ananda
INTELLECTUAL PROPERTY

"Nothing is more powerful than an idea whose time has come"
Victor Hugo

Newsletter - September 2011

LAUNCH OF ANANDA INTELLECTUAL PROPERTY LTD

I am delighted to inform you that I have founded Ananda Intellectual Property Limited, a dynamic, new intellectual property law firm in Bangkok, Thailand.

Ananda IP is directed and managed by myself and is supported with highcaliber talent and collaborators. It will grow to be a first–tier, dynamic, focused and strategic boutique intellectual property law firm.

I bring to Ananda IP eight years' experience as Managing Director of an international trademark and patent law firm, my networks, and professionalism.

We are also proud of our partnership with the well-established corporate law firm Law Solutions Limited, managed by Alexandre Dupont and Danai Triamchanchuchai.

The synergy between Ananda IP and Law Solutions will help both firms provide additional IP and non-IP services to all our clients.

We look forward to being at your service and hope you join us on this outstanding journey.

Franck Fougere

INSIDE THIS ISSUE

THAILAND'S COMPULSORY LICENSING PROGRAMME RE-EVALUATED

By Franck Fougere

Emerging economies are extremely attractive markets for pharmaceutical companies. While North American and European markets are saturated and highly regulated, South America and Asia (including China and India) are the new frontiers promising higher returns on investment.

Innovative and generic medicine manufacturers have been eyeing these markets for various reasons:

- In emerging countries, healthcare is financed largely out-of pocket (up to 60% in Asia) and the number of middle-class consumers is rapidly increasing;
- Governments and health authorities intervene less, which means fewer regulations and less demand for transparent drug pricing, as well as easier drug registration procedures;
- The cost for producing, developing and commercializing old and new drugs is significantly lower because of cheaper patent protection, lower production and drug registration costs, cheaper logistics and proximity to producers of active pharmaceutical ingredients;
- Emerging countries' rich biodiversity and traditional knowledge may help with the development of new drugs and methods of treatment; and
- Emerging markets are plagued by the triple threat of "old diseases" (tuberculosis and malaria, diarrhea and malnutrition), infectious diseases (SARS and H1N1), and silent healthcare pandemics (obesity, diabetes and cancer).

A recent study predicts that sales in 17 so-called "pharmerging" countries – including Thailand – will "in aggregate expand by $90 billion between 2009 and 2013".

This is unprecedented in the history of pharmaceutical industry. Civil society and international Non-Governmental Organizations (NGOs) are now using these figures to push for greater access to affordable medicines especially in poor and emerging countries.

"Of all the issues discussed at World Health Organization governing bodies, access to medicines consistently sparks the most potentially explosive debates," stated Margaret Chan, Director General of the World Health Organization (WHO) has stated. In Thailand, NGOs such as the Thai Network of People with HIV/AIDS, the Social Network for Cancer Patients, AIDS Access Foundation, Foundation for Consumers, Médecins Sans Frontières and Oxfam strongly lobby the Thai government to issue compulsory licenses.

Lower prices

Thailand initially resorted to compulsory licensing in 2006 and 2007 because original drug prices were perceived as extremely high. At the time, compulsory licenses were granted so that more patients could be treated.

Government statistics show that these goals were achieved. Compulsory licensing has saved 1.18 billion THB (US$40 million) on the purchase of anti-retroviral drugs alone. Total cost savings accrued to the Thai government is estimated at 7 billion THB (US$233 million) for the period between 2006 and 2011. Thailand's compulsory licensing forced down the prices of efavirenz and the lopinavir-ritonavir combination by 3.4 and 6.4 times, respectively, since the country announced its policy on HIV/Aids and cancer drugs in November 2006.

Access to drugs

Prior to compulsory licensing of the two drugs about 4,539 HIV-positive people had access to efavirenz and only 39 could afford the lopinavir-ritonavir combination.

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Compulsory licensing increased the number of patients receiving efavirenz to 29,360 ; more than 6,200 now receive the lopinavir/ritonavir combination. The Health Intervention and Technology Assessment Project found that compulsory licensing made drugs available to an additional 84,000 patients, half of whom needed the widely used heart drug, clopidogrel (Plavix).

TRIPs and transparency

From a legal perspective, Thailand clearly interpreted the rather vague conditions of the Doha Declaration (which allows a country to issue a compulsory license in the case of a public health emergency for the production of generics without the consent of the patent owner), Article 31 of the TRIPs Agreement, and its own legislation – (Thai Patent Act BE 2522 (AD 1979)) – to justify its resort to compulsory licensing. Section 51 of Thai patent Act allows government to grant compulsory license under specific conditions including "to carry out any service for public consumption". Section 51 also contains provisions regarding the royalty payments to the patentee or his exclusive licensee, a condition explicitly required by Article 31 of the TRIPs Agreement. It is said that the Thai government 'proposed royalty rate of 0.5% was rejected by some affected patent owners. Patent owners considered the royalty rate

arbitrary and too low, compared to other countries.

