The pharma maze: patent enforcement in Vietnam

Looking at a case study, Tilleke & Gibbins' **Loc Xuan Le** and **Linh Duy Mai** provide a practical view of pharma protection in the region

Vietnam is home to more than 90m people. With its large population and an expanding economy, the country has become an attractive market for pharmaceutical companies. Since local drug producers have not yet acquired sufficient research and development capabilities, they fight an uphill battle against international drug innovators. Under the circumstances, a number of local companies have resorted to patent infringement in an attempt to regain market share.

Patent linkage

Vietnam has not yet adopted a patent linkage system, in which marketing approval for generic drugs is not granted until the original drug's patent has expired. Without patent linkage in place, the Drug Administration of Vietnam (DAV) does not take any responsibility for determining whether drugs pending marketing authorisation have infringed any granted patents. Rather, the DAV assumes that the applicant for the marketing authorisation has proactively ensured that its generic drugs are non-infringing – a generous assumption, to be sure.

However, the regulations on drug registration, including Circular 44/2014/TT-BYT (which took effect on 15 January 2015, replacing Circular 22/2009/TT-BYT), set out an approach by which a patentee can call for the DAV's refusal of marketing authorisation for a generic drug. Under Article 13.3 of Circular 44/2014/TT-BYT, the DAV may decline to grant a marketing authorisation if it has solid grounds to believe that the drug pending registration could infringe the intellectual property rights (IPRs) of other entities. Patentees are thus advised to notify the DAV of their patents and any conclusions or decisions/judgments of patent infringement made by competent enforcement bodies or courts. As a matter of practice, once notified, the DAV will then disseminate an internal communique to its drug examiners, raising their attention regarding such patents in the process of drug registration. However, despite such internal communications, the DAV may still grant a marketing authorisation in some cases – the system has flaws.

The prevailing laws also create a mechanism to cancel the marketing authorisation of a generic drug that has survived the registration process and made it to market entry, upon a discovery of patent infringement. Under Article 13.4 of Circular 44/2014/TT-BYT, the DAV is obligated to revoke the marketing authorisation of an infringing drug upon a conclusion of patent infringement, made by either a competent enforcement body or the state agency in charge of administering IP in Vietnam. Under Vietnam's laws, the enforcement bodies empowered to deal with patent infringement include the court, customs, and the inspectorates of science and technology, while the state agency for IP administration is the National Office of Intellectual Property (NOIP). In principle, the NOIP does not have the power to rule on patent infringement for enforcement bodies. Thus, they often avoid issuing such conclusions. Rather, they will issue their expert opinion on the infringement at the request of the enforcement bodies.

For drugs which are allowed to enter Vietnam without any marketing authorisation licence under a "special import quota", (usually these are rare medicines or medicines required for special treatment needs of hospitals), the current regulations do not touch on the mechanism for revoking the special import quota if the products are found to be patent-infringing. However, in practice, based on the spirit of the regulations on drug registration, a patentee can seek the revocation of a special import quota on the strength of a conclusion of infringement from a competent enforcement body.

Enforcement options

There are several enforcement actions available for dealing with patent infringement, including administrative measures and civil litigation.

Administrative measures are carried out by administrative bodies such as the inspectorates of science and technology and customs. Both cost-effective and time-efficient, administrative measures are the most common route in Vietnam for patentees if their main priority is to stop ongoing infringement quickly. However, unlike civil actions, administrative measures do not provide patentees with a tool to recover damages incurred from the infringement.

During an administrative action, if the enforcement body has an express finding of patent infringement, they will likely impose sanctions upon the infringer. The sanctions include, *inter alia*, a monetary fine of up to VND 500m (USD 24,800) and destruction of the infringing drugs and infringing raw materials. Once the infringing goods are destroyed, the administrative action would come to an end.

As an alternative to an administrative action, a patentee can use a civil action (litigation) to enforce its patent rights. A civil action enables patentees to claim remedies available under law such as a compulsory cessation of the infringement, a public apology, compensation for the infringement, recovery of attorney fees, etc. It is worth noting that after an administrative action, the patentee can also commence civil litigation to claim damages and attorney fees, based on the evidence collected in the administrative action.

It is possible to obtain a preliminary injunction in Vietnamese courts. However, to the best of our knowledge, none have ever been issued for patent infringement cases. The court would therefore be very uncertain when determining such a request, and may prefer, for the sake of convenience, not to grant a preliminary injunction.

It is worth noting that in a civil action, unlike an administrative action, the patentee must bear an onerous burden in terms of the formality of the documentation submitted to the court. The statement of claims must be signed and sealed directly by the patentee. Typically, all the documents must be legalised. In some countries, the legalisation

process can last several months. On the whole, the formality issue will prolong the civil action.

Most IPR holders, especially patentees, avoid civil litigation in Vietnam when it comes to infringement of their IPR, due to the time and cost involved and the perceived lack of IP expertise of the Vietnamese courts. Thus far, few patent infringement cases have been handled by Vietnamese courts. However, due to the availability of a damage compensation mechanism, civil actions have recently been gaining a higher profile.

