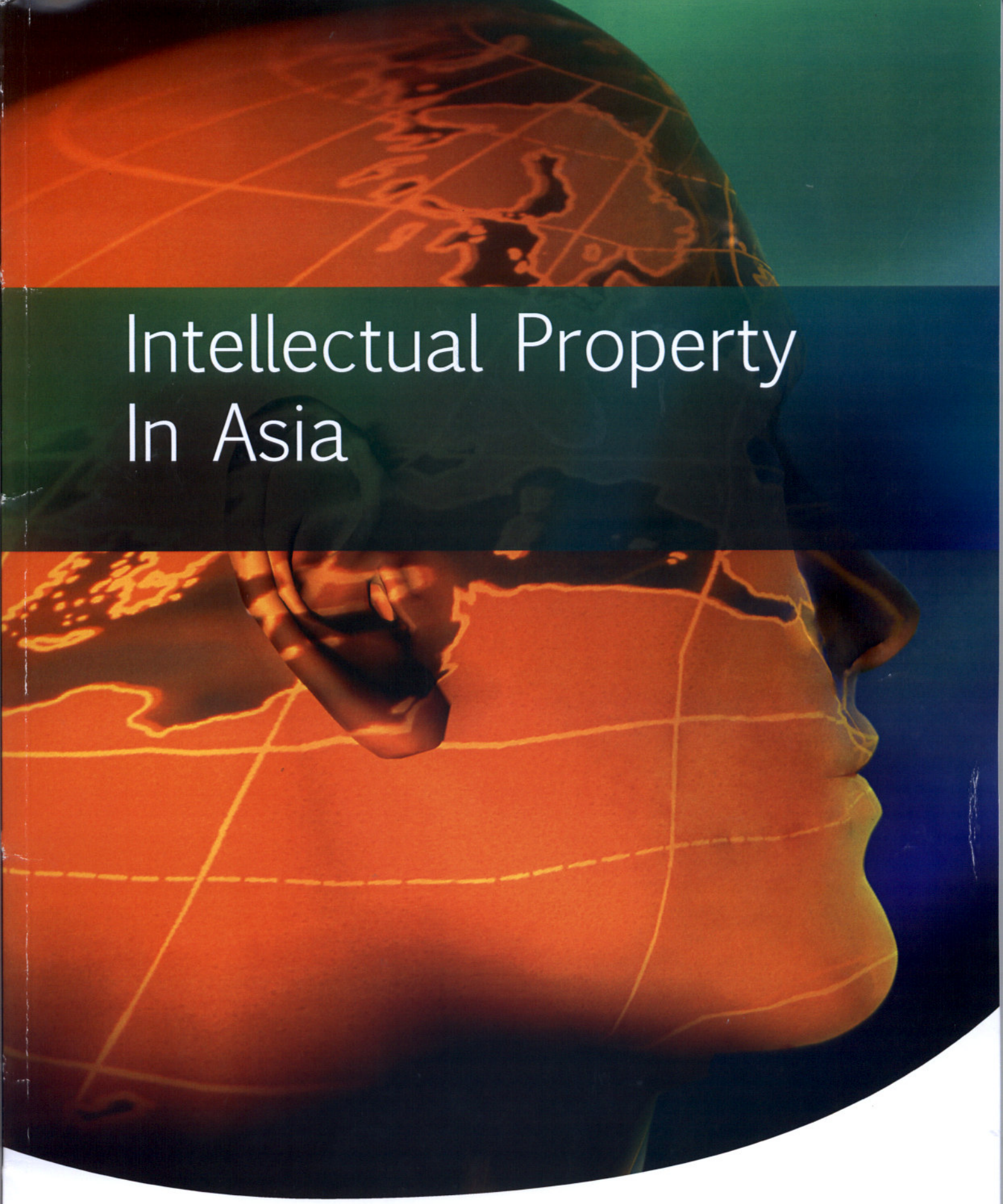

Intellectual Property In Asia

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Pharmaceutical industry in Asia

