Patent Linkage in Generic Pharmaceutical Marketing Approval System: A Critical Assessment of Experiences in the United States

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Abstract

As one of the most powerful countries in the world, the United States has been constantly promoting its legislations to countries around the world through trade negotiation and threat to sanction, for the purposes of abating trade barriers and pursuing its own interest. In recent years, for instance, the United States has been trying zealously to introduce the "patent linkage" system into Taiwan. "Patent linkage" means that the marketing approval of generic drugs or the payment of medical insurance are "linked" to the judgment of whether the generics infringe a valid patent held by a brand-name pharmaceutical company on the same type of drugs or not. Focusing on this issue, the authors firstly makes further discussion into the complexity of the patent linkage system in order to examine whether the system is fully justifiable, and try to evaluate whether it in reality resolves the problems it was set to settle and facilitates the development of domestic pharmaceutical industry. Secondly, this article evaluates thoroughly the pros and cons of the existing patent linkage system in the U.S. by means of literature review and case study. The authors find that most of the negative effects that the system now brings about result from its pro-brandname measures, which not only stifle generics competition and accessibility in the pharmaceutical market but also are not essential for the

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system to fulfill its mandate. Even if Taiwanese government finally chooses to adopt patent linkage, these injurious side measures should not be introduced altogether.

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