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Protecting Drug Patents and Pharmaceutical Data in Asia

Today's patent owners face two significant problems when doing business in Asia: the expiration of their patents and Asia's generally pro-generic stance on pharmaceuticals. This article explores the broad concept of "evergreening," which is even more crucial for companies operating in Asia, and a notable exception to the pro-generic policies in the region, the TRIPS+ or the "exclusive rights" approach.

Evergreening

In the February 2010 edition of *Informed Counsel*, Radeemada Mungkarndee discussed how "evergreening" is a term sometimes applied to tactics by patentees to prolong what may be patentable improvements to existing inventions. Evergreening is a particularly topical area of patent law at present. It can occur in any industrial field but it most commonly occurs in the pharmaceutical industry. It has been estimated that by the end of 2010, the patents of over 100 key drugs will expire. Beyond that, 2011 and 2012 will see a number of high-profile drugs coming off patent, including the world's current best-selling drug, Pfizer's Lipitor. Evergreening is sometimes seen, at least in the pharmaceutical industry, as a controversial tactic on the part of the patentee.

The definition of evergreening is quite broad and is not formally recognized as a legal concept, regardless of its links to patent law. Evergreening of patents occurs most typically when, toward the end of the patent's term, the patentee looks to patent minor improvements in the product or process or uses or delivery systems in relation thereto. Alternatively, it may seek to patent various different attributes of one product or process to obtain further 20-year terms of protection. However, there are other, broader issues to consider when talking about evergreening, beyond the actual patent itself.

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Drug pricing is an extremely sensitive issue in the developing world, particularly in Asia where cheaper generic drugs are often given preferential treatment by government health authorities. The quicker that generic drug manufacturers can get on the market and start to build up their own goodwill in their product, the more likely the generic companies will be able to take market share by fiercely competing on price.

When looking at Asia's legal regimes regarding generic manufacturers' ability to enter the market, generally speaking most countries provide generics companies with relatively easy access, when compared to the more developed Western regimes (with Singapore being a notable exception). So how can patentees deal with the tendency in Asia to promote generic drugs?

Common Evergreening Tactics

The term "evergreening" could be applied to the following practices employed by patentees:

Patenting improvements in the product. Most innovation occurs in this way—by improving on existing inventions. This recoups research and development (R&D) costs and secures a monopoly right. It is a common tactic in the pharmaceutical industry. It would be naive to assume that the purpose is to only prolong the period of protection—if the improvements are genuine and beneficial to the healthcare market, then there is a positive side to this. It should be remembered that patent examiners will only accept new and inventive improvements that are capable of industrial application. In addition, generics companies may still be able to enter the market by producing their version of the basic, unimproved product.

Patenting the process. If the company is able to invent a way of producing its drug, then this may be protected to add value and secure a type of monopoly right over the process.

Defensive patenting strategies. Defensive patenting strategies are designed to block market access to competitors. A tactic not just related to the pharmaceutical industry, this can prove quite costly, especially if challenged or litigated. Arguably, there is not much benefit to the consumer here.

Multiple patenting strategies. One product may well have several patents. This is similar to the patenting of improvements; but, in industries where more than one patent could cover one product, this is particularly relevant. If an infringer can reproduce and use one aspect of an invention (which may form part of a product or process), then it makes sense to try to patent each aspect as separate inventions to increase the scope of protection. Such patent groups, when pursued with defensive intentions, are often called patent thickets or clusters.

Litigation on patents and process patents. If there is good evidence of infringement, a product patent is a strong weapon (but only as strong as the patent). Litigation is a real threat and can be a highly effective tool for keeping competitors away from the patented product. Patentees will have to weigh the benefits of bringing actions toward the end of the patent term, as patent litigation is generally quite expensive. For process patents, most jurisdictions, particularly in Asia, require the defendant to assume the

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burden of proof where the plaintiff can prove that the products at issue are similar. This then enables the plaintiff to use the assumption that the defendant is infringing to bring proceedings for process patent infringement. Of course, evidence will be exchanged in the usual way, but the defendant will bear the burden of proving that its process does not infringe.

Securing goodwill in trademarks. By securing goodwill in trademarks, the IP owner can carry brand loyalty beyond the patent term. Branded drugs can maintain customer loyalty well after the expiry of the patent, but this approach should be coupled with a competitive pricing regime and high quality standards; otherwise, generics could be favored. By way of example, the trademark Aspirin demonstrates how, following expiry of the patent, brand loyalty can be maintained.