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The development of the pharmaceutical industry in Asia has been influenced by government policies and the growth in the laws and regulatory bodies that oversee various aspects of drug manufacture and sale. Most Asian governments heavily regulate the pharmaceutical industry, typically through the national food and drug administration and the health ministry. While most countries in Asia today have a body of laws that govern virtually all aspects of production and sale of pharmaceutical products, the implementation of these laws has been rather uneven. Government policy, with respect to intellectual property, plays a crucial role in shaping the pharmaceutical industry and its regulation. Key issues which permeate through most Asian nations are the quality of pharmaceutical products and the clash between original drugs and generics. Thailand, China and Vietnam have been at the centre of attention in recent years as they navigate the various challenges in this area.

I. Thailand

Thailand has quickly become the country to watch in the pharmaceutical field since the Thai Ministry of Public Health stepped in and issued compulsory licenses on various key patented drugs. In addition, the Health Ministry is pushing for a drug law reform and has proposed new drug legislation which contains a series of amendments to the current law. Many of the changes proposed will have direct effects on pharmaceutical companies. One of the most outrageous changes from a drug originator's point of view is the inclusion of "cost-effectiveness" as a requirement for drug registration in addition to drug safety, efficacy and effectiveness. The attempts of the Thai Ministry of Public Health to intervene in the pharmaceutical market have attracted considerable attention from governments, stakeholders and various interest groups and experts around the world. While the pharmaceutical regulatory system in Thailand operates independently of the IP system, interactions between the two systems are crucial to the existence of the pharmaceutical industry and directly affect the development of the health care system in Thailand.

The Thai pharmaceutical regulatory system is based on the Drug Act B.E. 2510 (1967) together with its four amendments, ministerial regulations and ministerial notifications. The fundamental basis of Thai drug regulation is that all activities in relation to the trading of pharmaceutical products must be licensed/approved by the competent authorities.

The Thai FDA is the main agency in charge of drug approval and regulation. Generally, the procedure for seeking marketing approval for drugs will depend on whether the applicant is the drug originator or a generic producer. Drug originators face the most onerous task, as each element of drug safety, efficacy and effectiveness must be demonstrated to the satisfaction of the Drug Control Division of the FDA. Generic producers, on the other hand, receive a more lenient treatment before the FDA. Such practice is partially due to the government's health care policy which seeks to improve access to medicines and make affordable drugs available to everyone. The Ministry of Public Health itself has taken various efforts towards these goals. The most recent and perhaps most controversial attempt to solve the problem of access to medicines was the Health Ministry's decisions to issue compulsory licenses on six key drugs which are still under patent in Thailand.

A. Compulsory licensing

During December 2006 and January 2007 Thailand's Ministry of Public Health, acting under a post-coup military-appointed administration, decided to issue the first set of compulsory licenses on three patented drugs. The Health Minister at the time, Dr Mongkol na Songkla, took a strong view against expensive patented drugs and believed that the issuance of compulsory licenses was the solution to improving access to medicines for Thai patients. The three drugs that were subject to compulsory licenses were Merck's antiretroviral *efavirenz* (*Stocrin*®), Abbott Laboratories' antiretroviral *lopinavir/ritonavir* (*Kaletra*®), and sanofi-aventis' heart disease drug *clopidogrel* (*Plavix*®). The legitimacy of these compulsory licenses was debated extensively both at home and abroad. As a policy matter, it was widely questioned whether the actions of the Health Ministry would benefit Thai patients and help to improve the healthcare system and access to medicines in the long run.

