The Development of Drug Patents in Thailand and the Effects of Free Trade Agreements on Drug Patent Issues*

Deunden Nikomborirak**

1. INTRODUCTION

The protection of intellectual property rights (IPR) is often the most controversial issue in any free trade agreement, in particular when it relates to drug patents. Thailand has been engaged in trade negotiations with developed economies, namely the European Union and the United States, which demand that Thailand strengthen its protection regime for IPR.

This report examines the possible implications of an increase in the level of protection for drug patents as proposed in various free trade agreements (FTAs). It is aimed at assisting relevant organizations in establishing an appropriate position and formulating strategies in the negotiating process. This report will also assess the overall efficiency of the Thai pharmaceutical industry and propose policy recommendations that could help to promote better accessibility to pharmaceutical drugs.

This article is divided into 10 sections, including this introduction. The second section reviews the domestic and international rules and regulations governing the regime of drug patents. The third section summarizes the substantive provisions governing patent protection in the draft Thailand-United States Free Trade Agreement (TUSFTA) and the Thailand-European Union Free Trade Agreement (TEUFTA). The fourth section explores in depth the three most important issues concerning the protection of drug patents in these agreements, namely the protection of clinical test data, the extension of the patent protection period, and the establishment of a linkage between the patent status of a drug and its registration. The fifth section identifies the potential costs and benefits associated with a stronger regime for drug patents. The sixth section examines in specifics the implementation of compulsory licensing, to which Thailand resorted in an attempt to curb the spiraling costs of state health insurance schemes. Section seven then weighs the potential costs and benefits associated with compulsory licensing. Section eight examines the structure of the Thai pharmaceutical industry in order to

identify whether there is sufficient competition in the market to ensure reasonable prices for drugs. The ninth section prescribes a regulatory regime for drug prices that would be required to protect consumers against excessive pricing. Finally, the tenth section assesses the overall condition of the current system of drug patents in Thailand and proposes a set of policy recommendations that could help to promote better access to pharmaceutical drugs.

2. DOMESTIC AND INTERNATIONAL RULES AND REGULATIONS REGARDING PATENTS AND DRUG PATENTS

A patent is a legal document issued to protect the inventor's rights over his/her innovation. Only the patent holder can reproduce, utilize, sell, or import the patented product during the period of protection. Patents are important from the economic perspective because they encourage innovation, investment, and technology transfer through the disclosure requirements in patent registration. On the other hand, granting an exclusive right to exploit an innovation can delay the adoption and dissemination of new technologies that would otherwise have benefited the public. Finding the optimal balance between providing sufficient incentives for the private

* *This report was submitted to the Department of Intellectual Property, Ministry of Commerce in March 2009.*

** *Dr. Deunden is Research Director for Economic Governance, Sectoral Economics Program, TDRI.*

sector to innovate and protecting the interest of the public is an extremely delicate and complex task, particularly when it comes to a sensitive issue such as pharmaceutical drugs.

Developing and developed countries often have very different opinions on drug patent issues. Developed countries often advocate a strong regime for patent protection because many of their businesses are patent "owners." Developing countries, on the other hand, often resist demands for a stronger patent regime simply because they have neither the financial resources nor the required technical capacity to innovate and so are mainly patent "users" rather than patent "owners." Also, with lower per capita income, developing countries can ill afford to buy expensive patented products.

A number of years ago, developed countries were successful in pushing a multilateral agreement that establishes the minimum level of protection for IPR for all member countries of the World Trade Organization (WTO). That agreement is known as the Trade-related Aspects of Intellectual Property Rights (TRIPS); it was adopted in 1994 at the end of the negotiations on the Uruguay Round of the General Agreement on Trade and Tariffs (GATT). Because ratification of TRIPS is compulsory for all WTO members, any country seeking to obtain easy access to the numerous international markets opened by WTO must enact the strict intellectual property laws mandated by TRIPS. For this reason, TRIPS is the most important multilateral instrument for the globalization of intellectual property laws.

However, the TRIPS agreement faced harsh criticism both from developing country members and many academics. It was seen as an agreement that clearly works against the economic and public interests of developing economies. As a result, during the Doha Development Round of negotiations, the Doha Declaration on the TRIPS Agreement and Public Health was adopted in November 2001. It reaffirmed the flexibility clauses in TRIPS that are intended to provide member states with the policy space required for designing their own patent regimes that suit local social and economic needs.

