Tilleke & Gibbins

# Thailand: IP Developments

A Publication of Tilleke & Gibbins' Intellectual Property Department June 2009

## Outsourcing Product Registration in Asia – Why Expert Assistance Helps!

by Paul Russell and Alan Adcock

*Left: Paul Russell, Of Counsel & Director Regulatory Affairs*
*Right: Alan Adcock, Deputy Director Intellectual Property*

As most ASEAN Food and Drug Administrations (FDAs) and Ministries of Agriculture (MoAs) labor under critical backlogs of product registration applications for the growing number of products being released into Asian markets, businesses are looking to new ways to facilitate approvals. Outsourcing product registration work to law firms is becoming an increasingly popular way for regulatory affairs departments to speed up applications as local knowledge and effective navigation go a long way in Asia.

### Outsourcing

As food, pharmaceutical, chemical, and cosmetic manufacturers around the world have grown, it has become clear that they have insufficient product registration and IP resources in-house, leading to a growth in the outsourcing of these needs to legal counsel.

Independent product registration firms usually have a diversified client base in multiple industries. Companies are outsourcing their registration work to independent registration firms because of their in-depth and extensive knowledge of consumers and the regulatory industry. Companies with product registrations are beginning to realize the convenience and cost-effectiveness provided by the cradle-to-grave approach of such firms.

### Asia Experience

Outside legal counsel that want to take advantage of the outsourcing trend should develop a product registration staff with a variety of product and industry skills. This should be a multidisciplinary staff consisting of, for example, lawyers and pharmacists, or scientists with the technical knowledge required to register pharmaceutical products.

Companies should look for a partner that has a proven track record and has been in business long enough to develop a good relationship with the regulatory authority. They should also have a client base that has enabled the firm to develop in-depth industry knowledge. In addition, they need to have a staff large enough to file successful product applications and to obtain registration licenses in the shortest possible time. Small firms that want to register their products in Asia should look for a registration company with flexible and cost-effective fee arrangements that meet their needs and expectations.

### FDA Procedure

In most of Asia, the company that files the registration application must be a local company because if there are issues with your product, the government of the country you are registering in needs to know that there will be someone local to take responsibility. This is particularly important in jurisdictions which have enacted product liability legislation.

While opening a local branch in the jurisdiction is most realistic for larger companies with the manpower and financial support to do so, for small and medium-sized companies, there are alternative options. In many cases, companies appoint a local distributor or franchisee as the party responsible for navigating the registration. They must obtain an import license for your product before filing, and then they take on the product liability, and their name appears on the product registration certificate.

While there are many benefits to this method, it is important that relevant safeguards are carefully woven into the contract between the original company and the nominated representative. Because the appointed company is the registrant of the product, if you have a disagreement with them you can be left with problems. You can protect against this in the initial contract by ensuring that safeguard clauses are implemented in accordance with the law of the specific country you are filing in. In some regions, you will be allowed to state that, in the event that you discontinue your relationship, the representative party must facilitate the transfer of registration rights back to your company. In others you will need to say that the other party must destroy the registration and provide proof to that effect.

Once your local branch has been established, the FDA/MoA will then review the description of your product and provide a product classification. After the application has been filed, it must be followed up on until the agency issues a registration license. This typically takes one to two years, depending on how often you follow up in person. Your relationship with the FDA is important, because the FDA and MoA are inundated with work. Making the effort in person reminds them to take your call; then later, your call reminds them to prioritize your application.

### Data Exclusivity

In Asia, data exclusivity is not always guaranteed, as the guidelines across the continent are often unclear. This can be particularly important for pharmaceutical companies which rely on the measure for protection of their patented products from generic drugs. Companies should

*Continued on page 6*

# Drug Originator's Liability for Damage Caused by Use of Generics

by Siraprapha Rungpry and Clemence Gautier

*Left: Siraprapha Rungpry, Consultant*
*Right: Clemence Gautier, Consultant*
*Intellectual Property*

After several years of consideration, Thailand has recently adopted a product liability law that holds business operators strictly liable for unsafe or defective products which cause harm to consumers. Product quality and liability concerns reached a high point in the summer of 2007 during the middle of the China scare, when a wide variety of shoddy products were recalled in the United States, such as faulty blade guards on electric saws that injure users, baby carriers and baby swings that injure children, tainted pet foods, cosmetics containing various toxins, and toys containing high levels of lead paints. As Thailand begins to embrace the product liability concept with very few precedents in this area, the possible extent of liability may be estimated by observing cases in the United States, where product liability law is well established.

