IP LAWS AND DRUG APPROVALS IN ASEAN

The Association of Southeast Asian Nations is attempting to speed up the approval process for pharmaceutical products by working more closely with the Food and Drug Administrations, as Areeya Ratanayu explains.

Recently, the members of Association of Southeast Asian Nations (ASEAN) attempted to improve product registration efficiency and marketing approval for pharmaceutical products. The ASEAN harmonisation regime hopes to improve the standard of the Food and Drug Administrations' (FDAs) regulatory reviews in ASEAN countries. Despite these efforts, however, the lingering obstacle of a lack of intellectual property understanding continues to leave pharmaceutical companies with difficulties when dealing with product registration in several ASEAN FDAs.

Slow process of drug registration

The most common difficulty that pharmaceutical companies face with ASEAN FDAs is the sluggish pace of obtaining marketing approval. For example, for a new drug in Thailand, the process will take at least two years. Nevertheless, the time it takes for generics to obtain registration is much shorter—six months to one year to obtain marketing approval is not uncommon. The shortage of capable officials and resources within the local FDAs is a familiar explanation. Although timing is crucial to some pharmaceutical products, it may take years before FDA approval is obtained. This is the price that drug innovators have to pay.

Pro-generic view of governments

Although not stated in official policy statements, the implementation of six compulsory licences in the last two years illustrates that Thai officials in healthcare agencies have developed a pro-generic view. While innovator drug companies must submit information, including clinical trial data, the registration process for generic products is much faster and more lenient compared to the registration process for original drugs. Whether this is intentional or not, this policy gives the impression that the government is more favourable towards generic companies.

The Philippines has also demonstrated a pro-generic approach, especially since the implementation of the latest Universally Accessible Cheaper & Quality Medicines Act 2008 (also known as the Cheaper Medicines Law). The aim of this Act is to facilitate the distribution of generics and reduce the price of drugs in the market. In order to facilitate the introduction of the generic version of patented drugs and medicines into the market immediately after the patents expire, the Cheaper Medicines Law has legitimised the 'early working' of such patented drugs and medicines.

Patent linkage

A patent linkage system has been in place in the US since 1984 due to the implementation of the Hatch-Waxman Act. The law requires drug developers to notify the FDA of all patents that exist in relation to a drug seeking marketing approval. The purpose of the FDA keeping the patent record is to prevent the registration of the generic drug before the patent of the original drug expires. Such a system helps minimise the chances that an infringing product would be easily available in the market.

Since 2005, the Filipino Bureau of Food and Drugs (BFAD) has been accepting and processing applications for product registration without the need to verify whether or not the pharmaceutical product being submitted for registration is under patent protection. Moreover, the BFAD can grant marketing approval of a generic even though it is aware of an existing patent.

Although the patent linkage system is becoming more and more common, it is still not widespread among ASEAN FDA agencies.

Bioequivalence and data exclusivity

Several local authorities in ASEAN countries allow generic drug manufacturers to rely on the data/dossier submitted to the FDA by innovator drug companies. The generic drug companies need to prepare their own bioequivalence studies and the FDA will make comparisons with the studies already finalised by the originator companies. Conducting a bioequivalence study is much simpler and less costly than carrying out a full-blown clinical trial, which the originator company is required to conduct. However, clinical studies are not required for follow-on generic applications.

In Thailand, in an attempt to provide assurance to drug innovators, the information owner has the right to request the FDA to maintain the confidentiality of the data submitted to the office, according to the Trade Secrets Act. The FDA would then have "the duties to maintain the trade secrets from being disclosed, deprived of or used in unfair trading activities".

A further regulation has slightly clarified the extent of the protection by stating that the FDA is only in charge of the protection of physical disclosure of confidential information for five years from the date of recordation. The regulation however fails to prohibit the FDA or generic companies from relying on the innovator regulatory data to approve the generic versions for a determined period of time.

Countries such as Indonesia do not have any regulations on data protection. However, in its pro-generic approach, a bioequivalence study is recognised for generic applicants seeking marketing approval.

Better understanding of IP issues

Several myths about intellectual property law persist among healthcare professions in ASEAN countries. For instance, because of the Bolar provision, non-IP practitioners often misunderstand the concept and believe that when the FDA gives marketing approval to any drug, that product is then cleared for marketing, regardless of any potential patent infringement issues. Furthermore, several of the healthcare professions understand that a drug patent lasts for 10 years, compared to the usual 20 years for an invention patent.

Another common scenario applies to trademark law and counterfeit drugs. Counterfeits of pharmaceutical products are an unacceptable threat to patients and can lead to dangerous risks, including death or permanent disablement. Drug regulators deem as counterfeit any drugs that contain incorrect ingredients, the incorrect amount of active ingredients, or no active ingredients compared to the genuine drug. In applying the trademark law, the definition of counterfeit drugs encompasses a broader range of circumstances. For example, the get-up of a product or trade dress can also invoke infringement actions.

Due to the lack of proper connection between the intellectual property law and regulatory compliance, the FDA is not obligated to check whether the name used for a generic drug is similar to the brand name of another drug, nor do they have to check whether the formula or compounds of the generic drug infringe any patents.

Speeding up product approvals

Obviously, the issue of regulatory compliance for health-related products coupled with the FDA's view of intellectual property makes the marketing approval process become even more problematic. Education is essential in order to adjust the mindset of FDA representatives with regard to their views on intellectual property law. Training should be supported and could be organised in association with local IP offices and/or third parties to introduce the concept to officials that rights granted by two agencies should not be contradictory.

Further strategies to overcome these issues

Direct contact with FDA representatives

When facing problems with the FDA, a business operator could draft a letter or set up a meeting in order to discuss the issues involved. Since most FDA representatives are scientists and do not comprehend intellectual property matters, a short explanation by phone or a face-to-face meeting with the FDA officers can clarify matters. Writing letters to these officials in English may not be a good strategy, especially to the FDA in ASEAN countries where English is not the official language. The recommendation is to conduct interactions with officials in their native language, which will usually facilitate discussions with the FDA's representatives.

Harmonisation of practices

By referring to the international practice as the standard, companies through industry associations should try to request and discuss harmonisation of the regulatory process and intellectual property rights. The point to be made is that the intellectual property rights conferred by the IP office would be undermined if they were overcome by other agencies.

Focusing on the consequences of delay

Although the law involving FDA practices and the administrative law allow the party that suffers as a consequence of an FDA delay to file an appeal to the administrative court or relevant bureau, few companies that must deal with the FDA on a daily basis utilise this channel. Among the ASEAN countries, the long-term relationship between business operators and local officers is something that must be maintained.

Therefore, communication between the FDA and companies seeking to expedite the process is a delicate issue. Instead of drafting a long complaint about the tedious and unproductive process that causes the delay of product approval, it is recommended that the consequences of the delay, such as the delay for consumers to have access to the drug, should be discussed.

These issues will not disappear until companies and other related agencies get involved and enhance the FDA's knowledge about IP rights and the risks involved when product approval is delayed.

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