From the legal perspective, the validity of the compulsory licenses issued by the Ministry of Public Health remains questionable. The Thai Patent Act limits issuance of

compulsory licenses to certain restricted circumstances and provides the procedures which must be followed. The various compulsory licenses pursued by the Ministry of Public Health were based on Section 51 of the Patent Act, which permits government ministries and departments to seek compulsory licenses for the following purposes:

1. To carry out any service for the public consumption or defence of the country;
2. For the preservation or acquisition of natural resources and environment;
3. To prevent or alleviate a severe shortage of food or medicine or other consumer goods or foodstuffs; and
4. For the sake of other public interests.

Compelling arguments could be made, that the Ministry of Public Health did not meet these requirements. Even if the purposes for which the Ministry decides to seek a compulsory license falls under one of the foregoing circumstances, a number of preconditions must be satisfied before the compulsory license can actually be obtained.

A careful reading of Section 50 and 51 of the Thai Patent Act is crucial to understanding the process for issuing compulsory licenses. It is also important to keep in mind that since Thailand is a member of the WTO, any interpretation of the Patent Act provisions must be consistent with the obligations under the WTO's Trade-Related Aspects of Intellectual Property Rights (TRIPs), although the TRIPs Agreement itself is not part of Thai law. By and large, the dispute on the legitimacy or validity of the compulsory licenses pursued by the Ministry of Public Health stems from the first paragraph of Section 51 which appears to authorise government ministries and departments to exploit a patented invention by way of compulsory license, but the government department is required to pay a royalty after a period of negotiation with the patent owner. The Ministry of Public Health and supporters of compulsory licenses have interpreted this to confer the authority on the Ministry to unilaterally issue the compulsory licenses without prior consultation with the patent owners or the Department of Intellectual Property. Thus, under this interpretation the patent owners would not have any opportunity to appeal the government's decision to issue the compulsory licenses or negotiate the terms and conditions thereof. This interpretation seems to bend Section 51 beyond credible limits.

However Section 51 states, in the second paragraph, that "the ministry or bureau or department shall *submit its offer* setting forth the amount of royalty 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 exclusive licensee, and the *provisions of Section 50 shall apply mutatis mutandis*." Section 50 sets out the process for negotiations of the parties and the procedures which must be followed before a compulsory license can be issued by the Director-General of the Department of Intellectual Property to the applicant. Section 50 specifically states that "when the royalty, conditions for exploitation, and restrictions have been prescribed by the Director-General, he shall issue a licensing certificate to the applicant." Section 50 also provides for an appeals procedure, which would allow the patent owners an opportunity to subject the decision regarding compulsory licenses to judicial review. Thus, a careful reading of Section 51 and its reference to the procedures for issuance of compulsory licenses under Section 50 would seem to suggest that the Ministry of Public Health has not taken the appropriate steps required by law in seeking to impose compulsory licenses on the patented drugs. This view, however, is not the prevalent view among Thai government authorities at present. Many people continue to argue that the compulsory licenses issued by the Health Ministry are valid and the role of the Department of Intellectual Property is merely as a mediator for the royalty negotiation.

When the Ministry of Public Health issued the first set of compulsory licenses, not only the companies whose drugs were subject to the compulsory licenses but also the research-based pharmaceutical sector as a whole, through Pharmaceutical Research & Manufacturers Association (PReMA), has made efforts to work with the Ministry of Public Health to improve Thai patients' access to medicines and resolve compulsory licensing issues through collaboration and dialogue. Towards the end of 2007, the Ministry of Public Health agreed to set up the "Joint Committee between Representatives of the Ministry of Public Health and PReMA to Develop Sustainable Health Service System."

Despite the appointment of the Joint Committee, the Ministry has insisted upon the implementation of its claim of right under the compulsory licenses to import generic products into Thailand through the state-owned Government Pharmaceutical Organisation (GPO). Earlier this year Dr Mongkol na Songkla, the Public Health Minister between September 2006 and February 2008, signed a further announcement of compulsory licenses on three cancer drugs before the end of his term as the Health Minister. The new set of compulsory licenses include the breast cancer drug *letrozole* produced by Novartis, the breast and lung cancer drug *docetaxel* made by sanofi-aventis, and the lung cancer drug *erlotinib* produced by Roche. In view of the newly elected government, it is yet to be seen whether the compulsory license policy will be continued or whether the new administration will adopt a less drastic measure to solve the problem of access to medicines.