In a nutshell, TRIPS stipulates that only inventions that are (a) new, (b) inventive steps, and (c) capable of industrial application will be protected. The agreement also requires that the granting of the patents should not be made without discrimination as to the place of invention, the field of technology, and whether products are imported or locally produced. The agreement, however, does not furnish definitions of the words "new" or "inventive steps." It is up to each member state to do so.

Concerning drug patents, TRIPS provides flexibility for member states in implementing public health measures. The "Bolar provision" allows manufacturers of generic drugs to import or produce original drugs for the purpose of conducting a "bio-equivalence test" in preparation for registering a generic drug. However, the drugs cannot be marketed before the expiration of the patent protection of the original drugs. The agreement also allows a member state to import patented drugs from a third country (parallel import) or grant a license to produce the patented drugs against the will of the patent owners in cases of national emergency or for non-commercial or public use. These measures are intended to ensure that access to essential drugs will not be blocked by patent protection.

Few developing countries made use of these flexibility clauses, however. This is partly due to their lack of technical capacity to design a regime that could effectively exploit the flexibility clauses without violating the strict protection rules. Also, small developing countries often depend on large developed countries for trade, investment and other bilateral assistance; thus, they avoid getting into conflict with multinational drug companies from such countries for fear that they would initiate economic retaliation. For example, the Doha Declaration states that the type of public health emergency that would warrant compulsory licensing includes the spread of HIV and concomitantly AIDS, malaria, tuberculosis, and other contagious diseases. While that list is by no means comprehensive, up until the time when Thailand decided to issue compulsory licensing orders on a variety of cancer and heart drugs in late 2006, no other developing country had ever tested the scope of the flexibility provision.

As a member of WTO, Thailand has had to comply with TRIPS. In 1992, the Thai patent law was amended to conform to the TRIPS agreement. The scope of its patent protection was expanded to include pharmaceutical products, and the protection period was extended from 15 to 20 years. On the contrary, the time period allowed for objections to a patent application was shortened from 180 days to 90 days in order to accelerate the patent-issuing process.

The Thai patent law in general conforms to the TRIPS agreement, but like laws in most developing countries, it does not facilitate effective exploitation of the flexibility clauses. For example, the current regulation does not support parallel imports because the importer needs to show evidence concerning the safety and efficacy of the drugs to be imported before securing approval for marketing from the competent authority. Such evidence, however, is usually exclusive to the drug inventors or protected under the Trade Secret Protection Law. In general, such data cannot be accessed without the permission of the owner. As a result, parallel import was practically impossible under the current law. It is worth noting that a parallel importer in the European Union is not required to present such evidence before marketing.

Another flexibility afforded by TRIPS is that the state may impose remedial measures in case a patent holder is found to have abused its IPR by monopolizing the market. For example, the competition authority may require that the particular technology be licensed if the price of the product concerned is found to be excessive.

Thailand had had a full-fledged competition law since 1999, but has not developed any rules governing the abuse of IPR. It is therefore of utmost urgency that such rules be passed in order to ensure fair competition in markets in which competition is restricted by patent protection.

3. DRUG PATENT ISSUES IN THE THAILAND-USFTA AND THE THAILAND-EUFTA NEGOTIATIONS

After a deadlock in the multilateral free trade negotiations in WTO, many countries have resorted to bilateral trade agreements in order to secure better access to markets overseas. Bilateral talks are especially preferred among developed economies such as the European Union and the United States as a way to demand that developing countries increase their IPR protection level beyond that established in TRIPS. Since developing countries normally have less bargaining power, experience, and preparation to negotiate with their more-developed counterparts, they usually accept strict IPR commitments in exchange for export markets and various types of trade and investment cooperation from the European Union and the United States.

1. The Thailand-United States Free Trade Agreement

Owing to the prominence of the pharmaceutical industry in the United States, patent protection on drugs is one of the most important negotiating issues for that country. In the past, the United States has demanded that trade partners:

(a) Extend their patent protection period to compensate for any delay in patent registration or marketing approval;

(b) Protect clinical test data submitted to the regulatory agency to prove the safety and efficacy of a new drug (data exclusivity);

(c) Require their pharmaceutical safety, quality and efficacy regulators to "link" their normal evaluation with an assessment of whether or not an impending generic product may breach an existing patent (drug patent linkage);

(d) Limit the use of parallel imports.

These demands are designed to limit competition to original drugs by delaying the entry of locally produced generic drugs and by restricting imported alternatives. More recently, the United States has been less aggressive with regard to its IPR demands due to strong opposition from its trading partners, and bad publicity, as well as to the change in policy direction in the country itself.

