration, the Department of Disease Control, the Government Pharmaceutical Organization, the Department of Intellectual Property, the Ministry of Foreign Affairs, the IHPP (which is doing a study on the compulsory licensing policy process), the nongovernmental organizations, the pharmaceutical industry and some consumer groups, including PLWD, and also discuss with the Minister of Public Health.

¹ See template in *Network for monitoring the impact of globalization and TRIPS on access to medicines* (WHO/EDM/PAR/2002.1).

Introduction

In the context of resolution WHA60.30, the Minister of Health of Thailand requested WHO, in collaboration with other competent international organizations, to provide technical and policy support on use of the flexibilities contained in the WTO TRIPS Agreement in order to promote access to pharmaceutical products.

WHO, in its Medicines Strategy (2004-2007), identified four key objectives; namely: the strengthening of national medicines policies; improving access to essential medicines; improving the quality and safety of medicines; and promoting their rational use. In order to ensure that national medicines policies are effectively implemented to achieve the objective of improving access to priority medicines, WHO has identified the need to support countries in their efforts to use public health safeguards in international, regional and bilateral trade agreements.²

WHO's policy perspectives are informed by the following basic principles:

- "Access to essential medicines is a human right
- Essential medicines are not simply another commodity, TRIPS safeguards are crucial
- Patent protection has been an effective incentive for R&D for new drugs
- Patents should be managed in an impartial way, protecting the interests of the patent-holder, as well as safeguarding public health principles
- WHO supports measures which improve access to essential medicines, including application of TRIPS safeguards"³.

Since 1997, resolutions of the World Health Assembly have provided WHO with a broad mandate in the area of intellectual property and access to medicines. More recently, resolution WHA60.30 of May 2007 requested the Director-General "to provide... in collaboration with other competent international organizations, technical and policy support to countries that intend to make use of the flexibilities contained in the agreement on Trade-Related Aspects of Intellectual Property Rights and other international agreements in order to promote access to pharmaceutical products".

Consistent with its mandate, WHO advocates to Member States the importance of the TRIPS flexibilities to protect public health and promote access to essential medicines and draws attention to the need to include them in national laws.

In accordance with the terms of reference of the mission, this report provides technical information and policy options on the general rules and mechanisms available to countries for use of the flexibilities contained in the WTO TRIPS Agreement.

I. Cost-containment mechanisms for pharmaceuticals products

The use of TRIPS flexibilities to improve access to medicines is one of several cost-containment mechanisms that may be used for patented essential medicines not affordable to the people or the public health insurance schemes. Medicine prices,

² WHO Medicines Strategy: *Countries at the Core (2004-2007)* (WHO/EDM/2004.2).

³ WHO Policy Perspectives on Medicines N° 3, *Globalization, TRIPS and access to pharmaceuticals*, March 2001 (WHO/EDM/2001.2).

however, depend on many other factors and various measures, not related to intellectual property, can be taken or are already used in Thailand to contain costs and increase access to patented and non-patented medicines.

To give a broader context to the use of TRIPS flexibilities as one of the possible mechanisms to contain and reduce medicine prices, this first chapter of the report briefly reviews the main non-intellectual-property-related cost-containment mechanisms that may be used in the pharmaceutical sector.

A sustainable system for the funding of medicines could be based on three components: 1) the creation or enhancement of a national/social health insurance scheme or medicine prepayment mechanisms; 2) the introduction and use of all possible cost-containment mechanisms; and 3) the use of TRIPS-compliant flexibilities.

National/social health insurance and prepayment systems⁴

A country's health system includes the totality of actions that society and the State undertake in relation to health. Health insurance is a specific form of health system. The only countries that have succeeded in guaranteeing access to medicines for the whole of the population are those that have a social security system, as is the case for most of the Western European countries where, for more than 50 years, the entire population has access to medicines as part of the right to health care.

There are various models of health insurance, with many alternatives which range from private, for-profit organizations to social security organizations financed with public resources.

Cost-effective medicine selection

Selection of cost-effective medicines at the primary health care, hospital or national level should be a major, if not the most important, component of cost-containment of medicines. Selective medicines lists for public health insurance schemes may include:

- Essential medicines lists
- Positive lists, setting criteria for new medicines to qualify for reimbursement
- Negative lists, as in some industrialized countries, which exclude medicines from coverage under the health insurance system for therapeutic or financial reasons.

Price information

Transparent pricing information enables rational decision-making about medicine selection, from the national level to individual prescriptions, and is a vital element in making use of other cost-containment mechanisms. As indicated in the box hereafter, WHO offers many medicine price information resources, as well as a methodology for sampling prices and comparing local prices with international reference prices.

⁴ Zerda A, Velásquez, G, Tobar F, Vargas J. *Health Insurance Systems and Access to Medicines. Case studies from: Argentina, Chile, Colombia, Costa Rica, Guatemala and the United States of America.* Washington, DC, Pan American Health Organization, 2001.

WHO medicines price information services⁵

WHO works with several partners to make price information easily accessible to governments, nongovernmental organizations, donor agencies and any institution involved in medicine procurement. WHO medicine price information services are accessible at :<<http://www.who.int/medicines/organization/par/ipc/drugpriceinfo.shtml>>.

Particular resources include: *International Drug Price Indicator Guide*: Details 252 active ingredients in 448 dosage forms. Indicative prices of generic products on the international market and selected tender prices. Produced by Management Sciences for Health and WHO.

Sources and Prices of Selected Drugs and Diagnostics for People Living With HIV/AIDS: Details 73 active ingredients in 110 dosage forms. Issued by UNICEF, UNAIDS, Médecins Sans Frontières and WHO. Covers antiretroviral (ARV) medicines, HIV/AIDS test kits for diagnosis and ongoing monitoring, and medicines for treating opportunistic infections, for pain relief, for use in palliative care, for the treatment of HIV/AIDS-related cancers, and for managing drug dependence.

Pharmaceutical Starting Materials/Essential Drugs Report: Details over 262 active ingredients. Issued by WHO and the International Trade Centre, a joint WTO-UNCTAD publication.

AFRO Essential Drugs Price Indicator: Nearly 300 essential medicines and dosage forms listed - details provided by 24 Member States and 2 international low-cost essential medicine suppliers. Published by the Regional Office for Africa and the WHO Collaborating Centre for the Quality Assurance of Medicines, University of Potchefstroom, South Africa.

Average Prices of a One Year Treatment with Antiretrovirals in Countries of Latin America and the Caribbean: Survey by Pan American Health Organization of ARV therapy in Latin American countries.

Antiretrovirals in Latin America and the Caribbean: Details prices and uses of ARV treatments, and access policies for these medicines. Also covers prices by country and by groups of countries.

International open tendering

Open tender is a formal procedure by which quotations are invited from any manufacturer or manufacturer's representative on a local or worldwide basis, subject to the terms and conditions specified in the tender invitation. In medicine procurement, the use of competitive international tendering has indisputable economic advantages and is one of the classic cost-containment mechanisms. According to the experiences of many countries, international tendering can reduce prices by 40 to 50 %⁶.

However, the economic advantages of this mechanism apply mainly to multi-source products where competition exists. Open tendering is not an option for medicines, such as the majority of ARVs, that are protected by patents, unless there are some means to ensure competitive bids (for example through parallel imports or compulsory licences).

Pooled purchasing arrangements

When several countries share the same pharmaceutical needs, and other conditions such as good communications among those countries are also met, international arrangements for pooled purchasing can generate additional price reductions through enhanced negotiation capacities and economies of scale in production and distribution. There have been various initiatives in this sphere, the most successful ones probably being the ones that concentrate country cooperation in the phase of price negotiations

⁵ Annual Report 2001 – Essential Drugs and Medicines Policy: Extending the Evidence Base (WHO/EDM/2002.1).