B. Cost-effectiveness as an element for drug registration

In addition to pursuing compulsory licenses on key patented drugs, for several years the Ministry of Public Health has been pushing for amendments to be made to the current Drug Act. One of the most controversial amendments, which seems to raise the most concern among drug originators, is the inclusion of cost-effectiveness as a requirement for drug registration.

Under the current law, in order to obtain marketing approval for a new drug, the drug originator must submit an application to the FDA to register the product for sales in Thailand. A full marketing approval application must be compiled to accompany the samples of the new drug. This stage corresponds with the NDA procedure before the US FDA and requires the applicant to submit a complete dossier demonstrating the efficacy, safety and quality of the new drug.

It has been suggested that the new Drug Act should require the inclusion of cost-effectiveness data in the application for marketing approval of pharmaceutical products. Given the enormous cost of health care nowadays, the assessment of comparative cost becomes an important consideration for the government's reimbursement and subsidy decisions. The proposed Drug Bill includes an additional requirement that the marketing approval applicant must also submit drug price structure and patent information to the Thai FDA. The FDA is

granted the authority to refuse registration if the drug has "unreasonable" or "unworthy" price structure.

Even though there is a global trend towards the use of cost-effectiveness evaluation, i.e. whether a product is better value for the money than alternative drugs; cost-effectiveness analysis usually comes into play in the drug reimbursement/subsidy process rather than at the initial marketing approval stage. In fact, most countries do not require cost-effectiveness data for obtaining marketing approval. The proposed inclusion of cost-effectiveness as an element for drug registration has raised considerable concerns from the industry, especially among research-based pharmaceutical companies. Although cost-effectiveness evaluation has gained much popularity in recent years, it has been criticised on many grounds, including accuracy and transparency. For instance, direct evidence of marginal costs of production is often denied to evaluators on confidentiality grounds. There is also a question of whether a country has sufficient resources to train enough pharmaco-economists to perform the evaluation. This is particularly an issue for the majority of developing countries.

In sum, many people remain sceptical about the criteria for evaluating whether a drug is "cost-effective." Others question the capabilities and resources required for the Thai FDA to conduct the cost-effectiveness analysis, not to mention the delays it will cause. Furthermore, there is a general concern that if the drug registration process is made more difficult than it should be, this will further reduce Thai people's access to medicines.

C. Generics approval and data protection

Generic drugs have accounted for a significant proportion of overall drug sales in the Thai market. This trend is likely to continue in light of the government's health care policy to make affordable drugs available to all. In fact, this policy seemed to have translated itself into an almost pro-generic policy before the Thai FDA. As is the case in many countries, an abbreviated form of approval is available in Thailand for generic drugs. The generic applicant only needs to submit bioequivalence data as opposed to conducting rigorous trials and tests to prove safety and efficacy of the chemical entity or biological molecule. In other words, the Thai FDA does not require the generic applicant to reproduce clinical trials or pre-clinical tests.

The extent to which a generic applicant can rely on clinical test data on file with the FDA has been subject to criticism and debate for many years. In 2002 Thailand enacted the Trade Secrets Act B.E. 2545 in compliance with TRIPs obligations. The Act creates a legal framework for the protection of trade secrets and other confidential information, rendering the unauthorised use and disclosure of such information an actionable offence, punishable by civil and criminal remedies. With respect to data or information submitted to the FDA by a drug originator in order to obtain approval to market a new drug, the Act recognises that such data or information, either wholly or in part, may amount to a trade secret in the form of testing result, or other information regarding its preparation, discovery or creation. In this case, the owner has the right to request that the FDA maintain the confidentiality of the data submitted. Upon such request, the FDA would have "the duties to maintain the trade secrets from being disclosed, deprived of or *used in unfair trading activities*, in accordance with the regulations prescribed by the Minister." The ministerial regulation on data protection was not issued until recently. In the absence of such regulation, the extent of data protection afforded to drug originators remained unclear.