The United States has not taken a clear stance on the drug patent issue with Thailand after the trade negotiations between both countries were suspended in 2007 following a military coup in Thailand. However, the Special 301 Report of the United States, which examines in detail the adequacy and effectiveness of IPR in foreign countries, usually addresses concerns about any delay in the patent issuance process, the insufficient protection of clinical data, and the excessive or inappropriate use of compulsory licensing.

2. The Thailand-European Union Free Trade Agreement

The trade agreements that the European Union signs with a developing country, such as that with the Caribbean, or CARIFORUM, did not cover drug patent protection, although they do require signatory countries to accede to various intellectual property conventions. However, more recently, the European Union has modified its negotiating approach regarding the issue of patents. The draft proposal for the European Union-ASEAN Free Trade Agreement negotiation demands an extension of the patent protection period and the protection of the clinical test data in much the same manner as that found in the draft FTAs with the United States.

4. THE KEY ISSUES TO BE NEGOTIATED: DATA EXCLUSIVITY, PATENT LINKAGE AND EXTENSION OF THE PERIOD FOR PATENT PROTECTION

For a generic drug to be registered, proof is required of its efficacy and safety, which must be obtained through very costly and extensive clinical testing. Hence, the requirement for proof of efficacy and safety poses a major deterrent to entry for generic drug makers. However, if a generic drug producer can access the clinical test data submitted by the original drug patent holder, then it would need to prove only the "bioequivalence" of the drug to the original version. In other words, the generic drug producer needs only to prove that the generic drug possesses the same amount of active ingredients in the same dosage form, and involves the same route of administration as the original version of the drug.

The clinical test data submitted by the owner of a drug patent can be protected by either the general law governing trade secrets or by a specific regulation that provides exclusivity to the owner of the data. Both methods have different implications for generic drug registration. Under the trade secret protection law, the government agency responsible for drug registration may use the clinical test data for the original drug as evidence to support registration of a generic drug without breaching the law. On the contrary, under the data exclusivity provision, the drug registration authority

cannot access the particular data until the period for patent protection expires. The data exclusivity period of an original drug differs across countries and across different types of drugs depending on the degree of innovation, but normally it ranges from three to five years. Therefore, although this method cannot prevent the entry of generic drugs into the market, it can delay their entry.

The idea about linking drug registration with its patent status originated in the United States. The two procedures are formally independent of each other. Drug registration is concerned only with the safety and efficacy of the new drug, whereas the drug patent process is concerned with whether the nature of the invention of the new drug warrants protection. The linkage between the two procedures was made in order to achieve better balance between drug innovation and competition from generic drugs. Briefly, in applying for registration of a new original drug, the innovator has to submit to the drug registration authority a list of all patents related to the particular drug, such as those pertaining to the active ingredients, the formulation, dosage form, and the use of the medicinal product. The submitted patent data enable generic drug producers to check the status of all patents related to the drug that they plan to register. Therefore, they can better prepare their production plan according to the expiration date of the patents. However, under such a scheme, drug registration would be conditional on the patent status of the particular new drug, that is, a drug that violates any patent protection provision would not be registered even if its efficacy and safety could be proven. Also, a patent holder may challenge as patent infringement a new generic drug under application for registration, which could seriously delay and raise the cost of introducing the cheaper generic alternative drug into the market.

The linkage scheme pioneered by the United States was later adopted in many economies, including Australia, Canada, the European Union, and Singapore, most of which were part of the free trade agreement that each economy signed with the United States. The present study finds that the Australian linkage scheme provides good guidance for Thailand on how to respond to the United States proposal regarding the linkage between patent status and drug registration approval.

Australia has designed a unique linkage system, containing two distinctive features, that serves to minimize a potential delay in the entry of generic drugs, as follows:

(a) A patent infringement challenge will not lead to a delay in new generic drug registration without a court verdict, which is different from the system in Canada and the United States where generic drug registration can be put on automatic hold for 24 and 30 months respectively pending investigation into alleged patent infringement;

(b) A mechanism to investigate and punish those that intentionally provide false information in order to delay registration of a new drug. For example, when a patent owner presents false patent information to prevent registration of a new drug, the injured party can petition the court to forfeit property of the patent owner valued up to A$10 million. In Canada and the United States, original drugs producers are able to enter non-relevant patents into the patent list submitted to the drug registration authority in order to prevent or delay as much as possible with impunity generic drug registration on the ground of a patent breach (also known as “linkage evergreening”).

If Thailand were to adopt the patent linkage regime, then a similar design would be desirable.

