

跨太平洋夥伴協定智慧財產權專章對於我國製藥產業之衝擊——一個法制面的觀察

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摘要

跨太平洋夥伴協定 (TPP 協定) 歷經數年談判, 12 個締約國於 2015 年 10 月 6 日正式達成協定。我國政府目前已有加入 TPP 協定之既定政策, 在談判結束、我國僅有全盤接受談判結果的情況下, 其中智慧財產權專章對於藥品專利法制與我國醫藥產業可能產生的衝擊, 為台灣醫藥與專利法界所密切關注。

欲了解 TPP 協定智慧財產權專章可能造成我國製藥產業與相關法制的衝擊與變革, 本文首先從製藥產業的特色切入, 並介紹部分 TPP 參與國與台灣製藥產業的情況。製藥產業為高知識密集的產業, 技術進入障礙高; 雖然成本高風險高, 但產品市場大、生命週期長、獲利高。在此前提之下, 製藥產業先進國家, 重視對智慧結晶的保護, 並希望透過國際協定使各國均提升至所期待之標準; 另一方面, 在新藥專利保護期間經過之後, 如何使學名藥快速上市, 亦為各國所關切。

是此, 本文將再介紹本次 TPP 協定智慧財產權專章中, 可專利性要件、專利權期間延長、資料專屬權與專利連結制度部分協定結果提出介紹; 最後並就協定結果與我國專利法制與藥政管理與製藥產業可能發生之衝擊提出評論。

Abstract

After negotiating for several years, 12 members reached the Trans-Pacific Partnership Agreement (TPP Agreement) on October 6th 2015. Taiwan's government has made the policy to join the TPP Agreement. Because the negotiating process has been completed, we have to accept all the agreement if we would like to join it. Therefore, our pharmaceutical industry, government and legal academia all follow closely the agreement and its possible impacts to our legal framework and industry.

This article starts with a brief introduction about pharmaceutical industry of its

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intensive knowledge and technology requirement, high risk and rewards of investment and products' long life-cycle and big market. Nations with superiority to research and develop pharmaceuticals emphasize the protection of intellectual property rights and expect to leverage other nation's protective level by international agreements. On the other hand, nations all have the public health interests to help generic drugs launched to the market as soon as possible right after brand drugs lose their patent protection. Therefore, I will introduce some TPP members and Taiwan's pharmaceutical industries in order to analyze the negotiation of pharmaceutical issues in TPP Agreement.

This article will introduce the provisions of TPP Agreement about patentability, extension of terms of patent protection, data exclusivity and patent linkage about pharmaceutical patents. Eventually, this article will discuss about the possible impact to Taiwan's pharmaceutical industry, patent law and environment of patent litigation.