



**Facts and Evidences on**  
*the 10 Burning Issues*

**Related to the Government Use of Patents  
on Three Patented Essential Drugs  
in Thailand**

**Document to Support Strengthening of Social Wisdom on  
the Issue of Drug Patent**

**By**  
**The Ministry of Public Health**  
**and**  
**The National Health Security Office**  
**Thailand**

**February 2007**

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Facts and Evidences on the 10 Burning Issues Related to the Government Use of Patents on Three Patented Drugs in Thailand.



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## Preface

The recent decisions of the Thai Ministry of Public Health to announce the Government Use of Patents on three patented drugs, i.e., Efavirenz (Stocrin<sup>®</sup>) of Merck Sharp and Dohme), Lopinavir+Ritonavir (Kaletra<sup>®</sup>) of Abbott Laboratory) and Clopidogrel (Plavix<sup>®</sup>) of Sanofi-Aventis), based on proposals from the National Health Security Office, have raised several questions among the public and also the concerned partners as well as the pharmaceutical industries, both in the country and internationally. Some questions and concerns are due to lack of information; others are intentional with the aim to create misunderstanding and objections to the announcements. Thus there is a need to clarify all the questions with the right information and evidences. The Ministry of Public Health staff had compiled all the questions and summarized into 10 burning issues that need to be addressed. Relevant answers and evidences have been collected to address each issue.



The Thai Ministry of Public Health views these decisions on the Government Use of Patents as a form of social movement that aims at improving access to essential medicines and the health of the people. The public health interest is thus the main and final goal of this social movement. We believe that for the sustainability and success of any big social movement, there need to be a good combination of three factors, i.e., knowledge and evidence, social support, and political commitment. This forms the so-called “Triangle that moves the mountain”. It is the educated and motivated society that will push for and support the political commitment to bring real and sustainable success to any social reform movement.



Thus this white paper on “The Facts and Evidences on the 10 Burning Issues Related to the Government Use of Patents on Three Patented Essential Drugs in Thailand” does not only aim at answering all the questions raised, but more importantly as a tool to inform and educate the Thai and Global Society as a whole, on the issue of pharmaceutical patent and the public health. This is to ensure the success of the future movements to improve the intellectual property systems so that it is more conducive to social development.

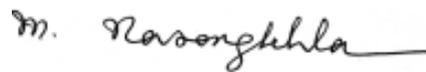
The Thai Ministry of Public Health firmly believes in a moderate and public interest oriented approach to implement the intellectual property right. We are convinced and committed to the view



that “Public Health interest and the life of the people must come before commercial interest”.  
*We do need innovative ways to provide incentives for drug research and development to improve access to essential drugs for all. We believe in what Albert Einstein once said:*

***“We shall require a substantially new manner of thinking if mankind is to survive.”***

This white paper was prepared with time constraint, so there may be some unintentional mistakes and we would expect the readers to understand the limitation and also read it with their own wise and fair judgment.



(Dr. Mongkol Na Songkhla)

Minister of Public Health,

Chairman of the National Health Security Board,

Thailand

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## **Issue No. 1 : What is the rationale behind the Government Use of Patents on the three drugs? Is this movement in compliance with the national and international legal framework?**

The rationale mainly lies in the mandate to achieve universal access to essential medicine for all Thais, under the National Health Security Act 2002. Since 2001, every Thai citizen is covered under one of the three main national public health insurance schemes (Figure 1), i.e.:

**2.1 The Civil Servant Medical Benefit Scheme (CSMBS)** covers around 5 million civil servants, public employees and their dependants. The scheme is paid totally from the general tax revenue based on a fee-for-services retrospective reimbursement system. Public facilities are the main providers under this scheme.

**2.2 The Social Security Scheme (SSS)**, a tripartite system contributed by employers, employees and the government on an equal share basis. It covers around 8.5 million private employees and temporary public employees. Public and private facilities have approximately equal share of the beneficiaries. This scheme pays the providers by the contract capitation system.

**2.3 Universal Coverage Scheme (the gold card scheme)** Since October 2001 universal coverage of the health insurance system was implemented by combining the previous social welfare health services and the voluntary health card scheme, and further expanded coverage to 18 million more people. This scheme covers around 48.5 million people, or 78 per cent of the population. It is financed solely from the general tax revenue. Public hospitals are the main providers; they cover more than 95 percent of the beneficiaries. About 80 private hospitals joined the system and register around 4 percent of the beneficiaries. It also pays the providers by the contract capitation system.

Some of the better off Thais, around 2 per cent buy private health insurance, and many of those better off who are covered by one of the above-mentioned three public health insurance schemes go to private facilities for their health services and pay out of pocket, in spite of their right to access to free care paid by the government. Around 20 percent of Thais pay out of their own pocket when receiving out patient services at private facilities.

All of the 62 million Thais who are covered by one of the three above-mentioned national public health insurance schemes **are entitled to full access of all medicines in the essential drugs list, including almost 900 items of drugs, many of them patented.**

The Thai government is also committed to the policy of **universal access to anti-retroviral drugs (ARVs) for AIDS patients, since October 2003.**

The government responded to these national commitments through several means. One was to raise the public health budget. The public health budget has been increasing from around 4 per cent of the overall national budget in the 1980s to 7 per cent in the 1990s and now to more than 10 per cent. The budget for access to ARVs also increased from around \$US 10 million in 2001 to more than \$US 100 million in 2007; increasing of more than 10 folds in 6 years. This level of spending from national public resources on access to ARVs is highest among the lower middle income developing countries. Thailand has employed the policy towards long-term sustainability of the universal access to ARVs since 2003. The budget supported by the Global Fund is used mainly for purchasing equipment and training of personnel. Less than 20 per cent of the total expenses on ARVs come from the Global Fund. With this quite high spending, the public health insurance schemes still can not afford to pay for the universal access to patented drugs in the essential drug list, including essential ARVs. It is the joint responsibility of the Ministry of Public Health and the National Health Security Office to ensure the right of universal access to essential drugs. So far the two organizations have not been able to fully achieve that goal due to high drug prices and a limited budget. Thus Government Use of Patent to get lower price generics for patients who are covered by the government is one important means to better achieve that goal.

According to the TRIPs agreement article 31 (b), and the Doha Ministerial Declaration on TRIPs and Public Health in 2001, which are clearly reflected in the Thai Patent Act B.E. 2522 as amended by the Thai Patent Act (No. 3) B.E. 2542 (Document No. 1, 2 and 3), there may be three broad mechanisms of using the patent rights by others than the patent holder.

**1. Non public use of patent right :** Under this category, those who would like to use the patent rights of some products, for example drugs, for commercial purposes, must first negotiate

with the patent holders to seek for their permission. The negotiation will include the terms of patent use as well as the royalty paid to the patent holder. If the negotiation is successful, it will then become a **Voluntary Licensing** of patent. But if it fails, then the Director General of the Department of Intellectual Property, Ministry of Commerce can be requested to rule on whether to allow the use of patent and also to fix the terms of patent use as well as the royalty fees. This then becomes **Compulsory Licensing**. (Thai Patent Act section 46 to 50).

**As this is for commercial use, prior negotiation with the patent holder is needed.**

**2. Public use of patent rights :** There are two categories on the public use of patents.

2.1 In order to carry out any service for public consumption or which is of vital importance to the defense 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 and department of government may***, by themselves or through others, exercise any right under Section 36 by paying a royalty to the patentee ***without the requirement for prior negotiation on the permission, the royalty fees or the term of patent use*** (Thai Patent Act section 51).

2.2 During a state of war or emergency, the Prime Minister, with the approval of the Cabinet, shall have the power to issue an order to exercise any right under any patent necessary for the defense and security of the country by paying a fair remuneration to the patentee (Thai Patent Act section 52).

The announcements of the Government Use of Patents on the three drugs in the National Essential Drug List, namely Efavirenz, Lopinavir+Ritonavir, and Clopidogrel, by the Director General of the Department of Disease Control and the Permanent Secretary of Public Health, are thus in full compliance with the Thai national and the international legal framework (mechanism 2.1 above). A more detailed explanation on the legal compliance with the Thai Law on Government Use Licenses has been clarified by Sean Flynn from the American University, Washington College of Law (Document No. 4). The details of the three announcements and the letters to the three patent

holders as evidences of complying with the existing legal framework are shown in Document No. 5-10.

This compliance with all legal frameworks has also been confirmed by the 22 US Congressmen in their letter to the Honorable Susan C. Schwarb (Document No. 11), the United States Trade Representative. It is also confirmed in her letter responding to the 22 US Congressmen (Document No. 12), stating that *“We have not suggested that Thailand has failed to comply with particular national or international law.”* She also stated that *“we have not sought to insert the US government into any such discussion”* (between the Thai authorities and the pharmaceutical industries). The Director General of the World Health Organization, Dr. Margaret Chan, also confirmed in her letter to the Thai Public Health Minister, that the announcement of the three Government Use of Patents, are fully in line with the TRIPs agreement and there is no need for prior negotiation with the drug companies (Document No. 13).

Under such legal frameworks, the announcement of Government Use of Patent is not limited to only emergency or extreme urgency situations and is also not limit to only drugs or ARVs. Furthermore, Thailand is not the first country to apply compulsory licensing or the Government Use of patent, developed countries including the USA, European countries, and other developing countries have previously attempted and implemented compulsory licensing and Government Use of Patents. Some recent examples of the use on drug patents and other patents are detailed in Document No. 14 and No. 15.

In conclusion, the announcement of the Thai authorities on the Government Use of Patents on three patented essential drugs is fully complied with the national and international legal framework. It allows the government to better achieve its commitment to universal access to medicines in the essential drug list and also is clear evidence of the government’s commitment to **put the right to life above the trade interest.**

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**Issue No. 2: Why did the Thai authority decide not to have prior negotiation in a constructive manner with the drug companies and avoid unnecessary conflict as well as achieve lower drug prices and more access to essential drugs? Can we consider the Government Use of Patent as a kind of uninformed expropriation of private property by the state, as mentioned by one of the senior managers in the drug industry?**

As mentioned in the response to issue No.1 that under all national and international legal frameworks, there is no need for prior negotiation with the patent holders before announcing and implementing the Government Use of Patent under category 2.1 above.

Nevertheless, even without the need for prior negotiation and discussion, the Ministry of Public Health had tried through several means and mechanisms between 2004 to 2006, to discuss and negotiate with the patent holders. In April 2005, a Working Group to negotiate for price reduction on patented drugs was established (Document No. 16). This working group is chaired by the Secretary General of the Thai Food and Drug Administration (FDA) with the representatives from the relevant departments in the Ministry of Public Health and the Ministry of Commerce. The working group received little cooperation from the patent holders to provide adequate information for the negotiation. After one year, a short report of the working group concluded the failure of their work to reduce the price of the patented drugs (Document No. 17). Furthermore, during 2004 to 2005, the Department of Disease Control, the biggest purchaser of ARVs in Thailand had several meetings with the patent holders as well as some official communications to request for the reduction of patented ARVs. They also reported the failure to achieve any significant price reduction. Some companies responded officially as to why prices could not be reduced (Document No. 18). Not until the rapid appreciation of the local Thai currency since early 2006 did a few patent holders decide to reduce the price of their products in Thai currency. The maximum price reduction was less than 20 per cent, not much higher than the level of currency appreciation.

Failure to negotiate for price reduction of monopolized drugs is not new in Thailand. In 1997,



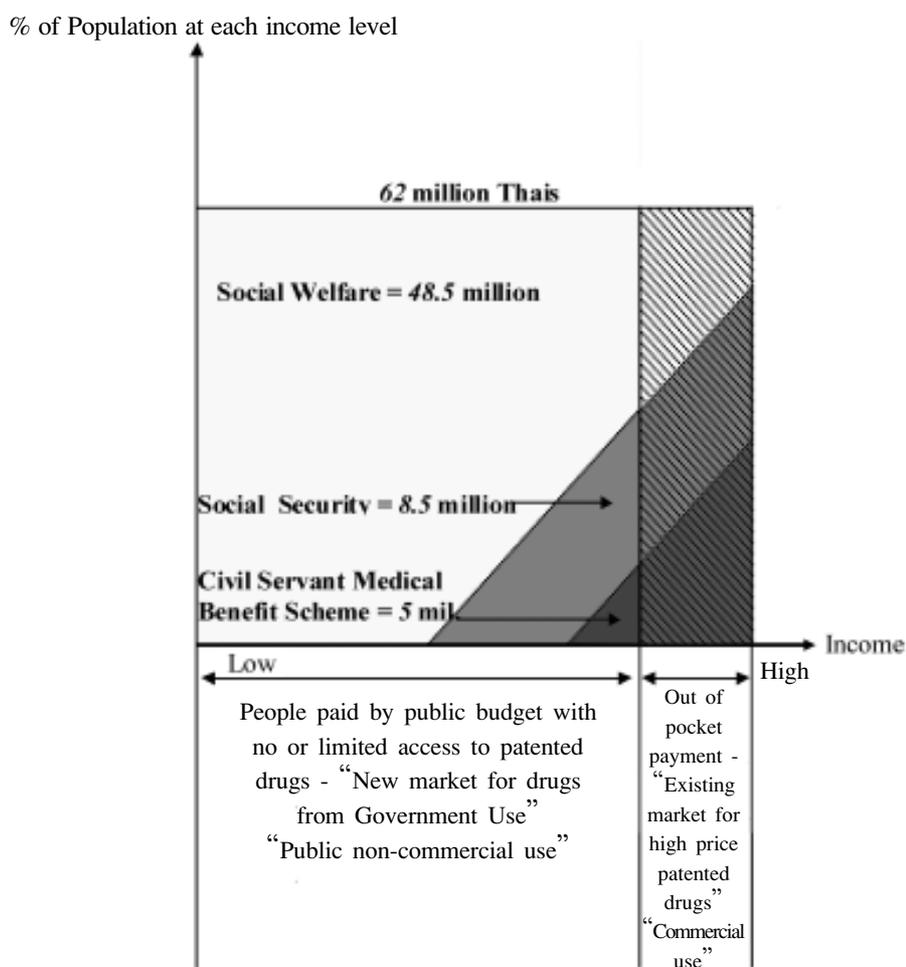
when the anti-fungal for opportunistic infection in AIDS patients, Fluconazole, was still monopolized, the Department of Disease Control tried hard to negotiate to reduce the price from more than 250 Baht per tablet, but were unsuccessful. However, after the monopolistic condition ended and with the emergence of several generic versions of Fluconazole, the price is now reduced by approximately 50 times. This is an experience that has been recognized globally and it has been concluded that ***“Prior negotiation with the patent holders is not an effective measure and only delays the improvement of access to essential medicines. It is only after the threat or the decision to use and implement Compulsory Licensing or Government Use of Patent that the negotiation will be more successful and effective”***.

Those who advocate for prior negotiation should realize these facts. The attempt to push for prior negotiation only delays improvement in access to patented essential medicines and puts more lives in less healthy or even dangerous situations.

It should also be noted here that the drugs derived from the Government Use of Patent in Thailand *will be distributed only to those patients who are covered by the government*. Those who are well off and can afford to pay out of their own pocket including around 2 million foreign patients still have to pay the high price of patented products. These well off people and the foreign patients are actually the only current market of the patented products. The patented products have little or no access at all, by the majority of Thais whose medicine cost are paid by the government. So they are not the effective market of the patented products. The Government Use of Patents has opened this new market, among those who cannot afford them, for these drugs (Figure 1). However, due to limited budget and the mandate to achieve universal access, the government cannot afford to pay the price of the patented products. Opening of this new market for competition among all generics as well as with the patented products will allow the government to provide good quality essential drugs at an affordable price to all Thais, to fulfill the legal and political commitment to universal access to essential medicine. With the Government Use of Patents, the patent holder still has the right to produce, import and sell their products. They still preserve the

right to grant voluntary licensing to anybody. So their patent rights are still fully preserved. Thus this cannot be considered as the expropriation of private asset. Furthermore, the Government Use of patent as determined in section 51 and 52 of the Thai Patent Act are in the same act as section 36 which provides them the monopolistic right to produce, import, sell and distribute the patented products. Thus the patent holders are all well aware of these flexibilities in the Thai law since the time that they apply for the patent.

Figure 1 Diagram to demonstrate that the Government Use of Patent does not affect much on the existing market size of patented products



**Issue No. 3: Why has the Ministry of Public Health turned down request from drug companies to discuss and negotiate, even after issuing the Government Use of patent? Is there any better way than compulsory licensing to improve access to medicines?**

The policy of the Ministry of Public Health and also the government is to build constructive, transparent and fair relationships with all private firms. Thus constructive discussion is always the main strategy of the ministry. The door for open constructive discussion was available before and after the announcement of the Government Use of Patent. The Ministry of Public Health has never turned down a request from any drug company to hold constructive discussion based on friendship terms. Even after the implementation of the Government Use of patent by importing patented drugs, the door for further discussion and negotiation is always open.

However, we cannot wait for the results of the discussion and negotiation as we do not want to delay the increase in access to these drugs for our people. Thus we started the process of production and importation of these drugs in parallel to the discussion and negotiation. For example, the GPO signed the contract with the Indian drug firm, Ranbaxy, to import 66,000 bottles of Efavirenz on January 5<sup>th</sup> 2007, 5 weeks after the announcement of the Government Use of Patents. The first batch of the drugs arrived in Thailand since the end of January 2007. This generic Efavirenz has reduced the price by more than half, from around 1,400 Baht per bottle to 650 Baht per bottle. This will allow the ministry to provide Efavirenz to an additional 20,000 AIDS patients with the same cost. We are also in the process of actively importing two other patented drugs under Government Use, while negotiation and discussion are in process.

Since November 29<sup>th</sup> 2006, at least two official discussions with Merck Sharp and Dohme and Abbott Laboratories Limited have been carried out in addition to a few more informal discussions. Some informal discussions have also been held with Sanofi-Aventis (Thailand) Ltd.

The discussions are all very friendly and constructive with both sides understanding the

concerns of each other. The drug companies understand the mandate of the Ministry and the National Health Security Office to achieve universal access to essential drugs and also understand that their current market for patented drugs will not be disturbed. They are ready to come up with better and more generous proposals to help the government to achieve the goal of universal access. The Ministry and the National Health Security Office understand the concerns of the drug companies in protecting their intellectual properties rights and profits to compensate for the huge expense on the drug research and development and are ready to consider any generous proposal from the companies. All agreed that this kind of constructive discussion should carry on. The Minister of Public Health signed a ministerial order to establish a new Committee for negotiation of patented drug prices, on February 16<sup>th</sup> 2007 (Document No. 19). This committee replaces the previous working group with wider participations. This committee will be responsible for all forms of negotiation, before and after announcing and implementing the Government Use of patents.

On February 6<sup>th</sup> 2007, Merck Sharp and Dohme has kindly proposed a very favourable new price for Efavirenz at 72 cents per tablet of 600 mg, with six conditions (Document No. 20). This is around 780 Baht per bottle, a price much closer to that of generics, which is 650 Baht per bottle. We are seriously considering this proposal. However, as the 66,000 bottles of Efavirenz from India will last for the next three to four months, we will have some time to compare the prices and conditions of the patented products with the generics before making the final decision.