Pharmaceutical companies are often targets of product liability claims, and sometimes their liability goes further than anyone would have expected. The U.S. Hatch-Waxman Act states that a generic manufacturer is not required to submit evidence on drug safety and efficacy. The generic manufacturer merely needs to certify that its product is bioequivalent with the brand-name drug and that the labeling and warnings information shall mirror those of the approved brand-name drug. A question arose in 1994 as to whether a pioneer manufacturer could be held liable for damage caused by the generic equivalent, since the generic was the bioequivalent of the brand-name drug and had the same labels and warnings. The Fourth Circuit Court stated that the pioneer manufacturer could not be held liable for the "injuries caused by other manufacturers' products over whose production the name brand manufacturer has no control." This case was followed by the U.S. courts until last November.

In a decision rendered in November 2008 by the California Court of Appeal for the First Appellate District, a pioneer pharmaceutical company was held liable for injury to a patient who took the generic version of its brand-name drug. The pioneer's drug was no longer being sold on the market. After taking the drug for almost four years, the plaintiff claimed that she developed significant complications.

According to the relevant U.S. law, only the manufacturer of the product injuring a patient can be sued. The plaintiff initially raised an inadequate warning claim on the product labeling, but the plaintiff's doctor did not actually remember reading the label provided by the generic manufacturer. Thus, no product liability claim could be raised against the generic manufacturer, nor could such claim be brought against the originator company, which did not manufacture the litigious drug. The Court authorized the plaintiff to reformulate her action by accusing the originator company of fraud, fraud by concealment, and negligent misrepresentation. In his testimony, the doctor testified that he may have relied on the label of the original drug, which he probably became aware of during his residency, implying an extension of duty of care owed by the originator company.

The Court of Appeal in California recognized the so-called "innovator theory" and stated that the originator company had the duty to warn patients whose doctors are relying on their

*Continued on page 4*

# Registration of Vowel-Reduced Trademarks

by Ruchiya Chuenchomrat

*Ruchiya Chuenchomrat, Trademark Executive*
*Intellectual Property*

I'm sur u cn read this messge. Rather than being a misspelling, it is immediately recognizable as the shorthand style of the instant-messaging generation. How are these missing vowels related to trademark law?

Product manufacturers and service providers consistently seek to create cool and modernized images to identify both themselves and the attributes of their goods and services. To this end, the elimination of vowels from trademarks has become an increasingly common trend. Yet, not all marks with vowel ellipsis have been successfully registered in Thailand. Obstacles in registering a mark with omitted vowels may arise because these marks may be deemed contrary to Section 7 paragraph 2 (3) of the Trademark Act, which states that a mark will be considered distinctive if it possesses or consists of "a combination of colors represented in a special manner, stylized letters, numerals or invented word."

One telecommunications company in particular has been a pioneer in the cell phone industry for trademarks that exclude certain vowels. It began to employ this type of mark to match with specific concepts of its individual mobile phone models: RAZR (short for Razor) is thin like a blade; ROKR (short for Rocker) is designed to cater to music lovers via its iTunes function; and PEBL (short for Pebble) is a round, smooth metal phone that allows users to operate and open it with one hand. Each of these marks has been successfully registered in Classes 9 and 38 for the goods "cellular telephones, headsets, computer game software for mobile handsets, other communications apparatus, etc." and services "wireless telephone services and electronic transmission of data and documents via computer terminals, etc." A possible reason behind these successful registrations is that the remaining vowels still enable the final consonant of each mark to be vocalized. The Registrar may have interpreted that the absence of certain vowels did not affect the distinct features of the word marks because there is only one way to pronounce them and they are still presented within the familiar structure of a word.