Since the Thai Patent Act clearly confers on generic drug manufacturers the ability to engage in various preparatory activities, with a view to seeking regulatory approval before a patent for a particular protected drug has expired (i.e. Bolar provision); generic manufacturers could submit applications for regulatory approval before the expiration of the patent. As a result, the extent to which the drug originator's data, submitted to the FDA, is protected, or in other words, the extent to which a generic drug manufacturer may rely on previously filed data which underpins the efficacy and safety of the drug to support the application for marketing approval for a generic becomes a critical issue.

Although the TRIPs Agreement mandates that member countries must provide protection against unfair commercial use of marketing approval data, countries do reserve considerable discretion to define "unfair" in the context of their national laws. Since the Trade Secrets Act does not specifically address this, the ministerial regulation needs to provide guidance as to whether the FDA's reliance on the data submitted by the drug originator, in order to assess a subsequent application constitutes "unfair commercial use." While the FDA in fact refrains from disclosing the data submitted by drug originators to third parties, generic manufacturers, i.e. direct competitors, clearly obtain a commercial benefit from the originator's confidential data.

The Thai FDA has taken the position that reliance on drug originators' clinical test data submitted to the FDA does not constitute unfair commercial use. The FDA has followed this policy since the enactment of the Trade Secrets Act in 2002 and has treated an originator's data on file as forming part of known scientific knowledge. Therefore, the FDA does not require a generic applicant to prove safety and efficacy of a drug compound. Follow-on applicants are usually required merely to conduct the less burdensome bioequivalence and/or stability testing to demonstrate that the follow-on genetic drug compound is either the bioequivalent or with the same bioavailability. Similarly, the generic manufacturer does not need to conduct research on ingredients and dosage forms that have already been approved for safety and effectiveness.

While enactment of the ministerial regulation was underway, the industry and legal experts had anticipated that the ministerial regulation would clearly establish the breadth of data protection and/or data exclusivity under the Trade Secrets Act. Unfortunately, the ministerial regulation issued in 2007 completely fails to provide a clear solution to this highly controversial issue and hardly protects data owners against unfair commercial use as prescribed by the Trade Secrets Act.

The regulation evidently sidesteps this issue and does not define the limits or boundaries of data protection in a meaningful way. Whereas the regulation purportedly establishes a standard for protection of data submitted to the FDA, the relevant sections merely address physical security of the documents submitted and simply prevent unauthorised disclosure. For instance, Section 16 provides that in case of application for drug registration, the data submitted must be stored in a securely locked cabinet, etc.; Section 18(2) merely states that government officials have the responsibility to protect/keep the trade secret information in a safe place.

Since the regulation does not really provide additional guidance for the implementation and enforcement of the Trade Secrets Act, in respect of data protection, the Thai FDA would likely stick to the narrow interpretation of its confidentiality obligation under the Act and continue to allow exploitation of drug originators' confidential data on file in favour of generic producers. Nevertheless, while it could be argued that the (indirect) use of data by the FDA, to approve a subsequent generic application would essentially confer commercial benefit to a third party and therefore constitute "unfair commercial use". Many believe that the use by a state agency in granting marketing approval to a follow-on applicant based on the second product's similarity to the originator's previously approved product cannot constitute an "unfair commercial use" of data. This is because the FDA itself is not a commercial entity. It remains to be seen whether such an argument has any merits when subject to a judicial review.