The company also announced a global price reduction of Efavirenz (Document No. 21). This is a very welcome movement from the company. *This proves that the Government Use of Patents in Thailand does not benefit only the Thai people, but also people around the world.*

It should be reiterated that the report of the WHO commission on Public Health, Intellectual Properties and Innovation clearly concluded that the access to essential health technologies depend on “3Ds”, i.e., discovery, development and delivery. There is a need to invest on research to discover the etiologies and mechanisms of diseases and some potential technologies to deal with them. Then further investment on developing these potential technologies into effective, safe and

good quality essential technologies is needed. Finally adequate financing to produce, purchase and distribute the technologies through adequate and effective health care delivery system is the last essential component. The conventional intellectual property based incentives for investment in the research and development of technologies has proved to be inadequate in response to the need of the people to get access to affordable essential technologies. It creates big financial barrier to the access. *The compulsory licensing is just one mechanism* to alleviate this problem and reduce the financial barrier only in some instance. It is not effective for every drug or technology. (See Issue No.4)

The world do need more innovative ways of providing incentives for research and development of essential health technologies as well as production of lower price technologies, apart from the intellectual properties based one. Several innovative incentives have been proposed, for example the R&D treaty, the advance procurement mechanism, and the special tax to support drug research and development.

***“We shall require a substantially new manner of thinking if mankind is to survive”***

***Albert Einstein***

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**Issue No. 4: What are the mechanisms and criteria used to determine which drugs to issue Government Use of Patent and also the royalty fees? Will there be additional Government Use for more drugs in the near future? Would these movements eventually lead to the failure of the intellectual property systems?**

The Subcommittee to implement the Government Use of patent on drugs and medical supplies established by the National Health Security Board on 17 April 2006 is a mechanism to consider which drugs to issue Government Use of patent (Document No. 22). This subcommittee is chaired by the Secretary General of the National Health Security Office, and involves all concerned departments in the Ministry of Public Health and Ministry of Commerce as well as consumer groups, communities of people living with diseases and medical specialists. The criteria to determine which drugs to issue a Government Use of patent includes drugs and medical supplies that are:

- listed in the National Essential Drug List, or
- necessary to solve important public health problems, or
- necessary in emergency or extreme urgency, or
- necessary for the prevention and control of outbreaks/epidemic/pandemics, or
- necessary for life saving

The price of these drugs and medical supplies must be too high to be affordable by the government to supply to the beneficiaries of the national health insurance schemes to achieve the universal access policy.

The level of royalty fees payable to the patent holders have been set at between 0.5 to 2 per cent of the sale value. This is the common range used in most developing countries in the case of public non-commercial use. For those drugs with high retail value, the royalty will be set at the lowest level of 0.5 per cent. For those with low retail value, the royalty will be set at the top level of 2 per cent. For the three drugs that Government Use has been announced, they are all in high demand and the expected retail value is high. So the royalty fees have been set at 0.5 per cent. However, these royalty fees can be negotiated if drug companies are not satisfied with the proposal from the Ministry of Public Health. If the negotiation fails, then the Director General

of the Department of Intellectual Properties will determine the fees according to several criteria as established in section 51 of the Thai Patent Act (Document No. 3).

The decision on whether to implement the Government Use on other patented essential drugs depends on the work of the Subcommittee and the evidences that they produce according to the above-mentioned criteria. The proposal from the Subcommittee of the National Health Security Board will be submitted to the Ministry of Public Health for consideration to announce the Government Use, on a case by case basis. This is because the National Health Security Office is not a ministry, or a bureau or a department of the government; it is an independent public agency established under the National Health Security Act. The Ministry of Public Health will consider announcing the Government Use of patent only in the case of real necessity to achieve the universal access to essential medicines. The proposals from the Subcommittee have to be supplemented by clear evidence to support the decision by the Ministry. So if there is a real need and enough evidences proposed by the Subcommittee in the future, the Ministry will consider implementing the Government Use of patent on a case by case basis.

From the Thai experience, compulsory licensing or Government Use may be applied successfully in only less than 15 percent of all patented drugs. The Thai figures showed that majority of the non-patented drugs remains monopolized due mainly to the complexities of production. In addition, around majority of the patented drugs do not justify applying Government Use. Some of them do not meet the criteria, for examples drugs for Erectile Dysfunction Syndrome, drugs for baldness, and drugs for acne. In addition, most of the new patented drugs are just “me-too” products and do not have any significant benefit over those existing low price non-patented drugs.

Besides, with Government Use, the patent holders still retain their rights and previous monopolized market (as described in Issue No.2). So, there is no need to worry that the Government Use and Compulsory Licensing will lead to the failure of the intellectual property systems.

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## **Issue No. 5: The Government Use of Patents will save the government some funds but what are the benefits to the people?**

The main objective of announcing and implementing the Government Use of patent is to *increase the access to essential medicines among the Thai people*. The government does not save any budget and in some cases has to spend more. For those ARVs which have limited coverage, like Efavirenz and Lopinavir+Ritonavir, many more people will have access to the drugs with the same budget level. In the case of Clopidogrel, the patients under the National Public Health Insurance Plan had no or very little access before, and the government had to pay an additional amount to allow access to the lower priced generic version of Clopidogrel. It should be reiterated that drugs derived from the implementation of the three Government Use of patent will be distributed only to those patients under any of the three public health insurance plans paid by the government. *The drugs can not be sold to the private sector or to those who are willing to pay out of pocket for their drugs.*

The benefits to the Thai people from the Government Use of patent on each drug are:

### **1. The case of Efavirenz patented by Merck Sharp and Dohme (Thailand) Limited**

Efavirenz is an effective first line ARVs. It is less toxic than Nevirapine which is used in the locally produced Nevirapine based triple ARV formula, GPO-VIR<sup>®</sup>. Around 20 per cent of patients using GPO-VIR<sup>®</sup> will develop adverse drug reactions, from mild to severe, which can be life threatening. Patients in developed countries use Efavirenz based triple ARVs as their first line treatment, including developing countries that purchase drugs through external aid budgets. In Thailand, due to the high price of Efavirenz, all new cases of AIDs patients will have to be put on the more toxic Nevirapine based triple ARVs as their first line treatment. Around 20 per cent of them develop adverse reactions to the GPO-VIR<sup>®</sup>. Only when they develop severe adverse drug reactions will they be switched to the Efavirenz based one, which is more than twice the price of GPO-VIR<sup>®</sup>. With the Government Use of Patent, the Efavirenz price dropped from 1,400 Baht per month to 650 Baht per month. This will allow 20,000 more new patients to be put on to this

Efavirenz based triple ARVs and reduce the risks from the toxicity of the Nevirapine based triple ARVs. If we allow competition to continue under the Government Use of Patent, it is expected that the price may go down further. If the price goes down to 20 per cent of the original price, then we will be able to support up to 100,000 patients with the same budget. This will allow all new patients to be treated with Efavirenz based triple ARVs in the next 5 years. There will be no need to subject the new AIDs patients with the more toxic Nevirapine based ARVs anymore.

## **2. The case of Lopinavir+Ritonavir patented by the Abbott Laboratories Limited**

The Department of Disease Control has done a study on drug resistance among patients taking the first line ARVs. They found that around 10 per cent will develop drug resistance and will require second line ARVs, in the first few years. This depends mainly on the compliance of the patient and the virus itself. There are now around 500,000 people living with HIV/AIDs in Thailand. In the near future, at least 50,000 of them will require second line ARVs. One of the good second line drugs is the combination between Lopinavir and Ritonavir, patented by Abbott Laboratories Limited, under the trade name of Kaletra<sup>®</sup>. The monthly price for the patented product is around 6,000 Baht in 2007. This means 72,000 Baht per patient per year. The budget required for 50,000 patients will amount to 3,600 million Baht. This is more than 100 per cent of the budget for ARVs in 2007. There is still the need to pay for the more than 100,000 patients on first line ARVs. If they do not receive second line ARVs, they will soon develop opportunistic infections and die. These are deaths occurring in the midst of the availability of the appropriate treatment. The high price of the second line ARVs are the major factors that hinders the attempt to save their lives. At the moment, we are able to support less than 2,000 cases of drug resistant patients. With the Government Use of Patent, we expect the drug price to go down at least to around 20 per cent of the current price, which will allow us to save an additional 8,000 lives. With more competition and increased budget, we will be able to save more lives in the near future.

## **3. The case of Clopidogrel patented by Sanofi-Aventis Limited**

This is an anti-platelet drug which is at least as effective as or more effective than Aspirin in preventing coronary obstruction. It is commonly used in patients with coronary heart diseases

which are estimated to be around 300,000 patients in Thailand. It is almost the only drug that can be used in the case of applying coronary artery stent. However, due to the very high price of 73 Baht per day, only around 30,000 patients can afford it, based mainly on out of pocket payment. So, the rest of the poor people who cannot afford to pay have to live with only Acetyl Salicylic Acid. The Permanent Secretary announcement of the Government Use of its patent will reduce the price at least 10 times to less than 7 Baht and allow patients under the universal health insurance scheme to also have access to the drugs. In this case the government and especially the contracted hospitals have to pay additional budget to support access to these generics. However, the lower price generics make it affordable by the government.

From the three examples above, it is clear that the Thai government's goal in implementing the Government Use of patent is to increase the access to the patented essential drugs, *rather than to save budget*. In the case of Clopidogrel, it is clear that more funds will be needed, but is within affordable limit.

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## **Issue No. 6: What will the implications on the Thai export and economy and multinational industries be in Thailand?**

The first thing to consider in addressing this question is that Thailand is implementing the Government Use of patent in compliance with national and international legal frameworks, based on solid evidences of the need to allow the Thai citizens to have more access to patented essential drugs. Furthermore, we are happy to negotiate and discuss with all the patent holders in a constructive manner for the benefits of all stakeholders. Thus there should not be inappropriate reactions and trade retaliation from our trade partners.

The Ministry of Public Health is fully aware that at least two-thirds of our economy depends on exporting of our goods and services. Furthermore, 15 to 18 per cent of our exports go to the USA, the country of origin of two of the patent holders that we have implemented the Government Use. If the US government applies retaliation measures on our exports which results in 10 per cent reduction of exports to the US market, it will mean a one to 1.2 per cent loss of economy and several hundred thousands job losses. So this is a very sensitive issue. Unless there is very important need for the people supported by solid evidences, we will not make these decisions. So the decision on the Government Use of Patent for the three drugs has been made very carefully based on solid legal and social grounds.

It should be noted that a few daily newspapers in Thailand had reported in mid February that the Trade Counselor of the US Embassy in Thailand has informed the senior official of the Thai Ministry of Commerce that the US will not use this case in their consideration of the status of Thailand in their list of countries trade relation. This is good news and it provides evidence of the US fair trade policy. However, there has been no official confirmation on both sides, so far. Nevertheless, if there is unfair trade retaliation against Thai products/services which is not in compliance with the WTO trade rules, we will have the right to bring the case to the Dispute Settlement Body of the WTO.



Furthermore, it should be reiterated that the Government Use of Patent does not touch on the out of pocket payment market, the current market of the patented drugs. The Government Use only opens new market for those who never have access to these drugs before. The patent holders have the full right to reduce their price to compete with the generics in this new market. So after the Government Use of Patent, there will be two drug markets in Thailand. One for those well off people and the two million foreign patients who pay out of pocket for the high price monopolized patented drugs. This market covers around 15-20 per cent of the population. The other is for those who are paid by the government for the lower priced competitive drugs. This is the majority of the Thai people who use their rights under the universal health insurance schemes.

In addition, the size of the Thai drug market is less than 0.5 per cent of the global drug market. It is even less for the market of patented drugs. So there should not be significant effect on the market and return of the research based drug companies.

On the contrary, the Government Use will allow the local pharmaceutical manufacturers, especially the Government Pharmaceutical Organization, to develop their capacities and products. In case that the discussion and negotiation leads to the agreement on voluntary licensing, there will also be technology transfer to further strengthen the local manufacturing capacity in Thailand.

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## **Issue No. 7 : Has the Ministry of Public Health consulted with other ministries and why not bring it to the decision of the Cabinet?**

The Ministry of Public Health has long built up close and constructive relationship with all concern ministries, not only on this issue but also on other health development issues. Representatives from the Ministry of Commerce are involved in the work of the Ad Hoc Working Group to negotiate the price of the patented drugs and the work of the Subcommittee to implement the Government Use of patented drugs. Furthermore, before announcing the Government Use of patent, the Ministry of Public Health held another consultative meeting to have a final analysis of the legal aspect of the announcement. The representative of the Ministry of Commerce, the Office of the Council of State, the Lawyer Council, and other concerned parties were invited and actively participated.

In the subsequent negotiation with the drug companies, we also invited the representative from the Ministry of Foreign Affairs. The new Committee to negotiate the patented drug price, chaired by the Secretary General of the Thai FDA also consists of representatives from all concerned departments as well as consumer groups and specialists.

Lastly, the Ministry of Public Health also played active role in working closely with the Department of Trade Negotiation, Department of Intellectual Properties of the Ministry of Commerce and the Department of International Economic Affairs and Department of America and South Pacific Affairs of the Ministry of Foreign Affairs in preparing common guidelines for explaining the situation on Government Use of Patent in Thailand.

It should be reiterated here that according to section 51 of the Thai Patent Act, *it is the authority of any ministry, bureau or department of the government, to issue the Government Use of patent.* There is no need to get prior approval from the Ministry of Commerce and the Cabinet. This is different from section 52, which applies in the situation of war and extreme emergency; the Prime Minister with the approval of the cabinet, can issue order for the Government Use of patent.



Finally, with so many unclear questions related to the implementation of the Government Use of patent, the Public Health Minister submitted an explanatory note to the Prime Minister as well as a copy to the Minister of Commerce, the Minister of Foreign Affairs and the Minister of Science and Technology.

An 80 page white paper to explain and provide evidence related to the Government Use of patent was also published and distributed on February 16<sup>th</sup> 2007. It is also available on the website at [www.moph.go.th](http://www.moph.go.th) and [www.nhso.go.th](http://www.nhso.go.th). Finally, this English version of the white paper was prepared and published on March 6<sup>th</sup> 2007. It is also available on the two websites.

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**Issue No. 8: Will the issuing of Government Use result in a step backward for development of Drug Research and Development in Thailand?**

Most research based drug companies invest only in some clinical and market research in Thailand. The purpose is mainly to obtain appropriate information for marketing of their products. The Thai drug market, although still very small, is growing and bigger than most ASEAN countries. So it is the interest of the research based drug companies to continue their businesses here. Thus they still have to invest in the clinical and marketing researches as mentioned above.

Thailand is developing its capacity and standard to support drug research and development, including the Good Laboratory Practice, the Good Clinical Practice, and the Good Manufacturing Practice. These capacities together with good research facilities and an adequate mix of good compliance patients will attract more researches from the drug industries. In the future if these capacities are up to international standards and cost-effective, they will automatically attract drug industries to invest in research in Thailand. If our quality is not up to the standard and too costly, drug industries will definitely carry out their research somewhere else. This has nothing to do with the Government Use of Patent or the level of protection of Intellectual Property Rights at all.

At the moment, most basic biomedical research is supported by the public budget, both nationally and from international organizations. The pharmaceutical industry puts very little effort to support this kind of research in Thailand, and there is no clear evidence of increasing efforts.

In the early 1990s when we were pressured to strengthen our patent act and to include product patents, we were also told that if we agreed to do so, there would be more investment in drug research and also technology transfer from the industries. We did revise our patent act to comply with the TRIPs since 1992, eight years before the 2000 WTO deadline. However, there has been no significant increase in drug research and development from the industries. For technology transfer, we only witnessed the transfer of their drug factories from Thailand to countries with lower wages and cost. The number of drug factories in Thailand declined from 188 in 1992 to 166 in 2006.

**Issue No. 9: What are the views of the World Health Organization and other international organizations on this movement in Thailand? Dose the Thai public support this decision?**

The Director General of WHO, Dr. Margaret Chan, sent a letter, dated 7 February 2007 (Document No. 13), to the Public Health Minister of Thailand confirming that WHO unequivocally supports the use of TRIPs’ flexibilities, including compulsory licensing. She also confirmed that Thailand’s actions fully complied with TRIPs and there was no need for prior negotiation with the drug companies. She also supports the constructive discussion with the companies, which is the same view as Thailand, as described in Issue No. 3.

In addition, the letter from the 22 US Congressmen to the US Trade Representative and the reply from the US Trade Representative also confirm the legal and social ground as that of the WHO DG.

Furthermore, there has been overwhelming support from various international organizations, for example UNAIDS (Document No. 23), Medecins Sans Frontieres (MSF-Document No. 24), the Third World Network (Document No. 25), the Consumer Project on Technology (Document No. 26), and the Clinton Foundation (Document No. 27).

This decision of the Ministry of Public Health has contributed to its being voted as the top appreciated ministry of the new government, according to public poll from the National Statistical Office in February 2007. This is the best evidence of the support from the Thai public in addition to many supportive articles and editorials in the popular local newspapers.

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**Issue No. 10: How can we be sure that the drugs derived from the Government Use of Patents will be equivalent in quality to the patented products?**

At least five mechanisms can ensure the equivalence of the drugs to those patented products:

1. For those drugs that WHO has a system for prequalification, especially ARVs, the anti-TB and the anti-malarial drugs, only WHO pre-qualified products will be imported under the Government Use of Patent system.

2. For all drugs, the quality of the product has to be approved by the Department of Medical Science, the Ministry of Public Health.

3. All drugs have to be registered by the Thai FDA and a bioequivalence study is needed in the registration process.

4. Before distribution to the public, the Government Pharmaceutical Organization, the designated body to implement the Government Use of patent, will have to carry out quality assurance of the products.

5. The Thai FDA, the Disease Control Department and the National Health Security Office will jointly carry out post-marketing surveillance of these drugs to ensure the quality.

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## **AGREEMENT ON TRADE-RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS**

### *Article 31*

#### *Other Use Without Authorization of the Right Holder*

Where the law of a Member allows for other use of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government, the following provisions shall be respected:

(a) Authorization of such use shall be considered on its individual merits;

(b) Such use may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time. This requirement may be waived by a Member in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use. In situations of national emergency or other circumstances of extreme urgency, the right holder shall, nevertheless, be notified as soon as reasonably practicable. In the case of public non-commercial use, where the government or contractor, without making a patent search, knows or has demonstrable grounds to know that a valid patent is or will be used by or for the government, the right holder shall be informed promptly;

**WORLD TRADE  
ORGANIZATION**

WT/MIN(01)/DEC/W/2

14 November 2001

**MINISTERIAL CONFERENCE**

**Fourth Session**

**Doha, 9-14 November 2001**

**DECLARATION ON THE TRIPS AGREEMENT AND PUBLIC HEALTH**

1. We recognize the gravity of the public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics.

2. We stress the need for the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) to be part of the wider national and international action to address these problems.

3. We recognize that intellectual property protection is important for the development of new medicines. We also recognize the concerns about its effects on prices.

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

***In this connection, we reaffirm the right of WTO Members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose.***

5. Accordingly and in the light of paragraph 4 above, while maintaining our commitments in the TRIPS Agreement, we recognize that these flexibilities include:

(a) In applying the customary rules of interpretation of public international law, each provision of the TRIPS Agreement shall be read in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles.

(b) Each Member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted.

(c) Each Member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency.

(d) The effect of the provisions in the TRIPS Agreement that are relevant to the exhaustion of intellectual property rights is to leave each Member free to establish its own regime for such exhaustion without challenge, subject to the MFN and national treatment provisions of Articles 3 and 4.

6. We recognize that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. We instruct the Council for TRIPS to find an expeditious solution to this problem and to report to the General Council before the end of 2002.

7. We reaffirm the commitment of developed-country Members to provide incentives to their enterprises and institutions to promote and encourage technology transfer to least-developed country Members pursuant to Article 66.2. We also agree that the least-developed country Members will not be obliged, with respect to pharmaceutical products, to implement or apply Sections 5 and 7 of Part II of the TRIPS Agreement or to enforce rights provided for under these Sections until 1 January 2016, without prejudice to the right of least-developed country Members to seek other extensions of the transition periods as provided for in Article 66.1 of the TRIPS Agreement. We instruct the Council for TRIPS to take the necessary action to give effect to this pursuant to Article 66.1 of the TRIPS Agreement.

