Managing Intellectual Property
The Global IP Resource

01 July 2010

New circular on drug registration

Circular 22/2009/TT-BYT issued by the Ministry of Health, effective May 24 2010, has clarified certain issues related to IP rights and drug marketing approval in Vietnam.

The Circular emphasises that the applicant for marketing approval for a drug shall be responsible for any infringement of IP rights used on or in relation to the drug. Consequently, proof of IP cleanness for a drug, such as search reports, registration certificates, application acceptance decisions, is no longer required by the Drug Administration of Vietnam (DAV) for obtaining drug marketing approvals. Applicants are strongly recommended to establish IP rights related to the drug and/or conduct a search on related IP rights before filing applications for marketing approval. If a drug contains an active substance that is being protected under a patent, the applicant is advised to submit a copy of the relevant patent to the DAV.

An application for marketing approval may be opposed by a third party if that party can submit a decision on infringement issued by an IP rights management or enforcement authority. Marketing approval shall be withheld if an opposition is well-grounded, demonstrating that an infringement of IP rights would occur if such marketing approval was granted. As for marketing approvals in effect, based on a request by the IP rights holder or a concerned third party and based on an award by a competent court or a final decision by an IP rights management or enforcement authority, the Ministry of Health shall revoke the marketing approval for a drug that is found to infringe IP rights.

In addition, it is noteworthy that the circular provides that two years prior to the expiry of a patent, drug companies may apply to obtain marketing approval for a generic version of a drug under the patent. In such cases, applicants are required to submit documents showing that the patent is about to expire and this must be clearly stated in the application.


Vu Thi Kim Dung and Nguyen Duy Dzung

Tilleke & Gibbins Consultants Limited
HAREC Building, 4th Floor
4A Lang Ha Street
Ba Dinh District
Hanoi, Vietnam
Tel: +84 4 3772 6688
Fax: +84 4 3772 5568
thuylien.v@tillekeandgibbins.com
www.tillekeandgibbins.com