*Continued on page 7*

# Claims for Food Products

by Paul Russell and Neetika Mutreja

*Left: Paul Russell, Of Counsel & Director*
*Right: Neetika Mutreja, Intern*
*Regulatory Affairs*

Recent years have witnessed a proliferation in the number of products available under the "nutritional food" heading. For companies to stand out from their competitors in this growing sector, marketing and advertising is integral for success. The ability to make claims regarding products is a significant aspect of this process. While the number of products has been on the rise, there has also been an augmentation in demand among consumers for healthier, more nutritious products. This, coupled with more aggressive advertising tactics, could lead to exaggerated or egregious claims. In order to balance the consumers' need for accurate information and the companies' commercial interest, regulations have been set forth that delineate the boundaries of permissible health claims. The European Union and the United States have similar regulations which allow for health claims, provided that there is scientific evidence to substantiate the claim. However, when many of these companies attempt to sell their products in Thailand, they find their advertising efforts thwarted by more stringent regulations and stricter approval procedures.

## Around the World

In the European Union, the legislation is set out with the purpose of protecting consumers from information which is false or misleading or which condones excessive consumption of a product. The regulation presents a harmonized list of claims. Each claim is defined by specific parameters, thereby associating each claim with precise and quantifiable values. For example, for a cereal to be able to claim it is high in fiber, a certain minimum amount of fiber is required. The list of advertised claims can be used by manufacturers without any hindrance. However, if they are looking to employ a more novel claim not already included in the list, they must submit an application and relevant scientific research to the European Food Safety Authority for approval. Nonetheless, some claims are completely prohibited; claims regarding weight loss or in relation to psychological functions, such as improved memory, are not permissible.

In the United States, admissible claims fall into three categories per U.S. Food and Drug Administration (USFDA) regulations: structure/function claims, nutrient content claims, and health claims. Different rules apply to each category.

Structure/function claims, which describe the role of a nutrient and how it affects the normal structure or function in humans (such as "calcium builds strong bones"), do not need preapproval by the USFDA prior to dissemination. This lends a certain leniency to manufacturers, although a disclaimer must be attached stating that the USFDA has not evaluated the claim.

Nutrient claims are used to characterize the level of a nutrient in a food, such as the use of the words "free," "reduced," or "only." The regulation is similar to that of the European Union, in that the nutrient must fall within certain quantifiable parameters to permit the use of such claims.

There is the most flexibility in the area of health claims, which describe a relationship between a food or ingredient and the reduction of risk of disease or other health-related conditions. The USFDA exercises its oversight of health claims in three ways. The company can petition a claim, which the USFDA will review along with the accompanying scientific literature. Further, if the company can provide an authoritative statement from a scientific body of the U.S. Government or the National Academy of Sciences, claims can be made simply by notification to the USFDA. Lastly, qualified health claims are permissible when there is emerging evidence to support the claim. On the whole, as long as a claim can be substantiated with scientific evidence, health claims will be permitted. Nevertheless, claims which appear to promise too much will be prohibited, such as a recent CHEERIOS ad claiming to lower cholesterol levels by 4 percent in six weeks.

## Thai FDA Policy

Any advertising or labeling for food products must be approved by the Committee on Advertising (the Committee) under the Thai Food and Drug Administration (TFDA) prior to circulation. The laws regulating the advertising are set out in the Food Act 1979 and the Consumer Protection Act 1979, but the stringency with which they are applied is at the discretion of the Committee. The pertinent provisions under Sections 40–42 of the Food Act prohibit advertising "which is false or which is a deceptive act leading to misconception." The law is quite broad and can thus be interpreted by the Committee in such a way as to be detrimental to the companies. The Committee has final say on the entire content of all advertising, from the material used (pictures and content) to the format and layout. All advertisements will be scrutinized for excessive use of superlatives. Claims of "uniqueness" or "special design" tend to be rejected. In particular, claims made for food supplement products are especially monitored to ensure that no claims exhibiting pharmaceutical-like qualities are approved. Even though the rules appear rigid, ambiguity still remains. While the regulations set out guidelines for use of words such as "fresh" and "organic," no guidelines are provided in the legislation with regard to health claims, allowing wide discretion for the Committee.