**GOVERNMENT USE OF PATENT ACCORDING TO  
THE THAI PATENT ACT B.E. 2522 (A.D 1979) AS AMENDED  
BY THE PATENT ACT (NO.3) B.E. 2542 (A.D. 1999)**

**PART V**

**LICENSES OF RIGHT COMPULSORY LICENSES AND GOVERNMENT USE**

**Section 45** Any patentee may, in accordance with the rules and procedures as prescribed in the Ministerial Regulations, apply to the Director-General for an entry to be made in the register to the effect that any other person may obtain a license.

At any time after an entry has been made, the Director-General shall grant a license under the patent to any person who applies for such a license on such conditions, restrictions and royalty terms as agreed upon by the patentee and the applicant. If the patentee and the applicant cannot agree within the period as prescribed by the Director-General, the Director-General shall grant a license on such conditions, restrictions and royalty terms as he deems appropriate.

Any of the parties may appeal the decision of the Director-General made under the preceding paragraph to the Board within thirty days from the receipt of the decision. The decision of the Board shall be final.

The application for and grant of a license under the second paragraph shall comply with the rules and procedures as described by the Ministerial Regulations.

Where an entry is made pursuant to the first paragraph, the annual fees in respect of the patent after the date of the entry shall be reduced as prescribed by a Ministerial Regulations, by at least one half of the annual fees which would be payable if the entry had not been made.

**Section 46<sup>(1)</sup>** At any time after the expiration of three years from the grant of a patent or four years from the date of application, whichever is later, any person may apply to the Director-General for a license if it appears, at the time when such application is filed, that the patentee unjustifiably fails to exercise his legitimate rights as follows:

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*(1) as revised by the Patent Act (No.3) B.E. 2542*

(1) that the patented product has not been produced or the patented process has not been applied in the country, without any legitimate reason; or

(2) that no product produced under the patent is sold in any domestic market, or that such a product is sold but at unreasonably high prices or does not meet the public demand, without any legitimate reason.

Whether it is an application under (1) or (2), ***the applicant for a license must show that he has made an effort to obtain a license from the patentee having proposed conditions and remuneration reasonably sufficient under the circumstances but unable to reach an agreement within a reasonable period.***

The application for a license shall comply with the rules and procedures prescribed in the Ministerial Regulations.

**Section 47<sup>(1)</sup>** If the working of any claim in a patent is likely to constitute an infringement of a claim in a patent of any other person, the patentee, desiring to exploit his own patent, may apply to the Director-General for a license under the patent of the other person under the following criteria:

(1) the invention of the applicant involves an important technical advance of considerable economic significance in relation to the invention for which the license is applied;

(2) the patentee shall be entitled to a cross-license on reasonable terms;

(3) the applicant shall not assign his right in the license to other persons except with the assignment of his patent.

The applicant for a license must show that he has made an effort to obtain a license from the patentee having proposed conditions and remuneration reasonably sufficient under the circumstances but unable to reach an agreement within a reasonable period.

The application for a license shall comply with the rules and procedures prescribed by the Ministerial Regulations.

**Section 47 bis<sup>(2)</sup>** If the working of any claim in the patent having obtained a license under

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(1) as revised by the Patent Act (No.3) B.E. 2542

(2) as revised by the Patent Act (No.3) B.E. 2542

Section 46 is likely to constitute an infringement of a claim in a patent of any other person, the applicant for a license under Section 46 may apply to the Director-General for a license under the patent of the other person under the following criteria:

- (1) the invention of the applicant involves an important technical advance of considerable economic significance in relation to the invention for which the license is applied;
- (2) the applicant shall not assign his right in the license to other persons.

The applicant for a license must show that he has made an effort to obtain a license from the patentee having purposed conditions and remuneration reasonably sufficient under the circumstances but unable to reach an agreement within a reasonable period.

The application for a license shall comply with the rules and procedure prescribed by the Ministerial Regulations.

**Section 48<sup>(1)</sup>** Where a compulsory license is granted under Section 46, 47 or 47 bis , the patentee shall be entitled to remuneration.

The licensee under Section 38 shall be entitled to remuneration where a compulsory license is granted under 46, 47 or 47 bis, provided that he has the exclusive right to grant licenses to other persons. In such circumstances, the patentee shall not be entitled to such remuneration.

**Section 49<sup>(2)</sup>** In an application for a license made under Section 46, 47 or 47 bis, the applicant shall set forth the amount of remuneration, the conditions for the exploitation of the patent and the restrictions on the rights of the patentee and the exclusive licensee under paragraph 2 of Section 48, and a request for a license. In the application for a license under Section 47, the applicant shall also offer a license under his patent to the other party.

Where an application for a license is filed pursuant to Section 46, 47 or 47 bis, the competent officer shall notify the applicant the patentee and the exclusive licensee under paragraph 2 of Section 48 of the date on which the application shall be considered. The patentee and the exclusive licensee shall be furnished with a copy of the application.

In the consideration of an application for a license under the preceding paragraph, the

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(1) as revised by the Patent Act (No.3) B.E. 2542

(2) as revised by the Patent Act (No.3) B.E. 2542

competent officer may require the applicant, the patentee or the exclusive licensee under paragraph 2 of Section 48 to appear before him to give any statement, or to hand over to him any document or any other item. When the application has been considered by the competent officer and the Director-General has made his decision, the applicant, the patentee and the exclusive licensee shall be notified of the decision.

The decision of the Director-General made under the preceding paragraph is appealable to the Board within sixty days of receipt of the notice.

**Section 50<sup>(1)</sup>** Where it is decided by the Director-General that a license shall be granted to the applicant under Section 46, 46 bis or 47, the Director-General shall set forth the royalty and the conditions for the exploitation of the patent and the restrictions on the rights of the patentee and the exclusive licensee under Section 48 paragraph 2 as agreed upon by the patentee and the applicant. 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 prescribed the conditions and restriction as he deems appropriate subject to the following requirements:

- (1) the scope and duration of the license shall not be more than necessary under the circumstances;
- (2) the patentee shall be entitled to further license others;
- (3) the license shall not be entitled to assign the license to others, except with that part of the enterprise or goodwill particularly of the part under the license;
- (4) the licensing shall be aimed predominantly for the supply of the domestic market;
- (5) the remuneration fixed shall be adequate for the circumstances of the case.

The decision of the Director-General made under the first paragraph of the Section is appealable to the Board within sixty days from the date on which such decision is received.

The issuance of a licensing certificate shall comply with the form, rules and procedures prescribed in the Ministerial Regulations.

**Section 50 bis<sup>(1)</sup>** A license issued under Section 46 may be terminated if and when the

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*(1) as revised by the Patent Act (No.3) B.E. 2542*

*(1) as revised by the Patent Act (No.3) B.E. 2542*

circumstances which led to it cease to exist and are unlikely to recur provided that the termination does not affect the rights or interests of the licensee under the license.

The application for termination of a license under the first paragraph shall be in accordance with the forms, rules and procedures prescribed in the Ministerial Regulations, the provisions of Section 49 paragraphs two and three and Section 50 applying *mutatis mutandis*.

**Section 51<sup>(2)</sup>** In order to carry out any service for public consumption or which is of vital importance to the defense 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, 46 bis and 47.

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*.

**Section 52<sup>(3)</sup>** During a state of war or emergency, the Prime Minister, with the approval of the Cabinet, shall have the power to issue an order to exercise any right under any patent necessary for the defense and security of the country by paying a fair remuneration to the patentee and shall notify the patentee in writing without delay.

The patentee may appeal the order or the amount of remuneration to the court within sixty days from the receipt of the order.

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(2) as revised by the Patent Act (No.3) B.E. 2542

(3) as revised by the Patent Act (No.3) B.E. 2542



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Program on Information Justice and Intellectual Property

## **Thai Law on Government Use Licenses**

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December 18, 2006

This note provides a brief explanation of Thailand's authority to issue a government-use compulsory license for Efavirenz under its own law. Section 51 of the Thai Patent Act makes clear that the Thailand Department of Disease Control is well within its rights in granting a license for the public purchase and use of generic efavirenz without further negotiation with the patent holder. The patent holder is given a right to appeal the terms of the license, including its royalty rate. The Department may, however, use the license to begin purchase of generic versions of patented medicines immediately, regardless of whether any dispute may exist or arise as to the reasonableness of the royalty or other terms established in the license.

### **Thailand's Compulsory License**

On November 29, 2006, a public notice issued by the Director General of the Department of Disease Control announced that it was authorizing the public use of patents on efavirenz to serve

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[HTTP://WWW.WCL.AMERICAN.EDU/PIJIP](http://www.wcl.american.edu/pijip)

its national treatment plan. The notice invokes Article 51 of the Thai Patent Act as the legal basis for the compulsory license.<sup>1</sup> It explains:

By the virtue of provisions of Article 51 of the Thai Patent Act B.E. 2522 (as amended by the Thai Patent Act no.2 B.E. 2535 and no.3 B.E. 2542), the Department of Disease Control, Ministry of Public Health, thus use the patent right of a medicine called Stocrin(r) (or efavirenz as a generic name) and endorse the Government Pharmaceutical Organization of Thailand to exercise the rights contain within Para 1 of Article 36 of the Thai Patent Act B.E. 2522 (as amended by the Thai Patent Act no.2 B.E. 2535 and no.3 B.E. 2542) under these conditions:-

- (1) The use of the above patent rights are effective from today to the 31st December 2011.
- (2) The use of the above patent rights will be limited to the provision of Efavirenz to not more than 200,000 patients per year, for those covered under the National Health Security System Act B.E. 2545, Social Security Act B.E. 2533, and the Civil Servants and government employees medical benefits scheme..
- (3) A royalty fee of 0.5 percent of the Government Pharmaceutical Organizations<sup>1</sup> total sale value of the imported or locally produced Efavirenz will be paid to the patent holder.

The Department of Disease Control, Ministry of Public Health will notify the patent owner and the Department of Intellectual Property, Ministry of Commerce immediately.

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<sup>1</sup> The full notice is available at <http://www.cptech.org/ip/health/c/thailand/thaic14efavirenz.html>

## **Section 51 of the Thai Patent Act**

Section 51 of Thailand's Patent Act defines the right of "any ministry, bureau or department of the Government," "by themselves or through others," to exercise the rights in any patent "for public consumption." Specifically, the section states:

In order to carry out any service for public consumption or which is of vital importance to the defense 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*.

## **Grounds**

Section 51 broadly authorizes the government use of patents to "carry out any service for public consumption" or to meet a list of specific public needs, including "to prevent or relieve a severe shortage of . . . drugs or other consumption items." The public notice contains adequate statements invoking both of these authorized grounds.

The notice explains clearly that the license is being used to help carry out a service for public consumption. Specifically, the notice explains that the license will be used only "for public health

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services,” and therefore is “clearly aimed for non-commercial purposes and for public interests.” This alone is sufficient grounds to permit the license. ***There is no obligation in Thai law (or U.S. law or the WTO TRIPS agreement) that the public use of patented technology be limited to emergency situations of extreme public need. The fact that the license will be used to support a public program is sufficient grounds to justify the license.***

***The public notice also demonstrates that a second independent ground for the license is met: namely “to prevent or relieve a severe shortage of . . . drugs or other consumption items.”*** The notice explains that the license is needed to respond to a shortage of Efavirenz in public treatment programs for people with AIDS:

More than 1 million Thais have been infected with HIV, among this, more than 500,000 people are still alive. These infected individuals will eventually need long-term uses of antiretroviral drugs to maintain their productive lives.. However, budget for health services in the national health security system allocated for HIV /AIDS patients in the fiscal year 2006 (B.E. 2549) is only 2,796.2 million baht for the target group of 82,000 patients.

. . . The Thai Government has launched a policy of universal access to anti-retrovirals since 1st October 2003, and has a budget specifically allocated for them. However, it is still difficult to get accessed to some effective and safer anti-retrovirals. The high price of these patented anti-retrovirals have hindered their accessibility under the universal access policy.

Efavirenz is a highly effective and safe anti-retroviral. It is also placed in the Thailand’s National List of Anti-retrovirals. However, the price of the patented Efavirenz is twice of those generics produced by WHO certified GMP factories in India. With this higher price, the budget allocated from the Thai Government can only cover some

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patients with Efavirenz, whereas the rest has to use other non patented more toxic anti-retrovirals

Although the license for efavirenz appears limited to use in the public health system, it is notable that Section 51 does not restrict the use of licenses issued under it so narrowly where the purpose is to address “a severe shortage of . . . drugs or other consumption items.” This ground is independent from the ground that the license is intended to be used “to carry out any service for public consumption.” Section 51 could, therefore, be used to authorize a compulsory license for use in the private sector if the purpose is to address a shortage of needed medicines.

## **Licensing Authority**

Under the Thai Patent Act, the Director General of the Department of Commerce is authorized to grant most types of compulsory licenses. *A public use license under Section 51, however, may be issued by “any ministry, bureau or department of the Government,” “by themselves or through others.” Thus, it is clear that the Department of Disease Control was within its authority to issue a public use license.*

## **Notice**

*Section 51 does not require prior negotiation with the patent holder. It rather 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 47 bis make 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,” Section 46, or (2) have “made an effort to obtain a license from the patentee having proposed conditions and remuneration reasonably sufficient under the circumstances,”*

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*Section 46 (failure to work); Section 47/47 bis (patent necessary for subsequent invention).*

## **Royalty**

Section 51 states that the ministry issuing the patent “shall submit its offer setting forth the amount of remuneration and conditions for the exploitation to the Director-General.” The royalty rate and terms shall either be (1) “as agreed upon by the ministry or bureau or department and the patentee or his licensee,” or (2) set in terms of Section 50, which “shall apply *mutatis mutandis*” (i.e. with necessary changes).

The reference to Section 50 makes clear that the authorizing ministry has the right to set a royalty absent agreement with the patent holder, subject to appeal. Section 50 discusses the right of the “Director General” to set a royalty rate. But this provision applies when the Director General (of the department of commerce) is the requesting authority. When another ministry is requesting the license under the terms of Section 51, then the command to apply section 51 “*mutates mutandis*” indicates that the references to the Director General should be read as applying to the authorizing ministry or department, in this case the Department of Disease Control. Thus, the applicable language in section 50, with necessary changes made, states:

If no agreement has been reached by the parties within the period prescribed by the [Department of Disease Control], the [Department] shall fix the royalty and prescribe the conditions and restriction as he deems appropriate subject to the following requirements: (1) the scope and duration of the license shall not be more than necessary under the circumstances; (2) the patentee shall be entitled to further license others; (3) the licensee shall not be entitled to assign the license to others, except with that part of the enterprise or goodwill particularly of the part under the license; (4) the licensing shall be aimed predominantly for the supply of the domestic market;

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(5) the remuneration fixed shall be adequate for the circumstances of the case.

The Department of Disease Control fixed a royalty and prescribed conditions of the license in its public notice and states the intent to “notify the patent owner and the Department of Intellectual Property, Ministry of Commerce immediately.” ***Negotiation over the terms and royalty of the license may follow this notice.***

## **APPEAL OF TERMS**

Should the patent holder and the government not reach agreement on the terms and royalty of the license, the patent holder may file an appeal of such terms without affecting the right of the Department to begin using the license immediately (i.e. through the purchase of generic medications for its treatment program).

Section 50 states in relevant part:

The decision of the [Department] made under the first paragraph of the Section is appealable to the Board within sixty days from the date on which such decision is received.

The decision made “under the first paragraph of the section” deals with the setting of the terms of the license, including the applicable royalty. It is not the ultimate decision to grant a license, which appears unreviewable under Thai law. ***Thus, as under U.S. law, the patent holder has no right to appeal the grounds for the decision to grant a government use license but rather is limited to contesting the compensation due for the expropriation. This also suggests that, as under U.S. law, a patent holder may not receive an injunction prohibiting the government from using the patented invention pending the outcome of an appeal of the royalty rate.***

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## **Certified Translation**

### **Notification of the Department of Disease Control, Ministry of Public Health Re: Exercising of Right under Drugs and Pharmaceuticals Products Patent**

---

By virtue 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), the Ministry, Sub-Ministry and Department are empowered to exercise the right under any patent without prior authorization of the patent holder. The objective of this provision is explicitly expressed that all service providers with non-commercial purpose, particularly the service providers of the State which provide such public service as public health, may lawfully exercise such right.

It is generally accepted that HIV (AIDS) epidemic is one of the most grievous public health problems. Approximately, more than one million Thai people have been afflicted with the HIV. More than five hundred thousand of this number are still alive and eventually need long term uses of HIV antiretroviral drug to maintain their productive lives. The budget allocated for health services of the people who have been infected with HIV as well as AIDS patients under the national health security system for the fiscal year B.E. 2549 (2006) is limited to 2,796.2 million Baht for the target group of 82,000 patients.

Even now there are many effective HIV antiretroviral drugs which are capable of extending life span of HIV infected persons and the Royal Thai Government has launched, since 1<sup>st</sup> October B.E. 2546 (2003), a policy to promote access to HIV antiretroviral drugs for all HIV infected persons and has also allocated budget for this purpose, but an accessibility to some kinds of HIV antiretroviral drugs which are effective and having low level of side-effect still be difficult in spite of an inevitable necessity for the HIV infected persons. This due to the fact that all those HIV antiretroviral drugs are under patent protection in accordance with the law on patent which enable the patent holders to dominate market without competition. The prices of those HIV antiretroviral drugs are, as a

result, very high and a hindrance for the State to acquire the drugs for distribution to all HIV infected persons.

Efavirenz has already been proved so far to be one of highly effective and safe HIV antiretroviral drugs with very low side-effect. It has also been placed in the National System for Secured Accessibility to HIV Antiretroviral Drugs. This HIV antiretroviral drug, however, is subjected to patent protection which deters the Government Pharmaceutical Organization or other manufacturers from manufacturing and importing this specific drug for sale in the market. The price of Efavirenz in Thailand is twice the price of the same drug which is generic drug in India. Budget allocated by the government is therefore sufficient to provide only some patients with Efavirenz, while the rest has to use non-patent drugs with higher level of side-effect than Efavirenz because of their lower prices.

According to the Doha Declaration on the TRIPS Agreement and Public Health, each member country has the right to protect public health, in particular, to promote access to medicines for all in case of emergency and for public benefit, especially accessibility to those relating to HIV/AIDS, tuberculosis, malaria, and other epidemics. In this regard, the Thai law on patent empowers the Ministry, Sub-Ministry and Department to exercise the right under any patent without prior authorization of the patent holders so as to provide public service as mentioned above.

Therefore, the Department of Disease Control, the Ministry of Public Health, hereby notifies, by virtue 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), that it is now exercising the right under drug patent of the drug under trade name “Stocrin®” (generic name: Efavirenz). In this regard, the Department of Disease Control entrusts the Government Pharmaceutical Organization to exercise the right in its name in accordance with section 36 paragraph one 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) subject to the following conditions:

- 1) the right shall be exercised from now on through 31<sup>st</sup> December B.E. 2554 (2011);

(2) the exercise of the right is limited to annually provision of drug having the aforesaid generic name to not exceeding 200,000 patients who are entitled persons under the National Health Security System Act, B.E. 2545 (2002), insured persons under the Social Security Act, B.E. 2533 (1990) and persons entitled to medical benefits for civil servants and government employees scheme;

(3) a royalty fee of 0.5 per cent of the total sale value of drug having the aforesaid generic name by the Government Pharmaceutical Organization shall be paid to the patent holder.

The Department of Disease Control, Ministry of Public Health, shall notify the patent holder and the Department of Intellectual Property for information without delay.

It is hereby announced.

Given on the 29<sup>th</sup> Day of November B.E. 2549 (2006).

