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[Patent Linkage under Article 60-1 of revised Taiwan Patent Act effective July 1, 2022]

The patent linkage system is related to drug regulations for market approval and patent protection, and may provide an early resolution for possible patent disputes or infringements. In recent years, Taiwan government has taken many efforts to introduce the linkage system between patents and medicines by revising the Pharmaceutical Affairs Act and the Patent Act, in order to be admitted to accede the Comprehensive and Progressive Agreement for Trans-Pacific Partnership (CPTPP). Following the relevant amendments of the Pharmaceutical Affairs Act enforced in 2019, the Patent Act was also revised on May 4, 2022 to add a new provision of Article 60-1, and then announced by the Executive Yuan to take effect as from July 1, 2022.

Below are the two main points of Article 60-1 of the Patent Act:

- The applicant for a generic drug license shall declare, in accordance with the provisions of the Pharmaceutical Affairs Act, that the patent right published on an approved new drug should be revoked, or that the generic drug does not infringe the patented new drug; the patentee, after being notified of the declaratory, may file a petition to eliminate or prevent the infringement of the patent right, according to Article 96-1 of Patent Act.

- If the patentee has not filed a lawsuit within the notification period as specified by the Pharmaceutical Affairs Act (45 days from the day after receiving the notification), the applicant of a generic drug license may file a declaratory suit, to confirm whether the generic drug constitutes the infringement of the patent right.

Generally, the patent linkage system is to balance the interests of new patent drug manufacturers, generic drug manufacturers, and the public. As patent drug manufacturers spend many years with huge amount of money to develop new drugs and apply for invention patents, new drugs are usually more expensive. Therefore, the lower-cost generic drugs appear on the market for patients or consumers who seek to reduce the burden of medication. Since the patent duration of a new drug is 20 years (counting from the filing date of an invention patent application, and may be extended for another five years), most of the generic drugs are sold after the patent duration of a new drug is expired, or its patent right is revoked and invalidated.

According to the relevant provisions of the Patent Act and the Pharmaceutical Affairs Act, when a generic drug company applies for a regulatory approval for marketing the generic drug, and declares that the patent right of a new drug is invalid, or asserts that the generic drug does not infringe the patent right, the new drug license holder shall be notified in writing; if the new drug license holder is different from the patentee (or an exclusive licensee) as listed, both should be notified as well. As such, the pharmaceutical company which developed and invented the new drug can file a lawsuit within the prescribed period during the review period of the generic drug, and this may delay the generic drug company to obtain a regulatory approval. If the new drug company does not file a lawsuit, then the generic drug company could also attack by filing a declaratory suit against the new drug company, avoiding any menace after the generic drug has been approved for sale and sold in the market. ※

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