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# REGISTRATION FIRMS EXPLORE OUTSOURCING OPTIONS

Paul Russell and Alan Adcock discuss the increasingly popular trend to outsource IP legal counsel in Thailand and the rest of Asia. Samantha Birch reports.


"ANY COMPANY WITH SERIOUS AMBITIONS OF GLOBAL REACH WILL AT SOME POINT NEED TO REGISTER ITS VALUABLE AND PROPRIETARY IP, AND ASSOCIATED PRODUCTS WITH THE REGION'S VARIOUS GOVERNMENT AGENCIES RESPONSIBLE FOR REGULATING THE SALE, DISTRIBUTION AND ADVERTISING OF THOSE PRODUCTS."

The attractions of expanding business in Asia are well known. So are the challenges. Any company with serious ambitions of global reach will at some point need to register its valuable and proprietary IP, and associated products with the region's various government agencies responsible for regulating the sale, distribution and advertising of those products. With Asia's unique culture comes a distinctive legal system, which requires local guidance to navigate.

Tilleke & Gibbins is the oldest and largest independent multi-service law firm in Thailand. Paul Russell, of counsel and head of regulatory affairs at Tilleke & Gibbins, has more than 15 years' experience in regional product registration and regulatory counsel in Asia, and is perfectly placed to review recent developments. He has worked with clients across all aspects of the field, specialising in local Food and Drug Administration (FDA) and Ministry of Agriculture (MoA) related work. Russell has made a point of understanding and interpreting the most recent changes to product registration regulations across the continent, focusing on the likely impact on the future of business in the region.

## Outsourcing

One recent trend in particular has been an increase in small and medium-sized food, pharmaceutical, chemical and cosmetic manufacturers around the world. As these companies have grown, it has become clear that they have insufficient product registration and IP resources in-house, which has led to a growth in the outsourcing of these needs to legal counsel. The concurrent increase in the stringency of registration requirements for these products has heightened the desire for external counsel, as companies seek niche expertise to ensure that their products are quickly and fully protected.

"This trend of companies increasingly turning to larger, more experienced independent registration firms such as Tilleke & Gibbins for assistance is something I have noticed through personal experience," says Russell. "Independent product registration firms usually have a diversified client base—multinationals, other corporations and entrepreneurs—in multiple industries. Companies are outsourcing their registration work to these firms because of their in-depth and extensive knowledge of consumers, and of the regulatory industry."

Companies are looking for external product registration and IP counsel with a range of core skills. A long, proven track record of successes, a tried and tested relationship with the regulatory authorities, and a breadth of available services are all key criteria.

"Companies are outsourcing their product registrations to large independent product registration firms with full-cycle services—preparation, filing and follow-up—for all product applications. Companies with product registrations are beginning to realise the convenience, relief from worry and cost-effectiveness that are provided by the cradle-to-grave approach of these large firms."

## Asia experience

A trend like this attracts various parties: there are the external IP legal counsel looking for clients; large companies that recognise the benefits of outsourcing and want to know more; and small and medium-sized businesses that need to know what scale of external firm would best suit them. Russell says his wealth of knowledge and experience allows him to guide them through the maze of possibilities.

Eager external regulatory and IP counsel in Asia should carefully consider their staffing before offering their expertise to large firms.

"The registration of food, pharmaceutical, chemical and cosmetic products requires different types of regulatory skills and knowledge. 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," Russell suggests. "This should be a multidisciplinary staff consisting of, for example, lawyers and pharmacists, or scientists with the technical knowledge required to register pharmaceutical products."

On the flip side, large firms potentially looking to hire should choose their external IP counsel carefully. In addition to appropriate staff demographics, they should consider prospective counsel's experience and the strength of their relevant local relationships.

"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," says Russell. "They should also have a client base that has enabled the firm to develop in-depth regulatory and required industry knowledge. In addition, they need to have a staff large enough to prepare, file and follow up on all product applications, as well as obtaining registration licences in the shortest possible time."

For smaller companies, though, a vast body of legal staff may not be necessary, and they may benefit more from a smaller external IP counsel firm that can offer one-to-one guidance.

