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WITH **Darani Vachanavuttivong, Co-Managing Partner; Alan Adcock, Partner; Tiziana Sucharitkul, Co-Managing Partner**

Tilleke & Gibbins

Practical Law Company nominated TILLEKE & GIBBINS the "Leading" Life Sciences firm in Thailand The nomination was based on firm and lawyer track records – could you describe what makes Tilleke & Gibbins so much better suited for pharmaceutical companies than its competitors?

Tiziana Sucharitkul: We stand out and are different due to the size and strength of our IP practice. We also stand out and differentiate ourselves because we have a regulatory affairs section, which is something relatively new to the firm. We have brought that in and integrated it into our Life Sciences practice, so we are able to serve clients on different levels for their legal pharmaceutical needs in Thailand.

Darani Vachanavuttivong: In addition to what Tiziana says, we also stand out because, unlike other firms, our team includes scientists and technical patent agents. We have more than ten patent agents, and we have three pharmacists working in regulatory affairs. In addition to that, we work closely with the Patent Office in Thailand to address problems of patent registration in relation with the pharmaceutical industry.

Alan Adcock: Our Life Sciences practice not only touches on registration, enforcement, and litigation of intellectual property rights, but it also deals with product registration at the Thai FDA and MOA, advertisement clearance, product registration, and lobbying the Thai FDA and MOA about new active ingredients or claims that maybe they have never seen.

But the third asset in our pharmaceutical practice that makes us more distinctive than any of the others is commercial agreement services. We draft and negotiate clinical trial agreements for our clients, we do informed consent agreements, site selection agreements. We have a very strong practice in clinical trial commercial contract drafting. We also deal with all the advertisements that have to be cleared before the Thai FDA allows them to be used; we negotiate on behalf of different innovator drug companies in terms of whether or not an advertisement would actually be approved by the Thai FDA. We even deal with distribution agreements; often our clients will ask us to draft a distribution agreement or to review the distribution agreement ourselves.

Tiziana Sucharitkul: At the same time, because we are a full-service law firm, we can also meet other legal needs of our pharmaceutical clients. For example, our Regulatory Affairs department has worked very closely with our IP department and our Dispute Resolution department in terms of advertisement irregularities that have been found and reported to Thai authorities. Therefore, as you can see with this example, we can assist clients across the full range of their legal needs.

Can you illustrate one of the strongest cases that the law firm won in our industry?

Alan Adcock: Tilleke & Gibbins litigates more pharmaceutical patents than any other law firm in the country. Obviously the majority of that litigation is for innovator clients, taking action against generic patent infringers. In Thailand there is a special provision under the Patent Act whereby the act of submitting a market authorization approval application to the Thai FDA is an exception for patent infringement. Generic companies know this exception to what is normally pharmaceutical patent infringement, so often generic reformulators will go ahead and present for approval at the FDA, which is then usually granted.

Now, that is fine with innovator drug clients because we know the rules and regulations are such. The problem arises when the generic infringer actually takes that authorization of the Thai FDA and then commits a traditional infringement act; maybe through a government hospital tender bid, or by speaking to government hospital procurement pharmacists about buying the now registered product. Tilleke & Gibbins does a lot of work on advising innovative manufacturers on pre-litigation strategy to immediately launch an infringement application before the IP&IT Court. “Do we monitor for a little while, or do we inform the infringer of our pre-existing patent rights?” That is the kind of pre-litigation strategy that sets us apart from others who might just immediately jump into court. Sometimes these generic reformulators will commit an infringement act, but not to a degree sufficient to implement their patent rights fully. That is the type of patent litigation that we handle normally for innovator drug clients.

When we were here in 2007, the Abbott situation was in full flow, and the international pharmaceutical community was obviously worried… do you see any improvements in IP protection? With initiatives such as Creative Economy and its membership of Patent Cooperation Treaty, How far is Thailand from being removed from the US Priority Watch List?

Darani Vachanavuttivong: You mentioned that you interviewed our former colleague Edward Madden in 2007, and not much has changed since. From the statistics of the DIP from 2005-2010, only very few pharmaceutical patents were granted; less than 2 percent of

the pharmaceutical patent applications were granted during this period. If we are talking about trade mark protection, I do not see major hurdles in Thailand; the process is quite fast. But for granting of pharmaceutical patents, it seems to be problematic. Thailand has strong NGOs that do not like to have patent protection for pharmaceuticals because they are worried that this will result in high drug prices.

Still, we have strong IP protection in place for all kinds of products, maybe with the exception of pharmaceuticals. Compulsory licensing was a key issue in 2006, which resulted in the country ending up on the US Priority Watch List in 2007.

In terms of non-pharmaceutical issues, many parties were very disappointed that Thailand could not launch the anti-camcording law; it will do so either at the end of this year or next year, which will be a great boost for Thailand to move off the US list and solve long-time problems.

When we spoke to Mr. Pipat of FDA, he told us that the agency is working hard to get the industry ready for ASEAN. Although pharmaceutical industry might be leading the way for the implementation of a harmonized regulatory scheme, we hear a lot of concerns about harmonization progress … With less than three years until the AEC is to be formed, according to you, is Thailand ready?

Alan Adcock: For harmonization within the ten nations of ASEAN? I don't think Thailand is ready. No one is. There are other sectors of FDA regulation that are nearer to being ready than pharmaceuticals. Cosmetics of course already enjoy harmonization; and medical devices are next on the bloc. I appreciate what Dr. Pipat has said, but innovator drug companies have not really been involved in those discussions. They happen at a government agency level, and there is very little request for input from the private sector in terms of the pros and cons of harmonization. I am not even sure whether many of the innovator clients would appreciate or support harmonization within ASEAN. Within the region, there are major distinctions between price points; pharmaceutical pricing in Thailand is a lot higher than in neighboring jurisdictions. Harmonization regarding the registration process may or may not be something that people or governments may want to encourage right now. Cosmetics absolutely, medical devices should be next, food and drugs willl probably be implemented at a later point in time.