⁶ Quick et al. *Managing Drug Supply*. Kumarian Press, 1997.

with pharmaceutical companies. Other successful initiatives have been coordinated by international organizations. One example is the longstanding purchase of childhood vaccines for the Expanded Programme on Immunization by UNICEF and, more recently, the Global Alliance for Vaccines and Immunization and its associated Vaccine Fund. The WHO-based Global Drug Facility for tuberculosis was created to respond to difficulties experienced by countries in the 1990s in finding and funding stable TB drug supplies, which in turn hindered the expansion of the TB control strategy.⁷

Voluntary discount agreements

There are two distinct categories of voluntary agreements between supplier firms and developing country governments to supply differentially priced products:

- a) initiatives where prices are negotiated at a central level, such as the Global Alliance for Vaccines and Immunization (GAVI) and the Green Light Committee (GLC);
- b) initiatives where prices are negotiated at a disaggregated level, between suppliers and countries⁸.

Voluntary agreements in the second category include those between firms and countries to supply discounted ARVs through the Accelerating Access Initiative (a collaboration between 5 UN agencies and programmes and 7 research-based pharmaceutical companies); as well as agreements between countries and Indian, Brazilian or other countries' public or private pharmaceutical manufacturers. These agreements need to be assessed in terms of their price level, volume assured, duration of the deal and any other conditions which may be requested by the manufacturer.

Voluntary licensing

Voluntary licensing arrangements between a patent holder and another party (licensee) in a country, or serving the country's market, may afford opportunities for significant cost-containment. As with negotiated discounts, the benefits of voluntary licensing arrangements depend crucially on the terms of the licence. For voluntary licences, the capacity of the licensee is also critical.

Patent holders may, at their discretion, licence to other parties on an exclusive or non-exclusive basis, the right to manufacture, import, and/or distribute a pharmaceutical product. Depending on the terms of the licence, the licensee may act entirely or effectively as an agent of the patent holder; or the licensee may be free to set the terms of sale and distribution within a prescribed market or markets, contingent on payment of a royalty. Either option, or arrangements in between, may allow for substantial price reductions. However, it is important to keep in mind that voluntary licences are contract negotiations between private parties. Terms in a voluntary licence may set price ranges, or include other terms that maintain prices at or near the same level as those offered by the patent holder. Or, terms may limit how many

⁷ WHO Commission on Intellectual Property Rights, Innovation and Public Health. *Public Health, Innovation and Intellectual Property Rights*. Geneva, WHO, 2006, p. 127.

⁸ Unpublished paper commissioned by WHO to Cheri Grace, 2002.

patients or which categories of patients are eligible to benefit from the lower prices provided by the licensee. Again, such matters depend on the terms of the licence contract. Voluntary licensing arrangements, at the discretion of the patent holder, are usually made for strategic reasons (e.g. market entry) rather than as price gestures and they may, in certain cases, not entail any price reduction at all. In developing countries, due to the lack of negotiating capacity of the licensee, voluntary licensing does not always translate into price reductions.

Local state production

Several experiences have shown the importance of the existence of a state medicines manufacturing capacity.

During the 1998 Asian financial crisis, the Indonesian Government was able to supply hospitals, health centres and other health facilities with essential medicines thanks to the existence of state-owned local pharmaceutical manufacturers. Privately-owned local and foreign companies practically halted production for several weeks as the collapse of the local currency and uncertainty in foreign exchange rates prevented them from importing necessary raw materials.

Another important example has been the success of the Brazilian policy to fight AIDS, which has relied crucially on state pharmaceutical manufacturing capacity. Brazil produces most of the ARVs required for the local market, at prices significantly lower than those charged by brand-name companies. In addition, the existence of a significant local capacity to manufacture medicines, among other factors, increased Brazil's negotiating power in discussions with brand-name companies over price discounts (see also Chapter IV).

Government price controls

Price regulation and negotiations

A competitive marketplace is the best way to ensure low prices for medicines. Proper organization of the market and application of anti-trust (monopoly) laws should facilitate price competition. However, if the pharmaceutical market is not competitive and/or there is a need to contain medicine prices, governments may choose to institute price controls.

Control or regulation of medicine prices may be based on:

- a) actual costs (cost-plus pricing based on manufacturer's or importer's cost plus a fixed mark-up),
- b) controlling companies' profit margins, or
- c) comparison with prices in other countries or prices of other medicines in the same therapeutic category (yardstick, benchmark, or reference pricing). Once initial prices are established, decisions must then be made about price increases.

Reimbursement controls

A further means of controlling costs to the government is to establish different levels of reimbursement and to increase the proportion of the cost paid by the consumer for certain products (those not included in the national essential medicines list, for example).

Economic evaluation

Medicine selection decisions and the establishment of standard treatments involve judgements about relative therapeutic value. The economic evaluation of medicines is a systematic method to identify which of a series of alternative therapies will achieve medical objectives most cost-effectively. It forms part of a newly-emerging discipline called pharmacoconomics.

Economic evaluation is being used in some industrialized countries to determine whether the magnitude of the benefit of a new medicine justifies the cost and then to subsidize those medicines that produce the greatest output in improved health in return for the lowest cost.

Policy-makers are faced with a lack of unbiased and accurate information on the trade-offs between competing product options. Economic evaluation is useful because it offers a logical framework for considering a new medicine for subsidy, for drug formulary management, or for price-setting. Yet it is not a proven means of budgetary control. It is a complex, time-consuming and resource-intensive process. Nevertheless, it would be a way to ensure that the medicines budget represents value for money. Frequent reassessment of decisions is necessary as more information becomes available.

Reduction of import and other taxes for essential medicines, and rational dispensing practices

Reducing import and other taxes on pharmaceuticals may serve to lower final prices to consumers. Where there is competition, such taxes will clearly add to the final price of a product, an add-on to the wholesale price. Where patent protections are in place, patent holders have much more pricing discretion, and may set wholesale prices with an eye to the final retail price. Thus, tax reductions may not translate into reduced retail prices, or price reductions equivalent to the tax reduction. Whether tax reductions thus benefit consumers will depend largely on the particularities of specific markets: whether products are patented, whether price controls are in place, how patent holders choose to act and pricing discretion available to pharmacies and dispensing agencies.

Pharmaceutical dispensaries may engage in significant price mark-ups or dispensing practices that favour use of brand-name and higher-cost products at the expense of generics and lower-cost alternatives. As is the case in many countries, Thailand may consider regulations to require or prefer generic substitution, where safe and effective generics exist. Many price-increasing dispensing practices relate to the percentage mark-up by dispensaries. To realign dispensary incentives, Thailand may consider regulations stipulating that pharmacies charge a flat fee per sale, as opposed to a percentage of the value of the product which provides inadvertent incentives to sell expensive products.

Public investment in R&D for new medicines: A mid- to long-term strategy

An option that developing countries with a large scientific base, such as Thailand, should explore more systematically is the strengthening and expansion of the R&D for medicines that are needed to address the diseases prevalent in those countries, including HIV/AIDS. Thailand may have significant cost advantages to undertake R&D in complex fields (including genomics, proteomics and other new fields) and become an important player in the invention of new medicines and treatment. This could be done on the basis of public investment at the national level, or through partnerships with other countries, for the public good, that is, in order to make available new therapeutic options for no-profit purposes. Several modalities may also be envisaged to recoup investment in R&D as well as to establish partners.

II. Non-voluntary licences for government use: practical aspects and procedures⁹

Article 31 of the TRIPS Agreement regulates “other use of the subject matter without the authorization of the right holder”, addressing what is commonly known as compulsory licensing. While, as was made clear in the Doha Declaration on the TRIPS Agreement and Public Health, the TRIPS Agreement leaves each Member free to determine the grounds on which compulsory licences can be granted, it does mention an number of possible grounds, including national emergency or extreme urgency, public non-commercial use, dependency of patents and to remedy anti-competitive practices.

This chapter specifically deals with the requirements and steps to be followed when granting a non-voluntary licence for government use. Similar requirements must also be complied with when granting non-voluntary licences under other grounds. Taking into account the provisions of the TRIPS Agreement, the granting of a non-voluntary licence for public non-commercial use would require a number of steps which are described below, and for which references to the Thai legislation are provided merely as an example of its national implementation.