The main concern of the TFDA is the protection of the consumer from false or misleading information. Claims which may seem to the manufacturer to simply be stating the purpose of the product ("this tea is designed to cleanse the body of toxins") can be perceived as an exaggeration by the Committee, and will consequently be rejected. In order to facilitate the approval of such claims, it is essential that companies compile sufficient evidence to support the claims being made. Since the TFDA considers all advertisements on a case-by-case basis, companies with well-developed registration strategies can use this fact to their advantage when seeking approval. Complete, persuasive evidence to support product claims can lead to approval in a manner that is actually quite similar to the processes that prevail in the European Union and the United States. ❖

# Proposed Legal Amendments to Strengthen IP Enforcement

by Darani Vachanavuttivong

*Darani Vachanavuttivong, Co-Managing Partner & Managing Director, Intellectual Property*

In another attempt to cope with the ongoing problems caused by counterfeiting and piracy, Deputy Minister of Commerce Alongkorn Pollabut has been persistent in pushing forward amendments of the Trademark Act and the Copyright Act to cover offenses for any person who buys or possesses counterfeit goods and pirated products in Thailand. In addition, the proposed amendments would allow for actions to be taken against landlords who provide rental of commercial spaces where the sale of counterfeit and pirated products takes place. The motivation underlying these amendments is to bring about a change in attitude among Thai consumers, making them more aware of the importance of IP rights and the criminal implications of counterfeiting and piracy.

To move forward with this objective, the Department of Intellectual Property has appointed a Committee of Development of Intellectual Property Laws to consider and proceed with the proposed amendments. The latest updated amendments (as of June 15, 2009) to the Trademark Act and the Copyright Act include the key proposals detailed below.

## Trademark Act

The current draft sets forth offenses for buying counterfeit goods: *"Whoever, without appropriate reasons, buys goods, while knowing or reasonably should have known that such goods have used forged trademarks, service marks, or collective marks according to Section 108, shall be punishable by a fine not exceeding THB 1,000."*

Rental of commercial spaces or places for selling counterfeit goods would also be deemed an offense: *"Whoever provides rental of spaces or places, including the owner or occupier of any building or space, while knowing or reasonably should have known that the user of the building or spaces or places therein sells, offers for sale, or possesses for sale goods which have used forged trademarks, service marks, or collective marks according to Section 108, or imitated trademarks, service marks, or collective marks according to Section 109, shall be punishable by imprisonment not exceeding one year or a fine not exceeding THB 200,000 or both."*

*Continued on page 8*

## Drug Originator's Liability

*(from page 2)*

labeling prescription, regardless of whether the patients are taking the brand-name product or its generic. The Supreme Court of California declined to hear the case.

Since this decision, rulings in February and March 2009 by U.S. District Courts in Texas, Oklahoma, and Iowa have rejected the claims of patients who were prescribed generic drugs against the brand-name manufacturers for allegedly failing to warn doctors about the risks associated with the generic products. Thus, this controversial California case may not be followed by other courts, but still must be taken into consideration by pharmaceutical companies.

If similar claims against drug originators were to be raised in Thailand by a patient who sustained injury from taking a generic version of a brand-name drug, under strict interpretation of applicable Thai laws, the chance of success for such claims would appear rather slim. Owing to the fact that the injured patient is using the generic drug, as opposed to the original drug, the patient would not have a cause of action against the originator company for product liability. In order to claim damages under the Thai Product Liability Act, the injury sustained must be caused by the product of that particular company. The Act specifically states in Section 6 that in order for the business operator to be held liable, the injured party "must prove that the injured party has sustained an injury from the product of the business operator."

In Thailand, if the product that caused damage to the patient was not manufactured by the originator company, the originator company should not be held liable as it did not make or sell the product to the injured patient. The same analysis would be equally applicable in the case where a patient used a counterfeit drug and consequently sustained injury because of it. The originator company cannot be held liable for such damage since it did not make or sell such counterfeit product to the patient. Similarly, where the patient developed complications due to taking a generic version of a brand-name drug, only the generic manufacturer who makes and/or sells the unsafe or defective product would likely be subject to liability under Thai product liability law.

Aside from the Product Liability Act, the Consumer Protection Act also prescribes general standards for product labels. Unlike the Product Liability Act, however, the Consumer Protection Act does not provide direct standing for consumers to bring an action in court. Complaints have to be submitted to the Consumer Protection Board for review and investigation. Additionally, the Drug Act requires drug companies to submit product labels to the Thai Food and Drug Administration (FDA) for review and approval. Subsequent to approval of the labels, the FDA is also responsible for monitoring to ensure that the information printed on the product labels and inserts is consistent with the text approved by the FDA.

