Combating Generics: Rising Pharmaceutical Patent Litigation Trend

by Siraprapha Rungpry

Siraprapha Rungpry, Consultant Intellectual Property

In recent years, Thailand has seen an increasing number of pharmaceutical patent litigations, launched by drug originators to combat infringing generic products in the market. Local generic manufacturers are becoming more active than ever owing to several driving factors. From the regulatory perspective, generic drug manufacturers are allowed to apply for registration of generic drugs with the Thai Food and Drug Administration (FDA) before the expiration of a patent covering a particular drug. This is primarily due to the FDA's current pro-generic, no-patent-linkage position and the Bolar exemption under the Thai Patent Act which confers generic manufacturers with the ability to engage in various preparatory activities with a view to seeking regulatory approval before a patent for the original drug has expired. Moreover, the Thai FDA treats originators' dossier and data previously filed with the FDA as forming part of known scientific knowledge which could be relied on in approving follow-on generic applications. Above all, there is an apparent development trend among local generic producers to catch up with the new technology and take advantage of the government's pro-generic policy at the moment. The recent compulsory license scheme also affected the policy and economic landscape as well as the general perception towards generic drugs. Consequently, several local generic manufacturers began to develop and market generics of various best-seller drugs and continued to add more products to their pipeline development despite the existence of valid patents covering these drugs in Thailand.

It is inevitable that drug originators facing low-price infringing generics are put in the position to defend their products. Given their prior dominant position and established relationships with customers and brand loyalty, drug originators have somewhat of an upper hand. Nevertheless, the price competition could cause serious problems in the long run and normally results in (significant) loss of sales to the generics.

Several legal options are available to tackle infringing generic products, ranging from informal enforcement measures to formal proceedings in court. In general, the first step is to send a warning letter and/or try to negotiate with the generic manufacturer. An ex parte preliminary injunction enjoining sales of infringing generic products may be applied for even before filing a lawsuit with the court, although the requisite evidentiary burden is rather high. Additionally, an ex parte Anton Piller order to seize evidence of infringement may also be possible. In terms of legal actions, Thai law allows for both criminal and civil actions against infringers. The choice would depend on the circumstances of the case. Normally, a civil action can be filed fairly quickly, and by this means drug originators could pursue damages and permanent injunction against infringing generic manufacturers.

A careful overall strategy must be formulated before taking any (active) steps against potentially infringing generic manufacturers, as one blunder or misstep could result in severe repercussions in the long run. The pharmaceutical patent owner also needs to pay particular attention to obtaining sufficient evidence to verify and confirm the infringement. When court proceedings are pursued, litigation strategy should be carefully crafted taking into consideration the relevant business concerns of the company. ❖