Identify relevant patents

In most cases, pharmaceutical products are protected by a patent on the active ingredient (the main patent) and by a number of patents on formulations, manufacturing processes, new indications, etc. (secondary patents). It is advisable to include all relevant patents in a compulsory licence to allow freedom to operate with the needed product. Otherwise, the use of the invention under the compulsory licence may be blocked on the basis of allegations of infringement of secondary patents (as illustrated by the well-documented case of didanosine in Thailand almost a decade ago), making it necessary to resort, for instance, to alternative drug formulations, such as powder forms.

⁹ *Cost-containment mechanisms for essential medicines, including antiretrovirals, in China* (WHO/EDM/PAR/2003.6).

Explore possible sources of supply based on local production

The analysis to be undertaken should include:

- availability of technical resources for reverse engineering
- cost and duration of developing manufacturing processes and formulations
- the need for technology transfer
- good manufacturing practices and quality assurance of products made by local producers
- estimates of the investment required and of the marginal cost of production.

Identify possible sources of importation of the required medicine

The analysis to be undertaken should include:

- compliance with good manufacturing practices and product quality assurance by potential suppliers
- cost comparisons vis-à-vis local production
- prices of supply over time
- the sustainability of the exporter's supply.

Marketing approval

Registration is an important safeguard to ensure quality of the product. However, registration requirements may pose obstacles to the speedy distribution of needed medicines (see, for example, Chapter III, Bolar exemptions), hence, analysis of the scope of such obstacles and identification of the required remedial measures may be needed. Countries could consider creating a fast-track mechanism and/or giving priority to the evaluation and registration of a medicine that is considered urgently needed or important.

Request for a non-voluntary licence for government use¹⁰

A compulsory licence or 'non-voluntary licence' allows a government to authorize itself or a third party to use the subject matter of a patent without the consent of the right holder for reasons of public policy. A 'non-voluntary licence' authorizing the government itself to use a patented invention is known as a government use authorization. Article 31 of the TRIPS Agreement allows the grant of compulsory licences subject to certain conditions, and the Doha Declaration reaffirms that countries have "the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted".¹¹ These rights and freedom do not mean that compulsory licences are not regulated. States have to fulfil certain procedures and criteria in order to grant a non-voluntary licence.

It has to be noted that the TRIPS Agreement does not define the meaning of "public non-commercial use". However, the Vienna Convention on the Law of Treaties

¹⁰ Flynn, S. *Thai Law on Government Use Licences*. American University, December 2006.

¹¹ WTO Ministerial Conference, *Declaration on the TRIPS Agreement and Public Health*, adopted on 14 November 2001, WTO/MIN(01)/DEC/W/2, 20 November 2001, paragraph 5(b).

commands, as a general rule of interpretation, to interpret a treaty “in good faith in accordance with the ordinary meaning given to the terms” (Article 31). Following this rule, it has been argued that the meaning of “public non-commercial use” may be found in the nature of the transaction or the purpose of the use of the patent. Regarding the nature of the transaction, “non-commercial” may be understood as “not-for-profit” use, while, as far as the purpose of the use is concerned, “non-commercial” may refer to the supply of public institutions that are not functioning as commercial enterprises. The fact that the licence will be used to support a public interest programme may be sufficient grounds for justification.

Article 31 of the TRIPS Agreement makes the use of the subject matter of a patent without the authorization of the right holder, including use by the government, conditional on its admissibility under domestic law. In the case of Thailand, for instance, non-voluntary licences for government use can be granted on the basis of Section 51 of the Patent Act B.E. 2522 (1979), as amended by the Patent Act (No. 2) B.E. 2535 (1992) and the Patent Act (No. 3) B.E. 2542 (1999). Section 51 of Thailand's Patent Act recognizes the right of "any ministry or department of the Government", "by themselves or through others" to exercise any right conferred by the patent in order to carry out any service "for public consumption".

Section 51 specifically states:

"In order to carry out any service for public consumption or which is of vital importance to the defence of the country or for the preservation or realization of natural resources or the environment or to prevent or relieve a severe shortage of food, drugs or other consumption items or for any other public service, any ministry, bureau or department of the Government may, by themselves or through others, exercise any right under Section 36 by paying a royalty to the patentee or his exclusive licensee under paragraph 2 of Section 48 and shall notify the patentee in writing without delay, notwithstanding the provisions of Section 46, 47 and 47bis."

In the circumstances under the above paragraph, the ministry or bureau or department shall submit its offer setting forth the amount of remuneration and conditions for the exploitation to the Director-General. The royalty rate shall be as agreed upon by the ministry or bureau or department and the patentee or his licensee, and the provisions of Section 50 shall apply mutatis mutandis."

Licensing authority

Under the Thai Patent Act, the Director-General of the Department of Intellectual Property is authorized to grant various types of compulsory licences. Complementing this, under Section 51, a public use licence may be also issued by "any ministry, bureau or department of the Government" by " themselves or through others."

Notice to the patent holder

Article 31 (b) of the TRIPS Agreement establishes as a general obligation to try to obtain authorization from the right holder on reasonable commercial terms and conditions when granting a non-voluntary licence. When such efforts are not

successful, the use of the patent's subject matter without the authorization of the right holder can be permitted. The same article waives this obligation in cases of public non-commercial use and national emergency or other circumstances of extreme urgency. In cases of public non-commercial use, there is an obligation to promptly notify the title holder. In cases of national emergency or urgency, this notification is required as soon as reasonably practicable.

Section 51 of the Thai Patent Act requires that the licensing authority "shall notify the patentee in writing without delay, notwithstanding the provisions of Section 46, 47 and 47bis." The exemption from the requirements of Section 46, 47 and 47bis makes clear that the Government is not required to: (1) wait until "the expiration of three years from the grant of a patent or four years from the date of application," or (2) have "made an effort to obtain a license from the patentee having proposed conditions and remuneration reasonably sufficient under the circumstances".

In relation with the aforementioned notification, a communication to the patent holder should be sent. The TRIPS Agreement is silent on the content of this notification. However, regarding compulsory licences in general and extrapolating the practice in certain countries with regard to the request to the patent holder,¹² the notification may include:

- information about the requesting party
- the expected volume of production;
- the royalty to be paid
- the form of payment
- the intended mode of use of the invention
- quality controls
- trademark to be used, if any
- the duration of the licence
- the licensee's right to control sales for determination of royalties due
- the applicable law and jurisdiction in case of disputes.

Scope and duration of the licence

According to Article 31 (c) and (g) of the TRIPS Agreement, the competent department will have to define the scope of the licence and its duration. The scope and duration shall be limited to the purpose which led to its authorization, and the authorization shall be liable to be terminated if and when the circumstances which led to it cease to exist and are unlikely to recur. In the same vein, the Thai Patent Act lays down that "the scope and duration of the license shall not be more than necessary under the circumstances" (Section 50.1).

It would be advisable for the scope to include all commercial and non-commercial uses of the relevant invention required to meet the purpose of the licence, and for the licence to last until the purpose which led to such granting so requires. In any case, authorization for such use should terminate if and when the circumstances which led to it cease to exist and are unlikely to recur. The fulfilment of this requisite can only be evaluated when a prudential period of time expires.

¹² WHO/EDM/PAR/2003.6, op. cit., p. 8.

Royalties

Article 31 (h) of the TRIPS Agreement affirms that “the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization”. The TRIPS Agreement allows Members “to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice” (Article 1). This is a broad authorization to design the mechanisms to implement TRIPS obligations, precluding the necessity to copy or follow the procedures that are in place in other countries.

Regarding royalties, it has to be taken into account that there are no internationally agreed criteria - and frequently, no national ones either - to set up the payable fee. This vacuum and the associated controversies not only affect government use licences, but also voluntary commercial licences, which are characterized by their variability. To reduce uncertainty and promote predictability in this regard, it is advisable to formulate explicit guidelines or criteria to determine the remuneration rate or royalty fee payable in the case of non-voluntary licences (see Chapter V).