Thus, if an injured patient were to raise a claim that the originator's product label does not provide sufficient information and/or warning with regard to side effects or complications which may result from taking the drug, such claim would have to be referred to the relevant government authority to review and determine whether such claim has any merits, rather than being able to bring an action in court directly. Otherwise, as more or less the last resort, the injured patient may try to bring a general tort claim against the drug originator. Given that the drug originator has not breached its duty under the law, the chance of success for such tort claim would be rather slim, as it would be difficult to establish causation in this particular scenario. ❖

# Historical Background of the IP&IT Court

by Inthupim Chokwaranun

*Inthupim Chokwaranun, Attorney-at-Law*
*Intellectual Property*

On May 1, 2009, the Central Intellectual Property and International Trade Court (IP&IT Court) reopened in a new location with state-of-the-art facilities. After spending its first decade at its original location, the Court has now moved to a recently constructed government property on Chaengwattana Road, namely The Government Complex Commemorating His Majesty the King's 80th Birthday Anniversary, 5th December, B.E. 2550 (2007). The Treasury Department made the decision to proceed with construction of the complex in order to create a new venue where various government departments can coexist effectively through joint use of the area. The common space is intended to allow greater cooperation among government departments, while providing citizens with a one-stop service center where they can access various public services within a single area. Thus far, a total of 29 departments and agencies have expressed their intention to make use of the more than 900,000 sq.m. of office space provided in the new complex, including the IP&IT Court, the Central Bankruptcy Court, the Central Administrative Court, the Department of Special Investigation, and the Ministry of Justice.

In its new location, the IP&IT Court will continue with its mandate to adjudicate intellectual property and international trade cases, as it has been doing since its establishment on December 1, 1997. The specialized court, which was established by the Act for the Establishment of and Procedure for Intellectual Property and International Trade Court (1996), provides a forum where cases can be heard by judges who possess competent knowledge and full understanding in intellectual property and international trade. The establishment of the Court represented an important development in Thailand's compliance with TRIPS requirements to ensure that these cases are heard by judges with specialized knowledge in the field, rather than by judges in general courts.

When the IP&IT Court was established, its territorial jurisdiction was envisioned to cover the whole Bangkok Metropolis and its neighboring provinces: Samut Prakarn, Samut Sakhon, Nakhon Pathorn, Nonthaburi, and Pathum Thani. This Central IP&IT Court was expected to be supported by Regional IP&IT Courts throughout the country. At present, however, these regional courts have not yet been established through the necessary legislative procedures. As a result, the territorial jurisdiction of the Central IP&IT Court currently extends throughout the Kingdom.

The IP&IT Court has the power to adjudicate both civil and criminal cases regarding intellectual property and civil cases regarding international trade. Civil cases regarding intellectual property may involve trademark, copyright, and patent issues, including cases arising from technology transfer or licensing agreement. Criminal cases tried before the Court may similarly pertain to infringement under the Trademark Act, the Copyright Act, and the Patent Act, as well as offenses relating to trade provided in the Criminal Code. Disputes over layout designs of integrated circuits, scientific discoveries, trade names, geographical indications, trade secrets, and plant varieties protection may also be heard by the IP&IT Court.

In addition to these intellectual property issues, the IP&IT Court has jurisdiction over a wide variety of civil actions in the area of international trade. This includes international sale, exchange of goods or financial instruments, international services, international carriage, and insurance and other related transactions, arrest of ships, and dumping and subsidization of goods or services from abroad. In terms of dispute resolution, the Court frequently encourages the parties to make use of its arbitration procedures before proceeding to trial. Any cases falling under the jurisdiction of juvenile and family courts will not be heard by the IP&IT Court.

Certain unique features differentiate the procedures of the IP&IT Court from those of other courts. Unlike most courts, the proceedings in the IP&IT Court must be continuous without adjournment until the hearing is completed, which ensures that trials will proceed efficiently. The Court's rules contain special procedures, such as interim injunction, Anton Piller order, pretrial conference, submission of depositions in lieu of oral testimony for the hearing of witnesses, hearing by means of video conference, and admission of computer records. These special procedures are important because they facilitate the proceedings in the Court in a fair and efficient manner. ❖