Opposing regulatory approval applications. Opposing applications for regulatory approval is very difficult, but one argument could be that with complex drugs, the chemical structure cannot be easily replicated and this could result in issues of quality and safety.

Competitive pricing. It can be extremely difficult to compete on price with generics companies. Certain traditionally R&D-based companies are adapting an "if you can't beat them, join them" approach by entering into the generics markets themselves, often by buying up generics companies.

Competition law issues. Invoking competition laws will depend on the individual countries, and any action will need to be carefully taken as most Southeast Asian countries will favor open access over exclusivity when it comes to such issues as drug registration and data exclusivity.

Trade secret-related actions. In many Asian countries, actions based on trade secrets are the next best alternative to the TRIPS+ or the data exclusivity approach of the Food and Drug Administrations (FDA). The actions, however, rarely go beyond what is set out in the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). Please see more on TRIPS+ below.

TRIPS+ or the "Exclusive Rights" Approach

Article 39.3 of TRIPS states that countries should prevent unfair commercial use of undisclosed data. In most jurisdictions, trade secret and other competition laws would govern the protection of such data, but the TRIPS+ approach goes one step further by specifically outlawing access to the originator's file until the patent has expired (or some other set amount of time).

The point at which R&D-based drug companies often get nervous is over FDA treatment of undisclosed data, which, just like a patent, has significant commercial value. The value here is the speed at which the generics company can access the market. If the regulatory body or the third party has access to the originator file, the generics application will go through much more quickly if it can be shown that the generic is bioequivalent to the originator by using the undisclosed data as a reference. Despite TRIPS providing guidance on how such access should be regulated, there is no definite standard around the world.

United States and Europe. The United States and Europe have adopted a system whereby generics companies must wait until the expiry of the patent before they can start the regulatory approval process for their generic drug. This approach is known as TRIPS+ or the "exclusive rights" approach. TRIPS does not require that exclusive rights be afforded to the originator of undisclosed data.

Asia. In Asia, there are many countries that do not grant TRIPS+ exclusivity and generics companies simply have to demonstrate bioequivalence to the originator to be granted marketing approval even before the patent has expired. The "Bolar provision," derived from Article 30 of TRIPS, allows "manufacturers of generic drugs to use the patented invention to obtain marketing approval—for example from public health authorities—without the patent owner's permission and before the patent protection expires."

In its free trade negotiations, the United States has put pressure on countries (for example, Singapore) to adopt the TRIPS+ exclusivity rules, but this has not sat well with developing Asian countries that have a pressing need for swift access to cheaper drugs. Singapore has adopted the TRIPS+ approach by affording exclusivity on undisclosed data and requiring a statement from the later applicant at the FDA attesting that the generic does not infringe any patent rights. Singapore's process is not typical of the approach to generics taken by other ASEAN members.

In Thailand, the overall position is pro-generics. The undisclosed data submitted by the originator to the FDA is available to generics companies prior to the expiry of the originator's patent. The generics company can rely on this data to facilitate swift market access. A degree of TRIPS-compliant protection is offered by Thailand's Trade Secret Act at Section 15, which provides protection only against "unfair trading activities."

Conclusion

The market in Asia is very polarized in terms of affluence of customer base, and so too is the pricing of products by R&D drug companies and by generics companies. The rich can afford and demand the patented, branded product while the poor have their decision made by their government or their own budget and typically get the cheaper generic. With this match of pricing and customer base, originators and generics should be able to coexist happily.

However, this model does not fit during the last few years of a patent's life. Evergreening tactics, which seek to prolong the monopoly, could restrict access to generic drugs.

In developing markets in Southeast Asia, governments have taken the view that either a drug is vital to the public, in which case they may grant a compulsory license, or it is important to the public, in which case the government allows generics to rely on undisclosed data in the originator file, providing swift access to cheap drugs for the public. Singapore takes a different stance, perhaps due to its status as a developed nation, but it should be noted that its TRIPS+ approach has been shaped by pressure primarily from Western TRIPS signatories.

Interestingly, faced with these issues, some companies may attempt a research-based approach as well as a generic one. Pfizer and Novartis have already entered the generics market. Conversely, for how long will Teva be the only generics company to have its own blockbuster drug? One thing is for sure: with the expiry of many important patents over the next few years and the increase in generics competition, all pharmaceutical companies will have to get more and more creative when it comes to protecting and enforcing their rights.