The Thai Patent Act, for example, in Section 51 states that the ministry or bureau or department issuing the non-voluntary licence "shall submit its offer setting forth the amount of remuneration and conditions for the exploitation to the Director-General [of the Department of Intellectual Property]". The royalty rate and terms shall be "as agreed upon by the ministry or bureau or department and the patentee or his licensee", and the provisions of Section 50 "shall apply *mutatis mutandis*" (i.e. with necessary changes).

After the granting of the compulsory licence, *bona fide* negotiations could be undertaken with the patent holder to evaluate the fee for the exploitation of the patent. Generally, fees are expressed as a percentage of the net sales price of the product made under the licence (and not the patentee's own product), but other modalities can be adopted, for instance, a fixed sum per unit sold.

Commercial practice in voluntary licensing is to use royalties ranging between 2% and 5%, though they may be higher or lower in certain cases. There is some evidence available on the royalties determined by national authorities in Canada, the USA¹³ and developing countries¹⁴ for the granting of compulsory licences. (A full discussion on how various countries have chosen to establish royalty rates is set out in Chapter V.)

Factors that may be considered in negotiating the fee include: launch date of the product; possible substitutes; coverage and possible invalidity (total or partial) of the patent(s); pending challenges to the patent(s), if any; accumulated sales and recovery of R&D investment made by the patent holder; global and local market for the product (units and value); expected volume of production and price under the compulsory licence; royalties agreed upon in voluntary licences on the same or similar products; and the nations' economic and health situation.

¹³ WHO/UNDP. *Remuneration Guidelines for Non-Voluntary Use of a Patent on Medical Technologies* (WHO/TCM/2005.1).

¹⁴ See Chapter IV.

Acceptance of the terms of the licence

The terms of the government use licence may be appealed by the title holder. Lacking an appeal, it will be legally understood that the licence's terms are accepted. The Thai Law does not expressly fix the period of time for the patent holder to accept or reject the terms of the licence for government use. However, this period is the same as that established for compulsory licences granted to remedy anti-competitive practices, dependent patents and the non-working of a patent (Section 50): should the parties fail to reach an agreement within the period prescribed by the Director-General, the Director-General will set forth the royalty and conditions, and this decision may be appealed to the Board of Patents within sixty days.

Determination of fee and conditions by the Director-General of the Department of Intellectual Property

Section 50 of the Thai Patent Act establishes that “if no agreement has been reached by the parties within the period prescribed by the Director-General, the Director-General shall fix the royalty and prescribe the conditions and restrictions as he deems appropriate” following a set of requirements also contained in Section 50.

Appeal

The relevant provisions in the TRIPS Agreement envisage that “the legal validity of any decision relating to the authorization of such use shall be subject to judicial review or other independent review by a distinct higher authority”, and “any decision relating to the remuneration provided in respect of such use shall be subject to judicial review or other independent review by a distinct higher authority” (Article 31 (i) and (j)). These provisions must be read in conjunction with Article 44.2 of the TRIPS Agreement regarding injunctions. This article establishes that Members may limit the remedies available against government use licences to those related to the payment of remuneration. This means that the decision to use the patent, to grant a compulsory licence for “government use”, need not be subject to injunctive relief (see also Chapter IV).

Section 50 of Thai Patent Act B.E. 2522 states that the decision of the Director-General of the Department of Intellectual Property on the terms and conditions of the compulsory licence is appealable to the Board of Patents within a period of sixty days. In turn, the Board's decision may be appealed to the Court also within sixty days, otherwise its decision will be final (Section 74). It should be noted that it is not the decision to grant a compulsory licence that it is appealable to the Board of Patents and later to the Court, but the terms of the licence. The explanation is as follows.

Section 50, to which refers Section 51 when defining the requirements of the government use licence, states that “the decision of the Director-General made under the first paragraph of the Section is appealable to the Board within sixty days”. The first paragraph of Section 51 deals with the conditions of the licence, but not with the decision to grant a licence, which is based either on Section 51 or Sections 46, 46bis or 47. This means that the evaluation of the grounds to grant a licence exclusively concerns the Director-General of the Department of Intellectual Property (and, in the case of public non-commercial use, any ministry, bureau or department of the

Government). Consequently, the possible appeal to the Board of Patents, and later on to the Court, does not suspend the execution of the compulsory licence, limiting possible judicial claims to the terms of the licence. Thus, the patent holder has no right to appeal the grounds for the decision to grant a government use licence but rather is limited to contesting the compensation due for the non-voluntary licence.

Other considerations

1) Patent holders (or their governments) may attempt to use legal measures, such as injunctions, to delay or prevent the execution of a non-voluntary licence.

2) It would also be useful to check the possible application of other instruments, such as bilateral agreements on investment (which often consider intellectual property as an “asset” subject to their rules) or free trade agreements with intellectual property provisions.

3) Article 31 (a) of the TRIPS Agreement lays down the requisite to consider on its individual merits the authorization of use without the consent of the patent holder. Each of the licences granted must be duly justified, which means that it is not possible to indiscriminately grant licences, but only after an assessment of their necessity has been undertaken.

4) The TRIPS Agreement also states that “such use shall be non-exclusive” (Article 31 (d)). This implies that the grant of a non-exclusive licence does not preclude the patent holder from exploiting the national market or exporting the patented product.

III. Other important TRIPS flexibilities to promote access to medicines

It is important to underline the fact that compulsory and government use licences are not the only flexibilities under the TRIPS Agreement that can have an impact on access to medicines. The range of measures that can be taken by governments under the TRIPS Agreement before a pharmaceutical patent is issued is often referred to as “pre-grant” flexibilities. “Post-grant” flexibilities, on the other hand, are policy options that, if incorporated into national law, are generally employed to address particular cases in the exercise of exclusive patent rights. The following non-exhaustive list of flexibilities is available to all WTO Members. It should also be noted that a number of these options are the subject matter of negotiations in preferential trade and investment agreements.

Pre-grant flexibilities

Many of the pre-grant flexibilities are intended to help ensure that the patent system confers upon an applicant the reward of exclusive rights for a true and genuine innovation. While certainly not exhaustive, the following flexibilities may be of particular interest to a developing country, such as Thailand, seeking to encourage the local production of low cost, high quality pharmaceuticals as one means to meet the objective of greater access to medicines.

First, the TRIPS Agreement is silent on the establishment of administrative procedures for patent opposition. Particularly relevant in this regard is the establishment of **observation procedures**. Observation procedures provide third parties with the possibility to file an observation with the patent office on a pending patent application.

Third parties may use the observation procedures to claim, for example, that there has been insufficient disclosure by a patent applicant (Article 29 requires Members to provide for sufficiently clear and complete disclosure of an invention when submitting a patent application). An important additional flexibility in this regard is contained in Article 29.1, which allows Members to require the applicant to indicate the **best mode** known to the applicant for carrying out the invention.

Another important pre-grant flexibility is that of being able to **define the criteria for patentability**. Article 27.1 states that inventions covering patentable subject matter need to be new, involve an inventive step, and capable of industrial application. None of these terms are defined in the TRIPS Agreement, however, and Members are generally free to define what constitutes a patentable invention. As an example, a strict novelty standard (which may stipulate that novelty should be judged internationally, rather than domestically), would narrow the scope of patentability. In the pharmaceutical context, new uses of an existing non-medical product for a medical purpose (first indications) and an existing medication for a new medical purpose (second indications) could conceivably be denied a product patent on grounds of lack of novelty. In this regard, it should be noted, for instance, that the new Indian Patent Act (2005) applies a strict standard on inventiveness (see also Chapter IV). Other countries apply relatively narrower or broader interpretations of the term “inventive step”. It should be noted, importantly, that existing practice differs considerably from country to country with the result that patent protection received in one country does not necessarily mean that such protection is granted in another country.

The TRIPS Agreement authorizes Members to **exclude certain subject matter from patentability**. Article 27.3 (a) permits Members to exclude from patentability diagnostic, therapeutic and surgical methods for the treatment of humans or animals. Some countries treat discoveries of substances existing in nature, extractions/purifications from natural substances as excludable on the grounds that they do not constitute an “invention” under Article 27.1.