5. ASSESSMENT OF THE IMPACT OF A STRONGER DRUG PATENT PROTECTION REGIME

In general, Thailand is unlikely to benefit from the stronger drug patent protection regime proposed in the draft FTAs with the European Union and the United States. Patent term extension, data exclusivity and restrictions on parallel import and compulsory licensing would likely translate into a prolonged absence of cheaper alternative drugs that would otherwise be available to consumers, because the entry of generic drugs would be delayed.

While the cost of a stronger patent protection regime is certain, its benefit is highly doubtful. Thailand is not a hub for pharmaceutical research and development (R&D), and will likely remain so even with stronger drug patent protection, because a multinational company’s decision regarding where to conduct its R&D depends on a multitude of factors. The level of patent protection is only one of those factors. Moreover, even if patent protection were to be the deciding factor, it is the “relative” level of protection rather than the “absolute” level of protection that matters. In other words, the fact that Thailand raises its patent protection level does not mean therefore that multinational corporations will suddenly relocate their R&D from elsewhere to Thailand as other countries may already be offering even higher levels of protection.

On that note, it is advisable that Thailand should reject the patenting of plants and animals, methods of treatment, and surgical operations, as such an approach would restrict access to such services. Moreover, granting patents for something which is neither inventive nor capable of industrial application is inconsistent with the TRIPS definition of inventions that warrant protection, as they would have little economic rationale. Likewise,

proposed restrictions on the use of parallel imports and compulsory licensing under the TRIPS agreement should be rejected.

In practice, outright rejection of the IPR demands of the European Union and the United States may not be so simple. It is therefore necessary for Thailand to be prepared to accept some of the issues that will be placed on the negotiating table.

On the issue of data exclusivity, there are several ways in which the negative impact of limited access to valuable clinical data can be minimized. First, it is possible to confine the scope of the exclusivity privilege only to information or data that are either undisclosed or related to new active ingredients in a particular drug. Exclusivity should not be granted to drugs patented on the basis of only a slight change in the formula, for example. Second, in exchange for data exclusivity, Thailand should insist on a regime which facilitates the pre-marketing registration of generic drugs in order to ensure their speedy entrance into the market after patent protection of an original drug has expired. Third, data exclusivity should not in any way obstruct Thailand's ability to exploit TRIPS flexibility clauses, such as parallel import and compulsory licensing.

6. REASON, PROCESS, AND PROCEDURE IN COMPULSORY LICENSING

The main reason why most countries, including Thailand, resort to compulsory licensing is because the prices of original drugs are perceived to be prohibitively high. The TRIPS agreement allows compulsory licensing to be administered by the domestic law in each member state. The agreement does not define the scope of drugs that can be subject to a compulsory licensing. It merely states that the scheme can be activated in such cases as a national emergency or one of extreme urgency, or in cases of public non-commercial use. However, the text mentions explicitly the drugs used for treating AIDS, tuberculosis, malaria, and epidemic diseases.

The Thai Patent Act stipulates that state agencies may impose compulsory licensing for the sake of the public interest, national security, environmental protection or to alleviate dire shortages of food, drugs or other public facilities. As the language used is rather vague, a broad interpretation of the provision can justify a compulsory licensing order for a variety of drugs.

In the past, compulsory licensing had been targeted at AIDS drugs only. When Thailand introduced a series of landmark compulsory licensing cases for a total of seven heart and cancer drugs beginning in late 2006, there were strong protests from both drug manufacturers and the countries where they are located. The reaction was by no means unexpected, as the Thai case will likely set a precedent with the effect that access to other drugs besides those for AIDS may also be treated as an issue that concerns public health, national emergency, or extreme urgency. The main points of contention of the drug manufacturers were that proper negotiations did not take place as mandated by TRIPS, the justification for the drugs being considered for use in a national emergency was not clear, and the rate of compensation offered was too low.

The present study finds that the rationale for the selection criteria of the three AIDS drugs that were subject to the first round of compulsory licensing was rather broad and vague. However, because the AIDS pandemic is universally accepted as an issue of serious public health concern, no controversy followed. In the case of the four cancer drugs, much more information was provided to support the decision on compulsory licensing. This included the turnover figures, the per unit retail prices in comparison with the generic versions, the name of the generic manufacturer in India, and the death rates due to cancer. It remains unclear, however, why these particular drugs were targeted. For example, there was no clear explanation on how "accessibility to the drugs was hindered" or why the "financial burden imposed in the national universal health plan was unsustainable." More interestingly, it could not even be confirmed that the patent protection of these drugs had not expired. By presuming protection, these compulsory licensing orders thus preclude the possibility of manufacturing or importing generic alternatives to such drugs, which might support greater accessibility to these drugs.

