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Enforcement of Patent Rights for Pharmaceuticals in Vietnam

Patents are engines of growth and are critical to the vitality of the pharmaceutical industry. They create the incentive for pharmaceutical companies to maintain their investments to find new and better cures for global health issues, and to improve the health of people around the world. From an economic perspective, patents also give their holders an upper hand over other competitors. For this reason, many generic pharmaceutical companies try to illegally use others' patented inventions in their own products, in order to gain an unfair advantage and compete with the patentees' drugs. In this article, we will address the process of enforcing patent rights in the pharmaceutical sector in Vietnam.

Enforcement Options

The overall goal of all pharmaceutical patent holders when carrying out enforcement measures is to force the infringers to cease the infringement, to get the market authorization of the infringing drug withdrawn or revoked, and to ultimately claim compensation for any damages incurred. These objectives can be achieved only if the patentee can select the most appropriate measures and strategies, while understanding that patent enforcement in the pharmaceutical sector in Vietnam is relatively new.

The available enforcement actions against patent infringers include administrative measures, border control measures, and civil litigation. Administrative measures, which are carried out by administrative bodies, not judicial bodies, are the most common, as they are both cost-effective and time-saving. However, only the Inspectorate of the Ministry of Science and Technology and customs are entitled to handle patent infringement through the administrative route. Border control measures, which, to some extent, are considered to be administrative in nature, are applied by customs at the borders of Vietnam. Civil litigation is also an option, although it takes a high degree of commitment to pursue this route due to the local courts' lack of IP expertise.

The Role of the Expert Witness

In Vietnam, the role of the expert witness in patent enforcement, especially in the realm of pharmaceuticals, is of great importance. Agencies offering such services, through their expert opinions and conclusions on infringement, provide guidelines for the competent authorities to resolve the case. Despite the opinions of expert witnesses being non-binding, they are almost always followed by enforcement agencies, which often lack experience in such matters. They also help to expedite enforcement actions.

Despite the importance of expert opinions, rights holders do not have many options available to them in terms of requesting assistance from examination agencies or agencies that provide expert advice, as the Vietnam Intellectual Property Research Institute (VIPRI) is, for the moment, the only functional agency authorized to provide expert opinions. Though the National Office of Intellectual Property now and then issues expert opinions upon the request of the enforcement bodies, in practice, its main role is to facilitate the procedures for establishing IP rights in Vietnam.

In most cases, to assess the possibility of patent infringement, VIPRI requests a prior physical testing of the putative infringing drugs. In some cases, however, VIPRI can judge the infringement based on the ingredients on the packaging and/or the inserts alone.

Complementary and Preventive Measures

Though some jurisdictions ensure "patent linkage," whereby marketing approval for generic drugs is not granted until the original drug's patent has expired, there is no such regime in Vietnam. Therefore, parallel to or even before conducting any enforcement measures, patent rights holders in the pharmaceutical sector are advised to undertake certain measures at the Drug Administration of Vietnam (DAV). Specifically, according to Article 15 of Circular No. 22/2009/TT-BYT, patentees are encouraged to notify the DAV of their patents. Once notified, the DAV will then send a notice to its drug examiners for them to consider the patents in the process of deciding on the marketing authorization of drugs belonging to other applicants.

After the dossiers of drug-related patents have been filed, if there are potential conflicts or potential patent infringements found in any drug registration dossiers, the DAV will require the applicants to clarify the legal status and/or contact the patent owners in order to resolve these conflicts. This process, however, is not mandatory for management agencies and the DAV may nonetheless grant drug market authorization. This is because, in practice, the overriding spirit of Circular No. 22/2009/TT-BYT is that issues that arise in relation to patents are the responsibilities of the parties involved, and the DAV does not play a role in review, arbitration, or adjudication of these disputes. The DAV is bound only to withdraw the market authorization of a medicinal product (if the authorization has been granted) or refuse to issue a market authorization (if the application is in the review process) once a decision confirming the infringement has been issued by the competent patent enforcement authorities, such as the Inspectorate of the Ministry of Science and Technology, customs authorities, or the court.

At present, Vietnam is actively participating in the Trans-Pacific Partnership (TPP) negotiations, and one of the agenda items relating to the TPP that has been put on the table is whether or not a pre-review mechanism should be created with respect to patents for medicinal products for which applications for circulation licenses have been filed. The majority opinion in Vietnam, however, is in opposition, due to worries about negative impacts on the time taken for people to get access to a supply of cheap drugs, as well as intellectual property barriers that the Vietnamese government wishes to avoid. Therefore, it is uncertain whether the TPP can live up to the expectations of pharmaceutical companies that are advocating a more effective enforcement mechanism in Vietnam. In any case, pharmaceutical companies should fend for themselves and employ a comprehensive and long-term enforcement strategy to protect their patent rights effectively in Vietnam's still-emerging patent enforcement regime.