VIETNAM

Drug innovator scores win

Tilleke & Gibbins
Hanoi

Loc Xuan Le and Linh Duy Mai

On September 11 2015, the Drug Administration of Vietnam (DAV) issued a decision to withdraw the marketing authorisations (MAs) for nine pharmaceutical products on the market. While this is a fairly routine occurrence, what was notable was that two of the drugs on the list had their MAs withdrawn as a result of *patent infringement* – one of the first times this has happened in Vietnam. The withdrawal makes a strong statement that Vietnam is getting serious about enforcing patent rights in the pharmaceutical realm.

Case summary

The pharmaceuticals in question were cardiac-arrest drugs in 5mg and 10mg sizes produced by a generic manufacturer based in southern Vietnam. In early 2015, these drugs came to the attention of a European pharmaceutical innovator which had developed and patented a cutting-edge compound that contributes to preventing heart attacks. The company had been widely marketing the compound under various brands and had gained significant market share. Believing that the generic drugs infringed its patent, the European pharmaceutical company called on the Inspectorate of the Ministry of Science and Technology (MOST) in April to handle the patent infringement administratively.

At the time the request was made, two other patent infringement cases at MOST had reached a state of stagnation, so MOST took cautious steps to examine the case and decided to raid the producer only after more than one month of case review. At the raid, the producer did not deny the infringement, but claimed to be ignorant of the laws relating to intellectual property. After inspecting the producer's records, MOST found that the producer had imported dozens of kilograms of raw materials for producing the infringing goods, and had sold almost 8 million of the infringing tablets.

In July, MOST issued a conclusion of infringement and ordered the infringer to withdraw its MA licences and to destroy the inventory of the infringing drugs. Strictly complying with these orders, the local producer destroyed the infringing drugs in the presence of a MOST witness, and requested the DAV to withdraw the MA licences of the infringing products.

The withdrawal of the MAs by the DAV on September 11 was a sweeping victory for the patent holder, as it will lead to a complete elimination of the infringing goods from the market and also establish a bar to future generic entry by the infringer. In addition, it was attained in an incredibly short time frame compared to most cases of patent infringement.

MA withdrawal: statutes versus reality

In Vietnam, there is no clear link between the expiration of pioneer drug patents and generic drug marketing approval. Consequently, the DAV can grant MAs without considering the validity of patents that cover the drugs, leaving the matter of patent enforcement in the hands of other agencies. Under the prevailing regulations, the DAV is required to withdraw an MA upon a verdict of patent infringement rendered by a competent enforcement body such as the court or MOST. However, it seems that such regulations had not been tested until MOST ruled in this case.

Despite the clarity in the statutes, the regime of MA withdrawal still faces obstacles in practice. The DAV often faces great pressure from both the mass media and other state agencies when ruling against local generic producers. Opponents allege that such rulings could play havoc with Vietnam's efforts in developing the local generic industry and will limit the public's access to low-price drugs – legitimate concerns in a developing country like Vietnam. Given the pressure, the DAV often lets the dust settle before deciding on MA withdrawal. So far, however, it seems that the dust around pharmaceutical patent infringement almost never settles.

Given the sensitive issues involved and the escalation of other cases, the DAV's decision to withdraw the MA in favour of the European pharmaceutical company came as welcome news. The withdrawal could signal improvement in Vietnam's patent enforcement regime, which has often fallen short of what is expected from a country that has been a member of TRIPs for years and wishes to join the Trans-Pacific Partnership, which aims for stronger IPR protection.

Tilleke & Gibbins acted for the pharmaceutical company in this case.