In the future, it is recommended that:

1. Regulations governing the selection of drugs for compulsory licensing should provide clear criteria for choosing a drug, and the decision should be supported by crucial information or data such as the total number of patients that require the drug, the number of patients that experienced difficulty in accessing the drug, the alternative drugs available, and information on the patent status of the particular drug.

2. The patent search system should be renovated in order to enable obtaining accurate information on the patent status of drugs targeted for compulsory licensing.

3. Competent authorities should develop clear plans about the production or importation of the generic version of the drug targeted for compulsory licensing in order to ensure that adequate supplies of such drugs are available immediately after the issuance of the compulsory licensing order. This is to avoid a repeat of the case when compulsory licensing for the cancer drug erlotinib was announced, i.e., on January 4, 2008; however, the responsible authority was still unable to procure the drug from sources overseas until the time that the present report was written in March 2009.

4. The negotiating process that takes place before the decision on compulsory licensing is made should be transparent and predictable with clear procedures and a timeframe for negotiation. Most importantly, the negotiating position should be flexible, allowing room for compromise. The present study finds that the reason why it was possible to come to an agreed price with the state authority for one of the four cancer drugs, imatinib, thereby avoiding compulsory licensing, was that the state did not insist that the price of the original drug be dropped to a level not exceeding 0.5 percent above its generic version. Such flexibility might have avoided the need to resort to compulsory licensing for the three other cancer drugs.

5. In negotiating an appropriate licensing fee, the Thai government should try to establish benchmarks against those offered in other countries. The present study finds that the compensation rate for the first three AIDS drugs that were subjected to compulsory licensing was also 0.5 percent. This rate is affirmed to be low relative to that in other countries, such as Brazil (1.5%) and Malaysia (4%). Although Thailand's rate is comparable to that of Indonesia (0.5%), Thailand's per capita income is significantly higher than that of Indonesia, indicating a higher ability to pay. The government may also wish to resort to the guidelines of the World Health Organization (WHO) and the United Nations Development Programme for determining the rate of payment for patent owners.

6. The government should examine other means for promoting the accessibility of drugs, such as promoting the local generic drug industry, supporting new research and development projects, and improving its drug distribution policy.

7. ASSESSMENT OF THE COSTS AND BENEFITS OF COMPULSORY LICENSING

A study conducted by the Health Intervention and Technology Assessment Project found that government-mandated compulsory licensing made drugs available to an additional 84,000 patients, half of whom were users of the widely used heart drug, clopidogrel (trademark name, Plavix). The present study calculated the total cost savings accrued to the Thai government to be approximately 7 billion baht for the period 2007-2011.

Possible negative effects related to the issuance of compulsory licensing include trade retaliation from countries that manufacture the original drugs, or a reduction in foreign investment and in R&D as the country's commitment to IPR protection may be questioned. Such negative effects have not been confirmed in countries that have issued compulsory licensing, such as Brazil, Canada, and Malaysia. In Malaysia, patent owners filed a lawsuit against the government for illegally issuing compulsory licensing and threatened to sell off their investments, but nothing major materialized.

Trade retaliation from the United States is probably the most feared outcome among Thais. Indeed, shortly after the issuance of the compulsory licensing in 2006, Thailand was downgraded from the "Watch List" to the "Priority Watch List" in the Special 301 Report, which evaluates the effort of foreign countries in enforcing IPR law. However, the present study finds no linkage between the downgrading and the United States Trade Representative's decision on whether or not to renew the preferential tariffs the United States grants to certain products imported from Thailand under the Generalized System of Preferences (GSP). This is because there are clear criteria for terminating GSP: (a) if the privilege has been renewed more than five times; (b) the volume of the import of the particular product under the scheme exceeds 50 percent of the total value imported, or (c) the value of the imported product under the scheme exceeds a predetermined threshold.

Finally, the present study did not find any relationship between the implementation of compulsory licensing and the size of foreign investment flow or R&D activities in the pharmaceutical industry. Interestingly, from surveys conducted by the National Science and Technology Development Agency during the period 1999-2006, out of the 29 pharmaceutical manufacturing companies surveyed, only 12 conducted R&D activities, all of which companies are wholly owned by Thai nationals. Obviously, there has always been very little foreign R&D in the pharmaceutical industry in Thailand, regardless of the compulsory licensing situation.

To conclude, Thailand did not seem to suffer any backlash from its compulsory licensing decision. However, this by no means suggests that the country should embark on a "compulsory licensing spree" to

solve its problems related to expenditures on drugs. As mentioned previously, to avoid controversy surrounding a decision to issue compulsory licensing, the procedures involved should be made as clear, open, predictable and fair as possible for all the parties involved.

