

# **Study on Patent Linkage System and its Related Issues of Competition Law**

## **Abstracts**

**Keywords:** Patent Linkage, Pharmaceutical Affairs Act, Generic Drugs, Reverse Payment, Fair Trade Law

In response to the negotiation of the “Trade and Investment Framework Agreement” (“TIFA”) between Taiwan and the U.S. and Taiwan’s active pursuit of the opportunity to join the “Trans-Pacific Partnership” (“TPP”), Taiwan intends to adopt a “patent linkage system” and a draft amendment of the Pharmaceutical Affairs Act (hereinafter as “PAA”) has been passed by the Executive Yuan on August 4, 2016. The patent linkage system prescribed in the said amendment overall is modeled after the U.S. patent linkage system, with slight differences only on the terms of Automatic Stay and Exclusivity periods (where the terms prescribed in the draft amendment of PAA are both shorter than their U.S. counterparts). However, since patent linkage systems have aroused a considerable number of competition law issues, this study will survey competition law issues related to patent linkage systems in countries where patent linkage systems are in operation, such as the U.S., Australia, Korea, and Canada, as well as introduces existing situations of the drug markets in various countries, looking at areas such as impact of insurance systems, competition between generic drugs and patented brand-name drugs, and the controversy over market delimitation in pharmaceutical industries, as a basis for analysis of possible impact after the patent linkage system is introduced in Taiwan. In addition, although the European Union does not employ a patent linkage system, cases of reverse payment settlement related to patent linkage have already occurred. Therefore, this study will also survey and analyze E.U.’s pharmaceutical market condition and related reverse payment settlement cases.

Competition law issues related to patent linkage system majorly include agreement of reverse payment agreements, improper listing and sham litigations. In addition, market definition is the important basis of Fair Trade Law for market competition analysis. After referring relevant enforcement in other countries, market definition theory, and experts' opinions, this study suggests that in the cases the brand-name drug manufacturers intend to delay the entry of generic drugs by entering into agreement with generic drug manufacturers, or by manipulating the patent linkage system, the product market should only include the brand-name drug in dispute and all corresponding generic drugs with the same major components. As for reverse payment agreements, unless the reverse payment agreement at issue involves any traditional cartel, such as express market division, it is inappropriate to directly determine such agreement as a "concerted action" under Article 14 and 15 of the Fair Trade Law. Instead, the better choice would be reviewing reverse payment agreement under Article 25 of the Fair Trade Law, and making the point of the size of payment made by the brand-name drug manufacturer to the generic drug manufacturers, and the entry timing of the generic drug under the agreement at issue.