

Should Vietnam Introduce Patent Term Extension?

Background

Patents play a key role in encouraging the development of pharmaceutical products. It can take several hundred million dollars to discover, develop, and gain regulatory approval for a new drug, and funding for research is obtained primarily from profits made while the innovators have exclusive rights to market their medicines. The length of this exclusivity is therefore an important aspect of patent policy for pharmaceuticals.

In most countries, including Vietnam, invention patents have a 20-year term from the date of filing the patent application. However, considering the time consumed by the examination process, including delays beyond the patentee's control, the actual effective life of a patent is less than 20 years—sometimes much less. Pharmaceutical patents, in particular, have a shorter effective period of protection than patents in other fields, as the application can take one year longer to process due to specification complexity, and it can take more than two years to complete regulatory procedures and conduct clinical trials before a patented pharmaceutical product can be launched in the market.

As a result, many countries, including Japan, South Korea, Australia, Singapore, Taiwan, the United States, and most European countries, have legislation to extend patent terms to compensate for patent time lost in satisfying regulatory requirements. Vietnam, despite having joined the WTO and ASEAN, has thus far remained silent on the issue of patent term extension.



Proposals for Vietnam

One of the main objectives of the patent system in any country is to reward inventors appropriately for their efforts, innovation, and investment. Patent terms are, in theory, determined on the basis of providing inventors (and/or owners) a reasonable return. Accordingly, owners of pharmaceutical patents, with a much shorter effective patent life, do not receive optimal returns for their efforts unless a patent term extension is granted. It is reasonable, then, that Vietnam should follow the lead of other countries and adopt a provision for extending the protection term of pharmaceutical patents to compensate for the time lost due to delays in examination at the National Office of Intellectual Property (NOIP) and the time taken to meet the country's strict drug regulatory requirements. We believe Vietnam should develop a policy for compensating owners of pharmaceutical patents to ensure fairness.

Creating a framework for extending the term of a pharmaceutical patent is complicated and involves multiple factors, many of which are beyond the scope of this article. However, there are several general principles that should be followed to introduce new regulations relating to patent term extensions in Vietnam.

Patent term extensions should require the patentee (the holder of a currently valid pharmaceutical patent) to submit a formal request, providing evidence of valid marketing authorization, evidence of delay due to the registry, and any other reasons for extension. The NOIP's approval, if granted, could be presented in an appropriate form, such as the Supplementary Protection Certificate (SPC) given in European countries. In any form, the approval for patent term extension would be national in effect as a basic patent, coming into force only after the corresponding patent expires, and relating to a specific product. A patent term extension would have a maximum lifetime of a set number of years, for example, five years as in Japan, South Korea, and Singapore.

Patent term extensions should only apply to pharmaceutical products which were approved to be marketed in Vietnam before the request for patent term extension, with a patent granted prior to the regulatory approval date. However, there could be some exceptions; for example, if the applicant could point out the obvious delay of the NOIP in the patent prosecution, then an extension may be applied to patents which were granted after the regulatory approval date.

Patent term extensions should be granted to patents protecting new substances which are active ingredients of any pharmaceutical product. This means the protection conferred by the patent during the term of the extension would only apply to substances which are active ingredients of the pharmaceutical products for which marketing approval was sought. This is reasonable because it often takes a long time to obtain marketing authorization for drugs with new active ingredients due to safety requirements.

An application for a patent term extension should be made within a specific duration, for example, six months from the granting date of the patent or the date that marketing approval was issued, whichever is later. The approval for patent term extension should be published in the Intellectual Property Gazette as well as the NOIP online database. Also, during the extension term, annuities on the basic patent should be charged.

Conclusion

Intellectual property protection is essential to incentivize investments and innovation in the research and development of new medicines which address unmet medical needs. Due to the non-standard circumstances and extensive time investments related to pharmaceutical discovery, development and regulatory review, we believe it is necessary and appropriate to take steps to maintain effective marketing exclusivity for pharmaceuticals through patent term extensions. At this time, Vietnam has not yet applied any policy of patent term extension for pharmaceuticals. However, as the Vietnamese government is increasingly open to public consultation, we believe that this matter should be considered in the coming time, when the Law on Intellectual Property is amended (perhaps in 2016 or 2017). ■

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