8. STRUCTURE AND COMPETITION IN THE DRUG MARKET IN THAILAND

The size of the pharmaceutical industry in Thailand has been rising continuously. In 2008, sales totaled roughly 96 billion baht, 70 percent of which was generated by original drugs. The rising share of imported drugs in Thailand's total can be attributed to both the higher relative price of original drugs and the lack of technological capability of local generic manufacturers, which has resulted in greater reliance on patented drugs.

At the aggregate level, the Thai pharmaceutical industry lacks concentration, as the top three manufacturers in 2008 accounted for only 19 percent of the market for medicine. However, when divided into therapeutic classes, high market concentration prevails in many cases. Of the 20 therapeutic classes with the highest turnover value in 2008, a single manufacturer controlled more than 50 percent of the market for three of them, which is the threshold market share used by the Thai competition authority to determine whether a company is "dominant," in which case its trade practices would be subject to certain regulations. For another seven therapeutic classes, three manufacturers jointly controlled more than 75 percent of the market, which is the threshold market share for determining "joint dominance" in the market. Indeed, the dominant players in the market are all foreign pharmaceutical manufacturers that produce original drugs.

While local generic manufacturers cannot hope to compete directly in the market for original drugs, they face even more restrictive conditions in the local generic drug market. According to the regulations of the Prime Minister's Office on government procurement, 1992, all state organizations must procure drugs from the Government Pharmaceutical Organization (GPO), provided that the price of the drugs does not exceed the "reference price" by more than 3 percent. Buying drugs from private generic manufacturers is allowed only when GPO is unable to fulfill the order. In many cases, GPO was not able to supply the drugs, and thus resorted to subcontracting. The revenue share of outsourced drugs nearly doubled from 7.49 percent in 2005 to 14.34 percent in 2008. If GPO is given priority in the state procurement market and at the same time is allowed to subcontract its drug supply, then eventually private manufacturers would all become its subcontractors since they could never compete with GPO in open bids. This situation is certainly grossly unfair.

The presence of GPO in the market has serious negative implications for the development of the Thai generic industry. As private manufacturers cannot predict when GPO will decide to compete in a market, demand uncertainty undermines their efforts to innovate the production of new drugs or higher quality drugs. For example, a generic manufacturer that decides to invest in the development of a recent off-patent drug may later discover that it is not possible to recoup the investment costs simply because GPO happens to produce the same drug, and thus can take all the state contracts.

To add insult to injury, GPO's drugs do not need to be registered before they are marketed. As a result, GPO is able to introduce new generic drugs much faster than its private competitors. The quicker the manufacturer can bring its product to market, the larger are the potential profits since competition is limited.

Expectedly, GPO's monopoly status enables it to generate handsome profits without much effort. Indeed, over 90 percent of the organization's sales in 2008 were those made to state organizations. GPO customers in general do not complain about the quality or safety of the organization's generic products but lament about the design of its labeling, which is very plain, making it difficult to distinguish one drug from another, a situation that could be dangerous for unaware users.

It is recommended that the government should revise the mandate of GPO. As a state enterprise, it should not compete with private businesses in the commercial pharmaceutical market. However, the organization could play a very important role in the development of vaccines and orphan drugs that are too commercially risky for the private sector but may yield significant health benefits for the public. Already, WHO has chosen to undertake a pilot project with GPO to fully develop influenza vaccine.

9. THE GOVERNMENT'S ROLE IN REGULATING DRUG PRICES OR CONTROLLING HEALTH EXPENDITURE

There are three reasons why drug prices may require regulation. First, drugs are a unique product in that, owing to health insurance schemes, many patients do not pay for the drugs they consume. As a result, demand may not be sensitive to price, enabling producers to determine price and doctors to dispense expensive drugs more freely. Indeed, insurers would need to establish the prices that can be reimbursed and to review prescriptions handed out by medical doctors in order to control their own costs.

In Thailand, there are three different health insurance schemes: (a) the state employees' health benefits scheme, (b) the private sector employees' social insurance healthcare scheme provided for private sector employees, and (c) the universal healthcare scheme (also known as the 30-baht scheme) provided for all Thai citizens that do not belong to the first two health insurance schemes. The second and third health insurance schemes are financed on a "capitation" basis, that is, the hospitals or health clinics that are enrolled in

the scheme are allocated a fixed annual fee for providing the service for each patient registered with them. Under that scheme, hospitals are incentivized to cut costs as much as possible in order to make a profit. There is therefore no need for the government to regulate the price of drugs procured by these hospitals.