**Case Statistics of the IP&IT Court — January 1, 1998 to May 15, 2009**

| | 1998 | 1999 | 2000 | 2001 | 2002 | 2003 | 2004 | 2005 | 2006 | 2007 | 2008 | 2009 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| International Trade Cases | 481 | 548 | 771 | 520 | 370 | 339 | 352 | 366 | 265 | 558 | 589 | 408 |
| Intellectual Property Cases (Civil Cases) | 90 | 70 | 102 | 138 | 157 | 173 | 212 | 191 | 167 | 201 | 192 | 46 |
| Intellectual Property Cases (Criminal Cases) | 1643 | 1721 | 2141 | 3252 | 3582 | 4001 | 5354 | 5565 | 4924 | 6965 | 6682 | 2938 |
| **Total** | **2214** | **2339** | **3014** | **3910** | **4109** | **4513** | **5918** | **6122** | **5356** | **7724** | **7463** | **3392** |

# Combating Generics: Rising Pharmaceutical Patent Litigation Trend

by Siraprapha Rungpry

*Siraprapha Rungpry, Consultant Intellectual Property*

In recent years, Thailand has seen an increasing number of pharmaceutical patent litigations, launched by drug originators to combat infringing generic products in the market. Local generic manufacturers are becoming more active than ever owing to several driving factors. From the regulatory perspective, generic drug manufacturers are allowed to apply for registration of generic drugs with the Thai Food and Drug Administration (FDA) before the expiration of a patent covering a particular drug. This is primarily due to the FDA's current pro-generic, no-patent-linkage position and the Bolar exemption under the Thai Patent Act which confers generic manufacturers with the ability to engage in various preparatory activities with a view to seeking regulatory approval before a patent for the original drug has expired. Moreover, the Thai FDA treats originators' dossier and data previously filed with the FDA as forming part of known scientific knowledge which could be relied on in approving follow-on generic applications. Above all, there is an apparent development trend among local generic producers to catch up with the new technology and take advantage of the government's pro-generic policy at the moment. The recent compulsory license scheme also affected the policy and economic landscape as well as the general perception towards generic drugs. Consequently, several local generic manufacturers began to develop and market generics of various best-seller drugs and continued to add more products to their pipeline development despite the existence of valid patents covering these drugs in Thailand.

It is inevitable that drug originators facing low-price infringing generics are put in the position to defend their products. Given their prior dominant position and established relationships with customers and brand loyalty, drug originators have somewhat of an upper hand. Nevertheless, the price competition could cause serious problems in the long run and normally results in (significant) loss of sales to the generics.

Several legal options are available to tackle infringing generic products, ranging from informal enforcement measures to formal proceedings in court. In general, the first step is to send a warning letter and/or try to negotiate with the generic manufacturer. An ex parte preliminary injunction enjoining sales of infringing generic products may be applied for even before filing a lawsuit with the court, although the requisite evidentiary burden is rather high. Additionally, an ex parte Anton Piller order to seize evidence of infringement may also be possible. In terms of legal actions, Thai law allows for both criminal and civil actions against infringers. The choice would depend on the circumstances of the case. Normally, a civil action can be filed fairly quickly, and by this means drug originators could pursue damages and permanent injunction against infringing generic manufacturers.

A careful overall strategy must be formulated before taking any (active) steps against potentially infringing generic manufacturers, as one blunder or misstep could result in severe repercussions in the long run. The pharmaceutical patent owner also needs to pay particular attention to obtaining sufficient evidence to verify and confirm the infringement. When court proceedings are pursued, litigation strategy should be carefully crafted taking into consideration the relevant business concerns of the company. ❖

**Outsourcing** *(from page 1)*

choose only those firms which enjoy known and trusted reputations if they are going to be passed confidential and proprietary information, such as clinical trial data, bioequivalence studies, trade secret formulations, recipes, etc.

Governmental promotion of the generic industry is the primary reason that data exclusivity is uncertain in Asia. In Thailand, for example, a protective regulation was adopted in 2006, but it only protects against unauthorized disclosure, and fails to provide a clear solution to the notion of unfair commercial use.

In addition, the period of keeping trade secret information is limited—only five years from the submission date of the trade secret in the secured locking system of the Thai FDA. Data exclusivity protection periods are directed at third party disclosure, but Asian FDAs often use the information during the course of their vetting of generic approval applications.

In the absence of stringent data protection, it is easier to rely on Asian Bolar provisions (research and noncommercial practice of another's patent) and do a bioequivalence, since the FDA treats the originator's data on file as forming part of known scientific knowledge.