(signed) Thawat Suntrajarn  
(Mr. Thawat Suntrajarn)  
Director-General  
Department of Disease Control

## **Unofficial Translation**

### **Notification of the Department of Disease Control, Ministry of Public Health Re: Exercising of Right under Drugs and Pharmaceuticals Products Patent For Combined Formulation of Lopinavir and Ritonavir**

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By virtue 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), the Ministry, Sub-Ministry and Department are empowered to exercise the right under any patent without prior authorization of the patent holder. The objective of this provision is explicitly expressed that all service providers with non-commercial purpose, particularly the service providers of the State which provide such public service as public health, may lawfully exercise such right.

It is generally accepted that HIV (AIDS) epidemic is one of the most grievous public health problems. Approximately, more than one million Thai people have been afflicted with the HIV. More than five hundred thousand of this number are still alive and eventually need long term uses of HIV antiretroviral drug to maintain their productive lives. Although the Royal Thai Government has launched a policy to promote access to HIV antiretroviral drugs for all HIV infected persons since 1<sup>st</sup> October B.E. 2546 (2003) and has also allocated budget for this purpose, an accessibility to some kinds of HIV antiretroviral drugs which are effective and having low level of side-effect is still difficult in spite of an inevitable necessity for the HIV infected persons. This due to the fact that all those HIV antiretroviral drugs are under patent protection in accordance with the law on patent which enable the patent holders to dominate market without competition. The prices of those HIV antiretroviral drugs are, as a result, very high and the budget allocated by the Government is insufficient for the State to acquire the drugs for distribution to all HIV infected persons. The budget allocated for health services of the people who have been infected with HIV as well as AIDS patients under the national health security system for the fiscal year B.E. 2550 (2007) is limited to 3,855.6 million Baht for the target group of 108,000 patients.

The combined formulation of Lopinavir and Ritonavir (available under trade name “Kaletra®”) has already been proved so far to be one of highly effective HIV antiretroviral drugs for patients resistant to basic formulations of HIV antiretroviral drugs. It has also been placed in the National System for Secured Accessibility to HIV Antiretroviral Drugs. This HIV antiretroviral drug, however, is subjected to patent protection which deters the Government Pharmaceutical Organization or other manufacturers from manufacturing and importing this specific drug for sale in the market. The price of the combined formulation of Lopinavir and Ritonavir in Thailand is currently a lot higher than the price of the same drug which is generic drug in some countries. Therefore, many patients who are resistant to basic formulations of HIV antiretroviral drugs are unable to access to this drug, leading to opportunistic infections and death. Hence, being able to domestically produce or to import HIV antiretroviral drugs with the same generic name into Thailand to replace the original one will lead to the price reduction and the increase in accessibility for patients to this HIV antiretroviral drug.

According to the Doha Declaration on the TRIPS Agreement and Public Health, each member country has the right to protect public health, in particular, to promote access to medicines for all in case of emergency and for public benefit, especially accessibility to those relating to HIV/AIDS, tuberculosis, malaria, and other epidemics. In this regard, the Thai law on patent empowers the Ministry, Sub-Ministry and Department to exercise the right under any patent without prior authorization of the patent holders so as to provide public service as mentioned above.

Therefore, the Department of Disease Control, the Ministry of Public Health, hereby notifies, by virtue 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), that it is now exercising the right under drug patent of the drug under trade name “Kaletra®” (generic name: Lopinavir and Ritonavir). In this regard, the Department of Disease Control entrusts the Government Pharmaceutical Organization to exercise the right in its name in accordance with section 36 paragraph one 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) subject to the following conditions:

- (1) the right shall be exercised from now on through 31<sup>st</sup> January B.E. 2555 (2012);
- (2) the exercise of the right is limited to annually provision of drug having the aforesaid generic name to not exceeding 250,000 patients who are entitled persons under the National Health Security System Act, B.E. 2545 (2002), insured persons under the Social Security Act, B.E. 2533 (1990) and persons entitled to medical benefits for civil servants and government employees scheme;
- (3) a royalty fee of 0.5 per cent of the total sale value of drug having the aforesaid generic name by the Government Pharmaceutical Organization shall be paid to the patent holder.

The Department of Disease Control, Ministry of Public Health, shall notify the patent holder and the Department of Intellectual Property for information without delay.

It is hereby announced.

Given on the 24<sup>th</sup> Day of January B.E. 2550 (2007).

(signed) Thawat Suntrajarn  
(Mr. Thawat Suntrajarn)  
Director-General  
Department of Disease Control

## **Unofficial Translation**

### **Notification of the Ministry of Public Health**

#### **Re: Exercising of Right under Drugs and Pharmaceuticals Products Patent For Clopidogrel**

---

By virtue 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), the Ministry, Sub-Ministry and Department are empowered to exercise the right under any patent without prior authorization of the patent holder. The objective of this provision is explicitly expressed that all service providers with non-commercial purpose, particularly the service providers of the State which provide such public service as public health, may lawfully exercise such right.

Myocardial ischemia and cerebro-vascular accident are the most serious public health burden because of high mortality and disability loss. Its mortality rate is in top three annual ranking. Both diseases cause much DALY loss and are in top ten ranking for Thai male and female. Even though these diseases could be prevented by diet control, mental and physical exercise, but the incidents are high and need medicine for treatment and secondary prevention from thrombosis which leads to morbidity and mortality.

Clopidogrel or the trade name in Thailand namely Plavix® has evidence based effectiveness for prevention of myocardial ischemia, cerebro-vascular accident and coronary stent implantation by inhibition of platelet aggregation. However, the medicine is expensive thus has hindered their accessibility. Owing to its patent exclusive right, there is no competition. Government Pharmaceutical Organization or other manufacturers can not produce or import the medicine for price competition.

Regarding the diseases incidents, only 45 millions members of the Universal Coverage scheme will need for 20.5 million pills per annum. However, since the high price and limited budget, 20 percent of patients covered under Universal Coverage scheme can access to the medicine. As a result of provision of market competition by imported or locally produced generics, price will reduce dramatically and accessibility will increase 6 to 12 times which will conform to the Universal Coverage policy.

According to the Doha Declaration on the TRIPS Agreement and Public Health, each member country has the right to protect public health, in particular, to promote access to medicines for all in case of emergency and for public benefit. In this regard, the Thai law on patent empowers the Ministry, Sub-Ministry and Department to exercise the right under any patent without prior authorization of the patent holders so as to provide public service as mentioned above.

Therefore, the Ministry of Public Health, hereby notifies, by virtue 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), that it is now exercising the right under drug patent of the drug under trade name “Plavix®” and drugs contain Clopidogrel in all formulas, including its derivatives patented in Thailand. In this regard, the Ministry of Public Health entrusts the Government Pharmaceutical Organization to exercise the right in its name in accordance with section 36 paragraph one 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) subject to the following conditions:

- (1) the right shall be exercised from now until the patent expired or no essential need;
- (2) the exercise of the right is limited to annually provision of drugs having the aforesaid generic name to unlimited number of patients who are entitled persons under the National Health Security System Act, B.E. 2545 (2002), insured persons under the Social Security Act, B.E. 2533 (1990) and persons entitled to medical benefits for civil servants and government employees scheme;
- (3) a royalty fee of 0.5 per cent of the total sale value of drug having the aforesaid generic name by the Government Pharmaceutical Organization shall be paid to the patent holder.

The Ministry of Public Health shall notify the patent holder and the Department of Intellectual Property for information without delay.

It is hereby announced.

Given on the 25<sup>th</sup> Day of January B.E. 2550 (2007).

(signed) Prat Boonyawongvirod

(Mr. Prat Boonyawongvirod)

Permanent Secretary, Ministry of Public Health

No. 0424.4/7/5271



Department of Disease Control  
Ministry of Public Health  
Tivanond Road,  
Nonthaburi 11000, Thailand  
Tel: 66 25903211  
Fax: 66 25903212

29 November B.E.2549 (2006)

Dear Manager of MSD Company (Thailand),

**Subject:** Public use of patent for Efavirenz

Having been carefully reviewed by Department of Disease Control, Ministry of Public Health, Efavirenz, an antiretroviral drug has been proved to be highly effective and safer for the treatment of HIV infection. Nevertheless, the price of the patented product is much higher than the generics produced in India. The limited budget allocated for HIV/ AIDS patients under the National Health Security Systems and its high price has thus limited the access to Efavirenz.

To increase access to Efavirenz under the universal access to antiretrovirals policy, the Department of Disease Control, Ministry of Public Health has decided to use the patent rights of the products, permitted under Article 51 of the Thai Patent Act BE 2522 (as amended by the Thai Patent Act no. 2 B.E. 2535 and no.3 B.E. 2542) and authorized the Government Pharmaceutical Organization (GPO) to import or produce Efavirenz for public interests. This will significantly make the drug more accessible under the national health insurance schemes. The detail and the conditions are contained in the attached announcement.

Please keep us informed if any recommendation regarding this matter is concerned.

Yours sincerely,

Dr. Thawat Suntrajarn

Director General

Department of Disease Control

Manager of MSD Company (Thailand)

19<sup>th</sup> Floor, Emporium Tower, 622 Sukhumvit Road, Klongtoey, Bangkok, 10110

Encl. Announcement of the Department of Disease Control, Ministry of Public Health, Thailand  
on the Public use of patent for Pharmaceutical Products for Pharmaceutical Products

No. 0424.1/346



Department of Disease Control  
Ministry of Public Health  
Tivanond Road,  
Nonthaburi 11000, Thailand  
Tel: 66 25903211  
Fax: 66 25903212

26 January B.E.2550 (2007)

Dear the patent holder of Kaletra®,

**Subject:** Public use of patent for Kaletra (Lopinavir+Ritonavir)

Having been carefully reviewed by the Department of Disease Control, Ministry of Public Health, Kaletra®, a combination of Lopinavir and Ritonavir medicines, has been proved to be highly effective for drug resistance among patients taking the first line antiretrovirals. As protected by its patent and monopolized by your company, Kaletra® is very costly. This certainly limits HIV/AIDS patients under the National Health Security Schemes access to such a good second line medicine.

To increase access to Kaletra® under the universal access to antiretrovirals policy, the Department of Disease Control, Ministry of Public Health has decided to issue compulsory licensing, permitted under Article 51 of the Thai Patent Act BE 2522 (as amended by the Thai Patent Act no. 2 B.E. 2535 and no.3 B.E. 2542) and authorized the Government Pharmaceutical Organization (GPO) to import or produce Kaletra® for public use with a royalty fee paid at 0.5 per cent. The detail and the conditions are contained in the attached announcement.

Please accept the assurance of our highest consideration.

Yours sincerely,

Dr. Thawat Suntrajarn

Director General

Department of Disease Control

Manager of Abbott Laboratory Limited

9/F Nai Lert Tower, 2/4 Wireless Road, Lumpini, Pathumwan, Bangkok 10330

Encl. Announcement of the Department of Disease Control, Ministry of Public Health, Thailand  
on the Public use of patent for Pharmaceutical Products for Pharmaceutical Products [Kaletra®  
(Lopinavir+Ritonavir)]

No. 0201.041/548



Ministry of Public Health  
Tivanond Road,  
Nonthaburi 11000, Thailand  
Tel: 66 2590 1438  
Fax: 66 2590 1434

12 February B.E.2550 (2007)

Dear Manager of Sanofi-Synthe'labo (Thailand) Ltd.

**Subject:** Public use of patent for Clopidogrel

Clopidogrel, an anti platelet drug, is highly effective for preventing coronary obstruction. Having been protected by its patent and monopolized by your company, Clopidogrel is very costly. This certainly limits patients with coronary heart diseases under the National Health Security Schemes access to this patented drug.

To increase access to Clopidogrel under the National Health Security Schemes, Ministry of Public Health has decided to issue compulsory licensing, permitted under Article 51 of the Thai Patent Act BE 2522 (as amended by the Thai Patent Act no. 2 B.E. 2535 and no.3 B.E. 2542) and authorized the Government Pharmaceutical Organization (GPO) to import or produce Clopidogrel for public use with a royalty fee paid at 0.5 percent. The detail and the conditions are contained in the attached announcement.

In this regard, Ministry of Public Health is pleased to open an official discussion concerning the royalty fee and others in accordance with Article 51 with the company. Date of discussion is to be confirmed.

Yours sincerely,

Dr. Prat Boonyawongvirot  
Permanent Secretary

Manager of Sanofi-Synthe'labo (Thailand) Ltd.

10-11th Floor Gypsum Metropolitan Tower no. 539/2 Sri-Ayudhaya Road Kwaeng Thanon Payathai,  
Bangkok

Encl. Announcement of the Ministry of Public Health, Thailand, on the Public use of patent for  
Pharmaceutical Products for Pharmaceutical Products (Clopidogrel)

**Congress of the United States**  
**Washington, DC 20515**

January 10, 2007

The Honorable Susan C. Schwab  
United States Trade Representative  
600 17<sup>th</sup> Street, NW  
Washington, DC 20508

Dear Ambassador Schwab:

We are writing to urge that the United States respect the decision of the Thai government to issue a compulsory license on the AIDS drug efavirenz.

Thailand's HIV/AIDS treatment initiative has been recognized as among the most successful in the developing world. By producing generic first-line antiretroviral (ARV) therapies since before the medicines were patented in the country, Thailand's Government Pharmaceutical Organization (GPO) has made treatment widely accessible to tens of thousands of patients in government clinics and hospitals.

However, increasing numbers of Thai HIV/AIDS patients need access to newer, second-line treatment options because they have developed resistance to, or severe side effects from, the first-line regimens. Because second-line drugs, including efavirenz, are under patent in Thailand, they are currently only available from their brand name producers. The high price of these medicines has created a significant obstacle to the expansion and sustainability of the Thai program.

Thailand's November 29 announcement of its intent to issue a government-use compulsory license on efavirenz is a demonstration of its commitment to improve treatment options for the nearly 600,000 Thai citizens living with HIV.<sup>1</sup> As has been demonstrated in many other contexts, the availability of generics greatly lowers the price of HIV drugs over time and increases access to these life-savings medications.

Further, Thailand's action is entirely consistent with international trade rules. The World Trade Organization's 1994 Agreement on Trade Related Aspects of Intellectual Property (TRIPS) specifically permits compulsory licensing, and the 2001 Doha Declaration reaffirmed each country's "freedom to determine the grounds upon which such licenses are granted."<sup>2</sup> Under TRIPS, Thailand is not required to negotiate in advance with the patent holder because the drug will be produced in the near-term future by the GPO and distributed for non-commercial public use by Thailand's national program.<sup>3</sup>

<sup>1</sup> Bureau of AIDS, TB, and STI, Department of Disease Control, Thailand Ministry of Public Health, [www.aidsthai.org](http://www.aidsthai.org)

<sup>2</sup> Paragraph 5(b), 'Declaration on the TRIPS Agreement and Public Health', WTO Ministerial Conference – Fourth Session, WT/MIN(01)/DEC/2, 20 November (2001).

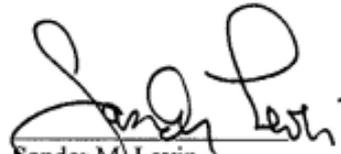
<sup>3</sup> World Trade Organization, *Agreement on Trade-Related Aspects of Intellectual Property Rights* (1994), Article 31.

Unfortunately, it is our understanding that the United States government may be attempting to intervene in the Thai government's decision to issue and implement the compulsory license for efavirenz. As you are aware, the Trade Promotion Authority Act of 2002 mandates that United States trade policy respect other nations' public health initiatives under Doha.<sup>4</sup> We therefore call on you to respect the rights of Thailand and other nations to implement important and permitted public health safeguards.

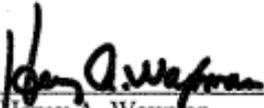
Sincerely,



Tom Allen  
Member of Congress



Sander M. Levin  
Member of Congress



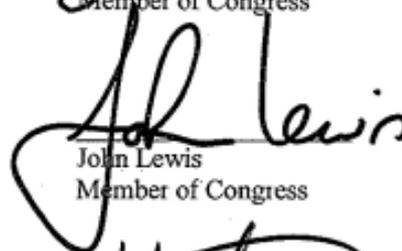
Henry A. Waxman  
Member of Congress



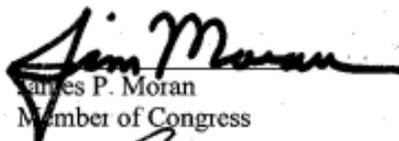
Jim McDermott  
Member of Congress



Fortney Pete Stark  
Member of Congress



John Lewis  
Member of Congress



James P. Moran  
Member of Congress



Lloyd Doggett  
Member of Congress

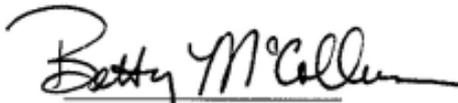


Earl Blumenauer  
Member of Congress



Charles A. Gonzalez  
Member of Congress

<sup>4</sup> U.S. Trade Promotion Authority Act (P.L. 107-210), August 6, 2002 § 2102(b)(4)(C)

  
Betty McCollum  
Member of Congress

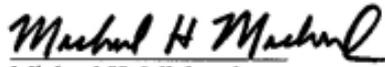
  
Linda T. Sánchez  
Member of Congress

  
Carolyn B. Maloney  
Member of Congress

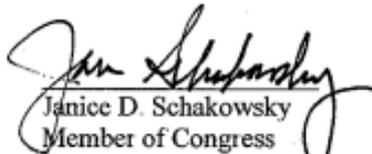
  
Hilda Solis  
Member of Congress

  
Dennis J. Kucinich  
Member of Congress

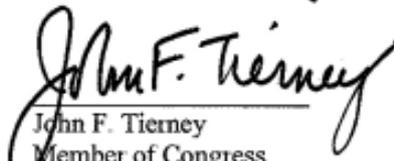
  
Barbara Lee  
Member of Congress

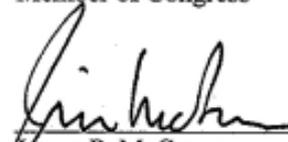
  
Michael H. Michaud  
Member of Congress

  
Loretta Sanchez  
Member of Congress

  
Janice D. Schakowsky  
Member of Congress

  
Maxine Waters  
Member of Congress

  
John F. Tierney  
Member of Congress

  
James P. McGovern  
Member of Congress

EXECUTIVE OFFICE OF THE PRESIDENT  
THE UNITED STATES TRADE REPRESENTATIVE  
WASHINGTON, D.C. 20508

The Honorable Sander M. Levin  
U.S. House of Representatives  
Washington, D.C. 20515

JAN 17 2007

Dear Congressman Levin:

Thank you for your letter concerning the Thai Government's announced intention to issue a compulsory license on the AIDS drug efavirenz.

The Administration's trade policy continues to advocate strong protection of intellectual property rights as an essential element in fostering innovation in the development of life-saving medicines, including those medicines necessary in the global fight against HIV/AIDS. Countries like Thailand, facing major public health crises, need to play a role in and benefit fully from the development of new and more advanced treatments. Strong protection of intellectual property, including through patents, remains a vital part of that process.

The Administration also remains fully committed to the flexibilities established within global and national intellectual property regimes enabling countries to address effectively significant public health emergencies. As recognized in the 2001 Doha Declaration, these flexibilities include recourse to the issuance of compulsory licenses. We are continually striving to strike the right balance between strong intellectual property protection as a means of promoting innovation, and appropriate use of flexibilities to address urgent situations. These objectives are both achievable.

With respect to the recent announcement of the Thai Government, we have taken care to respect fully the Thai Government's ability to issue compulsory licenses in accordance with its own law and its obligations as a member of the World Trade Organization (WTO). We have not suggested that Thailand has failed to comply with particular national or international rules. We have indicated that it would be appropriate for the Thai authorities to respond to any requests for direct discussions by concerned stakeholders, including, among others, the patent holder; we have not sought to insert the U.S. Government into any such discussions.