During an enforcement action, the infringers may seek invalidation of the patent in question in an effort to hinder or prolong the legal process. However, the invalidation counter-attack will not necessarily slow administrative measures, because under Decree 99/2013/ND-CP, if the patentee can confirm the validity of the patent under oath, the enforcement bodies can continue to handle the case rather than stay the proceedings. Under a civil action, it is more likely that the court will suspend the proceedings pending the resolution of the invalidation request by the NOIP. Still, in a recent case of patent infringement handled by the Ho Chi Minh City Court, the court decided to move forward with the trial despite the respondent's invalidation request.

In practice, sending a cease-and-desist letter usually does not work in pharmaceutical patent infringement cases. In most cases, the infringers are the holders of market authorisation licences for the potentially infringing drugs. They might have gone to great lengths to obtain these licences and, in addition, there is no punishment that may be imposed upon them in further legal proceedings for ignoring the cease-and-desist letter. Thus, it is difficult to get them to voluntarily withdraw the licence and stop the infringement with a cease-and-desist letter alone. In theory, sending a cease-and-desist letter prior to the legal action could even harm the action in the future. The letter could possibly trigger fierce reactions from the putative infringer, possibly leading the infringer to seek an invalidation of the patent in question, as mentioned above.

Pre-emptive enforcement actions at the border

Apart from administrative measures and civil litigation, patentees can use border control measures as a pre-emptive action against patent infringement at the border. In most cases, as a prerequisite to border control measures, the patentee must record its patents with customs. By virtue of the recordal, customs will be on the lookout for any generic version that could infringe the recorded patents and seize infringing shipments that cross the borders of Vietnam. In the event of customs seizure, patentees can then call on customs to continue handling the case through the administrative route.

It is worth noting that, in the few hours from the declaration of the importation to the customs clearance, it can be difficult for customs agents to determine patent infringement (unlike trademark infringement) simply from the appearance of the drug. Hence, providing customs with detailed information about specific infringing drugs will be vital to the effectiveness of customs recordal of patents.

Customs will not seize outbound shipments, as exportation of infringing goods does not constitute patent infringement (Articles 124.1 and 126 of the IP law). However, they will monitor the shipments and may temporarily suspend them. If evidence of infringement is found, the patentee can possibly take action against the manufacturer of the infringing drugs as well as the exporter.

Expert opinions

In Vietnam, expert opinions often play an important role in dealing with patent infringement as they provide guidelines for enforcement bodies (administrative agencies and courts) to resolve disputes. Although such opinions are non-binding, the authorities, which often lack expertise and experience in IP, almost always follow the conclusions set out under the opinions. To some extent, expert opinions can be said to be the decisive factor in the success of enforcement actions against patent infringement.

Expert opinions are a statutory mechanism in the area of IP, and can only be issued by a licensed expert agency. Currently, the Vietnam Intellectual Property Research Institute (VIPRI), a quasi-governmental agency under the Ministry of Science and Technology (MOST), is the only agency licensed to provide expert opinions in the IP field. The NOIP, in some cases, can also give their opinion on the possibility of infringement at the request of enforcement bodies. However, they often avoid such practice as they prefer to focus on their main role of IP registration and administration.

In many cases, VIPRI will require a prior testing of the putative infringing products before judging the infringement. However, in some cases, and particularly depending on the scope of protection of the concerned patent, the agency can give out an expert opinion without any testing, based purely on the ingredients of the drugs as indicated in the inserts or on the packaging, or even in the public registration information of the drugs.

Case example

In early 2015, the Inspectorate of MOST administratively handled a case of patent infringement committed by a local generic producer in the South of Vietnam. The American patentee, one of the largest pharmaceutical companies in the world, holds a cutting-edge patent in Vietnam covering an active ingredient which contributes greatly to the treatment of diabetes, as it brings about the benefit of fewer side effects in the control of blood glucose values. The patentee became aware of the market entry of a product containing the patented ingredient in late 2014.

The patentee opted for an administrative action to deal with the potential infringement. To facilitate the action, the patentee successfully obtained a favourable VIPRI expert opinion, in which VIPRI confirmed the infringement based on the registration information of the drugs in question. On the strength of the positive expert opinion, the patentee succeeded in calling for a quick action carried out by MOST.

In January 2015, MOST carried out a raid on the generic producer. During the raid action, MOST seized hundreds of infringing finished drugs and more than 117kg of infringing raw material – enough to allow the infringer to produce more than 2m infringing tablets. Given the fact-finding in the raid action, the authority ordered the infringer to cease and desist from the infringement and to withdraw the market authorisation licences for the infringing drugs at the DAV.

The resolution of this case is an example of how pharmaceutical companies, with the right strategy, can successfully protect their valuable patents in Vietnam.

Authors


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