The state employee's benefit scheme is the only scheme that is financed on a "fee-for-service basis," meaning that enrolled state hospitals and health centers may file claims for actual costs incurred from the delivery of the health service to the beneficiaries. Here, the Comptroller's Department under the Ministry of Finance has set a schedule of reimbursement prices as shown in Table 1. One can easily detect from the formula that such a reimbursement schedule would encourage the hospitals to dispense expensive drugs. For example, a hospital may choose to prescribe a generic drug that costs 1 baht per tablet and produces a 50-satang profit. However, if it instead chooses to prescribe an original drug that costs 100 baht per tablet, the profit will be 21 baht (13 + 90*1.2) per tablet. It is therefore no surprise that pushing expensive drugs has become a major source of income for state hospitals. Although these hospitals claim that they need the extra revenue to compensate for the loss incurred from the delivery of the universal healthcare service, such cross subsidy is not only economically inefficient, but it is also dangerous, because excessive consumption of drugs can lead to many health problems. It is therefore most urgent that the government revise the existing drug reimbursement price schedule in order to reduce the much-inflated expenditure on drugs, which contributes to almost 80 percent of the total budget required to finance the state employees' health benefit scheme.

Table 1 Reimbursement Price of Drugs under the State Employees' Health Benefit Scheme

Price per unit (baht)	Price reimbursed (baht)
0.01-0.20	0.50
0.21-0.50	1.00
0.51-1	1.50
1.01-10	1.50+125% of value exceeding 1 baht
10.01-100	13+120% of value exceeding 10 baht
100.01-1,000	126+115% of value exceeding 100 baht
> 1,000	1,161 + 110% of value exceeding 1,000 baht

Source: Ministry of Finance Regulation on Health Service Fee Schedule for Reimbursement of Healthcare Service Expenditure in State Hospitals.

The second reason why the state may need to step in to regulate drug prices is that, unlike most buyers, bed-ridden patients are not able to shop around for the least expensive drugs and ancillary products; therefore, hospitals may charge with impunity for so-called "hospital drugs," such as morphine, anesthetics or saline solution. The present study finds that the price of the exact same drug is very different when sold in a pharmacy and when sold in a hospital where the market is more or less a captive one. Even more interesting is the fact that the price of the same drug in the same hospital is different when dispensed to out-patients and when administered to in-patients. For example, a tablet of paracetamol costs 1 baht at a pharmacy, 3 baht for out-patients in a hospital and 10-13 baht for in-patients. Although the prices may vary somewhat across hospitals, the structure of the price discrepancy appears to be universal. Such a pricing scheme reveals that the prices of drugs sold in hospitals, particularly to in-patients, are excessive. The less choice the consumer has in choosing a substitute, the higher is the price. Such price discrimination is perfectly consistent with the optimal monopoly pricing theory found in standard economic textbooks. It is therefore imperative that the government step in to ensure that the pricing of drugs in private hospitals is not unfair to consumers.

The third and final reason why the state may need to intervene in the setting of drug prices is because many drugs are protected by patents such that patent owners may set prices excessively in the absence of competition from substitutes. As seen in the previous section, the market for drugs in certain therapy groups is highly concentrated. It is important to note that being protected by a patent does not imply freedom to price the product at whatever price the market can bear.

In most developed countries, there are competition rules against "abuse of IPR." For example, in South Africa, the competition authority found that the drug manufacturer GlaxoSmithKline abused its patent protection rights by pricing its AIDS drugs excessively. As a result, the company had to license its patent to three local drug manufacturers, one of which later became a major drug manufacturer providing drugs to the state market. Similarly, the Italian competition authority ordered Merck to license its technology for the production of the drug finasteride after having established that the company had abused its IPR by pricing that drug excessively.

Thailand has had a competition law since 1999 but has never enforced it. Perhaps if the law were administered properly, Thailand would not need to issue the controversial compulsory licensing for the seven previously mentioned heart and cancer drugs. TRIPS allows WTO members to enact and apply national competition laws to IPR-related anti-competitive practices. With an anti-competition case in its pocket, the government can certainly expect to have the upper hand in negotiating with drug manufacturers about measures to reduce drug prices.

To conclude, regulation of drug prices in Thailand is in dire need of major reform. To control the runaway cost of the state employees' health benefit scheme, the government would need to revise its existing flawed drug price reimbursement scheme which has prompted hospitals to prescribe as much as possible

the most expensive drugs for patients. At the same time, it cannot ignore its role in protecting consumers that pay for drugs out of their own pocket. Since roughly half the country's healthcare expenditure is incurred privately despite the existence of various health insurance schemes, the government would need to intervene in the pricing of drugs in hospitals.