Our trade policy dialogue with Thailand will continue to emphasize the importance of effective intellectual property protection as an element in that country's effort to strengthen its investment climate and promote economic development. We will stress the importance to Thailand of abiding fully by its WTO obligations, but -- as we have done to date -- within the context of a full respect for the Doha Declaration and for Thailand's ability to make appropriate use of the flexibilities embodied in WTO rules.

Again, thank you for your letter and for your views on this important and sensitive issue.

Sincerely,



Susan C. Schwab



**World Health  
Organization**

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Document No. 13

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In reply please  
refer to: DGO

Your reference:

Mr Mongkol Na Songkhla  
Minister of Public Health  
Ministry of Public Health  
Royal Thai Government  
Tivanond Road  
Nonthaburi 11000  
Thaïlande

7 February 2007

Dear Minister,

It was a pleasure to meet you last week in Bangkok, and I must express my deep appreciation to you and your staff for the warm welcome, hospitality and great efficiency demonstrated throughout my brief visit to Thailand.

It was a great honour for me to have an audience with His Majesty the King, and with her Royal Highness Princess Maha Chakri Sirindhorn, in her capacity as Chair of the Board of Trustees and President of the Prince Mahidol Award Foundation.

I was particularly impressed with the field visit, which provided me with an opportunity to witness the work of dedicated health professionals and the community in Khon Kaen and Nam Phong. The pride and professionalism of the staff and the support of the community was obvious and most encouraging.

I also appreciated the opportunity to hear more about the work of the National Health Security Office and the National Health Promotion Foundation. I was pleased to witness the commitment of the Royal Thai government to universal coverage with effective health care services, and to the health of the people of Thailand. I welcome the increasing budget for the universal coverage scheme, which I know understand amounts to close to 2,000 baht per person per year, and includes treatment for people with HIV/AIDS with antiretrovirals.

cc: The Minister of Foreign Affairs of Thailand, Bangkok  
Permanent Mission of Thailand to the United Nations Office at Geneva and the  
Specialized Agencies in Switzerland

منظمة الصحة العالمية • 世界卫生组织

Organisation mondiale de la Santé • Всемирная организация здравоохранения • Organización Mundial de la Salud

I deeply regret that my comments at the close of the briefing at the National Health Security Office were misrepresented in the media, and may have caused embarrassment to the government of Thailand. They should not be taken as a criticism of the decision of the Royal Thai government to issue compulsory licences, which is entirely the prerogative of the government, and fully in line with the TRIPS agreement.

Thailand is making good progress towards increase budget allocations for health, while simultaneously control rising health care costs with greater efficiency. Medicines are a substantial element of health care costs, and it is entirely appropriate and necessary for the government of Thailand to find means of reducing these costs to ensure sustainable financing of health care.

As I mentioned in the recent Executive Board, I firmly believe that the pharmaceutical industry - generic manufacturers and R&D companies - are part of the solution. I am committed to dialogue with industry to find ways of ensuring that access to high quality essential medicines is not limited by cost considerations. I am equally committed to dialogue with people who suffer from HIV/AIDS and other conditions, and with civil society groups and NGOs.

WHO unequivocally supports the use by developing countries of the flexibilities within the TRIPS agreement that ensure access to affordable, high quality drugs. This includes the use of compulsory licensing, as described in paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health. The decision whether to issue a compulsory license for a pharmaceutical product is a national one. There is no requirement for countries to negotiate with patent holders before issuing a compulsory licence. As a global community we need to ensure the right balance between the immediate and urgent pressing need to provide affordable medicines to the many that need them, and the need to provide continuous incentives for innovation. It is in this regard that I noted that prior negotiations with industry is a pragmatic approach that may ensure countries have access to high quality medicines at affordable prices.

Where there are urgent needs, the bottom line is that people need access to medicines.

I trust this clarifies the position of WHO concerning compulsory licensing of medicines, and I look forward to further opportunities to discuss these important issues with you in the future.

Yours faithfully,



Dr Margaret Chan  
Director-General

**Recent Examples of Implementing Compulsory Licensing/Government Use for Pharmaceuticals**  
 March 2005

Country	Description	Date of Issue	Date of Expiry	Royalty	Drugs Covered	Patent Holders
India	Granted automatic authorization to continue generic production of drugs after 1 January 2005, even if those drugs will receive patent protection after the patent "mailbox" was opened in January 2005. <sup>1</sup>	23 March 2005	None	To be determined, but must be "reasonable."	All drugs being produced as of 1 Jan 2005, for which patent applications were filed in India from 1995-2005 (potentially 8926 patents). Will include some 2 <sup>nd</sup> -line antiretrovirals.	Multiple
Malaysia	Authorization for import of antiretrovirals for use in government hospitals ("government use").	1 Nov 2003	1 Nov 2005	Payment after each importation	Didanosine (ddi) 100 mg tablets  Didanosine (ddi) 25 mg tablets  Zidovudine (AZT) 100 mg capsule Lamivudine (3TC) 150 mg + Zidovudine (AZT) 300 mg	Bristol Myers Squibb (BMS)  BMS  GlaxoSmithKline (GSK) GSK

<sup>1</sup> The mailbox system is a TRIPS-imposed obligation on developing countries that wished to benefit from the TRIPS transitional period by delaying granting of patents for pharmaceutical products until 2005. In exchange for not granting patents, these countries had to establish a "mailbox" system for receiving and filing patent applications from the beginning of the transitional period in 1995. The mailbox provision allowed applicants to file for patents and thereby establish filing dates, while at the same time permitting member countries to defer the granting of the patent for pharmaceutical products.

Country	Description	Date of Issue	Date of Expiry	Royalty	Drugs Covered	Patent Holders
Indonesia	Authorization for domestic production of antiretrovirals ("government use").	4 Oct 2004	None stipulated	0.5% of net selling value of generic products	Nevirapine (NVP) Lamivudine (3TC)	Boehringer Ingelheim (BI) Biochem Pharma Inc (originator company, sold rights to GSK)
Zambia	Compulsory license for local production of a fixed-dose triple combination of antiretrovirals.	22 Sept 2004	31 July 2009	Maximum 2.5% of net sales.	Stavudine (d4t) + Lamivudine (3TC) + Nevirapine (NVP)	GSK for 3TC, BI for NVP (no patent on D4T in Zambia)
Mozambique	Compulsory license for local production of a fixed-dose triple combination of antiretrovirals.	5 April 2004	When HIV/AIDS related emergency ends	Maximum 2% of net sales.	Stavudine (d4t) + Lamivudine (3TC) + Nevirapine (NVP)	BMS for d4t, GSK for 3TC, BI for NVP
Zimbabwe	Compulsory license to produce, import or use any drug used in treatment of HIV/AIDS or HIV/AIDS-related conditions.	24 May 2002	Ongoing	Unknown	All HIV-related drugs	GSK, BI, Hoffman-La Roche
South Africa	In a negotiated settlement to an anti-competition lawsuit (for excessive pricing), GSK and BI agreed to extend voluntary licenses to 4 generic firms in South Africa for importation, production and/or exportation of ARVs to other African countries.	10 Dec 2003	None stipulated	Maximum 5% of net sales	Zidovudine (AZT) Lamivudine (3TC) Nevirapine (NVP)	GSK GSK BI
Cameroon	Authorization for public procurement agency to buy generic antiretrovirals when prices are lower than originators'. <sup>2</sup>	2000	None stipulated	Unknown	Antiretrovirals	GSK, BI, Hoffman-La Roche

<sup>2</sup> "Determining the patent status of essential medicines in developing countries". Health Economics and Drugs, EDM Series no. 17. WHO, 2004.

**Table 2. Recent Examples of Using Compulsory Licensing/Government Use as Negotiating Tactic:**

Country	Description	Date	Drugs Covered	Patent Holders
Brazil	Threat to use compulsory licenses if voluntary licenses not granted by 4 April 2005 for 3 antiretrovirals that the government is currently importing at high cost.	17 March 2005	Efavirenz, lopinavir+ritonavir, tenofovir	Merck, Abbott, Gilead (respectively)
Brazil	Threat to use compulsory license if prices not discounted further for imports of branded products; manufacturers all offered further price cuts after the threat.	September 2003	Lopinavir, efavirenz, nelfinavir	Abbott, Merck, Roche (respectively)
USA	Threat to use compulsory license after anthrax scare, due to feared shortages of the antibiotic ciprofloxacin.	2001	Ciprofloxacin	Bayer
Canada	Threat to use compulsory license after anthrax scare, due to feared shortages of the antibiotic ciprofloxacin.	2001	Ciprofloxacin	Bayer

**Recent examples of the movements on the use of compulsory licenses around the world.**

James Love, CPTech / [www.cptech.org](http://www.cptech.org) / <mailto:james.love@cptech.org> /

**1. North America****1.1 United States***(1) Mandatory compulsory license patents whose term was extended by GATT implementation*

For patents that were extended by the change from 17 years from the patent grant to 20 years from the patent application (the delta period), the Congress created a mandatory compulsory license. The compulsory license applied to over 100 brand name pharmaceutical products. However, drug registration issues that were not addressed in the GATT implementation legislation undermined the benefits of the compulsory license in the pharmaceutical sector.

*(2) Cases involving government use under 28 USC 1498*

In 2001, DHHS Secretary Tommy Thompson used the threat to use 28 USC 1498 to authorize imports of *generic ciprofloxacin*, for stockpiles against a possible anthrax attack.

In 2005, the US Department of Justice cited its right to use patents in 28 USC 1498 when it opposed injunctive relief for infringement of the patents relating to the Blackberry email services supplied to both the government and private firms that used the Blackberry device to communicate with the government.

In a November 2005 Congressional hearing, DHHS Secretary Michael Levitt testified before the House of Representatives that he had threatened to override the patents *on treatments for Avian Flu* if companies had not expanded US production facilities.

*(3) Cases involving Bayh-Dole Act*

In 2001, the Department of Health and Human Services used its authority to exercise March-In rights for *patents on stem cell lines* held by the Wisconsin Alumni Foundation as leverage to secure an open license on those patents.

In 2004, DHHS refused to grant march-in rights in two cases brought by Essential Inventions, involving patents on the *AIDS drug ritoanvir* and the *glaucoma drug latanoprost*.

In 2006, the Centers for Disease Control threatened to use US Bayh-Dole "march-in" rights to issue compulsory licenses on patents on *reverse genetics*, which are needed to manufacture vaccines for avian flu.

*(4) Cases involving merger reviews*

In 2002, the US FTC ordered a compulsory cross-license of the *Immunex tumor necrosis factor (TNF) patent*, to Serono, including the "freedom to practice in the research, development, manufacture, use, import, export, distribution and sale of TNFbp-I Products and certain glycosylated and nonglycosylated fragments, derivatives and analogs thereof in the United States."

In 2005, the FTC ordered a compulsory license of Guidant intellectual property surrounding the RX delivery system for Drug-Eluting Stents.

*(5) Cases involving non-merger remedies to anticompetitive practices*

In 2002, the US Department of Justice required Microsoft to license on reasonable and non-discriminatory terms intellectual property rights in a number of different protocols needed to create products that were interoperable with Microsoft Windows.<sup>5</sup>

*(6) Cases involving the new US Supreme Court standard for granting injunctions on patents.* [eBay Inc. v. MercExchange, L.L.C., 126 S. Ct. 1837, 1839-1841 (U.S. 2006)].

In June 2006, a court granted Microsoft a compulsory license to use two patents owned by z4 Technologies that relate to digital rights management systems used by Microsoft for its Windows and MS Office software programs.

In July 2006, a court granted DirectTV a compulsory license to use the Finisar patent on integrated receiver decoders (satellite set top boxes), for a royalty of \$1.60 per device.

In August 2006, a court granted Toyota a compulsory license on three Paice patents for hybrid transmissions, for a royalty of \$25 per automobile.

In September 2006, a court granted Johnson and Johnson a compulsory license to use three of Jan Voda=92s patents on guiding-catheters for performing angioplasty.

**1.2 Canada**

In a September 2001 Speech on the Myriad Gene Patent, the Ontario Health Minister called for compulsory licensing of patents on genes relevant to tests for breast cancer. In January 2002, the

Ontario Advisory Committee on New Predictive Genetic Technologies published "the Ontario Report to Premiers: Genetics, Testing & Gene Patenting: Charting New Territory in Healthcare." This report noted that the Doha Declaration calls upon nations to take measures "to protect public health and, in particular, to promote access to medicines for all," and concluded: In order to prevent the statement from providing a hollow right, the concept of promoting access to medicines for all must include providing access to the diagnostic procedures necessary to determine when and which medicines to provide. The federal government should, therefore, amend the Patent Act to specifically allow the potential for compulsory licensing of patents relating to the provision of genetic diagnostic and screening tests should this power be necessary.

On October 18, 2001, Health Canada overrode the Bayer *patents on ciprofloxacin*, and authorized generic manufacture for purposes of building a stockpile as protection against an attack of certain strains of anthrax. In announcing the action, Paige Raymond Kovach, a spokeswoman for Health Canada, said: "These are extraordinary and unusual times . . . Canadians expect and demand that their government will take all steps necessary to protect their health and safety."

On May 14, 2004, Canada passed BILL C-9: An Act to amend the Patent Act and the Food and Drugs Act. The law came into force on May 14, 2005 creating Canada's Access to Medicines Regime (CAMR). The purpose of the legislation is to allow Canadian manufacturers to export medicines to countries lacking manufacturing capacity. Proposed royalties paid to the patent holder vary according to the importing country's Human Development Index. The benefits of the Act are limited to products listed on "Schedule 1," the list of patented pharmaceutical products that are eligible to be exported under the compulsory license. Civil society groups supported the passage of the legislation, yet they also pointed out a number of flaws in the bill.

There have been three requests for compulsory licenses under the CAMR. The first was a December 14, 2004 request from Essential Inventions, for the manufacture and export of *Imatinib Mesylate* to Chile. The Canadian government was not responsive. The second was a request from Apotex and MSF for the manufacture and export of a fixed dose combination for the treatment of AIDS. The third was a February 13, 2006 request from Biolyse Pharma Corporation, for *patents on oseltamivir phosphate*, a product sold by Roche under the brand name Tamiflu.

On August 31, 2005, Schedule 1 of the Patent Act was amended to add lamivudine (150 mg) + nevirapine (200 mg) + zidovudine (300 mg) tablets - the fixed dose combination in the Apotex/MSF application.

On July 1, 2006, the Canadian government published a proposed amendment to Schedule 1 of the Patent Act to add oseltamivir phosphate (75 mg capsules and 12 mg/mL powder for oral suspension), which is used in the treatment and prophylaxis of Type A and Type B influenza. In September 2006, the product was included in Schedule 1.

Apotex claims as defense to an infringement claim, that its sales of generic copies of AstraZeneca Zestril and Merck Prinivil tables are permitted under terms of a compulsory license. A trial started in January 2006.<sup>6</sup>

On May 7, 2004, Torpham successfully appealed a rejection of a compulsory license application involving Merck patents for the manufacture and sale of Lisinopril. Torphan had sought a license to use the patents for purposes of manufacturing and exporting to the United States. The court held that the request for the compulsory license had sufficient merit to be proceed to the next stage. The court held that serving export markets abroad constitutes Canadian demand for the patented product.

On September 16, 1998, Brantford asked a Canadian federal court for an order compelling Merck to licence patents needed to manufacture SESIC. On April 30, 1999, Brantford filed another application for a compulsory license. The case involved a number of procedural disputes and appeals, such as a February 2, 2005 court decision rejecting Merck's efforts dismiss the compulsory licensing application on certain procedural grounds.<sup>8</sup> A hearing on the compulsory license was held in April 2005 before the Patent Appeal Board. On September 1, 2005, the Patent Appeal Board upheld an earlier rejection of the compulsory license. Brantford appealed to the court. On November 7, 2006, a court in British Columbia upheld the rejection of the compulsory license, holding the Commissioner of patents had not erred in determining that patent abuse had not been established, since it was reasonable for the Commissioner to find on the evidence that there was no genuine market demand for the product, and that it was reasonable to find that not enough

time had been afforded Merck to respond to Brantford=92s request for a licence, and Merck=92s silence could not be construed as a refusal to license.<sup>9</sup>

## 2. EUROPE

On April 29, 2004, the European Court of Justice issued a preliminary ruling on compulsory licensing of intellectual property rights under European competition law, in the *IMS Health vs NBC* case. The ECJ held that under certain circumstances an obligation to license an intellectual property right exists. The four conditions were:

1. The intellectual property right should constitute, upstream, an indispensable factor in the downstream supply of a (secondary) product.
2. The potential licensee should intend to produce new goods or services not offered by the owner of the right, and for which there is a potential consumer demand.
3. The refusal should not be justified by objective reasons.
4. The refusal should be of such a nature that it reserves for the owner of the right the market for the provision of the product, by eliminating all competition on that market.

### 2.1 United Kingdom

Following the passage of Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the Legal Protection Of Biotechnological Inventions, the United Kingdom amended its patent law to provide for mandatory compulsory cross-licenses of certain biotechnology inventions used for agriculture. The license is available to plant breeders who demonstrate a technical advance. The December 6, 2006 UK Gowers Review noted the British Society of Plant Breeders complained the provision is 'ineffective in the UK at least', because to prove an advance the product must actually be created, thereby infringing the patent, in calling for an expanded research exception, to permit broader use of the compulsory license.

### 2.2 Germany

In 2000, Roche asked the German government to grant a compulsory license on a patent protecting the Blood Screening HIV Probe owned by Chiron. On May 22, 2001, a licensing agreement was reached between Roche and Chiron. In return for its license, Roche agreed to end its attempts to obtain a compulsory license.

### 2.3 France

#### *(1) RU 486*

France considered the use of compulsory licenses in the case of the abortion pill RU 486, which was developed by the French pharmaceutical manufacturer ROUSSEL UCLAF. In response to threats of boycotts by pro-life organizations, the company withdrew the product from the market. In the subsequent efforts by the French government to reverse the decision, a court ruled the government could obtain access to the medicine by using the ex-officio license system. Earlier, however, the product was already back on the market, so the ex officio license was not needed

#### *(2) BRAC1 and BRAC2 patents on breast cancer tests*

France was among several European countries who were outraged by the high prices of breast cancer diagnostic tests, because of the Myriad gene patents. In 2004, France amended its patent law to allow the broader use of ex officio licenses, and in particular, to authorize the government to issue ex officio licenses to patents on certain diagnostic technologies. The new act provide that: Where the interests of public health demand, and in the absence of a voluntary agreement with the patent holder, the minister responsible for industrial property, may, by order of the minister responsible for public health, request ex officio licenses in accordance with Article L. 613-17 for any patent granted for:

- a) a medicine, a medical device, a medical device for in vitro diagnosis, a related therapeutic product;
- b) processes for obtaining them, [or] for products necessary in obtaining such medicines or for processes for manufacturing such products
- c) a diagnostic method ex vivo.

### 2.4 Belgium

Belgium modified its patent law in 2005, creating a new compulsory cross-license for biotechnology inventions, and also a new compulsory license for public health purposes.

## **2.5 Italy**

### *(1) SORIN BIOMEDICA/SNIA*

On June 14, 1994, Sorin Biomedica S.p.A. filed a lawsuit with the Court of Milan, Italy against Chiron Corporation and Ortho Diagnostic Systems S.p.A. for a declaration of nullity and noninfringement of the Italian counterpart to Chiron's European Patent 0 318 216 (the " '216 patent"). Sorin additionally filed a request with the Italian Ministry of Industry, Commerce and Artisanry ("ICA") for compulsory license to the '216 patent. Chiron filed a counterclaim and sought a finding that the patent is valid and infringed by Sorin. The ICA suspended Sorin's request for compulsory license pending the outcome of the litigation.

