

VIETNAM

Improving pharmaceutical IP protection

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Vietnam's IP enforcement system has seen great improvements over the past few years. In particular, the Inspectorate of the Ministry of Science and Technology (MOST) has handled many complex disputes in the pharmaceutical sector related to patent infringement, unfair competition and trade mark infringement. Rights holders have generally been quite pleased with the decisions reached by MOST, as well as the expert opinions provided in various cases by the National Office of Intellectual Property (NOIP) and the Vietnam Intellectual Property Research Institute (VIPRI), which are often a precursor to a MOST administrative enforcement action. Nevertheless, with a few tweaks when Vietnam amends its Law on Intellectual Property this year, the system can be improved even further to help better protect IP in the pharma sector. Below are a few suggestions for improvement.

Patent linkage: At present, there is no strong or efficient route to have a marketing authorisation (MA) blocked or withdrawn in the event of patent infringement. Even when the Drug Administration of Vietnam is notified about a drug's potential infringement, an MA for the drug in question may still be approved. An MA may only be ordered withdrawn after a lengthy administrative or civil suit for patent infringement. In this regard, there needs to be stronger coordination between the IP enforcement and health agencies.

Preliminary injunctions: So far, preliminary injunctions have not been granted in pharmaceutical patent infringement cases, even in a case where the rights holder submitted to the court three decisions/opinions (from MOST, the NOIP and VIPRI) affirming infringement. The infringer is still being allowed to participate in and win drug

tenders at state-owned hospitals, and the rights holder cannot stop the sale despite overwhelming proof that it faces imminent, irreparable damage and will succeed on the merits of the case. Preliminary injunctions should be made available in these situations.

Fast-tracking of invalidation actions:

In some cases, such as a case involving agrochemical patents, the court has ruled on patent infringement even though an invalidation action was pending. However, in other cases, the filing of a frivolous invalidation action by the defendant has resulted in a stay being imposed on an administrative or civil action. However, such invalidation actions may take years to resolve, while damages continue to be incurred by the rights holder. Vietnam should adopt systems employed in other countries where invalidation actions heard by the patent office are fast-tracked, and/or a stay is not granted if the invalidation action is not considered to have a high chance of success on its merits.

Damage calculations: In order to effectively deter patent infringement, Vietnam should adopt a system where patent damages can be trebled in the event that the infringer knowingly infringes a patent (such as by continuing to infringe after receiving a cease-and-desist letter, or after an administrative decision finding patent infringement has been issued). Moreover, the burden of proof of damages in IP cases is higher in Vietnam than in most countries. As mentioned, there are several hurdles in patent litigation in Vietnam, and it is therefore inappropriate that damages should be low if a rights holder can successfully overcome these hurdles and has suffered damages.

Specialised IP court: Vietnam would be wise to consider adopting a specialised IP court. When Thailand established its IP Court, a strong message was sent to investors that the country was focusing on improving IP enforcement, and also helped consolidate the best experts in IP jurisprudence under one court for consistent handling of cases.

Compulsory licensing: Vietnam is considering draft regulations on compulsory licensing. However, the draft regulations are missing several key components, such as allowing the rights

holder to take part in the proceedings, and not requiring failed licence negotiations as a prerequisite to a compulsory licence being granted. Compulsory licensing has not been granted in Thailand since 2007, and has never been granted in Japan; thus, Vietnam should reconsider whether it is truly needed, and in any case needs to ensure that any regulations comply with international commitments.

Parallel imports: Vietnam should consider adopting stricter regulations on parallel imports in the pharmaceutical sector. Pharmaceuticals can be imported from countries with different storage conditions (for example, different climates) and other regulatory requirements, or misleading information on origin, which can result in pharmaceuticals being imported into Vietnam that do not meet quality standards, or which mislead consumers. The Market Management Bureau of Hanoi should be commended for its stance against parallel-imported pharmaceuticals when regulatory violations are involved, as demonstrated in one case in 2016 when it raided a pharmacy, seized the medicines and imposed a fine.

Special import quotas (SIQ): Many IP-infringing pharmaceuticals are imported via fast-tracked special import quotas. There is rarely any public information available on the application or decision to grant the SIQ. As a result, the rights holder cannot take action until the market has already been flooded by the infringing product, thus adding to the damages to the rights holder. Further transparency is needed.

Trade marks incorporating INNs:

Vietnam's trade mark registry contains many trade marks that inappropriately incorporate INNs. The registry should adopt a trade mark examination system where objections can be raised automatically in certain circumstances involving INNs, and the burden is placed on the applicant to rebut the inference of non-registrability.