Nevertheless, in Thailand, data protection is provided under the Trade Secrets Act of 2002, which recognizes that information submitted to the FDA by a drug originator in order to obtain approval to market a new drug may amount to a trade secret.

Tilleke & Gibbins' Regulatory Affairs Department is seeing a marked increase in product registration work from companies who have historically handled this themselves, as well as post-registration maintenance, transfer, and cancellation work. Work is expanding also in the area of negotiating with FDAs across the region to correct misconceptions about the interplay between intellectual property and regulatory compliance, particularly in terms of dealing with generic manufacturers who attempt to register colorably similar versions of internationally recognized chemical compound names as brand names for generic products. ❖

# UPDATE: THAILAND WILL BECOME A PCT MEMBER THIS YEAR

by Darani Vachanavuttivong

*Darani Vachanavuttivong, Co-Managing Partner & Managing Director, Intellectual Property*

Based on recent developments, it is highly likely that Thailand will become a member of the Patent Cooperation Treaty (PCT) during the second half of this year.

In March 2009, the Council of State completed its review of the draft of the Ministerial Regulation to support the accession to the PCT. This included a clarification of the procedures for setting up a receiving office and accepting PCT applications. The Department of Intellectual Property (DIP) is now waiting to receive the reviewed draft from the Council of State. The DIP will then affirm the reviewed draft and submit it to the Cabinet for approval. After approval by the Cabinet, the DIP will submit its request for Thailand's accession to the PCT to the Ministry of Foreign Affairs. The Ministry of Foreign Affairs will be responsible for depositing an instrument of accession to the PCT to the World Intellectual Property Organization. Ninety days after the deposit date, Thailand will officially become a Contracting Party of the PCT.

The DIP has been closely monitoring the progress being made by the Council of State in its review in anticipation of receiving the reviewed draft. Once the DIP receives the draft—which should happen in the near future—the remaining procedures described above should be completed within one month. Thailand's accession to the PCT could therefore take place as early as July or August 2009, and the DIP may possibly begin accepting PCT applications by October or November 2009.

However, it is important to note that the PCT national phase filing will not be retroactive for foreign applications that had already been filed in a foreign country before the effective date. PCT procedures for claiming priority will benefit applicants only if the first foreign application is filed after the effective date. Therefore, applicants must continue to be aware of the need to comply with the current requirements when claiming priority based on international applications filed before the PCT becomes effective in Thailand. ❖

**REGISTRATION** *(from page 2)*

Conversely, the same company has faced significant difficulties in gaining protection for the marks SLVR (short for Silver), KRZR (short for Crazer), SLDR (short for Slider), and SCPL (short for Scalpel) for products and services in Classes 9 and 38. Each of these trademarks was denied by the Registrar as being composed of nonstylized letters. Although most of these marks were allowed to lapse at the Registrar's examination stage, Appeals were filed for the marks SLVR and KRZR in Class 38 with the Board of Trademarks. The Appeals sought to refute the examiner's objections by focusing on the availability of the products bearing the marks in Thailand for an extended period of time and the origins of the marks in the words silver and crazer.

In its respective rulings, the Board upheld the Registrar's rejection by reasoning that the marks were composed of plain block letters and were not graphically represented in stylized manners, which made them contrary to Section 7 paragraph 2 (3). The Board further found that the evidence submitted, including supporting documents from Web sites, promotional materials, and brochures bearing the marks, was insufficient to demonstrate the extensive use of the marks in Thailand. Clearly, the Board did not give credence to the applicant's argument that the marks had backgrounds as defined words. These vowel-dropping marks were treated in the same manner as other marks consisting of letters that cannot be read as a word. For instance, a disclaimer was required for the letters "FX" included in the mark spaFX.

What conclusion can be drawn from the different treatment of these marks? The above examples indicate the crucial findings that removing all of the vowels in a mark seems to have a very negative effect on its registrability. When an applicant seeks registration of an entirely vowel-free mark, the Registrar and the Board are likely to perceive it as a lettering mark, not a word mark, due to the fact that there is no clear pronunciation for the mark. Marks with at least one vowel remaining, on the other hand, are likely to remain pronounceable, and thus the chances of success in registering such marks increases substantially. In sum, dropping one vowel can make all the difference.