## **3. ASIA**

### **3.1 China**

In 2005, China used the threat to a compulsory license to obtain voluntary licenses to manufacture generic Tamiflu.

### **3.2 Malaysia**

On September 29, 2004, the Malaysian Minister of Domestic Trade and Consumer Affairs issued a two-year government use compulsory license to import from India didanosine (ddI), zidovudine (AZT) and lamivudine +zidovudine (Combivir).

### **3.3 Indonesia**

On October 5, 2004, Indonesia issued a compulsory license to manufacture generic versions of lamivudine and nevirapine, until the end of the patent term in 2011 and 2012 respectively. The license is for government use, and includes a *royalty rate of 0.5%* of the net selling value.

### **3.4 Korea**

On January 30, 2002, the People's Health Coalition for Equitable Society, the Association of Physicians for Humanism, and the Korean Pharmacists for Democratic Society jointly filed for a compulsory license for Glivec, a drug to treat chronic myelogenous leukemia (CML), and gastrointestinal stromal tumor (GIST). The request was rejected.

In October 2005, the Korea Food and Drug Administration (KFDA) announced it was considering a compulsory license for the manufacture of generic versions of Tamiflu.

### **3.5 India**

In February 2005, India amended its patent law, to provide for patent protection for pharmaceutical inventions. The legislation created a mandatory compulsory license for products that were already manufactured and marketed in India.

### **3.6 Taiwan**

On July 26, 2004, the Taiwan Intellectual Property Office (TIPO) issued a compulsory license to Gigastorage for 5 patents related to CD-R of Phillips. The term of the license is through the expiration of the patent terms.

In November 2005, Taiwan issued a compulsory license for patents needed to manufacture and sell generic versions of Tamiflu. According to this report by Deutsche Presse-Agentur dpa:

The Intellectual Property Office (IPO) granted compulsory licensing to Taiwan pharmaceutical companies after talks with Roche and Gilead Science - the U.S. developer of Tamiflu - broke down. 'Roche and Gilead insisted they can supply enough Tamiflu if bird flu erupts in Taiwan. Our argument was: When there is a bird flu pandemic, millions of people will be hospitalized or dead, and some countries might confiscate Tamiflu or ban its export. We cannot gamble our people's lives on their unreliable promise,' Lai Chin-hsiang, secretary-general of the Department of Health (DOH), told Deutsche Presse-Agentur dpa. Under the compulsory license, valid until December 31,

2007, Taiwan drug firms can make Tamiflu for domestic use and should use it only when there is a shortage of supply from Roche.

### 3.7 Thailand

The ministry of Public Health issued government use on the patent of Merck's Efavirenz on November 29, 2006. The Government Pharmaceutical Organization has ordered 66,000 bottles of the drugs from Ranbaxy India and the drugs have arrive in late Jan 2007. It also issued government use on the patent of Abbott's Kaletra and Sanofi-Aventis's Clopidogel. While the movement to order the two generics from India is going on, the negotiation with the companies also move on in parallel.

## 4. LATIN AMERICA

### 4.1 Argentina

On October 18, 2005, Health Minister Gines Gonzalez Garcia announced the government would issue compulsory licenses on the patents for Tamiflu.

### 4.2 Dominican Republic

There have been requests for compulsory licenses on the patents for Plavix, a heart disease drug. On May 14, 2002, the French embassy in DR wrote to Sr. Hugo Guillani Cury, Secretary of State of the Dominican Republic, expressing opposition to the compulsory license.

### 4.3 Chile

In December 2004, Essential Inventions requested a compulsory license to supply Glivec to Chile.

### 4.4 Peru

In 2004, the government issued a compulsory license in the *patents on d4T*.

### 4.5 Ecuador

Something happened here, but we are still investigating.

### 4.6 Brazil

On January 8, 2001, 12 days before President Clinton left office, USTR filed a complaint over the Brazil compulsory licensing law in the WTO Dispute Settlement Body. USTR officials called this the 'Merck' case. At issue was Article 68 of Brazil's patent law, which allows compulsory licenses to be issued in situations where the patent holder does not locally manufacture the patented product (known as a "local working" provision). The US received a large amount of negative publicity, and on June 25, 2001, the Bush administration withdrew the complaint. However, under the agreement between the two countries, Brazil agreed to provide the US with advance notice if a license is issued under Article 68 of the Brazil patent act, and disputes would be discussed through a bilateral "Consultative Mechanism." The agreement was not made public.

In early 2001, Brazil announced it was considering compulsory licenses for patents on nelfinavir and efavirenz.

In March 2001, the Brazil government reached a settlement with Merck, for price discounts on efavirenz, in return for not issuing a compulsory license.

On August 22, 2001, Brazilian Health Minister Jose Serra announced the Brazilian government would issue a compulsory license for the manufacture of the antiretroviral drug nelfinavir (sold under the brand name Viracept by Roche) to the Brazilian pharmaceutical producer Far Manguinhos. On August 28, the two parties resumed talks, and on August 31, they reached an agreement; Roche will sell the drug in Brazil at an additional 40% discount, and Brazil will not issue the compulsory license.

On September 5, 2003, the Brazilian government issued a decree that would allow it to produce or import generic anti-AIDS drugs without the consent of companies holding the patent on those medications. The health minister made it clear that the decree was meant to apply to antiretroviral drugs - specifically lopinavir, efavirenz and nelfinavir. The ministry said in a statement it had negotiated with the name-brand companies in August seeking a reduction of more than 40%, but was offered a maximum discount of 6.7%. Brazil and Merck reached an agreement in November.



In 2005, Health Minister Humberto Costa signed a decree declaring the patent of Kaletra in the public interest and appropriate for compulsory licensing. A subsequent settlement with Abbott reduced the price of by 46 percent.

In 2005, the government of Brazil declared that they were considering issuing compulsory licenses to permit the manufacture of Viread. As a result of discussions with the Brazilian government Gilead reached agreement with the Brazilian Health Ministry in May 2006 to reduce the price of Viread in Brazil by approximately 50%.

Brazil also used the threat of compulsory licenses on the patents for Gleevec to obtain a price discount of more than 65 percent.

## **5. AFRICA**

Compulsory licensing in Africa is now fairly common, but often not widely publicized. A typical compulsory license may be based upon model authorizations prepared by organizations who are engaged in providing treatment for AIDS, in order to satisfy donor requirements that purchases of generic medicines are consistent with trade rules.

### **5.1 Cameroon**

On January 2005, the nonprofit corporation Essential Inventions requested the Minister of Public Health to grant ex officio licenses for the patents relevant for importation, manufacture or sale of generic versions of the following medicines used in the treatment of HIV/AIDS: Nevirapine (Brand name Viramune) Lamivudine (Brand name 3TC) Fixed dose combinations of Lamivudine and Zidovudine (Brand name Combivir). The request is still pending.

### **5.2 Guinea**

On April 18, 2005, the Ministry of Health issued compulsory licenses on patents on drugs to treat AIDS.

### **5.3 Ghana**

On October 26 2005, the Minister of Health issued a government use compulsory licenses for importation into Ghana of generic HIV-AIDS medicines.

### **5.4 Eritrea**

On June 5 2005, the Minister of Health issued a compulsory license for for importation into Eritrea of generic HIV-AIDS medicines.

### **5.5 Mozambique**

On April 5, 2004, Mozambique's Deputy Minister of Industry and Commerce issued Compulsory License no. 01/MIC/04 for patent rights to lamivudine, stavudine and nevirapine. The license was granted to Pharco Mozambique Lda, a local producer that plans on manufacturing the antiretrovirals as a fixed-dose combination. Royalties are not to exceed 2% of sales.

### **5.6 SouthAfrica**

On March 7, 2001, Indian pharmaceutical manufacturer CIPLA formally requested the South African Department of Trade and Industry issue compulsory licenses to patents on the following HIV drugs: nevirapine, lamivudine, zidovudine, stavudine, didanosine, efavirenz, indinavir and abacavir.

On September 19, 2002, Hazel Tau, working with the Treatment Action Campaign (TAC), filed a complaint with South Africa's Competition Commission against GlaxoSmithKline (GSK) and Boehringer Ingelheim (BI). Twelve parties would join the complaint, which charged GSK and BI with excessive pricing in respect of ritonavir, lamivudine, ritonavir+lamivudine and nevirapine. On October 16, 2003, after an extended investigation, the South Africa Competition Commission issued a statement, saying:

"pharmaceutical firms GlaxoSmithKline South Africa (Pty) Ltd (GSK) and Boehringer Ingelheim (BI) have contravened the Competition Act of 1998. The firms have been found to have abused their dominant positions in their respective anti-retroviral (ARV) markets".

In particular the Commission has found the firms have engaged in the following restrictive practices;

- \* Denied a competitor access to an essential facility
- \* Excessive pricing

\* Engaged in an exclusionary act

On December 10, the competition commission announced it had reached a settlement with GSK. The settlement required GSK to

- \* extend a voluntary licence granted to Aspen Pharmacare in October 2001 in respect of the public sector to include the private sector;
- \* grant up to three more voluntary licences on terms no less favourable than those granted to Aspen Pharmacare;
- \* permit the licensees to export the ARVs to sub-Saharan African countries;
- \* permit the importation of the drugs for distribution in South Africa if the licensee does not have manufacturing capability in South Africa;
- \* permit licensees to combine the relevant ARV with other antiretroviral medicines; and
- \* charge royalties of no more than 5% of the net sales of the relevant ARVs.

Shortly thereafter, a similar settlement was reached with BI.

### **5.7 Swaziland**

On April 20, 2004, the Ministry of Health and Social Welfare in Swaziland noted the existence of an emergency relating to AIDS, and authorized procurement of medicines for HIV/AIDS =93 in the best cost/effective way possible on the international market irrespective of the existence of any patent or other Intellectual Property protection applicable in Swaziland until such time as it will no longer be considered essential to address the current Public Health crisis related to HIV/AIDS.=94

### **5.8 Zambia**

On September 21, 2004 the Zambian Minister of Domestic Trade and Consumer Affairs issued a compulsory license for lamivudine, stavudine and nevirapine. The license was granted to Pharco Ltd., a local producer, which will produce a triple fixed-dose combination. A maximum royalty rate of 2.5% applies.

### **5.9 Zimbabwe**

On May 27, 2004, Zimbabwe's Minister of Justice, Legal and Parliamentary Affairs declared a Period of Emergency in order to override antiretroviral drug patents. With assistance from India, Zimbabwe has begun local production of antiretrovirals.

## **6. Middle East**

### **6.1 Israel**

In January 1992, BTG-Israel filed an application in the Israeli Patent Office for a compulsory license to manufacture BTG's Bio-Hep-B under Biogen's Israeli patent which license, upon approval, would enable BTG to produce the vaccine in Israel and likely to export the vaccine to countries in which neither Biogen nor others have been granted a blocking patent. In September 1995 the Registrar ruled in an interlocutory decision that BTG-Israel is entitled to a compulsory license to the Biogen patent. Biogen's appeal of the interlocutory decision was rejected.

Biogen appealed the Registrar's decision to the District Court of Tel Aviv, Israel, and moved for a stay of the license, which was granted ex parte pending hearings with both parties. Following hearings which took place in December 1996, the motion was denied in January 1997; however, the ex parte stay was left in force pending Biogen's appeal to the Supreme Court and maintained by the Supreme Court pending the decision by the District Court on the merits of Biogen's appeal. The District Court heard the appeal in early March 1997, and in June 1997 the District Court denied Biogen's appeal and subsequent motion for a stay pending Biogen's appeal of the District Court decision to the Supreme Court on the merits. In March 1998 the Supreme Court granted Biogen the right to appeal the District Court's decision. A date has not yet been set for the hearing. In the absence of any action by the Supreme Court, the compulsory license is now effective and allows BTG-Israel to produce the vaccine in Israel upon receipt of regulatory approval and to export the vaccine to countries in which neither Biogen nor others have been granted a blocking patent.

The Biogen Israeli patent expired in December 1999, before the Supreme Court ruled on the compulsory license.

## **Public Health Ministerial Order No. 360/B.E.2548 (A.D. 2005)**

### **Re: Appointment of the Ad Hoc Working Group for Price Negotiation of the Patented Essential Drugs**

With great concerns on some important public health problems, such as AIDS, tuberculosis, etc, the Ministry of Public Health has found that a large number of people do not have access to the essential drugs for treating these diseases. One of the causes is the high price of drugs due to the patent protection. This inaccessibility will cause negative impacts on public health services and drug security in the country, especially impacts on the success of the government policy on the national universal health insurance scheme. Therefore, to achieve reasonable and affordable priced patented essential drugs, the Ministry of Public Health hereby appoints the Ad Hoc Working Group for Price Negotiation of the Patented Essential Drugs whose component and responsibilities are as follow:

Component of the Ad Hoc Working Group:

- |  |                       |
|--|-----------------------|
| 1. Deputy Permanent Secretary of the Ministry of Public Health<br>Chief, Cluster of Health Service Support | Advisory              |
| 2. Secretary General of the Food and Drug Administration   | Chair                 |
| 3. Deputy Secretary General of the Food and Drug Administration  | Member                |
| 4. Director of the Bureau of AIDS, TB and STIs   | Member                |
| 5. Director of Patent Office or Representative   | Member                |
| 6. Representative from the Department of Health Service Support  | Member                |
| 7. Representative from the Department of Internal Trade  | Member                |
| 8. Director of the Drug Control Division   | Member                |
| 9. Mr.Suchart Chongprasert   | Secretariat           |
| 10. Representative from the Bureau of AIDS, TB and STIs  | Assistant secretariat |

11. Ms. Farsai Chanjaruporn

Assistant secretariat

Responsibilities of the Ad hoc Working Group:

1. to study and analyze situations and problems arising from price of patented drugs;
2. to specify patented drugs whose price negotiation are needed;
3. to negotiate for reasonable price of the specified patented drugs;
4. to study and set plans and guidelines, including other necessary measures to facilitate the successful negotiation;
5. to report results of the price negotiation to Ministry of Public Health;
6. other responsibilities as recommended by Ministry of Public Health.

The Ministerial Order shall be effective from now on.

Given on the 4<sup>th</sup> Day of April B.E. 2548 (2005).

(signed) Supachai Kunaratanapruk

(Mr. Supachai Kunaratanapruk)

Deputy Permanent Secretary

Chief, Cluster of Health Service Support

## **Brief Report of the Output from the Ad hoc Working Group for Price Negotiation of the Patented Essential Drugs**

### **Background:**

At present, difficulties in getting access to some drugs (especially, drugs used for treatments of HIV/AIDS, chronic diseases, including heart diseases and cancers) are facing a great number of populations in Thailand. Although the Patent Act, B.E. 2522 (1979) as amended by the Patent Act (No. 3) B.E. 2542, provides the flexibilities to government agencies to exercise the right under any drug patent without prior authorization of the patent holder, the Thai government has never exercised such right.

The Ministry of Public Health, therefore, issued a Ministerial Order on 4<sup>th</sup> April B.E. 2548 (2005) appointing the “Ad Hoc Working Group for Price Negotiation of the Patented Essential Drugs” to work on price negotiation of some selected patented drugs. This Ad Hoc Working Group works is chaired by the Secretary-General of the Food and Drug Administration. Members are composed of representatives from related organizations, such as Department of Disease Control, Department of Internal Trade, Department of Intellectual Property, and Department of Health Service Support. The main objective of this Ad hoc Working Group is to set plans or measures to facilitate the successful price negotiation, and *Government Use of Patent* is also considered as an important tool or measure for the price negotiation.

### **Actions taken:**

The Ad Hoc Working Group has conducted an investigational study and survey on pricing structure. In the initial phase, the Ad Hoc Working Group focuses on antiretroviral drugs (ARVs) because the issue raised by the representative from the Department of Disease Control shows that there is a great need of some ARVs whose prices are very high and many patients have limitation in accessing these drugs.

The following three ARVs were thoroughly investigated on their pricing structures:

1. Efavirenz (Strocrin from MSD)

2. Lopinavir/Ritronavir (Kaletra from Abbott)
3. Atazanavir (Reyataz from BMS)

(These above mentioned names are classified as second-line drugs that are needed for HIV/AIDS patients resistant to GPO-Vir.)

After requesting for information on pricing structures from the patent holders, the working group did not receive good cooperation from the 3 companies. However, from the information available, the Ad Hoc Working Group found that drug pricing was not considerably based on the cost of the active pharmaceutical ingredients (APIs) and the production cost. Rather, drug pricing was based mainly on managerial costs and other costs related to depreciation. Also, the patent protection in accordance with the law enables the patent holders to dominate pharmaceutical market with very high prices without competition.

With little cooperation from drug companies in providing information regarding drug pricing structures and on price negotiation, the Ad Hoc Working Group has finally concluded that exercising a compulsory license by government would be an effective measure for more successful price negotiation for patented essential drugs.

### **Conclusion:**

The establishment of the Ad Hoc Working Group for Price Negotiation of the Patented Essential Drugs can be one effective measure in managing intellectual property to allow better access to patented essential drugs. It may provide good and constructive solutions that are acceptable by both the government and the patent holders, in achieving better access to essential patented drugs. Nevertheless, exercising a compulsory license by government increases the negotiation power of the working group and can facilitate more effective and successful negotiation.

Lastly, in considering exercising the compulsory licensing by government, it is necessary to consider the public health needs, the capability of domestic companies to develop or produce, as well as the possibility to import such generic drug with same quality as the original one from abroad.



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Ph. (66) (02) 255-5090  
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สำนักโรคเอดส์ วัณโรค และ  
โรคติดต่อทางเพศสัมพันธ์  
โรคติดต่อทางเพศสัมพันธ์  
เลขรับ. 1310  
วันที่ 9 - ก.พ. 2548  
เวลา 622

27 January 2005

Director, Department of Disease Control  
Department of Disease Control  
Ministry of Public Health  
Tivanond Road,  
Muang,  
Nonthaburi 11000

Subject: Pricing of Antiretroviral Drugs from MSD Thailand

This is in response to your letter no D424.4/7, requesting MSD (Thailand), Ltd., to further consider a price reduction of Stocrin and Crixivan for the Department of Disease Control in order to increase access for patients to HIV treatment.

Since March 2001, Merck and its MSD subsidiaries across the world have implemented a policy to offer Stocrin and Crixivan at the no profit prices to developing countries with a high burden of disease (i.e., HIV/AIDS adult patients prevalence >1% of the population) - this includes Thailand. I assure you that our corporate goals and policies regarding pricing of Stocrin and Crixivan in Thailand are in line with providing optimal ARV access to HIV patients. We have been selling Stocrin and Crixivan to the DDC at the no profit price inclusive of locally incurred costs such as custom duties, import duty, VAT and MSD delivery costs.

Most of these additional costs are related to the conditions of sales required by the DDC/MOPH. For example:

- MSD is required to accept returned goods no less than 5 months from the expiry date
- MSD will be fined a penalty fee at a daily rate of 0.20% on the total amount as a result of any late delivery.
- MSD have to accept extended payment terms.
- MSD must ship products that are within 12 months from the production date.

If these conditions were to be eliminated, we can decrease the price accordingly.

I look forward to working with you and other colleagues at the Thai MOPH to improve access to high quality medicines for HIV/AIDS patients in Thailand.

