

專利有效性判斷雙軌制下 臺灣專利連結制度觀察及建議

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摘 要

美國法院判決專利無效，即拘束其後所有訴訟當事人；是以，在專利連結制度下，當有學名藥廠取得專利無效判決，美國食品藥品監督管理局（USFDA）於另一學名藥廠申請上市時，不再啟動暫停核發許可證。臺灣專利有效性判斷則採雙軌制，雖然民事法院得自為判斷專利有效性，惟僅生個案拘束力；因此，專利連結在臺灣施行後，即使系爭專利曾經民事法院認定無效，只要未經舉發撤銷，臺灣衛生福利部食品藥物管理署（TFDA）在另一學名藥廠申請上市時仍於法定期間暫停核發許可證。由此可知，同樣的專利連結制度，適用臺灣專利法制後產生有別美國的法律效果，系爭專利將繼續啟動暫停核發許可證的法定效力，遞延第二、三家學名藥廠進入市場的時間，進而影響藥品價格與製藥產業發展。鑑於上述問題，本文研究美國修法歷程與韓國立法例，在臺灣公私法二元與雙軌制的結構下提出專利連結制度的規範配套建議，調和現行臺灣專利連結制度在專利有效性判斷雙軌制下可能形塑的市場壁壘。此外，臺灣有別美國，尚未允許學名藥廠主動提起確認系爭專利應撤銷或未侵權之訴，於訴訟啟動完全處於被動；甚至在專利連結

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下擬制侵權訴訟中對原開發藥廠訴訟理由有重大影響的專利資訊有疑義時，得否爭執亦未可知。本文建議臺灣未來在專利法增訂專利連結下擬制侵權態樣時，應確保配套規定學名藥廠得於原開發藥廠未於法定期間起訴時，提起確認專利未侵權之訴；並基於專利資訊為該擬制侵權的重要基礎，規定學名藥廠得於專利連結訴訟中提請法院審酌專利資訊適格與正確性，以平衡現行制度下學名藥廠的弱勢地位。

關鍵詞：專利連結、公私法二元與雙軌制、藥品專利登載、擬制侵權、暫停核發藥物許可證、銷售專屬期間

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Observations and Suggestions on Taiwan's Patent Linkage System in Bifurcated Patent Litigation System

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Abstract

In the U.S., once a patent owner's patent(s) is declared as invalid, he cannot bring an infringement suit against other implementers any more. Therefore, when a generic drug company successfully challenges patent(s) validity in a Hatch-Waxman litigation, the US FDA will not grant other 30-month stays of regulatory approval to brand-name drug company because the patent(s) corresponding to new drugs is invalid. However, patent law in Taiwan follows the bifurcation system. Accordingly, although Taiwan civil courts are allowed to decide the validity of patent right at issue, its opinion binds only the parties in suits. For that reason, after the patent linkage system is implemented in Taiwan, the statutory 12-months stays will be triggered automatically if the patent(s) corresponding to new drugs have not been revoked, even the civil courts had decided the patent(s) is invalid based on the merit of the case. Obviously, patent linkage system in Taiwan's bifurcated patent litigation system will delay the latecomer generic drug companies who sell the same drug entering the market. The generic pharmaceutical industry and the right

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to access medicine in Taiwan will subsequently be jeopardized. Furthermore, Taiwan civil courts are not allowed to invalidate a patent or decide whether patent(s) corresponding to new drugs is infringed by a counterclaim or declaratory judgment. On top of that, it is still unknown that whether the generic drug company could question the patent information in the Hatch-Waxman litigation if it seems inappropriate. As a result, this article digs into U.S. Statute law revision and suggests Taiwan civil courts should shoulder the burden of verifying the information after requested by the generic drug company in the litigation with the objective of striking a balance between brand-name and generic drug company.

Keywords: Patent Linkage, Bifurcated Patent Litigation System, Drug Patent Listing, Artificial Act of Infringement, Automatic Stay, Market Exclusivity