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Sanctioning of Patent-Infringing Drugs in Vietnam

The effective protection of pharmaceutical patents has always been very important in national systems of intellectual property law. While effectiveness can be measured in many ways, any effective system must include a transparent and swift mechanism of legal enforcement with a clear link between the sanctioning of IP infringements and the elimination of infringing products from the market. In this respect, the current patent system in Vietnam still faces considerable challenges, particularly as Vietnam continues to pursue deeper and more widespread integration into the global economy through multilateral trade agreements, such as the recently negotiated EU-Vietnam Free Trade Agreement (EVFTA) and the Trans-Pacific Partnership (TPP).

Legal Obstacles

In recent years, patent infringement cases—especially in the pharmaceutical sector—have been on the rise in Vietnam. Despite this trend, in practice, the fundamental rules of the legal system have yet to provide a clear legal framework to serve as a precedent for an effective enforcement process. Although the 2005 Law on Intellectual Property contains provisions that could be viewed as quite standard, including an entire chapter on the protection requirements for patents (Chapter VII, Section 1), and details on the rights of patent owners and the enforcement measures to be implemented should violations occur (Chapter IX, Section 1), these provisions are quite solitary in the context of the provisions necessary for effective enforcement of pharmaceutical patent protection.

As an example, the Law on Pharmacy—another key legal document which is supposed to exist in parallel with the Law on Intellectual Property—is completely silent on how to deal with drugs that are considered patent infringements. This law should, at the very least, be expected to have basic principles for addressing this problem. Specifically, neither the 2005 Law on Pharmacy (in effect through December 31, 2016) nor the 2016 Law on Pharmacy (taking effect on January 1, 2017) includes any provision directly setting out the mechanism for dealing with the trading and circulation of drugs that have been concluded to be patent infringements—not even at the minimum level, such as clauses simply referring to the regulations on intellectual property. The 2005 Law on Pharmacy contains only one provision on "industrial property," under the definition of counterfeit drugs, where the term is limited to the "counterfeiting of names and industrial designs that have been registered for protection" (Article 2.24(d)). The law still states in Article 35.4 that the Minister of Health will provide specific details on the withdrawal of drug registration numbers.

The 2016 Law on Pharmacy is no clearer, providing guidance on IP and patents only in terms of encouraging the protection of traditional medicines (Article 7.7) and facilitating the registration for circulation of generic drugs after patents have expired (Articles 7.5, 7.6, and 8.2). The new law still has no provisions on the mechanism for removing drugs from the market if they are found to be patent infringements, not even in the form of revocation or withdrawal of the drug registration numbers that have been granted to these products. No bridge has been built between the Law on Intellectual Property and the Law on Pharmacy to create a linkage mechanism in the process of enforcing patents in the pharmaceutical sector.

Despite these obstacles, the Ministry of Health has attempted to enact regulations to provide clearer guidance on vague provisions of the law, such as the revocation of the marketing authorization of an infringing drug once a conclusion of infringement is issued by the competent authorities. An example is Circular No. 44/2014/TT-BYT, dated November 25, 2014, which is currently in force and has an entire chapter dedicated to the issue of IP with respect to registered drugs. However, since this circular was issued, the regulations on IP with respect to registered drugs have been inconsistently applied. Even though, in many cases, the patent holders provided all of the necessary documents and evidence to request that the regulations be applied, the marketing authorizations of patent-infringing drugs were not withdrawn or revoked.

What Does the Future Hold?

In the next few years, the number of patent dispute cases in the pharmaceutical sector is anticipated to continue on an upward trend. As the dispute resolution mechanism currently in place has not been satisfactory in past cases, it is not an appropriate model for the future. However, if the government of Vietnam is truly determined to build and set up a mechanism for settlement of patent disputes in the pharmaceutical sector, perhaps this is not such a difficult task. As discussed above, the lack of a bridge between the laws on intellectual property and pharmacy has led to uncertainty in addressing the consequences of patent infringement cases. This situation, whether inadvertently or intentionally, remained unresolved in the new Law on Pharmacy, with Articles 58 and 62 of the law only setting out cases in which marketing authorizations and drugs are to be revoked or recalled from the marketplace due to issues of quality, safety, and efficacy. Nowhere does the law mention the revocation or recall of marketing authorizations and drugs from the marketplace due to IP/patent violations. Additionally, there is no "catch-all" provision, as found in many other Vietnamese laws, allowing the recall of marketing authorizations and drugs for "other cases prescribed by the law."

The most easily envisioned scenario is that in the future, the Ministry of Health of Vietnam will step aside and consider the handling of patent infringements in the pharmaceutical sector to be completely independent of the processes of granting marketing authorization and recalling drugs already circulating in the market. If this happens, a situation will arise where the authorities handling pharmaceutical patent infringements can issue judgments or decisions in cases prohibiting sale or circulation or ordering the withdrawal of certain drugs, while the state authorities for pharmacy remain completely outside the process of handling the cases. The marketing authorization of a drug will still persist, unless the violator voluntarily has it withdrawn. In practice, if this option is chosen, it will be a step backward in the process of building a truly effective enforcement mechanism for pharmaceutical patents, when even the Ministry of Health, local health management agencies, and hospitals consider the existence of a marketing authorization to be "sufficient" to prove the legality of the sale and circulation of the related drug. Meanwhile, these agencies pay almost no regard to the coexisting provisions on patents.

Another approach in a "new" but "old" direction is that when the 2016 Law on Pharmacy comes into effect on January 1, 2017, the Ministry of Health may have to issue a circular amending Circular No. 44/2014/TT-BYT. In our opinion, this amended circular must have clear terms defining situations where drugs or marketing

authorizations may or may not be revoked or withdrawn in the event of an effective decision or conclusion on patent infringement. (We note that cases of revocation and withdrawal of drug marketing authorizations are already defined in Circular No. 44/2014/TT-BYT, but this regulation has, in reality, never been applied correctly.)

Ultimately, it is not so difficult to create a clear, transparent, and interconnected legal framework to effectively resolve the issue of handling pharmaceutical patent infringements. The difficulty lies in the true determination of the management agencies to make the change. The thin line between speech and action will be the measuring stick of whether or not the government of Vietnam truly wishes to establish an effective enforcement regime in the field of pharmaceutical patents.

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