"Small firms that want to register their products in Asia, but that have very limited resources due to their size, should look to a small or medium-sized product registration firm, but still one that has a proven track record and tested relationship with the regulatory authorities," suggests Russell. "They should look for a registration company with flexible and cost-effective fee arrangements that meets their needs."

## FDA procedure

Whether you choose to follow the flock and outsource your IP counsel, or forge your own path with in-house staff, it is important to understand the nuances of FDA and MoA registration procedures in Asia—what you are required to file, how you are expected to follow up, and how long the process is likely to take.

"The company that files the registration application must be a local company," says Russell, "because if your product does not work, or any issues are raised with it, the government of the country you are registering in needs to know that there will be someone local to take responsibility."

While opening a local branch in the jurisdiction is an obvious option, it 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," says Russell. "They must obtain an import licence 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 evident benefits to this method—cost and time savings to say the least—it is important that the method is conducted with caution, and with the relevant safeguards carefully woven into the contract between the original company and the nominated representative.

"In Asia, it can be difficult, because the appointed company is the registrant of the product, so if you have a disagreement with them or decide to terminate your work with them, you can be left with problems," explains Russell. "You can protect from this in the initial contract between you, 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, this will not be legal and, so instead, you will need to say that the other party must destroy the registration and provide proof to that effect." Maintaining an ongoing, uninterrupted supply of product during disputes is obviously the goal.

Once your local branch has been established, or representative company nominated, the FDA/MoA will then review your description of your product and provide a product classification. Then, Russell says, it is important to ensure that the application you file with the agency includes all of the documents required for the specific class of product.

"After the application has been filed, it must be followed up on a regular basis, until the agency issues a registration licence. In any country in Asia, this typically takes one to two years, but the duration depends on how often you follow up in person," says Russell. "Your relationship with the FDA is important, because the FDA and MoA are inundated with work throughout Asia. Making the effort in person reminds them to take your call; then later, your call reminds them to prioritise your application. It's important to realise that you cannot and must not ask them to bend the rules in your favour—you can only ask them to remember your application."

## Data exclusivity

It is such a commonplace clause, that data exclusivity is often assumed when filing patent or product registration applications. In Asia, though, this protection is not always guaranteed, as the guidelines across the continent are often unclear. This can be particularly concerning for pharmaceutical companies, which rely on the measure for protection of their patented products from the development of competitive generic drugs.

It is governmental promotion of the generic industry that is the primary reason that data exclusivity is uncertain in Asia, according to Alan Adcock, deputy director of intellectual property at Tilleke & Gibbins. Legislation was nonetheless approved in Thailand in 2007 to provide some extra protection.

"In Thailand, a ministerial regulation on 'Governing Keeping of Trade Secret of Pharmacopoeia Register Information' was adopted and published on September 6, 2007," says Adcock. "This regulation only protects against unauthorised disclosure, though, and fails to provide a clear solution to the notion of unfair commercial use, such as reliance on such information by the FDA or third parties."

Another important issue with this legislation is that 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. On expiration of this protection period, the information would no longer be protected and third parties would have a right to see it. Data exclusivity protection periods in Asia are directed at third party disclosure. In practice, however, Asian FDAs often use the information during the course of their vetting of generic approval applications, which is currently deemed permissible.

China has provided provisions in relation to data exclusivity in the PRC Implementing Regulations of the Drug Administration Law, effective from September 15, 2002. Under these provisions, an originator for "drugs containing new types of chemical ingredients" is entitled to six years of data exclusivity, during which time no one may use the data for "unfair commercial use" without the consent of the originator. Unauthorised disclosure raises liability for compensation. However, the law empowers the drug administrative authority to disclose the data in certain circumstances such as for "the interest of the public".

"In the absence of stringent data protection," says Adcock, "it is easier to rely on Asian Bolar provisions (research and non-commercial 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 contains a provision intended to safeguard the confidentiality of marketing approval data submitted to the FDA. The Act recognises that data or 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, as a whole or a part, in the form of a testing result or other information regarding its preparation, discovery or creation. The unauthorised use and disclosure of such information may lead to an actionable offence punishable by civil and criminal remedies.

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