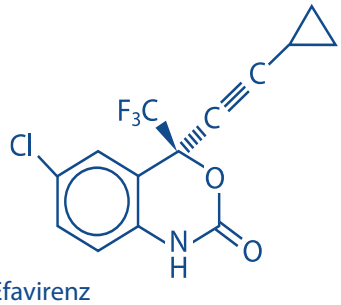
To avoid future conflicts, greater transparency is needed. It is needed now and over any future compulsory licenses.

Negotiations with affected patent owners should be made transparent before any compulsory licensing decisions are made. In addition, clear selection criteria for choosing a drug should be developed and incorporated into the Thai Patent Act or its Regulations.

Reassessing the GPO

Thailand must reassess and review the role of the Government Pharmaceutical Organization (GPO). The GPO's profit role is not the main issue: the GPO's profits are supposed to be used for the public good, such as to produce medicines in response to emergency situations like the influenza pandemic, and to produce orphan drugs.

The issue of contention is the GPO's status. The GPO is currently the largest domestic drug manufacturer and has a near monopoly over the country's public hospitals. Public hospitals are legally obliged to purchase 80% of their drugs from the GPO.



Efavirenz

Drug manufacturers perceive the monopoly enjoyed by GPO as unfair competition. Such a monopoly could prevent new drugs (including generics) from being commercialized in Thailand. Generic drug manufacturers hesitate to enter the Thai market for fear that the GPO could easily take over their investment. Ironically, the dominant position of the GPO could undermine the efforts of Thai authorities to develop the generic drug market, increase dependency on branded medicines and, ultimately reduce consumer access to affordable medicines.

*A complete version of this article is published in the May edition of Managing IP.

Franck Fougere

THE UNKNOWN RISKS OF COUNTERFEIT PRODUCTS

By Prathana Rebecca Knapp

Destruction of 22 tons of counterfeit medicines on 25 January 2011, Phnom Penh, Cambodia

Conference on Harmful Counterfeit Products on April 7, 2011 organized by FSP Mekong Project and French Cultural Center (Phnom Penh) with guest speakers, Mrs. Delia Bethell, WWARN and Franck Fougere. (Pictures USAID/FSP MEKONG)

Asia and Southeast Asia has long been a hub for both the production and consumption of various counterfeit products. Fake luxury goods for sale in Patpong and photocopies of Lonely Planet in Siem Reap might hurt only the IP rights (IPR) owner's bottomline, but other counterfeit products actually harm consumers.

Counterfeiters will make and sell anything for which there is a demand. Undiscriminating and lower-income consumers are ready buyers of substandard, unlicensed goods. The unfortunate truth is that many of the poor become consumers of harmful counterfeit goods unknowingly – usually due to lack of knowledge and, in some cases, the unavailability of properly manufactured products.

A case in point is that of anti-malarial drugs in rural Cambodia. Fuelled by the cost of branded medicines and simply by the lack of access to genuine medicines (due to the lack of infrastructure), the trade in counterfeit/substandard/falsified medicines has grown in Cambodia.

Many first-line-of-defense antimalarial drugs are widely counterfeit. Popularly counterfeited are Artesunate, Quinine, Chloroquine and Mefloquine. Counterfeits usually contain little or no effective ingredients, thereby leading to complications and secondary illnesses. Most significantly, the use of counterfeit anti-malarial medicines in Cambodia has led to the evolution of drug-resistant strains of malaria. The earliest strain of drug-resistant malaria was identified in Cambodia in 1970. As use of counterfeit medicines become more prevalent, increasing numbers of pathogens evolve into drug-resistant strains.

It is impossible to determine the current number of annual fatalities caused by harmful counterfeit products. What is certain is that counterfeit products do cause harm. In 1999, 30 Cambodians died after taking counterfeit anti-malarials prepared with sulphadoxine-pyrimethamine but sold as Artesunate. Other common harmful counterfeit drugs are those used to treat HIV/AIDS and tuberculosis.

It is obvious that there are potential risks associated with the use of

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pharmaceuticals. Less obvious is the exponential increase of risks when counterfeit pharmaceuticals are used.