Sincerely yours,

Douglas Cheung  
Managing Director

นายสมชาย ใจดี  
ผู้อำนวยการ  
กรมควบคุมโรค

- ขอขอบคุณ MSD ที่ช่วยเหลือผู้ป่วย  
โรคเอดส์ และโรคติดต่อทางเพศสัมพันธ์  
ในประเทศไทยให้ได้รับยาต้านไวรัส  
ที่มีคุณภาพดีและปลอดภัย. ขอขอบคุณ  
นาย Douglas Cheung

บริษัท เมอร์ค จำกัด 7/1 Wireless Road, Pathumwan, Bangkok 10330 โทร. (66) (02) 255-5090 โทรสาร (66) (02) 255-5095

**Public Health Ministerial Order**  
**No. 163/B.E.2550 (A.D. 2007)**

**Re: Appointment of the Committee for Price Negotiation of  
the Patented Essential Drugs**

With great concerns on some important public health problems, such as AIDS, tuberculosis, heart disease, diabetes, hypertension, and cancers, the Ministry of Public Health has found that a large number of people do not have access to the essential drugs for treating these diseases. One of the causes is the high price of drugs due to the patent protection. This inaccessibility will cause negative impacts on public health services and drug security in the country, especially impacts on the success of the government policy on the national universal health insurance scheme aiming to promote access to all drugs in the National List of Essential Medicines for all Thai people. Therefore, to achieve reasonable and affordable priced patented essential drugs for the increased accessibility to these drugs, the Ministry of Public Health hereby:

1. Repeals the Public Health Ministerial Order No. 360/B.E.2548 (2005), dated 4<sup>th</sup> April B.E. 2548 (2005), Re: Appointment of the Ad Hoc Working Group for Price Negotiation of the Patented Essential Drugs;

2. Appoints the Committee for Price Negotiation of the Patented Essential Drugs whose component and responsibilities are as follow:

2.1 Component of the Committee:

- |       |  |         |
|-------|--|---------|
| 2.1.1 | Permanent Secretary of the Ministry of Public Health     | Advisor |
| 2.1.2 | Secretary General of the Food and Drug Administration    | Chair   |
| 2.1.3 | Director General of the Department of Disease Control    | Member  |
| 2.1.4 | Director General of the Department of Health Service     | Member  |
|       | Support  |         |
| 2.1.5 | Director General of the Department of Trade Negotiations | Member  |
|       | Ministry of Commerce                                     |         |

2.1.6	Director General of the Department of Internal Trade Ministry of Commerce	Member
2.1.7	Director General of the Department of International Economic Affairs Ministry of Foreign Affairs	Member
2.1.8	Secretary General of the National Health Security Office	Member
2.1.9	Deputy Secretary General of the Food and Drug Administration (As appointed by Secretary General of the Food and Drug Administration)	Member
2.1.10	Ms. Jiraporn Limpananont	Member
2.1.11	Mr. Jade Donavanik	Member
2.1.12	Director of the Drug Control Division Food and Drug Administration	Member
2.1.13	Mr. Suchart Chongprasert	Secretariat
2.1.14	Ms. Nithima Sumpradit	Assistant secretariat
2.1.15	Ms. Farsai Chanjaruporn	Assistant secretariat

## 2.2 Responsibilities of the Committee:

2.2.1 To study and analyze situations and problems arising from price of patented drugs, as well as consequences of having compulsory licensing exercised for certain drugs by the Ministry of Public Health;

2.2.2 To negotiate for reasonable price and/or for technology transfers through voluntary licensing of certain patented essential drugs (including those that have already had compulsory licensing exercised by the Ministry of Public Health or any departments under the Ministry of Public Health, and those that have not been yet exercised such right);

2.2.3 To study and set plans and guidelines, including other necessary measures to facilitate the successful negotiation;

2.2.4 To report results of the price negotiation to the Ministry of Public Health;

2.2.5 To appoint any sub-committee or working group, as necessary, to facilitate the Committees work;

2.2.6 Other responsibilities as requested by the Ministry of Public Health.

In this regard, efficient cooperation on sharing of related information and other necessary supports from all agencies under the Ministry of Public Health, National Health Security Office, and the Government Pharmaceutical Organization is requested.

The Ministerial Order shall be effective from now on.

Given on the 16th Day of February B.E. 2550 (A.D.2007).

(Signed) Mongkol Na Songkhla  
(Mr. Mongkol Na Songkhla)  
Minister of Public Health

Where patients come first  MSD

**MSD (Thailand) Ltd.**  
 The Offices at Central World, Floor 37th  
 999/9 Rama 1 Road,  
 Pathumwan,  
 Bangkok 10330  
 Tel. (66) 2255-5090  
 Fax. (66) 2255-5095

6 February 2007

Dr. Thawat Suntrajarn  
 Director-General of Department of Disease Control  
 Minister of Public Health  
 Thivanon Road,  
 Nonthaburi 11000 Thailand

**STOCRIN 600mg x 30 Tablets per Bottle**

Dear Dr. Thawat,

We refer to our letter to you dated 15 December 2006 and the subsequent discussions we have to improve the access of Thai patients to STOCRIN.

We are pleased to offer the new price based on the terms and conditions of sale as follows:

1. Selling Price: United States Dollar [US\$] based selling price @ US\$20.21 per Bottle of thirty (30) Tablets excluding Value Added Tax [VAT] or @ US\$21.63 per Bottle of 30 Tablets inclusive of 7% VAT.
2. Invoicing Parties: Invoices shall be issued by our sole and exclusive distributor B.L.H. Trading Co., Ltd. [BLH] to Department of Disease Control [DDC].
3. Payment Terms: Within thirty (30) calendar days from invoice date, payable in full by DDC to BLH.
4. Delivery Terms: Goods shall be delivered by BLH to the twelve (12) DDC regional distribution centres and to some hospitals in Bangkok.
5. Lead-time for Delivery: ex-Stock basis from Bangkok, based on confirmed orders or official forecast quantity, as given by DDC to BLH at least one hundred and twenty (120) calendar days prior to actual delivery date.
6. Goods Return: All goods once sold or delivered are not returnable, exchangeable or refundable.

Product supplied on these terms would only be available for domestic use and not for re-export.

We look forward to receiving a positive response to our offer from the Minister of Public Health within 20 February 2007.

Yours sincerely,

  
 Douglas Cheng  
 Managing Director  
 MSD (Thailand) Ltd.

## PRESS RELEASE

### Merck & Co., Inc., Again Reduces Price of STOCRIN (efavirenz) for Patients in Least Developed Countries and Countries Hardest Hit by Epidemic

*February 14, 2007 5:00 p.m.*

Second Reduction in Less Than a Year

Will Help Expand Access to HIV/AIDS Care and Treatment

WHITEHOUSE STATION, N.J. (BUSINESS WIRE) February 14, 2007

Merck & Co., Inc.(1), today announced a reduction in the price of its HIV/AIDS medicine, STOCRIN (efavirenz), in the least developed countries of the world and those hardest hit by the epidemic. The price of the 600 mg formulation of STOCRIN has been reduced by 14.5 percent to US \$0.65 per day, or US \$237.25 per patient per year, from \$0.76 per day, for purchasers in countries in the low category of the Human Development Index (HDI) and in medium HDI countries with an adult HIV prevalence of 1% or greater. In medium HDI countries with an adult HIV prevalence of less than 1%, the price of the 600 mg formulation of STOCRIN will be reduced by 5.8%, to US \$1.80 per day, or US \$657.00 per patient per year, from US \$1.91 per day.

Merck is lowering the price of the 600 mg formulation of STOCRIN due to efficiencies resulting from improved manufacturing processes. This is the second time that the Company has reduced the price of this formulation in less than a year. The prices of other formulations of STOCRIN and Merck's other HIV/AIDS medicine, CRIVAN (indinavir sulfate), remain unchanged.

"Merck has long been a leader in efforts to broaden access to our medicines for those who need them around the world," said Merck Chief Executive Officer and President Richard T. Clark. "Today's price reductions reflect our continuing commitment to improve the lives of people living with HIV/AIDS throughout the developing world."

As a result of Merck's differential pricing policy, at the end of 2006 some 500,000 patients in 76 developing countries were being treated with antiretroviral regimens containing STOCRIN and CRIXIVAN.

#### Merck pricing policy for its HIV/AIDS medicines

These prices are available to all HIV/AIDS care and treatment providers who can demonstrate with reasonable assurance their capacity to ensure increased patient access. For example, providers include governments, international organizations, non-governmental organizations (NGOs) and private sector organizations (such as employers, insurers and hospitals). Under the MSD HIV/AIDS pricing policy, the medicines must be used in the country where they are sold and may not be exported. Merck first announced that it was reducing the prices of STOCRIN and CRIXIVAN in developing countries to prices at which the Company makes no profit on March 7, 2001. Since then, access to HIV medicines has accelerated in the least developed countries and those countries where HIV/AIDS has hit hardest.

#### Improving access through public-private partnerships

In addition to Merck's ongoing HIV/AIDS antiretroviral and vaccine research programs, the Company continues to work in many public-private partnerships focused on increasing access to treatment and care. These partnerships play a critical role in the developing world by helping to build the health systems capacity necessary to ensure sustainable access to health care and treatment. Some of these programs include: African Comprehensive HIV/AIDS Partnerships (ACHAP) in Botswana, Merck Mectizan Donation Program, China/Merck HIV/AIDS Partnership, Merck Vaccine Network-Africa and Merck Medical Outreach Program (MMOP). (For further details, see [www.merck.com/about/cr](http://www.merck.com/about/cr).)

#### About STOCRIN

STOCRIN is a once-daily, non-nucleoside reverse transcriptase inhibitor (NNRTI) used in combination treatment for HIV. People living with HIV/AIDS have the option of taking one 600 mg STOCRIN tablet once-daily instead of three 200 mg capsules. The 600 mg tablet is approved in more than 90 countries.

STOCRIN in combination with other antiretroviral agents is indicated for the treatment of HIV-1 infection. This indication is based on two clinical trials of at least one-year duration that demonstrated prolonged suppression of HIV-RNA. STOCRIN should not be administered concurrently with astemizole, cisapride, triazolam, midazolam, or ergot derivatives because competition for CYP3A4 by efavirenz could result in inhibition of metabolism of these drugs and create the potential for serious and/or life threatening adverse events (e.g., cardiac arrhythmias, prolonged sedation or respiratory depression).

The chemical entity of STOCRIN, efavirenz, was discovered by Merck Research Laboratories in 1992 and licensed to The DuPont Merck Pharmaceutical Company (now Bristol-Myers Squibb Company) in 1994 for development and marketing in certain countries. Bristol-Myers Squibb has exclusive marketing rights to efavirenz in the United States (including territories and possessions), Canada, United Kingdom, Republic of Ireland, France (continental only), Spain, Italy and Germany, and markets efavirenz under its trademark Sustiva. Through its subsidiaries and marketing partners, Merck has exclusive marketing rights in all other countries worldwide, and markets efavirenz under the trademark STOCRIN.

### **About Merck**

Merck & Co., Inc. is a global research-driven pharmaceutical company dedicated to putting patients first. Established in 1891, Merck currently discovers, develops, manufactures and markets vaccines and medicines to address unmet medical needs. The Company devotes extensive efforts to increase access to medicines through far-reaching programs that not only donate Merck medicines but help deliver them to the people who need them. Merck also publishes unbiased health information as a not-for-profit service. For more information, visit [www.merck.com](http://www.merck.com).

### **Forward-Looking Statement**

This press release contains “forward-looking statements” as that term is defined in the Private Securities Litigation Reform Act of 1995. These statements are based on management’s current expectations and involve risks and uncertainties, which may cause results to differ materially from



those set forth in the statements. The forward-looking statements may include statements regarding product development, product potential or financial performance. No forward-looking statement can be guaranteed, and actual results may differ materially from those projected. Merck undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events, or otherwise. Forward-looking statements in this press release should be evaluated together with the many uncertainties that affect Merck's business, particularly those mentioned in the cautionary statements in Item 1 of Merck's Form 10-K for the year ended Dec. 31, 2005, and in its periodic reports on Form 10-Q and Form 8-K, which the company incorporates by reference.

(1) Merck & Co., Inc., Whitehouse Station, NJ, USA, operates in most countries outside of the United States as Merck Sharp & Dohme, or MSD.

CONTACT: Merck & Co., Inc.

Media: Chris Loder, 908-423-3786

or

Investor: Graeme Bell, 908-423-5185

SOURCE: Merck & Co., Inc.

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**National Health Security Board Order**  
**Number 4/B.E. 2549 (A.D.2006)**  
**Re: Appointment of the Subcommittee for Implementing the**  
**Government Use of Patent on Essential Patented Drugs**

To facilitate the efficient function of the National Health Security Board, the Board with its authority under Article 20 of the National Health Security Act B.E. 2545 (A.D. 2002), and according to its resolution at the meeting on 12 January 2006, decides to establish the Subcommittee for Implementing the Government Use of Patent on essential patented drugs, with the following composition, functions and authorities.

1. Composition:

- |   |              |
|---|--------------|
| (1) Mr. Sanguan Nitayarumphong  | Chair        |
| (2) Miss Sumlee Jaidee  | Deputy Chair |
| (3) Representative of the Department of Disease Control<br>Ministry of Public Health  | Member       |
| (4) Representative of the Department of Medical Services<br>Ministry of Public Health | Member       |
| (5) Representative of the Food and Drug Administration<br>Ministry of Public Health   | Member       |
| (6) Representative of the Office of the Council of State                              | Member       |
| (7) Representative of the Consortium of Medical Schools                               | Member       |
| (8) Representative of the Department of Intellectual Property<br>Ministry of Commerce | Member       |
| (9) The Chairman of Thai Network of People living with AIDS                           | Member       |
| (10) Secretary of the Friend of Cancer Patients Network                               | Member       |
| (11) Mrs. Renu Srisamit   | Member       |
| (12) Mrs. Wandee Pokakul  | Member       |
| (13) Mr. Suchart Chongprasert   | Member       |

(14) Miss Yuwadee Patanawong	Member
(15) Mr. Chairat Sangarun	Member
(16) Mrs. Achara Eksaengsri	Member
(17) Miss Sureerat Trimanka	Member
(18) Mr. Winyu Pitakpakorn	Member
(19) Mr. Vithaya Kulsomboon	Member
(20) Mr. Pongpisut Jongudomsuk	Member
(21) Mr. Charay Vichathai	Member and secretary

2. Functions and authorities:

- (1) Development of criteria for selecting drug and medical equipment which are entitled to Government Use
- (2) Proposing (1) to National Health Security Board for approval
- (3) Selecting drugs or medical equipment in line with the criteria approved by the Board and informing the National Health Security Office to proceed with appropriate processes for implementing of Government Use of Patent on these drugs
- (4) Monitoring the consequences after implementation of Government Use of Patent and proposing recommendations.

This Order shall be effective from 12 January 2006

Given on the 17<sup>th</sup> Day of April B.E. 2549 (A.D.2006)

(Signed) Phinij Jarusombat

(Mr. Phinij Jarusombat)

Minister of Public Health

Chairman of National Health Security Board



*Executive Director*

**Reference:** EXO/PP/TM/sh

H.E. Mr. Mongkol Na Songkhla  
Public Health Minister  
Thano Tiwanond  
Amphoe Muang  
Nonthaburi 11000  
Thailand

26 December 2006

Excellency,

I would like to take this opportunity to commend you and the Government of Thailand for your strong and steadfast efforts to provide access to antiretroviral treatment, including through the local manufacturing of generic medicines, to people living with HIV.

Your latest decision to import generic Efavirenz until Thailand is able to manufacture the drug itself, is a good example of that commitment. It is also a sign of the need to urgently and consistently lower the cost of antiretroviral treatment in developing countries so that it not only becomes more affordable, but financially sustainable.

Please accept, Excellency, the assurances of my highest consideration.

Dr Peter Piot

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SWITZERLAND

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Fax +41 22 791 4187  
www.unaids.org

c.c.: Dr. Suwit Wibulpolprasert, Senior Advisor on Health Economics, Ministry of Public Health, Thailand  
H.E. Mr Chalyong Satjipanon, Ambassador & Permanent Representative, Thai Mission, Geneva

Uniting the world against AIDS



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Fax: (212) 679-7016

Web: [www.doctorswithoutborders.org](http://www.doctorswithoutborders.org)

Honorable Condoleezza Rice, Secretary of State  
U.S. Department of State  
2201 C Street NW  
Washington, DC 20520

Ambassador Susan Schwab, United States Trade Representative  
600 17th Street, N.W.  
Washington, DC 20508  
United States of America

New York, December 29, 2006

Dear Secretary Rice and Ambassador Schwab:

I am writing to express Doctors Without Borders/Médecins Sans Frontières (MSF)'s concern that the United States Department of State and the United States Trade Representative have intervened in the decision by the government of Thailand to issue a compulsory license on patents for the AIDS drug efavirenz, and to explain why the US government should refrain from such actions.

The US government is reportedly asking the Thai government to engage in prior negotiation with patent owners before issuing compulsory licenses. Not only is this not required under the World Trade Organization (WTO) rules when the compulsory license is for government use, it is not required under US law. What the WTO does require is that Thailand "promptly" notify the patent owner when it issues a compulsory license. Thailand has clearly done this. The US government should not be overseeing the management of Thailand's dealing with the patent owners as long as Thailand abides by its WTO TRIPS obligations.

In 2001, the United States government and every other member of the World Trade Organization (WTO) announced the signing of the Doha Declaration on TRIPS (Trade-related Aspects of Intellectual Property Rights) and Public Health. This historic agreement said:

<start quote>

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

In this connection, we reaffirm the right of WTO members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose.  
</end quote>

Thailand is obviously trying to do exactly what the Doha Declaration promised it could. Respecting Thailand's decision to exercise its right under the Doha declaration is a matter of urgent concern for Thai patients in need of affordable AIDS treatment.

The drug efavirenz, which is recommended by the World Health Organization (WHO) for HIV/AIDS treatment, is currently patent protected in Thailand, and the monopolistic situation has affected both

supply and affordability in the country. The price the patent holder Merck charges in Thailand (1,400 baht/month — US \$39) is double of what Indian generic manufacturers charge for the drug (650 baht/month — US \$18). In addition, on several occasions, Merck has been unable to supply the drug in Thailand. It is estimated that at least 12,000 people in Thailand currently need efavirenz, but that due to cost and supply difficulties, the number receiving the drug is significantly lower.

MSF has worked in Thailand since 1976. The organization began providing ARV treatment to people with HIV/AIDS in 2000 and we have witnessed the development of the Thai AIDS treatment program. Generic production is the cornerstone of Thailand's universal HIV/AIDS treatment program. Before generic production, the cost of standard HIV/AIDS treatment in Thailand was over 33,330 baht per patient per month (US \$924), and only 3,000 people were getting treatment. In 2002, Thailand launched a generic version of HIV/AIDS triple therapy, resulting in an 18-fold drop in the cost of treatment. Thanks to this, over 85,000 people with HIV/AIDS are today receiving treatment. UNAIDS reports that Thailand is the only Southeast Asian country to have over half of the total number of people on AIDS treatment who need it.

Both the WHO (in August 2005) and the World Bank (in August 2006) have predicted dramatically rising drug costs in Thailand due to the fact that patients need to switch to newer and more expensive drugs in cases of resistance and toxicity. Both organizations recommend the use of public health safeguards enshrined in the Doha Declaration on TRIPS and Public Health.

Issuing and executing a compulsory license, allowing both importation and local production, will increase supply and affordability of efavirenz to the benefit of Thai patients. Creating a competitive generics market for efavirenz and other newer AIDS drugs that are patented in Thailand and other markets is critical to maintaining patients under treatment as natural resistance to first-line ARV therapy increases, as well as to scaling up ARV treatment.

Thailand's decision will have important consequences, not only for Thailand, but for any developing country that needs to obtain low-cost generic products. If Thailand follows through and begins to buy from generic suppliers, it will create a larger global market for generic products, stimulate competition, and lower prices everywhere for the newer products.

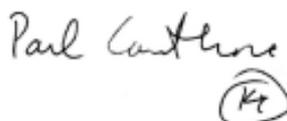
While the benefits of expanded generic competition are widely appreciated, many developing countries have been reluctant to issue compulsory licenses because of fears that the United States government will oppose such actions and exert pressure.