D. Combating counterfeit drugs

In recent years counterfeit drugs have become a severe problem both in Thailand and worldwide. The Thai government is aware of the problem and recognises that counterfeit medicines create a major health risk for Thai people. As part of the overall efforts to clamp down on counterfeits, the Memorandum of Understanding (MOU) on "Operation to Prevent and Suppress Drugs Violating Intellectual Property" was entered into by government agencies and the industry on February 14, 2008. The signatories include the Department of Intellectual Property (i.e. the Thai equivalent of the USPTO), the Customs Department, the Royal Thai Police, the Department of Special Investigation and the Pharmaceutical Research & Manufacturers Association (PReMA). However, the Thai FDA, which is the main drug regulator, did not take part in this co-operative effort covered by the MOU. Therefore, significant doubts remain with regard to whether this MOU will have any effect in practice.

II. China

In the summer of 2007, China's image as the world's factory for all things made fast and cheap and good came to a screeching halt. Spurred by the US media, revelations of countless examples of poor quality, faulty and harmful products coming from China made the world stop and ask itself whether low prices were really worth potentially harmful products. The number and types of shoddy products recalled in the United States alone were disturbing, especially products posing the most immediate risks like food and pharmaceuticals.

Investigations made by the US media confirmed that at least, with regards to food and drug imports, China is considered a regular source of products containing carcinogens, illegal pesticides and additives, and other banned antibiotics and preservatives. The US Consumer Product Safety Commission has reported that as much as 60 percent of recalled goods in the United States are Chinese-made. The usual course of action most governments take is to return such products to their country of origin, but many times, the same goods will be re-shipped or sent to other countries with less onerous inspections.

Following the initial finger pointing and blame game between US companies and China, we saw some very positive outcomes from the otherwise tragic situation. First, many new policies, regulations and procedures concerning pharmaceuticals which had been in the ministerial pipeline for years were fast-tracked and implemented. These included policies for things such as more transparent drug approval and registration procedures, pricing standards, advertising controls, retail/wholesale directions and harsher criminal penalties for dealing in fake products.

Second, the Chinese consumer is now more aware of issues regarding product quality which naturally leads to a greater understanding and appreciation of intellectual property rights. Poisoned products affect the Chinese too. In 2004, at least 50 infants died when they were fed unsafe and fake infant formula and another 200 or so were left severely malnourished. On July 10, 2007, Zheng Xiaoyu, the former head of the State Food and Drug Administration (SFDA), was executed after antibiotics approved under his watch were responsible for the deaths of 10 people before they were recalled from the market. Zheng was found to have accepted over US$800,000 in bribes and gifts from various drug manufacturers to fast-track approval of the poisonous drugs. The court held that Zheng had failed in his duty to "make careful arrangements for the supervision of medicine production, which is of critical importance to people's lives."

A. SFDA shake-up

The SFDA was established in its current form in 2003. Before this, the regulation of food and pharmaceuticals was overseen by a host of ministries and respective agencies. Bringing this all-together under one regulatory roof was intended to streamline procedures and bring China's system in line with those in other countries. What was not foreseen, however, was how consolidation might result in a concentration of approval authority in the hands of select ministers with little or no oversight in terms of how they carried out their duties. Zheng Xiaoyu's execution was seen as Beijing's shot across the SFDA bow to shape up.

On the day of Zheng's execution, the *New Measures for the Administration of the Registration of Pharmaceuticals* ("New Measures") were released by the SFDA and became effective on October 1, 2007 (the PRC's National Day). These New Measures replaced the earlier 2005 Measures. The New Measures have significantly curtailed individual regulator authority over drug registration and approval, clinical trials, generic pharmaceutical approval and manufacturing. While data protection safeguards remain in place, in terms of new drug application dossiers, most of the SFDA's internal procedures and requirements which before were arbitrarily and sometimes inequitably disseminated and practiced are now to be made publicly available, mostly online. By separate measures in 2007, SFDA officials were precluded from investing in pharmaceutical companies and as of April 2007 were meant to have completely divested themselves of interests they had held.