Post-grant flexibilities

As far as post-grant flexibilities and the patent application procedures are concerned, an important flexibility is the freedom given for Members to have a system where **opposition** of a patent is permitted. Under this option, a third party may file an opposition with the patent office after a patent has been granted, within a pre-determined period after the publication of the patent grant. The grounds for opposition are left open to each country, and may be the same as that for pre-grant observation procedures.

National laws may also permit **parallel importation** of patented products. This is related to a concept that needs to be addressed in the national law, namely that of the

exhaustion of patent rights. Upon the first sale of a patented product, the patent holder loses the right to control the further distribution and resale of that particular product. Parallel importation involves the purchase of certain patent-protected products at lower prices and their importation into higher priced countries. These lower priced imports are not counterfeits, but merely lower-priced patented products that are purchased and subsequently re-sold by a third party. Parallel imports can be facilitated or hindered depending upon the type of exhaustion regime a country decides to adopt. Under international exhaustion regimes, distribution rights available under the domestic patent will be exhausted by a first sale abroad in the same way as if that first sale happened domestically (thereby facilitating parallel imports). National exhaustion limits exhaustion to the domestic market and first sales of patented products outside the country will not affect the domestic patent (thereby inhibiting parallel imports).

In addition, a number of limited **exceptions to patent rights** exist under Article 30 and related TRIPS jurisprudence. Legally, this type of flexibility permits others to engage in activity that would normally be considered a patent right violation absent the consent of the right holder, due to overriding policy concerns. The two most notable ones, from the perspective of local pharmaceutical production and access to medicines, are the *scientific research/experimental use exception* (creating a safe harbour for scientific activities that might otherwise be blocked by patents – particularly for basic research and experimentation) and the *regulatory review (Bolar) exception*, which allows generic manufacturers to make use of a patented substance before the actual date of expiry of the patent for the sole purpose of obtaining marketing approval for that product.

An important flexibility exists in the compulsory licence system as well. Under Article 31 (f), pharmaceuticals produced under compulsory licence should normally be predominantly for the supply of the domestic market. The 2003 WTO Paragraph 6 Decision created a means by which it is possible to obtain a waiver from this general rule and therefore permits the production of a drug solely for export to needy countries. The TRIPS Agreement sets out, *inter alia*, detailed notification requirements for exporters and importers to avail of the waiver. In this regard, while least developed countries automatically qualify as an importing country under the system, developing countries may also take advantage of the system as importers if they can establish that they have insufficient or no manufacturing capacities.

A final post-grant flexibility that could potentially be of interest to Thailand is the use of **competition law** to address the abuse of the exercise of exclusive intellectual property rights. This flexibility is contained first in Article 8.2, which authorizes Members to adopt appropriate measures to prevent: the abuse of intellectual property rights by right holders, the resort to practices which unreasonably restrain trade, and practices which adversely affect the international transfer of technology, as long as such measures are TRIPS compatible. Further, Article 40.2 recognized the right of Members to take action against licensing practices or conditions pertaining to intellectual property rights which restrain competition and have adverse effects on trade and impede the transfer and dissemination of technology. The flexibility to use competition law and its related remedies (including fines, price regulation, compulsory licences (under Article 31(k)), etc.), requires not only enabling legislation that reflects the interrelationship between intellectual property and competition, but

also professional and well-functioning competition authorities and interagency cooperation among the relevant authorities (in the case of pharmaceutical patents, between the patent and competition authorities and the ministry of health).

A comprehensive examination of Thailand’s patent law vis-à-vis the above flexibilities is an exercise that is beyond the scope of this mission report. The mission recognizes that a number of flexibilities, such as the “best mode” requirement and pre-grant observation procedures, are already incorporated into Thai law. This report is meant only to list key TRIPS Agreement flexibilities that may be of interest to Thailand, with the understanding that the extent to which Thailand opts to deploy any of these flexibilities is a strategic one to be made by the Government.

IV. Information on country experiences¹⁵ with the use of TRIPS flexibilities to protect public health and access to medicines

Use of compulsory licensing and government use by developing countries

In the past decade, several developing countries have issued compulsory licences in order to increase access to medicines. These include for example:

<i>Date</i>	<i>Country</i>	<i>Product</i>	<i>Duration</i>	<i>Royalties</i>
April 2003	Zimbabwe	all HIV/AIDS-related medicines	not indicated	not indicated
Oct. 2003	Malaysia	- didanosine, - zidovudine - FDC didanosine+ zidovudine	2 years	not indicated
Sept. 2004	Zambia	FDC lamivudine+ stavudine+nevirapine	until notification of expiry of the compulsory licence	2.5%
Oct. 2004	Indonesia	- lamivudine - nevirapine	7-8 years (end patent term)	0.5%
Nov. 2006	Thailand	efavirenz	until 31 December 2011	0.5%
Jan. 2007	Thailand	lopinavir/ritonavir	until 31 January 2012	0.5%
Jan. 2007	Thailand	clopidogrel	patent expiry or no longer needed	0.5%
March 2007	Indonesia	efavirenz	until 07 August 2013	0.5%
May 2007	Brazil	efavirenz	5 years	1.5%

Zimbabwe

Zimbabwe issued a compulsory licence for all HIV and AIDS-related medicines on 8 April 2003. The licence was issued after a period of emergency on HIV/AIDS was declared; a declaration of emergency is a precondition under Zimbabwe’s national law. The compulsory licence allows a local company, Varichem Pharmaceutical Ltd, to produce ARVs or HIV/AIDS-related medicines during the emergency period. The licence requires the company to supply three quarters of its production to state-owned

¹⁵ The examples provided in this chapter do not represent a complete or comprehensive list.

health institutions and specifies that the medicines produced under the licence will be subject to price controls¹⁶.

Varichem reportedly launched its first ARV in Zimbabwe in October 2003 and has since launched several other ARVs. It supplies both the government and private sectors 50%¹⁷.

Malaysia

In November 2002, after efforts to negotiate price reductions had failed, the Ministry of Health of Malaysia proposed the use of “government rights” to the Cabinet. Upon receiving approval, the Ministry of Health applied, in January 2003, to the Ministry of Domestic Trade and Consumer Affairs (custodian of the Patents Act) for an authorization to import patented generic ARVs. In spite of the Cabinet approval, the authorization was opposed by some other government agencies, citing concerns that it would deter foreign investors^{18, 19}.

On 29 October 2003, the authorization for the exploitation of a patented invention on behalf of the government (government use authorization) was issued. It allowed a local company, Syarikat Megah Pharma & Vaccines, to import didanosine tablets, zidovudine tablets and a fixed-dose combination (FDC) of didanosine+zidovudine from Cipla in India. The authorization was valid for a period of two years starting 1 November 2003. It required that the medicines be labelled with the words “Ministry of Health Malaysia” and imposed several other conditions; these included a maximum price and a requirement that royalties be paid to the patent holder(s) within 2 months of importation of each successive batch²⁰. While the authorization did not specify the royalty rate, the MOH reportedly offered the patent holders 4% royalties. The patent holder however showed little interest in accepting or negotiating the proposed remuneration²¹.

One of the patent holders filed a lawsuit against the government use authorization, which however was never activated²². Complaints from the affected companies were also received at some of the Malaysian Embassies²³.

As a result of the government use authorization, the average cost of treatment was reduced by about 80%. The number of patients treated in government hospitals and clinics increased from 1 500 to 4 000. The target is 10 000 when there is more

¹⁶ Government of Zimbabwe (2003). Authority by the Minister of Justice, Legal and Parliamentary Affairs.

¹⁷ Oh, C. *Compulsory licences: recent experiences in developing countries*. International Journal of Intellectual Property Management, 2006, 1: 22-36.

¹⁸ Chee Yoke Ling. *Malaysia's Experience in Increasing Access to Antiretroviral Drugs: Exercising the "Government Use" Option*. Penang, Third World Network, 2006.