We ask that the United States government refrain from any opposition or interference with the Thai efforts to use WTO flexibilities to buy generic AIDS medicines -- including pressuring or otherwise seeking to persuade Thailand to engage in negotiations with Merck rather than proceed to execute the compulsory license it has issued.

Sincerely,



Nicolas de Torrente  
Executive Director  
Doctors Without Borders/Médecins Sans Frontières (MSF-USA)



Paul Cawthorne  
Head of Mission, MSF-Thailand



## Third World Network

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23 February 2007

Dr Mongkol Na Songkhla  
The Minister of Health  
Thailand

Dear Dr Mongkol Na Songkhla,

The Third World Network would like to congratulate you and your colleagues for the actions you have taken on issuing the three compulsory licenses for three importantly needed medicines in Thailand.

As a network of NGOs in developing countries, with its headquarters in Penang (Malaysia), the Third World Network (TWN) has long been involved in issues relating to access to medicines. A few years ago we published a manual on public-health sensitive patent law, which was written by international legal and health experts. The manual laid out clearly the legal requirements of the TRIPS agreement and the flexibilities that can be used, such as compulsory licensing, government use order and parallel importation.

Our experts believe that the actions you took on the three compulsory licenses are consistent with the TRIPS agreement. Moreover, as the licenses are for products for government use, it is correct to say that there is no requirement for prior negotiation with the patent holders. I believe this point has now also been clarified by the WHO Director General. Moreover, Thailand is not the only country that has issued compulsory licenses; in our region, Malaysia and Indonesia have also done so.

We share the belief that life and health are the most important priority, and that providing the public with medicines (especially the poor who cannot afford it otherwise) at affordable cost is a duty of government. We therefore congratulate your actions to make use of the flexibilities of TRIPS, which all the Ministers in charge of WTO affairs agreed is not only lawful but also important to do, in their Doha Ministerial declaration on TRIPS and Public Health.

THIRD WORLD NETWORK is a grouping of organizations and individuals involved in Third World and development issues. The International Secretariat is based in Penang, Malaysia

We hope that with these actions, the people of Thailand will have greater access to medicines that they need. We hope that when the need arises for more affordable medicines, that you and your colleagues will make further use of the TRIPS flexibilities.

We are also confident that the example of your actions will help other countries to make their own decisions on how to improve access of their people to medicines.

With best wishes,



Martin Khor  
Director  
Third World Network

## Consumer Project on Technology

1621 Connecticut Avenue, NW, Washington, DC 20009

December 11, 2006

Ambassador Susan C. Schwab  
United States Trade Representative  
600 17th Street, N.W.  
Washington, DC 20508  
United States of America

Dear Ambassador Schwab:

We ask that the United States government not interfere with the Thai government decision to issue a government-use license on patents covering the AIDS drug efavirenz.

There is a concern that the USTR may have suggested to the Thai government that the WTO TRIPS agreement requires prior negotiations with patent owners before a compulsory license is issued. If so, the assertion was wrong. Article 31 of the TRIPS does not require prior negotiation before authorizing non-voluntary use of a patent, in *any* of the following cases:

- (1) a national emergency or other circumstances of extreme urgency,
- (2) cases of public non-commercial use, or
- (3) where such use is permitted to remedy a practice determined after judicial or administrative process to be anti-competitive.

In this particular case, the non-voluntary use was a case of a government owned entity that is providing medicines for a national program to treat AIDS. Under the WTO rules, there is no obligation for prior negotiation with patent owners in such cases.

There is also no requirement for prior negotiation with patent owners under the various US bilateral (and regional) trade agreements the United States has recently negotiated. The reason for this is obvious. In the TRIPS and the bilateral or regional trade agreements, these sections on prior negotiation were written to accommodate US law and practice. Our own government is not required to negotiate with patent owners or copyright owners before authorizing use by or for the government.

The main United States statute regarding use of a patent in such circumstances is 28 USC 1498. There is no obligation for prior negotiation or prior notice with the patent owner under 28 USC 1498, when a non-voluntary authorization is for the government.<sup>1</sup> This includes uses by third parties:

<sup>1</sup> TRIPS Article 31.b states "In the case of public non-commercial use, where the government or contractor, without making a patent search, knows or has demonstrable grounds to know that a valid patent is or will be used by or for the government, the right holder shall be informed promptly." There is a similar

*For the purposes of this section, the use or manufacture of an invention described in and covered by a patent of the United States by a contractor, a subcontractor, or any person, firm, or corporation for the Government and with the authorization or consent of the Government, shall be construed as use or manufacture for the United States.*

As trade officials charged with promoting US norms for intellectual property protection, it is useful to review what those norms actually are. The United State has a number of mechanisms to issue compulsory licenses on patents. These include, in addition to 28 USC 1498, the following:

- Mandatory patent licenses under Section 308 of the Clean Air Act (see: <http://www.epa.gov/docs/fedrgstr/EPA-AIR/1994/December/Day-30/pr-251.html>). *This statute is unfortunately not consistent with the provisions of the US FTA agreements negotiated with Jordan (2000), Singapore (2003), and Australia (2004).*
- Compulsory licenses for patents "affected with the public interest" that are of primary importance in the production or utilization of special nuclear material or atomic energy, for non-military purposes (See 42 USC 2183). *This statute is unfortunately not consistent with the provisions of the US FTA agreements negotiated with Jordan (2000), Singapore (2003), and Australia (2004).*
- The Bayh-Dole Act march-in rights for patents on inventions conceived with federal funding,
- Remedies to anticompetitive practices.
- Compulsory licenses issued under the procedures set out by the US Supreme Court in the recent eBay decision. *This approach is arguably not consistent with the provisions of the US FTA agreements negotiated with Jordan (2000), Singapore (2003), and Australia (2004).*

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provision in NAFTA. NAFTA Article 1709(10)(b) also requires that patent owners be notified "promptly," but *not* before a compulsory license is issued. See also: Executive Order 12889, Implementation Of The North American Free Trade Agreement, December 28, 1993:

Sec. 6. Government Use of Patented Technology. (a) Each agency shall, within 30 days from the date this order is issued, modify or adopt procedures to ensure compliance with Article 1709(10) of the NAFTA regarding notice when patented technology is used by or for the Federal Government without a license from the owner, except that the requirement of Article 1709(10)(b) regarding reasonable efforts to obtain advance authorization from the patent owner:

- (1) is hereby waived for an invention used or manufactured by or for the Federal Government, except that the patent owner must be notified whenever the agency or its contractor, without making a patent search, knows or has demonstrable reasonable grounds to know that an invention described in and covered by a valid United States patent is or will be used or manufactured without a license; and
- (2) is waived whenever a national emergency or other circumstances of extreme urgency exists, except that the patent owner must be notified as soon as it is reasonably practicable to do so.

The following are a just few recent examples of the use of compulsory licenses by the United States:

- In 2001, DHHS Secretary Tommy Thompson used the threat to use 28 USC 1498 to authorize imports of generic ciprofloxacin, for stockpiles against a possible anthrax attack.
- In 2001, the Department of Health and Human Services used its authority to exercise March-In rights for patents on stem cell lines held by the Wisconsin Alumni Foundation as leverage to secure an open license on those patents.<sup>2</sup>
- In 2002, the US FTC ordered a compulsory cross-license of the Immunex tumor necrosis factor ("TNF") patent, to Serono, including the "freedom to practice in the research, development, manufacture, use, import, export, distribution and sale of TNFbp-I Products and certain glycosylated and nonglycosylated fragments, derivatives and analogs thereof in the United States."
- In 2002, the US Department of Justice required Microsoft to license on reasonable and non-discriminatory terms intellectual property rights in a number of different protocols needed to create products that were interoperable with Microsoft Windows.<sup>3</sup>
- In 2005, the FTC ordered a compulsory license of Guidant's intellectual property surrounding the RX delivery system for Drug-Eluting Stents.
- In 2005, the US Department of Justice cited its right to use patents in 28 USC 1498 when it opposed injunctive relief for infringement of the patents relating to the Blackberry email services supplied to both the government and private firms that used the Blackberry device to communicate with the government.<sup>4</sup>
- In a November 2005 Congressional hearing, DHHS Secretary Michael Levitt testified before the House of Representatives that he had threatened to override the patents on treatments for Avian Flu if companies had not expanded US production facilities.<sup>5</sup> More recently, the Centers for Disease Control threatened to use US Bayh-Dole "march-in" rights to issue compulsory licenses on patents on reverse genetics, which are needed to manufacture vaccines for avian flu.

<sup>2</sup> September 5, 2001, "National Institutes of Health and WiCell Research Institute, Inc., Sign Stem Cell Research Agreement," <http://www.nih.gov/news/pr/sep2001/od-05.htm>.

<sup>3</sup> United States Of America, Plaintiff V. Microsoft Corporation, Defendant. Civil Action No. 98-1232 (CKK), FINAL JUDGMENT, (November 12, 2002). For a detailed account of work to implement the order, see: INTERIM JOINT STATUS REPORT ON MICROSOFT'S COMPLIANCE WITH THE FINAL JUDGMENTS, <http://www.usdoj.gov/atr/cases/f201300/201386.htm>

<sup>4</sup> The United States' Statement Of Interest, November 2005., NTP, INC., Plaintiffs, V. RESEARCH IN MOTION, LTD., Defendant., Civil Action No. 3:01CV767.

<sup>5</sup> See video excerpts from November 8, 2005 Hearings of the Subcommittee on Health of the House Committee on Energy and Commerce, <http://www.cptech.org/ip/health/tamiflu/hearingexcerpts11082005.html>

- In June 2006, a court granted Microsoft a compulsory license to use two patents owned by z4 Technologies that relate to digital rights management systems used by Microsoft for its Windows and MS Office software programs.<sup>6</sup>
- In July 2006, a court granted DirectTV a compulsory license to use the Finisar patent on integrated receiver decoders (satellite set top boxes), for a royalty of \$1.60 per device.<sup>7</sup>
- In August 2006, a court granted Toyota a compulsory license on three Paice patents for hybrid transmissions, for a royalty of \$25 per automobile.<sup>8</sup>
- In September 2006, a court granted Johnson and Johnson a compulsory license to use three of Jan Voda's patents on guiding-catheters for performing angioplasty.<sup>9</sup>

The point of this history lesson is to emphasize a point that some USTR officials seem to overlook. The flexibilities in the TRIPS agreement are there for good reasons. As evidenced by the many cases described above, there are many situations where *any* country will want to limit or create exceptions to the exclusive rights of a patent.

In the case of efavirenz patents, Thailand is clearly seeking to create a policy that will strengthen competition among generic suppliers, and enhance its own capacity to manufacture AIDS medicines. The benefits of this policy will be more pronounced over time, as competition, economies of scale and learning by doing lead to more efficient production by generic producers.

Looking more closely at Thailand, one can see why this is so important. The United States has a much higher national income than Thailand, but a much lower rate of HIV infection. When compared to Thailand, the US has thirty-five times the income per HIV patient.<sup>10</sup>

	United States	Thailand
Population (2005)	297 million	64 Million
GNI (2005)	13 trillion	177 billion
GNI per capita (2005)	\$ 43,740	\$ 2,750
HIV+ population	1,200,000	580,000
Rate of HIV infection (per 100,000)	404	906
GNI per HIV+ person	\$10.8 million	\$ .3 million

<sup>6</sup> This case was decided under the new US Supreme Court standard for granting injunctions on patents. See eBay Inc. v. MercExchange, L.L.C., 126 S. Ct. 1837, 1839-1841 (U.S. 2006)).

<sup>7</sup> Ibid.

<sup>8</sup> Ibid.

<sup>9</sup> Ibid.

<sup>10</sup> Assuming that the ability to pay is linear in terms of income, a second line AIDS drug that is sold for \$1,000 in Thailand would be equivalent to a product selling for \$70,000 in the United States. With health care budgets rising faster than incomes, the impact is even worse for the lower income country.

Because of US trade policies, including the 1993 agreement negotiated by former USTR Mickey Kantor,<sup>11</sup> Thailand has been slow to provide treatment to its very large population of AIDS patients. Until November 2006, Thailand had not used the compulsory licensing provisions that are permitted in the TRIPS. Thailand started its treatment program by relying extensively on a handful of older AIDS drugs that were off patent in Thailand. These products are not the best that modern science offers. Many Thai AIDS patients suffer from the predictable side effects associated with the older medicines. In any case, over time, AIDS patients everywhere develop resistance, and cannot be treated without access to new medicines.

Thailand will need sustainable access to second line AIDS drugs at affordable prices. If Thailand does not issue compulsory licenses on the patents for these medicines, it will have to limit access to treatment. This will mean much suffering and death, an outcome that is avoidable.

The United States should not pressure Thailand on the issue of issuing compulsory licenses on patents for AIDS drugs. It should accept the fact that Thailand, like all WTO members, has an obligation to take measures to “promote access to medicines for all.”<sup>12</sup>

The United States and other high-income countries are increasingly realizing that they too have to consider using compulsory licenses on patents for medical inventions. For example, Canada and several European countries have threatened to use compulsory licenses on the Myriad patents for tests used to identify the risks of breast cancer -- tests that are not widely available in the United States, because of the high price.<sup>13</sup> It is increasingly difficult for high-income countries to afford the prices for new treatments for cancer or other severe illnesses. With our own aging population, we cannot have a sustainable program of access to the latest medical discoveries, without having the ability to at least threaten to override the exclusive rights of a patent.

The tough USTR positions on patents, pharmaceutical test data and drug prices in trade negotiations are an attempt to deal with the global problem of funding medical R&D. They focus entirely on measures that raise drug prices. In our opinion, this is a mistake. We believe the United States would be better off embracing a new approach, one that focuses on sharing the costs of medical R&D -- not just through high drug prices, but through any mechanism that supports relevant R&D efforts. For example, we would benefit if our trading partners would engage with the NIH to share the costs of medical R&D for global health problems, provide sustainable funding for the many new non-profit product development ventures, or if they would fund new mechanisms to stimulate R&D, such as advanced marketing commitments for new vaccines, or “prize funds” that reward medical innovations that improve health outcomes.<sup>14</sup>

<sup>11</sup> <http://www.cptech.org/ip/health/c/agreements/thai-1994-ip.html>.

<sup>12</sup> Paragraph four of the 2001 Doha Declaration on TRIPS and Public Health.

<sup>13</sup> The tests are more widely available in countries that have shipped patient tests to offshore testing labs where patents are not in effect.

<sup>14</sup> Aidan Hollis. An Optional Reward System for Neglected Disease Drugs, 2005; Joseph Stiglitz, Give Prizes not Patents. *New Scientist*, September 16, 2006; Thomas Pogge on Online Opinion. "A New

Last week the World Health Organization (WHO) convened the first meeting of its new Intergovernmental Working Group on Intellectual Property Rights, Innovation and Public Health. At this first meeting, thirty-three countries, including Thailand, supported work on a new treaty or agreement to provide sustainable sources of R&D for global health priority projects. It is in the interest of the United States that other countries, rich and poor, do more to pay the costs of such research. For many of our trading partners, this is a more appropriate and acceptable framework than one that only seeks to raise drug prices.

As the new head of USTR, you have the opportunity to reframe our trade policy so that it provide a rational, effective and ethical solution to the global free rider problem. We need to ensure that everyone contributes fairly to the costs of medical R&D, but we also need to ensure people have access to new inventions.

I would like to meet with you and your staff to discuss these matters.

Sincerely,

James Love  
Director  
Consumer Project on Technology

Cc:

Karan K. Bhatia, Ambassador, Deputy U.S. Trade Representative

Victoria A. Espinel, Assistant U.S. Trade Representative for Intellectual Property Rights

Barbara Weisel, Assistant U. S. Trade Representative for Southeast Asia-Pacific and Pharmaceutical Policy

Senators Edward Kennedy, Hilary Clinton, Barack Obama, Sherrod Brown, Bernie Sanders, Chuck Schumer, Diane Feinstein, Barbara Boxer, Trent Lott, Chuck Grassley, Byron Dorgan, Richard Durbin, Ron Wyden, Patrick Leahy

Speaker Nancy Pelosi, Representatives Charles Rangel, Henry Waxman, John Dingell, Tom Allen, Janice Schakowsky, Rahm Emanuel, Dan Burton, Rosa DeLauro, Jo Ann Emerson, Dennis Kucinich, Barbara Lee, Sander Levin, Jim McDermott, Maxine Waters,

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Approach to Pharmaceutical Innovations," June 21, 2005; James Love. "Measures to Enhance Access to Medical Technologies, and New Methods of Stimulating Medical R&D." Paper for the WIPO Open Forum on the draft Substantive Patent Law Treaty (SPLT), March 2006.



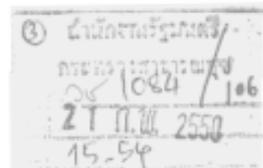
Peter Stark, Charles Gonzalez, John Lewis, Xavier Becerra, John Larson, Linda Sanchez,  
Lloyd Dogget, Howard Berman, Lois Capps, Joe Crowley, Mark Udall, Betty McCollum,  
Raul Grijalva, Hilda Solis

Dr. Margaret Chan, Director-General Elect, World Health Organization

Dr. Howard Zucker, Assistant Director-General, World Health Organization

Dr Suwit Wibulpolprasert, Senior Advisor on Health Economics, Ministry of Public  
Health, Thailand

Cecilia Oh, UNDP



February 16, 2007

His Excellency Dr. Mongkol Na Songkhla
Minister of Public Health
Royal Government of Thailand
Triwanond Road
Nonthaburi 11000
Thailand

Dear Excellency:

I am writing to express the support of the William J. Clinton Foundation for the measured use of compulsory licenses by the Royal Government of Thailand to ensure more affordable access to high quality antiretroviral drugs, including the combination lopinavir/ritonavir used in second-line treatment

As you know, the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) was negotiated during the Clinton Administration, and its provisions were deliberately crafted to enable members of the World Trade Organization (WTO) to take appropriate steps to protect public health. This intention was reaffirmed in the Doha Declaration on the TRIPS Agreement and Public Health in 2001, which clarified that TRIPS "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." In cases of national emergency, such as the threat posed by HIV/AIDS, TRIPS explicitly authorizes members to issue compulsory licenses in the absence of prior negotiations with patent holders. These rights extend to middle income countries, such as Thailand, which represent half of all HIV-positive people on treatment in the developing world.

The Clinton Foundation recognizes the importance of adequate incentives for the research and development of new pharmaceuticals, as well as the central role of patents in creating such incentives. However, the appropriate and targeted use of compulsory licenses by developing countries does not pose a threat to these incentives. Indeed, in the worldwide market for antiretroviral drugs, patent holders derive roughly 90 percent of sales from high-income nations, largely in America and Europe. Moreover, many patent holders recognize the role of licenses and have pursued voluntary schemes to allow for the export of high quality generics to nearly one hundred developing countries, including Thailand.

Compulsory forms of licenses represent an additional tool for ensuring affordable access to medicines, which may be particularly appropriate in cases where the patent holder has not taken steps to offer affordable pricing or to issue voluntary licenses.

As a lower middle income country with 100,000 people on antiretroviral drugs, Thailand faces significant budgetary pressure to sustain its laudable national HIV/AIDS treatment program. Lopinavir/ritonavir is currently available to Thailand for \$2,000 per patient per year, four times the price available to African nations and an order of magnitude higher than the price of the three-drug combinations used as first-line treatment. With thousands of people in need, Thailand is justified, in this case, for seeking to enable access to high quality, lower-cost generic sources of this medicine.

The Clinton Foundation offers it support to the Royal Government of Thailand as it continues to ensure access to affordable and high quality antiretroviral drugs to fight HIV/AIDS.

Sincerely,

[Handwritten signature of Ira C. Magaziner]

Ira C. Magaziner
Chairman
Clinton Foundation HIV/AIDS Initiative