One of the cornerstones of the current Eleventh Year Plan is technological innovation. To encourage this in the field of pharmaceuticals, the New Measures provide for a number of new procedures such as definite timetables for the approval of new drugs, a revised definition of "new drugs" which for the first time specifically precludes mere reformulations of existing pharmaceutical products which have no improved qualities (such reformulations may now be submitted for generic approval) and a new fast track approval procedure for certain specially emphasised medicine products such as those used in

the treatment of HIV/AIDS, rare diseases and medicines for the treatment of terminal illnesses. The conduct of preclinical and clinical trials especially in terms of onsite inspections and testing has been expanded including local FDA inspections of generic applicants and approved manufacturers. Increased inspections of pharmaceutical manufacturers were actually mandated by the SFDA back in 2004 when Good Manufacturing Practice (GMP) certification was first required of all drug factories in China. With nearly 200,000 licensed drug manufacturers in China, most experts predict that a majority will fail these GMP certification inspections which are meant to be completed this year.

B. Advertising controls

On March 3, 2007, the SFDA and the State Administration for Industry and Commerce jointly issued their *Provisions for Pharmaceutical Advertisement Standards* ("Provisions"). Drug advertisement and drug labeling has always been the responsibility of local meaning either provincial or municipal FDAs, but this joint national directive is intended to end differences in how drug products are marketed and labeled through the use of countrywide standards. In addition to further establishing what type of information is required in adverts and labels, the Provisions also dictate prohibited content such as unsubstantiated touting, product comparisons, efficacy guarantees, product association with medical institutions or organisations, and also a preclusion against language which evokes fear of a disease or illness.

C. Product safety and liability

Moving even higher up the authoritative ladder, the State Council issued its *Special Provisions Regarding the Strengthening of Supervision and Administration of Food Products Safety* on July 25, 2007 which establishes China's first recall procedure for food and pharmaceutical products. On August 31, 2007, the General Administration of Quality Supervision, Inspection and Quarantine (AQSIS) set up a system for tracking and recalling unsafe food and toys in the domestic Chinese market as well as food and toy products for export (a system for recalling defective automobiles and auto parts had been in place since October 1, 2005 and this served as a platform from which to build programs in other sectors). Before last year, defective drug products were questionably subject to recall under Article 14 of the *Rules Regarding the Implementation of "Some Regulations on the State Supervision and Testing of the Quality of Products"* of February 2, 1987.

Now, the government can recall products which are dangerous or unapproved and issue consumer alerts. Manufacturers must stop making and selling products that are unsafe by other countries' standards, even if they abide by Chinese laws and regulations. Provincial and municipal authorities have also issued their own recall guidelines.

The protection of consumer rights has long been a cornerstone of the Party's commitment to the welfare of people. The *General Principles of Civil Law of the PRC*, effective since January 1, 1987, the *Product Quality Law of the PRC* of February 22, 1992, and the *Law of the PRC on the Protection of the Rights and Interests of Consumers* of October 31, 1993 all contain provisions relating to the protection of consumer interests and liabilities for manufacturers and distributors of defective and dangerous goods.

D. An uncertain future

Last year marked Beijing's first real commitment to remove dangerous goods from the market and penalise those responsible for the damages they cause. With the growing popularity of product liability insurance within the domestic pharmaceutical industry and the closing of non-GMP certified factories, the situation is meant to improve. Although nearly a year has passed since the SFDA shake-up, there remain periodic examples of how far China still needs to go. In April 2008, the blood thinning agent *heparin* was found to be defective and responsible for at least four US deaths and hundreds of cases of allergic reactions, many serious. Investigations revealed that the factory, located outside Shanghai and owned by a US-based company, had never been inspected by the SFDA although it had been approved by the US FDA for Active Pharmaceutical Ingredient (API) supply to the United States. China is now the world's number one API supplier and as the country becomes more integrated into the global pharmaceutical industry, further strengthening of its regulatory regime will be a consumer demand the country will be forced to comply with.