It is recommended that, at the minimum, hospitals should be required to itemize in the receipt they give patients the drugs dispensed to the patients instead of allowing the current practice of lumping the entire expenditure into one line labeled "drugs." Alternatively, hospitals could be barred from selling drugs, as is the case in most developed countries. Instead, doctors may provide prescriptions directly to patients, who would in turn obtain their medication from the pharmacy of their choice. However, given the problems with counterfeit or fake drugs in the marketplace and for the sake of the patients' convenience, the hospitals could be allowed to host a pharmacy or pharmacies that they certify within their compound. However, such stores would have to comply with the price labeling rules in the same way as other pharmacies outside the hospital have to do. In such a way, patients would be informed of the price of the drugs before making a decision whether to purchase the drugs from the pharmacy at the hospital or from elsewhere.

As for the price of drugs administered to in-patients, the state may wish to prohibit price discrimination between in- and out-patients. For drugs that are used for in-patients only, the hospitals should be required, at the minimum, to itemize the quantity and per unit price of the medication administered in the receipt issued to the patients. If excessive pricing continues to prevail, then certain price regulations might be considered.

10. PATENT SYSTEM IN THAILAND

Thai patent protection underwent a major change in 1994 as a result of pressures from the United States and in compliance with the TRIPS agreement. Previous research indicates that the stronger patent protection resulted in a widening gap between the number of patents registered by foreign nationals and those registered by Thais. This is because it is mostly foreign multinational companies which can reap gains from the elevated protection offered by patents owing to the companies' superior financial standing and access to qualified personnel and technology.

Greater patent protection may be particularly worrisome when the Department of Intellectual Property faces human resources constraints in examining patent applications, with the effect that there would likely be patents that do not deserve such generous protection. Five suggestions for improving the patent system in Thailand are furnished below.

1. Adopt a level of intellectual property rights protection that fits well with the country's level of development

Thailand should not extend protection to the patenting of rules and theories in science and mathematics or expand the current scope of "patentable subject matter" to include plants, animals, software, and management methods. Thailand should also do away with criminal penalties for violation of IPR in order to avoid discouraging potential innovations. While reverse engineering should not be permitted, it should not be criminalized. The current wording in the patent law regarding the exemption provided for reverse engineering is vague; thus, it should be amended.

2. Adjust the fee structure for registering and extending patents

The Department of Intellectual Property should increase the fee for patent registration and renewal. The current registration fee is 500 baht, compared with the equivalent of 8,190 baht in the European Union and 11,682 baht in the United States. However, the government may offer to subsidize the registration fee for persons, educational institutions, research institutions, and small business enterprises. A higher fee would deter frivolous applications that burden the system, and generate extra revenue that could be used to upgrade the Department's capacity to handle patent applications and improve its patent search system.

3. Increase the quality of patents

Several measures could be taken to improve the quality of the patents registered. First, the Department of Intellectual Property should set up a commission comprising representatives from relevant state agencies and academics from educational institutions to design a "patent examination guideline" that would clearly describe the patents that should be registered and those that should not. The model patent examination guidelines from WHO, the International Center for Trade and Development and the United Nations Conference on Trade and Development could be adapted for use to fit the Thai patent system.

Second, in order to raise the quality of the patents registered, the Department should not make its key performance indicator the number of patents registered per staff member because that would encourage officials to go through as many applications as quickly as possible, rather than taking their time to examine the quality of each one.

Third, the period of time allowed for protesting the registration of a proposed patent should be increased from 90 to 180 days and the announcement should be

promptly advertised among all the stakeholders involved in order to ensure thorough scrutiny of the application.

4. Increase the number of patent staff and adjust the organizational structure

The Department of Intellectual Property urgently needs to increase the number of patent examination staff. In 2006, there were only 29 patent examiners in the Department handling about 215 patents each year. The number of applications handled per person was 66.2 in the United States and 75.7 in Europe, but 324.4 in Japan. The salary of the patent staff in Thailand is also very low compared with that in the private sector despite the fact that the task is skill-intensive. An organizational restructuring that would make the patent office a semi-autonomous agency would be necessary to enable greater flexibility in the management of human resources and the determination of staff remuneration rate and benefits.

5. Support the academic and private sectors to participate in the patent registration process

The government should allow experts in the academic sector or in non-profit organizations to take part in the examination of a patent application so that more attention would be paid to sectors that are of public concern, such as drugs.