VIETNAM

Registered drugs not immune from infringement charges

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Recent patent infringement cases in Vietnam's pharmaceutical sector have revealed the ambiguity of competent authorities' roles in determining whether a patent has been infringed. Such vagueness has caused unexpected delays in legal proceedings.

In a recent suit between a leading international pharmaceutical group and a local generic producer, the court requested the Drug Administration of Vietnam (DAV) to clarify in writing whether the DAV had taken patent issues into account when considering approval of marketing authorisation (MA) for the defendant's pharmaceutical products. In response to the court, the DAV issued a letter confirming, for the very first time, that they have no responsibility by law to examine any IP infringement issues during drug registration.

In the pharmaceutical sector, alleged patent infringers often defend themselves from the accusations by pointing to their MA registrations. They argue that any pharmaceutical products authorised to the market by the DAV must, by nature, be legitimate, and free from IP infringement issues. Therefore, holders of granted MAs should be released from any infringement liability.

Some infringers even contend that IP holders should instead place the blame on the competent authorities, such as the DAV, who approved the suspected infringing pharmaceutical products for circulation and distribution in the market. They presume that the DAV's responsibility to carefully review drug registration dossiers prevents any potential IP infringement prior to the market entry of products. As a result, they argue, the DAV must be liable for any patent-infringing drugs on the market.

An examination of the prevailing laws, however, reveals that such arguments are unjustified. The Law on Intellectual Property explicitly requires every individual and organisation to respect the intellectual property rights of IP owners. Meanwhile, the independent and separate laws on drug registration contain no provisions stipulating the DAV's power and role to consider any IP issues with respect to drugs seeking MA registration. Furthermore, under Article 13 of Circular 44/2014/TT-BYT, the law clarifies that drug registrants or registering entities must themselves be responsible for IP-related issues both during the course of registration and after the drug has been granted a MA number.

Regardless of the clear stipulation by law, the unjustified arguments of putative infringers have raised concerns among the courts in relation to the DAV's role in the management of drug registration, including IP-related issues. The courts seem to be inclined to side with the defendants and thus continue to seek the DAV's opinions on patent infringement.

In its letter to the court, the DAV strongly confirmed its independent position regarding IP-related issues during the process of drug registration, and reiterated the laws confirming that the Ministry of Health grants MA numbers for pharmaceutical products based only on the evaluation of their safety, effectiveness, and quality, with no obligation to review IP-related issues. The drug registrants, instead, are responsible for any matters relating to IP rights when the drugs are in circulation. In other words, the DAV has no responsibility by law to examine any IP infringement issues during drug registration. Therefore, drug registration does not render MA holders immune from IP infringement charges.

The DAV also acknowledges that under the law, when there is a judicial decision or final conclusion of the IP authorities on the infringement of IP rights, the DAV only needs to consider whether or not to revoke the MA or suspend the sale of a drug. Previously, such a decision or conclusion was grounds for mandatory revocation, but under the new Law on Pharmacy 2016 and Decree No. 54/2017/ND-CP, the DAV seems to be given more discretion. In a number of cases, the DAV has been reluctant to withdraw an MA even when there has been an infringement conclusion from an authority such as the Inspectorate of the Ministry of Science and Technology. Thus, there is no clear regime for an IP holder to force the DAV to withdraw and/or cancel an MA, regardless of any decisions on IP infringement from competent authorities.

If the drug registry body has no responsibility to consider IP-related issues during the MA procedures, the courts need to play a proactive role in settling patent disputes to effectively and expeditiously protect the legitimate rights of IPR holders. In the absence of coordination between drug registry authorities and IP enforcement authorities, a drug can be authorised for the market by the DAV if it meets requirements for drug registration, without IP-related issues ever being considered. However, if such drug is later found by the court to infringe others' IP, it could be banned from circulation by an authority like the court, the MOST Inspectorate, or Customs regardless of the MA.