II. Protection of test data in Vietnam

Vietnam's population is approximately 86 million. The statistics of the Ministry of Health and the World Health Organisation (WHO) show that the total revenue of the country's pharmaceutical sector was in the region of US$1 billion last year, and the market is increasing at about 12 to 15 percent per year. The market share of imported drugs alone is approximately 60 percent of the country's drug market. These figures explain why Vietnam's drug market is so attractive to foreign pharmaceutical companies. This market became even more promising for foreign manufacturers after the signing of the Vietnam – United States Bilateral Trade Agreement and, especially, after Vietnam's accession to the World Trade Organisation (WTO).

Thanks to Vietnam's accession to the WTO, a key change in the pharmaceutical field was the introduction of the protection of test data as one of Vietnam's commitments upon its accession.

The protection of test data was introduced for the first time in Vietnam in the Law on Intellectual Property (the "IP Law"), Decree No. 103/2006/ND-CP dated September 22, 2006 on "Providing Guidelines for Implementation of a Number of Articles of the IP Law", Decree No. 106/2006/ND-CP dated September 22, 2006 on "Penalties for Administrative Breaches in the Industrial Property Sector", and in particular, the "Regulations on Data Protection Applied to Drug Registration Dossiers" that were promulgated by Decision No. 30/2006/QD-BYT dated September 30, 2006 of the Ministry of Health.

Under the Regulations on Data Protection Applied to Drug Registration Dossiers, data protection is not provided automatically; rather a pharmaceutical manufacturer must request data protection when filing for registration of their drug. This makes Vietnam an exceptional country where no system of automatic data protection is in place. Most of the countries that provide for data protection do not require this additional step and many manufacturers and organisations have sought the removal of this exceptional requirement.

In accordance with the "Regulations on Data Protection Applied to Drug Registration Dossiers", to qualify for protection data must be undisclosed information that required a considerable effort to produce, can be used in business, was created by (or lawfully assigned to) the person who requests the data protection, and for which the owner applies necessary security measures to maintain its confidentiality. In theory, the effort must have been significant in economic terms or from a technical point of view. In practice, however, a listing of the applicant's financial investment in the creation of this data should be sufficient. A request for data protection is examined within six months. If it is approved, any subsequent application for drug registration filed within the following five years using essentially the same data should be refused. This data protection is only applied to drugs which utilise new chemical entities or new combinations of known entities only. Protection cannot be sought for new indications, new modes of administration, new preparation forms and new dosages of an original preparation. This test data protection term and the limitation in subjects qualified for data protection should be considered reasonable and acceptable under the current technological and economic conditions of Vietnam.

Pharmaceutical manufacturers are concerned about the extent to which data is considered undisclosed and, therefore, is qualified for protection. The regulations on examination of requests for data protection are still being drafted by the Drug Administration of Vietnam. It is essential that the new regulations address this issue. This may have been the reason that although the Regulations on Data Protection Applied to Drug Registration Dossiers have been in effect for more than a year (since November 11, 2006), only two requests for data protection have been filed.

Vietnam is a promising market for pharmaceutical manufacturers. The country is introducing more and more appropriate legal provisions that will help develop a healthy investment environment and make the country increasingly attractive in the eyes of foreign investors.

IV. Conclusion

The pharmaceutical industry in Asia has been growing rapidly in recent years. While most countries generally promote the development of the pharmaceutical industry, there are challenges which have yet to be overcome. Main issues include access to medicine, quality of pharmaceutical products and counterfeit problems, legal protection for original pharmaceutical products, data protection, and generics approval processes. What we have seen in Thailand, China and Vietnam clearly demonstrates that government policies with regard to these issues are crucial to the growth and development of the industry and national healthcare systems, which in turn impact economies and quality of life.

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