¹⁹ Musungu, SF, Oh, C. *The use of flexibilities in TRIPS by developing countries: can they promote access to medicines?* Geneva, South Centre/WHO, 2006.

²⁰ Government of Malaysia (2003). Authorisation for exploitation of patented invention in Malaysia. (translated from original).

²¹ Musungu, SF, Oh, C. op. cit.

²² Chee Yoke Ling. op. cit.

²³ Musungu, SF, Oh, C. op. cit.

awareness of ARV availability and more outreach by the public health system to the needy patients²⁴.

On 1 November 2005, the authorization expired. It was not renewed, since price reductions offered by the patent holders were considered satisfactory²⁵.

Zambia

On 29 September 2004, Zambia issued a compulsory licence to allow a domestic company, Pharmco Ltd, to manufacture a FDC of lamivudine+stavudine+nevirapine. The licence specifies that the product cannot be exported, and that the total amount of royalties shall not exceed 2.5% of the turnover of the product²⁶.

Indonesia

On 5 October 2004, a presidential decree was issued in Indonesia authorizing the Minister of Health to appoint a manufacturer to exploit patents on lamivudine and nevirapine on behalf of the Government. The decree specifies a royalty rate of 0.5% of the net sales price. The authorization lasts for seven years (nevirapine) and eight years (lamivudine), i.e. until the end of the patent term²⁷. In March 2007, the decree was amended to include efavirenz²⁸.

Brazil

Brazil is one of the countries at the forefront of fighting HIV/AIDS. The Brazilian response to the HIV/AIDS pandemic arose from initiatives in both civil society and the Government, and Brazil's commitment to provide AIDS medicines reportedly "resulted, in part, from pressure from civil society"²⁹

Brazil has used the fact that it is capable of producing generic versions of crucial HIV medicines locally, and that it would be willing to issue a compulsory licence if necessary, to negotiate with patent holders. This strategy has been quite successful, and Brazil has obtained substantial price discounts on several ARVs³⁰.

However, on 24 April 2007, the Minister of Health passed Decree n° 866, declaring that efavirenz would be eligible for compulsory licensing for public non-commercial purposes³¹. This was followed, on 4 May 2007, by the issuing of a compulsory licence for public non-commercial use of efavirenz. The licence is valid for a period of five years, and allows for importation of efavirenz for use by the National AIDS Programme. It specifies a royalty rate of 1.5%³².

²⁴ Chee Yoke Ling. *op. cit.*

²⁵ Chee Yoke Ling. *op. cit.*

²⁶ Government of Zambia (2004). Compulsory licence No. CL 01/2004.

²⁷ Government of Indonesia (2004). Decree of the President Republic of Indonesia number 83 year 2004 regarding exploitation of patent on antiretroviral drugs by the Government.

²⁸ Government of Indonesia (2007). Decree of the President Republic of Indonesia number 6 year 2007, amending Decree number 83 year 2004 regarding exploitation of patent on antiretroviral drugs by the Government.

²⁹ Galvão, J. *Brazil and Access to HIV/AIDS Drugs: A Question of Human Rights and Public Health*. American Journal of Public Health, 2005, 95(7): 1110–1116.

³⁰ TRIPS, intellectual property rights and access to medicines. Briefing note. WHO SEARO/WPRO, 2006.

³¹ Portaria No-866/GM, Diário Oficial, República Federativa de Brazil, n° 79, DOU, 24/4/2007.

³² Decreto n° 6.108/2007, Diário Oficial, República Federativa de Brazil, n° 86, DOU 7/5/2007.

Price negotiations with the patent owner had started in 2006, but failed. The time lag between the passing of Decree nº 866 and the issuing of the compulsory licence was intended to allow the patent owner to submit a better price offer. Reportedly a 30% price reduction was offered; however this was considered insufficient, since the patent holder had offered a considerably lower price to Thailand³³.

Use of compulsory licensing and government use by developed countries

Canada

Before it adhered to the NAFTA in 1992, Canada's policy was to encourage local manufacture of patented products. In this context, 53 applications for a compulsory licence were made between 1935 and 1970; in 11 cases a compulsory licence was granted, 9 were refused, 32 applications were withdrawn or abandoned and in one case the outcome is not known. Canada also made extensive use of compulsory licensing to promote the public interest: between 1969 and 1992, there were 1 030 applications to import or manufacture medicines under such licences, of which 613 were granted³⁴.

Use of other TRIPS flexibilities and anti-competition law

As mentioned in Chapter III, compulsory licensing is but one of the mechanisms to safeguard public health and access to medicines. The examples below illustrate the use of some of these other mechanisms.

South Africa

Several people living with HIV/AIDS and a nongovernmental organization filed a complaint with the competition commission of South Africa against Glaxosmithkline and Boehringer Ingelheim. According to one of the complainants, the complaint was filed after a global campaign that lasted nearly four years, requesting pharmaceutical companies to issue unconditional voluntary licences, against a fair royalty rate of 4-5%. Since companies failed to respond, "now we are asking the Competition Commission to investigate the complaint and to refer it to the Competition Tribunal"³⁵.

The case was settled on 9 December 2003. Boehringer Ingelheim agreed to offer licences for nevirapine to Aspen Pharmacare Holdings Ltd and to two other appropriate "entities". According to the settlement, these licences would allow supply to both the public and private sectors, permit export to other sub-Saharan African

³³ Ministério da Saúde. *?Brasil decreta licenciamento compulsório do Efavirenz?*,

http://portal.saude.gov.br/portal/aplicacoes/noticias/noticias_detalhe.cfm?co_seq_noticia=29717

³⁴ Reichman, J, Hasenzahl, C. *Non-voluntary licensing of patented inventions: historical perspective, legal framework under TRIPS, and an overview of the practice in Canada and the USA*. Geneva, ICTSD/UNCTAD, 2003.

³⁵ Treatment Action Campaign. Statement by TAC on Excessive Pricing Complaint to Competition Commission. TAC news service, 19 September 2002.

countries and carry a maximum royalty rate of 5%³⁶. A very similar settlement was concluded with Glaxosmithkline for zidovudine and lamivudine³⁷.

Since receiving these licences, Aspen has obtained WHO prequalification for several of its products³⁸. Its prices for the public sector are competitive; in March 2005, the company had been granted a significant share of the South African Government's ARV tender³⁹.

Rwanda

In July 2007, Rwanda notified the WTO secretariat of its intention to import 260 000 packs of a FDC of zidovudine+lamivudine+nevirapine from Apotex, a generic manufacturer in Canada⁴⁰. This is the first attempt to make use of the system set up under the WTO Paragraph 6 Decision, which allows production of a pharmaceutical product under a compulsory licence for export to a country that lacks manufacturing capacity. The notification states that Rwanda reserves the right to modify the quantity as necessary. It furthermore states that Rwanda will make use of its right, as a least developed country, not to enforce any patent rights that may have been granted with regard to this product.

Following this request, the Canadian Commissioner of Patents granted, in September 2007, a compulsory licence to Apotex, allowing Apotex to manufacture the concerned product exclusively for export to Rwanda. This licence is valid for a period of two years⁴¹.

Italy

In March 2007, the Italian Competition Authority ordered Merck & Co. Inc. to provide free, non-exclusive licences for generic versions of its antibiotic combination medicine, imipenem/cilastatin. The order was issued to rectify alleged abuse of a dominant market position⁴².

India

In March 2006, a coalition of public-interest groups filed an opposition against Glaxo's application for a patent on Combivir (a FDC of zidovudine+lamivudine). Referring to section 3(d) of India's Patents Act⁴³, they argued that "a combination of

³⁶ Settlement agreement between the twelve complainants and Boehringer Ingelheim in connection with case no 2002 Sep 226 submitted to the Competition Commission of South Africa.

³⁷ Settlement agreement between the twelve complainants and Glaxosmithkline in connection with case no 2002 Sep 226 submitted to the Competition Commission of South Africa.

³⁸ Access to HIV/AIDS drugs and diagnostics of acceptable quality. Prequalification programme. 55th Edition. Geneva, WHO, 2007.