Most surprising, however, is that counterfeit versions of seemingly benign consumables can also cause grave injury. Counterfeit versions of beauty products, foods and drinks, and cigarettes can also be lethal. In March 2010, a 23-year-old Cambodian woman died after using a skin-whitening cream that contained high levels of mercury. Counterfeiters trade on the rightful IPR owners' reputation and consumers' lack of money and awareness. Production standards, quality control, and actual ingredients are irrelevant to these makers of harmful goods. The best defense for all consumers anywhere is to buy trusted brands, from reputable businesses. IPR owners can best defend against the disrepute caused by harmful counterfeit products by protecting their IPRs and working with local authorities to develop the necessary safeguards.

Prathana Rebecca Knapp

ANANDA IP NEWS

PUBLICATIONS

- "Finding a Middle Ground, Edward Kelly and Franck Fougere debate the merits of Thailand's program of compulsory licensing for pharmaceutical patents", Managing IP, May 2011, pages 100-103.

CONFERENCES & SEMINARS

- The Dangers of Counterfeit Medicines and Substandard Products, April 7, 2011, Centre Culturel Français, Phnom Penh, by Delia Bethell and Franck Fougere;
- The Protection of Patent Designs in Europe, April 26, 2011, WIPO IP Day, Bangkok, by Franck Fougere;
- Seminar and training on counterfeit products, April 29, 2011, organized by French Ministry of Foreign Affairs, FSP Mekong Project, Phnom Penh morning session by Franck Fougere, Edward Kelly, Co-Head of Siam Premier and Anne Devaud, Global Anti-Counterfeiting Manager Sanofi-Aventis; and
- The European Approach to Design Protection and Examination, ASEA-NUSPTO Workshop on Design Examination, May 10- 12, 2011, Bangkok, by Franck Fougere.

STUDIES

- ECAP III-AIPA Regional Study on Status of ASEAN IP Professionals by Franck Fougere and Prathana Knapp; and Fighting Harmful Counterfeit Products in Cambodia: Challenges and Recommendations, FSP Mekong Project, French Ministry of Foreign Affairs by Franck Fougere.

NEW RECRUIT AT AIP

Prich Kasettham

Prich Kasettham joined our firm in August 2011 as Trademark Lawyer. He graduated from Assumption University, where he obtained a Bachelor Degree in Law (2011). Prich is a member of the Asian Law Student Association (ALSA), AIESEC and IPAT (Intellectual Property Association of Thailand) and fluent in English.

ANANDA IP PARTNERS AND COLLABORATORS

Franck Fougere, Managing Partner

In creating Ananda Intellectual Property in 2011, Franck lays the groundwork for our services with his extensive experience. Franck brings to Ananda Intellectual Property over eight years' experience as Managing Director of an international IP firm in Asia. In addition to servicing several high profile multinational corporations in Europe, China, and Southeast Asia, Franck is a frequent speaker of cutting-edge IP issues at professional symposiums and conferences. A recognized expert, Franck is a regular lecturer for the World Intellectual Property Organization (WIPO) and has authored numerous studies and articles. Franck Fougere is also the current President of the Franco Thai Chamber of Commerce (FTCC).

Danai Triamchanchuchai, Partner

A graduate of Chulalongkorn University and a member of the Law Society, Danai has extensive experience in Business Law and Thai law. His areas of Expertise include Corporate Establishment, Real Estate Transactions, Business Promotion, and Trademark Law.
Danai is a founding partner of Law Solutions Limited, a well established corporate law firm associated with Ananda IP.

Prathana Rebecca Knapp, Partner

Rebecca is a graduate of UC Hastings College of the Law and a member of the California Bar Association. After receiving her JD, she practiced Corporate Law at Herbert Smith, Thailand where she was involved in many multi-million international M&A projects. Rebecca's law articles have been published by eminent media such as the IFLR (International Financial Legal Review), Bloomberg Law, and Director magazine. She has also co-authored/edited studies and research papers on various legal issues, including IP. Strategic planning and Contract Drafting are Rebecca's areas of expertise. She is fluent in Thai and English.

Alexandre Dupont

Alexandre is a graduate of the School of Law, University of Lille (II), where he obtained a Masters in private law (1998) and a Masters in International and European law (1999). Alexandre has advised and assisted European clients in Thailand for more than 10 years. Alexandre has lectured on and authored several academic, commercial articles, and presentations at Business forums. Alexandre is a founding partner of Law Solutions Limited. He also serves the Franco-Thai Chamber of Commerce as Honorary Secretary.

Ananda Intellectual Property Limited

SUGGESTIONS WELCOMED

Have an IP related question or topic you would like us to answer or cover?

Email us at aip@ananda-ip.com

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