

Intellectual Asset Management

International reports



New experimental-use exemption builds a more level playing field

[Formosa Transnational - Taiwan](#)

[Yulan Kuo, Anita Chen](#)

03 Apr 2013

Previously, the experimental-use exemption doctrine in Taiwan was very narrow. In order to fall within the exemption under the former Patent Act, the use could not be profit seeking. Thus, a generic pharmaceutical company which inherently sought to profit from the launch of generic pharmaceutical products was hindered from performing certain tests on a generic version of a reference product (usually a patented one) in order to seek approval.

The specific experimental-use exemption – known as the "Bolar exemption" – was introduced into Article 40-2 (5) of the Pharmaceutical Affairs Act in February 2005. This provided a defence to patent infringement to those conducting tests for obtaining data to support applications for the approval of new drugs and to any consequential practical requirements (eg, importing or manufacturing the pharmaceutical product to be used in those tests). However, this exemption was still rather narrow compared to the typical Bolar-type exemption existing in other countries, as it extended only to new drugs and not medical devices, and was applicable only to pharmaceutical companies, according to the restrictive definition of the term "new drug" set out in the act.

In order to solve this predicament, Articles 59(2) and 60 of the new Patent Act, which came into effect on 1st January 2013, broaden the scope of both the experimental-use exemption doctrine and the Bolar exemption. Under Article 59(2) the experimental-use exemption doctrine is amended to be applied in necessary acts to practise the patent (eg, manufacture, sale, offering for sale, import and use) for research or experimental purposes, no matter whether such acts seek profit. Eliminating the discrimination between for-profit and non-profit enterprises caters to the needs of basic research, while preserving the incentives for technological innovation.

As for Article 60, the new Bolar defence applies if research, experiments and necessary acts thereof at pre-clinical or clinical trial stage are being conducted to obtain registration and market approval of drugs under the Pharmaceutical Affairs Act or to obtain market approval of pharmaceuticals from a foreign country. This article covers all "medicaments", including drugs and medical devices as defined in Article 7 of the Pharmaceutical Affairs Act. Notably, the new Bolar defence is applicable not only if the approval sought is for a generic drug in Taiwan or abroad, but also if the tests are being conducted to provide data to support an application for approval of an innovative drug.

Remarkably, as explained in the legislative reasons for the amendments, listing trials (unique test procedures in Taiwan held after approval is obtained according to requests from hospitals for their purchasing requirements) still fall outside the Bolar exemption due to their failure to meet the requirement to obtain registration and market approval of drugs under the Pharmaceutical Affairs Act. This leaves pharmaceutical companies open to liability for patent infringement when performing listing trials. The broadened experimental use exemption doctrine may be a proper defence in such scenario, but this will need to be further construed by the courts.

A patentee can obtain a term extension in Taiwan if the patent covers a product that has been subject to a regulatory review period before it can be marketed or used. Pharmaceuticals and agricultural products are subject to such a review period, and new drug products in particular often involve a lengthy application and testing process. Under the former Patent Act, if the term extension for a pharmaceutical or agricultural product to obtain government approval was less than two years after the patent issued, the patent term could not be extended. To help patentees that take less than two years to obtain government approval to seek a term extension, Articles 53 and 147 of the new Patent Act eliminate the former minimum threshold of two years with respect to the time to obtain the government approval.

Arguably, the new Patent Act builds a more level playing field for the pharmaceutical industry and is clearly an important development which will go a significant way towards making Taiwan a more attractive place to conduct clinical trials.



Yulan Kuo



Anita Chen



Intellectual Asset Management

International reports



For further information please contact:

Yulan Kuo
Formosa Transnational
www.taiwanlaw.com
Email: yulan.kuo@taiwanlaw.com
Tel: +886 2 2755 7366

Intellectual Asset Management magazine (www.iam-magazine.com) is a publication that reports on intellectual property as a business asset. The magazine's primary focus is on looking at how IP can be best managed and exploited in order to increase company profits, drive shareholder value and obtain increased leverage in the capital markets. Its core readership primarily comprises senior executives in IP-owning companies, corporate counsel, private practice lawyers and attorneys, licensing and technology transfer managers, and investors and analysts.