³⁹ Espicom business intelligence (2007). Aspen Pharmacare Company Intelligence Report. Available at <https://www.espicom.com/Prodcats/Search/00000018?OpenDocument> [10 February 2008].

⁴⁰ World Trade Organization (2007). Notification under paragraph 2(a) of the Decision of 30 August 2003 on the implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health. IP/N/9/RWA/1.

⁴¹ World Trade Organization (2007). Notification under paragraph 2(c) of the Decision of 30 August 2003 on the implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health. IP/N/10/CAN/1.

⁴² Coco, R, Nebbia, P. *Compulsory licensing and interim measures in Merck: a case for Italy or for antitrust law?* Journal of Intellectual Property Law & Practice, 2007, 2(7):452-462.

⁴³ Section 3(d) excludes from patentability "the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery

two drugs in one pill is not considered an invention under Indian patent law”⁴⁴; therefore no patent should be granted. Following the filing of the pre-grant opposition and public protests, in June 2006, Glaxosmithkline announced the withdrawal of pending patent applications for a FDC of zidovudine+lamivudine in India and Thailand^{45, 46}.

In 1998, Novartis filed a patent application for the beta crystalline form of imatinib mesylate, the active ingredient of the anti-cancer drug Gleevec. The application was opposed by several Indian generic manufacturers as well as a cancer patient group, who alleged, among others things, that the application was not patentable under section 3(d) of the Patent (Amendment) Act 2005. Section 3(d) states that a new form of a known substance which does not result in the enhancement of the known efficacy is not patentable. According to the opponents, Gleevec is a polymorph form of imatinib mesylate; section 3(d) considers polymorphs to be the same substance unless they differ significantly in proprieties with regard to efficacy - which they held was not the case. The patent office rejected the application, i.e. no patent was granted in India^{47, 48}.

Novartis challenged the decision to reject the patent application in Court⁴⁹. Moreover, in a separate court case, the company challenged the relevant section of the Patents Act under both the Indian Constitution and the TRIPS Agreement. The Chennai High Court found the concerned article did not run counter to the Indian Constitution, and dismissed the second challenge, on the ground that it has no jurisdiction to decide compliance with TRIPS⁵⁰.

V. Guidelines and tools on the use of TRIPS flexibilities to promote access to medicines

Although the right of countries to make full use of the TRIPS flexibilities, including the granting of compulsory licences, for public health purposes is affirmed by the Doha Declaration on the TRIPS Agreement and Public Health, the absence of an appropriate national administrative and legal infrastructure and/or procedures to implement the compulsory licensing system may prevent effective exercise of this right. In this context, a number of issues were brought to the attention of the mission

of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant.” It is accompanied by the following explanation: “For the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy.”

⁴⁴ Pepper, D. *Patently unfair*. Fortune Magazine, 18 September 2006.

⁴⁵ Glaxosmithkline (2006). *GSK patents and patent applications for Combivir*. Available at <http://www.gsk.com/media/archive.htm> [10 August 2006].

⁴⁶ Sargent, C. *Glaxo AIDS Drug Draws Opposition for Indian Patent*. Bloomberg, 30 March 2006.

⁴⁷ Sukumar, CR. *Novartis loses patent claim on cancer drug - Patents Controller upholds Natco contention*. The Hindu Business Line, 25 January 2006.

⁴⁸ Iren, T, Gerhardsen, S. *Novartis Persists With Challenge To Indian Patent Law Despite Adversity*. Intellectual Property Watch, 19 October 2006.

⁴⁹ The case was transferred, in April 2007, to the Intellectual Property Appellate Board. As of 6 February 2008, it is still pending.

⁵⁰ Madras High Court (2007). *Novartis AG v. Union of India and others*.

on which further guidance and technical support would be of use. These include the following:

- Guidelines and processes for public health-sensitive intellectual property rights management to ensure a clear and efficient decision-making process;
- A coherent approach that takes into account medium to long-term considerations for increasing access to medicines, including issues related to competition policy, technology transfer and local production;
- Relevant information and lessons learnt from experiences of other countries in the exercise and use of the TRIPS flexibilities;
- Access to relevant pharmaceutical patent data and determining the patent status of essential medicines; and
- Technical assistance, in particular, in relation to the determination and calculation of the remuneration rate for non-voluntary use of a patent.

This section below provides a summary of the options available to governments in terms of guidelines and tools on the use of TRIPS flexibilities.

Guidelines and processes for public health-sensitive management of intellectual property rights

It is acknowledged that the decision to grant compulsory licences and use other TRIPS flexibilities is often complicated and involves different stakeholders. It is therefore important to establish clear decision-making processes, including the determination or designation of the authorities or bodies charged with responsibility for the various stages of decision-making. It is noted that the TRIPS Agreement does not specify the nature of the authority or process that is mandated to grant compulsory licences or determine the level of compensation.

In this regard, WTO Members may designate the appropriate competent authority(ies) and process or system for the processing and granting of compulsory licences. It is noted that the systems vary in different countries, with some adopting administrative procedures and others a mixed system, where initial decisions relating to the grant of compulsory licences and compensation are made administratively and appeals are made to the judicial system.

The UK Commission on Intellectual Property Rights⁵¹ in its 2002 Report identified some of the key features for such a system, as follows:

- legislation that fully exploits the flexibilities in the TRIPS Agreement for determining the grounds for compulsory licensing, as well as for non-commercial use by government;
- straightforward, transparent and fast procedures;

⁵¹ UK Commission on Intellectual Property Rights. *Integrating Intellectual Property Rights and Development Policy*. London, September 2002.

- clear, easy-to-apply and transparent guidelines for setting royalty rates; and
- a procedure for appeals that does not suspend the execution of the compulsory licence or government-use provision.

Some of the specific features of an appropriate administrative system are discussed in further detail below.

A coherent approach

As described above, different authorities and/or bodies may be charged with the responsibility of ensuring the careful consideration of factors and requirements involved in the grant of compulsory licences. While these are not required under the TRIPS Agreement, it is also advisable to facilitate the consideration of the medium- to longer-term considerations relevant to ensure the effective and sustainable use of the TRIPS flexibilities as well as to meet the objectives of increased access to medicines. The introduction of an appropriate monitoring and data collection system to assess the impact of the use of the TRIPS flexibilities is an important consideration. Other considerations that may be made within or outside the designated decision-making process for compulsory licensing could include issues related to competition policy, technology transfer and local production, for example.

Country experiences and lessons learnt in the exercise and use of TRIPS flexibilities

As described in Chapter IV above, a number of countries, in the recent years, have used compulsory licences as one means of promoting access to medicines. Information is also provided on the use of compulsory licensing in developed countries, as well as the use of other TRIPS flexibilities by countries in the pharmaceutical sector. Information on the policy and legal measures adopted by other governments in the exercise of their rights in this area could provide useful lessons for others.

Determining the patent status of medicines

Accurate and up-to-date information about the patent status of pharmaceutical products is not always easily accessible or available in an easily understood form. This may stem from the lack of capacity and/or resources in national patent offices to administer the patent system (including managing effective search mechanisms) and to respond to the public health needs. The patent status of essential medicines is clearly a crucial factor in ensuring effective decision-making on use of TRIPS flexibilities.

Patent searches are complicated and highly technical endeavours. Searches are much more difficult where national patent data is not available electronically in robust form and is not incorporated in public or commercial databases. Moreover, patent information is generally searchable by technical description of the patented invention. In the case of pharmaceuticals, searches can be done on the chemical compounds, formulations or compositions related to the medicine but not on the brand-name (or generic name) of a product in which the invention is eventually incorporated.

Although professional patent search companies are available, they are often expensive and may not present a feasible option for under-resourced agencies.

