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Bolar Provision Revisited: Thailand's Approach in the Age of Patent Expiry

Usually, during the life of a patent, acts of manufacturing or importation are considered an infringement of the patent owner's rights. The "Bolar provision" exempts from infringement all uses of a patented product that are required for the Food and Drug Administration (FDA) approval process for drugs not previously registered. The point in time, during the life of a patent, when a generic drug company can apply for FDA approval is, and has been for some time, rather vague in Thai law.

Applying for marketing approval (the first stage in an FDA drug application) normally takes around two years for a new generic product. Therefore, the practice that has developed is for new generic product applicants to apply for their marketing approval two years prior to the expiry of the patent, of which they are claiming bioequivalence from the originator product.

As many drugs come off patent over the next few years, this procedure will become increasingly relevant. For many big pharmaceutical companies, the "patent cliff" has already been reached. This article will examine the issues and discuss how pharmaceutical originator companies can seek to maximize their IP protection under the current law and regime.

"New Generics" and "Generics"

The Thai FDA differentiates a "new generic" from a "generic." A "new generic" is the first generic version of a previously patented originator drug. Therefore, there are certain bioequivalency tests that must be carried out to obtain new generic status. The process takes around two years to complete, and the new generic product applicant must also supply patent details regarding the originator from which it claims bioequivalency.

Patent Expiry Issues

The patent cliff has already started to allow for generics companies to enter the market. Generics companies will therefore seek to rely on Bolar provisions to gain quick access to the market.

If the originator drug company then patents an improvement, for example on a novel formulation or combination, then both the generics company and the originator company should be able to compete on some level—the generics company will be able to make a drug according to the disclosure in the original patent, and the originator company will be able to sell, exclusively, its improved product.

This would work efficiently and seamlessly if the originator could rely on certain legal protection. The originator must be able to obtain a granted patent on its improvement and ensure that the generics company does not "jump the gun" in taking its product to the market.

In Thailand, there are a few barriers to such protection. The first is that pharmaceutical patents are taking far too long to be granted—potentially up to ten to twelve years in many cases. Many patent applications for such improvements therefore have not yet been granted, resulting in uncertainty in the market over the availability of exclusivity for such products. However, it should be noted that originators can use the FDA's Safety Monitoring Program to obtain two to four years of market exclusivity upon applying for marketing approval (this would typically be toward the start of the patent term).

A second barrier is that the Thai Patent Office has recently trended toward disallowing "new use" patent applications and method of use/treatment claims. Nevertheless, the current position remains that it is still possible to obtain certain medical use patents, despite some restrictions in the scope in recent years.

Data Exclusivity and Trade Secret Issues

The owner of a patented originator drug chooses to make certain information publicly available, in return for a grant of 20 years of market exclusivity for the drug covered by that patent. However, there is also certain information that is not disclosed in the patent, such as the testing results (e.g., for efficacy and safety), the preparation information, or any other details of creation or discovery. Such additional information is often required by the FDA and held on file.

It is important, therefore, for pharmaceutical companies to be able to rely on the FDA to maintain the confidentiality of such information during the life of the patent and thereafter. There is a seldom-used Trade Secret Notification system for new drugs that are classified as New Chemical Entity products, which guarantees confidentiality for five years. Due to the time constraint, though, this system has not been popular.

Importantly, when a new generic applicant applies for bioequivalency, the information (some of which may be trade secrets) is not disclosed to the new generic applicant, but clearly some commercial advantage has been gained by reliance on it. The Trade Secrets Act 2002 only prevents direct disclosure of such information to third parties. It does not deal with "unfair" commercial use of such data, and the practice of allowing generic manufacturers to indirectly benefit from the existence of such information on the FDA files continues. Notably absent from this procedure is any form of consent from the owner for such "use" of the confidential information—the patentee.

Infringement and Preliminary Injunctions

If you are an originator company with evidence that a generics company is infringing your patent within the last few years of its life, what action can you take? With strong supporting evidence, you could apply for a preliminary injunction. But if the activity you are complaining about is not resulting in any damage—for example, if the generics company is merely preparing for future use (such as R&D or import for regulatory marketing approval)—then your application may be refused. In seeking a preliminary injunction, the key would be to show a strong prima facie case with specific acts of infringement, risk of irreparable damage, and an emergency situation (for example where the goods are about to be sold or exported). Of course, this assumes that the originator has obtained a granted patent in time.

ASEAN and the Future

The procedures of each ASEAN member's drug regulation department have to be in harmony by 2015. For new drug applications, the process has been partially harmonized already (on quality, safety, and efficacy requirements). One concern is if certain countries in ASEAN grant marketing approval earlier than others and their regulatory changes are not aligned. From 2015, goods are supposed to move freely from one country to the other; however, such an irregularity in standards of marketing approval, combined with a situation where an originator company only has limited patent coverage across the region, will be disruptive to the industry. For example, an originator company may have patent coverage in Thailand and Vietnam, but not in Cambodia and Laos. Cambodia and Laos may then allow marketing approval for a generic product much earlier, which would give them access to the Thailand and Vietnam markets under ASEAN Economic Area principles. Such free movement of goods will have to be carefully monitored in the years to come.