And how can Tilleke & Gibbins help its clients to get ready for this?

Alan Adcock: We are an international firm with offices in Thailand and Vietnam. We are a member of various international law firm associations, so we have great access to comparative perspectives on how market

harmonization or integration has been rolled out in other parts of the world; North America and Europe, for example.

We do act for the world's largest innovator drug companies, so we are familiar with their patent drafting strategies; we understand how a product goes from idea to laboratory and on to innovation, formulation, patenting, and market access; because we have access to such good international practice and comparative understandings, we feel that we are unique in terms of competitors because we are privy to that information and can share it with our clients, and that is how we can participate in advising our clients on the status of 2015—which products are next, what are the pros and cons. And we can take our understanding of what is happening locally and use it in the context of what our clients have taught us internationally in order to develop and deliver better advice.

Of course there are international standards and procedures, but on the other hand there are local regulations; how do you commensurate the differences between the two?

Alan Adcock: Just like in Europe; it is one integrated economy, but with different rules and regulations for each of the member states. A good lawyer will understand the different laws in which their clients have to operate. So if there are differences between local Thai regulations versus ASEAN FDA pharmaceutical regulation, we navigate between regional and local legal compliance. And that is what we do every day in our practice. As a member of the regulatory affairs group this is the type of advice that we have to give daily; yes, the Thai FDA does operate differently, and the Thai FDA requires five additional documents to what you are probably used to supplying to a European regulator. We already have that kind of experience, and as we get closer to 2015, that kind of strategic advice and identifying the differences between the system here and the system that our clients are probably more comfortable with in their jurisdictions is going to be a bigger part of the advice that we have to give.

Darani Vachanavuttivong: When we provide advice to clients, we have always provided a planning analysis of the possibility of getting IP protection, not only in Thailand but in Indochina and other ASEAN countries. Even in Europe or the USA. We have not been waiting for 2015. We are already assisting with IP protection regionally. We work with our clients to help them develop and then commercialize their products.

With the pharmaceutical landscape changing quickly – rising generics, branded generics, AEC integration, how do you expect the number and nature of cases to develop?

Tiziana Sucharitkul: I think the Thai government makes sound decisions in terms of pharmaceutical access for the people. We have three medical insurance schemes in

Thailand, and those are serving as models for neighboring jurisdictions. Two months ago the Thai and the Vietnamese FDA signed a Memorandum of Understanding for a knowledge share to provide Vietnam with the opportunity to look at the Thai three-level insurance scheme and to see how it may be implemented in Vietnam. As long as innovators are still here importing or manufacturing, as long as there are generic alternatives as well, and as long as those generics are not infringing in terms of any patent rights, then both innovators and generics can co-exist in the market as they do in most countries.

Will it become more of a challenge to protect the consumer from sub-standard drugs and companies from IP infringement with the free flow of goods following trade harmonization under AEC integration?

Alan Adcock: I think we have to look at other countries and see what the pharmaceutical landscape is like in those countries. The Indonesian pharmaceutical market for instance is very difficult to enter; you cannot formulate pharmaceuticals unless you have a factory there.

If we would come back in five years for the next edition of our report, where will you have taken TILLEKE & GIBBINS's pharma practice?

Darani Vachanavuttivong: Although the only other country in which we are physically present is Vietnam, with offices in Hanoi and Ho Chi Minh, we are already serving clients on a regional basis throughout ASEAN in Indonesia, the Philippines, Laos, and Cambodia. I hope that when you come back in another five years, our regional work will have extended and have become more deeply rooted. In 2015 with the opening up of the region, we hope to be one of the first ones to tackle new challenges which might not even be on the horizon yet.

Alan Adcock: One of the opportunities that we would excel at would be multi-jurisdictional clinical trials, a phase 1 with trials in Thailand, Myanmar, Cambodia and Vietnam, if those clinical trial regulations would allow us to do that.

What is your final message to the pharmaceutical community about TILLEKE & GIBBINS's commitment to ensuring a safe working environment for the pharmaceutical community in Thailand?

Alan Adcock: For multinational corporations, our 122 years of existence should provide a significant amount of comfort in terms of their selection of a legal service provider in Thailand. We are also the oldest licensed foreign law firm in Vietnam, and because of this long-term expertise on both ends of the Indochinese peninsula we are beginning to see a lot more scope to provide advice and legal services, not just on the peninsula but also in other ASEAN member states. There are not many companies in this part of the world with

a history as long and as diverse as ours, and it is a main calling card in terms of services that we offer and in how we can distinguish ourselves throughout ASEAN.

Tiziana Sucharitkul: We are a Thai firm with Thai lawyers and we know better than others how to operate in this environment. Yet we are also an international firm and we understand Western clients. Our Thai lawyers, many of whom have spent a significant number of years abroad, together with our foreign lawyers who have spent a significant amount of time in Asia, know what it takes to get the job done and to achieve success for all our clients.

Darani Vachanavuttivong: The firm is very committed to the pharmaceutical practice. We have a lot of clients with this focus and because of that and because of our talented lawyers and staff, we are committed to exploring innovative solutions for clients. If a client has unique legal needs in the region, they can feel confident that we are making the necessary investments in our pharmaceutical services in order to be able to meet their needs. As far as we are concerned, we definitely will be investing in this area, we definitely will be at the cutting edge of legal services for the pharmaceutical industry because it is an extremely important part of our legal practice.