Other examples substantiate these observations. The mark ALTRX was successfully registered in Class 10 with the disclaimer for "X" owing to the fact that the applicant was able to prove that the mark is read as a disyllabic word /altr-x/ based on the actual use. Similarly, the mark BIMATRX was smoothly registered for golf clubs in Class 28, despite the absence of the "I."

From this, the conclusion can be drawn that trademarks are likely to be registrable if some, but not all, vowels are removed. The exclusion of all vowels negatively affects the registrability of a mark because the Registrar and the Board perceive the mark to be an unpronounceable collection of nonstylized letters, rather than a coined word.

The trend of vowel-reduced trademarks continues to be on the rise among businesses hoping to create fanciful, modern, and fun brands that appeal to a mass audience. By remaining mindful of the distinction between vowel-reduced and vowel-free marks, brand owners will be able to ensure that they can enjoy full protection of their marks under the trademark law. Try registrng a trademrk missng a vowl and u may b succssfl. ❖

**PROPOSED AMENDMENTS** *(from page 6)*

### Copyright Act

It is likely that the copyrighted works to be covered by this amendment would be limited to only music, film, and software (made available as CDs, DVDs, or other electronic formats, but not including such works accessed through the Internet).

Buying pirated products would constitute a violation of the amended Act: *"Whoever, without appropriate reasons, buys goods, while knowing or reasonably should have known that such goods have been made by pirating any others' copyrights, shall be deemed to violate the Copyright Act.*

*"Whoever violates the Copyright Act as mentioned above shall be punishable by a fine not exceeding THB 1,000."*

Similar to the proposed amendment to the Trademark Act, landlords could be held liable for renting their premises to tenants who sell pirated products: *"Whoever provides rental of spaces or places, including the owner or occupier of any building or space, while knowing or reasonably should have known that the user of the building or spaces or places therein performs any action in violation of the Copyright Act, shall be deemed to violate the Copyright Act.*

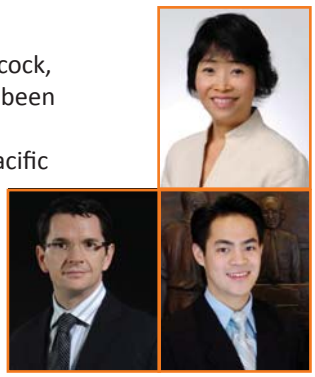
*"Any person who violates the Copyright Act as mentioned above shall be punishable by imprisonment not exceeding one year or a fine not exceeding THB 200,000 or both."*

These amendments have not yet been finalized and are subject to change as they move further along in the legislative process. Any updates on further revisions to these amendments will be presented in the next issue of *Thailand: IP Developments.* ❖

## THAILAND IP FIRM OF THE YEAR

At Managing Intellectual Property's 4th Global Awards ceremony held at The Dorchester Hotel, London, on March 31, 2009, Tilleke & Gibbins was announced the winner of the "Thailand IP Firm of the Year" award for 2009. This marks the third consecutive year that the firm has been voted the winner in this category. The Global Awards ceremony marks the culmination of MIP's five-month-long World IP Survey research and brings together the leading firms from major jurisdictions around the world.

## LEADING LAWYERS



Darani Vachanavuttivong, Alan Adcock, and Suebsiri Taweepon have each been identified as Leading Lawyers in Intellectual Property in the Asia-Pacific region by the 2009 *Asialaw Leading Lawyers* survey. Darani has now received this honor seven times, while this is Alan's fifth inclusion and the second for Suebsiri.

## MUSEUM OF COUNTERFEIT GOODS ATTRACTS ATTENTION

Tilleke & Gibbins' Museum of Counterfeit Goods—newly renovated after the relocation of the firm's Bangkok office—has been attracting a great deal of media attention this year. In the past three months alone, more than 20 television, radio, and print journalists have toured the museum and interviewed the firm's lawyers about its contents. Profiles of the museum have recently appeared in a number of prominent publications, including *The Christian Science Monitor* and *TIME* magazine. The Thai government's ongoing crackdown on counterfeit and pirated goods has also led to a large number of museum visits by Thai media, thereby raising awareness among local consumers of the issues surrounding IP infringement. Tours of the museum can be arranged by appointment.

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