For this reason, the WHO Commission on Intellectual Property Rights, Innovation and Public Health (CIPIH) had recommended the creation of a patent database for key pharmaceutical products, maintained by international organizations such as WHO and WIPO, in order to increase transparency of the patent system and to remove potential barriers to availability of and access to products and to facilitate informed decision-making⁵². WHO, UNAIDS and MSF jointly published, in 2004, a patent status analysis of 18 ARV and HIV-related medicines in 29 developing countries, which included the priority patent numbers and the corresponding patents in these countries. The document provides patent data related to the chemical compound, key formulations or modifications of the selected medicines, and where available, patent data on the combination of the selected medicines with other medicines⁵³. WHO has also initiated a project⁵⁴ to develop a methodology to obtain patent data from public sources, including from the databases maintained by the drug regulatory agencies of the US and Canada, which makes publicly available the lists of medicines approved for marketing and the patents claimed as relevant to them. This patent information provides an initial list of potentially relevant patents from which searches can be made to identify corresponding application and patent documents in other countries. It should however, be noted that there are limitations to this methodology; the most notable being that it will not work for drugs or drug combinations not marketed in the US or in Canada.

Developing a public health perspective for the examination of pharmaceutical patents

Although only a small number of new chemical entities are approved annually, the number of patents applied for protection of pharmaceutical products are increasing. In the circumstances, the criteria applied to examine and grant pharmaceutical patents are extremely relevant for public health policies, and not only a matter of concern for patent and industrial policy. In this specific context, Thailand has been very much involved in the WHO/UNCTAD/ICTSD project to examine the various categories of patent claims for pharmaceutical products. The project suggests some of the mechanisms that may be adopted to incorporate public health perspectives in procedures for the granting of pharmaceutical patents. It proposes a set of general guidelines for the assessment of pharmaceutical patent claims, and suggests elements for development of public health sensitive guidelines for the evaluation and review of pharmaceuticals patents at the national level in developing countries⁵⁵.

Guidelines for determining adequate remuneration for compulsory licensing

⁵² CIPIH Report recommendations 4.16 and 4.17. op. cit.

⁵³ *Determining the Patent Status of Essential Medicines in Developing Countries*. WHO/UNAIDS/MSF (WHO/EDM/PAR/2004.6).

⁵⁴ See Communication from WHO to WTO TRIPS Council, Technical Cooperation Activities: Information from Other Intergovernmental Organizations – World Health Organization (WHO), IP/C/W/478/Add.4, 23 October 2006.

⁵⁵ *Guidelines for the examination of pharmaceutical patents: developing a public health perspective*. Working Paper. Geneva, WHO/ICTSD/UNCTAD, January 2007.

Article 31 (h) of the TRIPS Agreement provides that “the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization”. Most national legislation adopts a similarly flexible approach, using terms such as “reasonable” or “adequate”, including the Thai legislation which provides that “the remuneration fixed shall be adequate for the circumstances of the case”⁵⁶.

There are a number of considerations related to the determination of the remuneration rate. The term “adequate remuneration” is not defined in the TRIPS Agreement, and WTO Members are free to determine their approach. The TRIPS Agreement allows Members “to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice” (Article 1). This is a broad authorization to set up the appropriate mechanisms to implement TRIPS obligations. There is however, no internationally agreed criteria for determining the adequate rate of remuneration⁵⁷. Similar issues exist in the case of voluntary commercial licences.

State practice regarding the determination of “reasonable” royalties or “adequate” remuneration is extensive and varied. A number of royalty systems have also been adopted or proposed in recent years, and establish useful frameworks for consideration. The evidence of compensation for voluntary technology licensing in the private sector also provides an important context for making determinations of remuneration rates. These different options are documented in the WHO/UNDP publication, *Remuneration Guidelines for Non-Voluntary Use of a Patent on Medical Technologies*⁵⁸, and can be summarized as follows:

i) The remuneration rates paid by developing countries in recent cases of compulsory licensing. They range from the aforementioned 0.5% of Indonesia to a royalty rate of 4% in Malaysia.

ii) The UNDP royalty guidelines for compulsory licences, which are simple and predictable, contributing to ease the non-voluntary licensing process. The standard UNDP royalty is 4% of the price of the generic product, which can be raised or reduced by 2% depending on a set of circumstances, such as the therapeutic value or the government contribution to the costs of R&D.

iii) The Canadian approach, as set out in the Use of Patented Products for International Humanitarian Purposes Regulations (P-4 - SOR/2005-143)⁵⁹, establishes a sliding scale of 0.02% to a maximum of 4% royalty rate on the price of the generic product, based on the rank of the importing country in the United Nations Human Development Index (UNHDI). For most developing countries, the royalty rate would be less than 3%. The formula is: add 1 to the number of countries on the UNHDI, divided by the number of countries on the UNHDI, multiplied by 0.04. This rate is

⁵⁶ Section 50.5, to which refers Section 51, on compulsory licences in the public interest.

⁵⁷ “There is wide variation in the way responsible government agencies and courts have set the amount of remuneration awarded to patent holders when patents have been subject to compulsory licensing”. Scherer, FM. *The Economics of Compulsory Drug Patent Licensing*, Paper presented at the World Bank, 2 June 2003.

⁵⁸ (WHO/TCM/2005.1), op. cit.

⁵⁹ Use of Patented Products for International Humanitarian Purposes, SOR/2005-143, available on: <http://laws.justice.gc.ca/en/p-4/sor-2005-143/text.html>

then applied to the generic sales price. The application of this formula to Thailand, 79 in the 2007/2008 UNDP Index, results in a 2.259% rate.

iv) The Japanese Patent Office guidelines for setting royalties on government-owned patents. The standard royalty under these guidelines ranges from 2 to 4%, but it can be increased or decreased by as much as 2%, resulting in a range of 0 to 6%. The criteria to determine the precise rate are diverse, such as the public interest in working of the patent, the importance of the patented invention to the final product or the novelty of the product.

A framework for remuneration

In determining appropriate policies and practices for determining reasonable royalties or adequate remuneration for the manufacture or sale of a medicine, countries should consider approaches that address practical concerns regarding the administration of a system, as well as policy objectives. Two factors can be considered in establishing systems for determining remuneration in compulsory licensing cases.

1. the system of setting remuneration rates should not be overly complex or difficult to administer, taking into account the capacity of the government managing the system. Guidelines will reduce complexity and provide guidance for adjudicators, as well as increase transparency and predictability. Such guidelines, or any system for setting remuneration for compulsory licensing, should anticipate and address the need to divide royalty payments among various patent holders when the product is subject to multiple patents.
2. the amount of the remuneration should not present a barrier for access to medicines. Where a compulsory licence is issued on a pharmaceutical product, the purpose will be to lower price and improve access. Remuneration mechanisms should be designed so as to assist rather than defeat this purpose.

For countries able and willing to make somewhat more complex determinations of royalties, a range of appropriate factors should be assessed, though not all are required, and not all will apply in any given circumstance. These include but are not limited to:

- therapeutic value of the medicine, including the extent to which it represents an advance over other available products;
- the ability of the public to pay for the medicine;
- actual, documented expenditures on development of the medicine;
- the extent to which the invention benefited from publicly funded research;
- the need to respond to public health exigencies;
- the importance of the patented invention to the final product;
- cumulative global revenues and profitability of the invention; and
- the need to address anti-competitive practices.

Final remarks

1. In seeking greater access to essential medicines, national authorities may consider the full range of mechanisms available to contain costs of essential medicines and examine how the various tools may complement one another.
2. A sustainable system for the funding of medicines could be based on 3 main components: 1) the creation or enhancement of a national/social health insurance or of medicine prepayment mechanisms; 2) the introduction and use of all possible cost- containment mechanisms, and 3) the use of TRIPS-compliant flexibilities. The TRIPS Agreement contains a range of mechanisms and options to protect public health that countries can consider when formulating intellectual property laws and public health policies.
3. The use of compulsory licence and government use provisions to improve access to medicines is one of the several cost-containment mechanisms that may be used for patented essential medicines not affordable to the people or to public health insurance schemes.
4. WHO supports measures which improve access to essential medicines, including application of TRIPS flexibilities.

Annex 1: Letter from the Minister of Public Health dated 17 July 2007

Annex 2: Programme for the Mission

Reference material has already been provided to the Thai officials during the mission.