

當「杜哈公共衛生宣言」遇上 TRIPS-Plus——

藥品專利連結是否會阻礙強制授權的實施？

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摘要

本文的目的為探討藥品專利連結是否會損及強制授權的效果。世界貿易組織的《與貿易相關智慧財產權協定》(Agreement on Trade Related Intellectual Property Rights, 以下簡稱 TRIPS 協定)在「杜哈 TRIPS 協定與公共衛生宣言(Declaration on the TRIPS Agreement and Public Health)」及其後續的發展下,對於開發中國家會員因重大公共衛生事由需要實施強制授權的規定,朝向提升與保障藥物可近性與健康權的方向詮釋與發展。惟另一方面,工業化國家將專利連結制度與資料專屬權等偏向保障藥品專利權人,且未規定於 TRIPS 協定中的制度納入區域性貿易協定與自由貿易協定中,而成為所謂的 TRIPS-Plus,以維繫自身利益與競爭優勢。本文嘗試就制度與法規面探討專利連結制度是否會限制藥品強制授權促進藥物可近性與保障健康權的效果,並從實施強制授權的會員是否具有生產學名藥的能力,或是需要倚賴外國學名藥廠協助生產之後再進口等不同情況進一步分析其中差異。

關鍵字：專利連結、強制授權、TRIPS 協定

Abstract

This paper aims to deal with a question—could patent linkage be an obstacle for issuing compulsory licenses? “Declaration on the TRIPS Agreement and Public Health” led the rules of compulsory licenses in the WTO TRIPS Agreement towards the direction to meet the needs of Members to issue drugs compulsory licenses to address serious public health events so as to prompt the accessibility of medicines and preserve health rights of people. TRIPS-plus however reflects another trend that industrialized countries tend to introduce mechanisms such as patent linkage and data exclusivity, which are not under the regime of the TRIPS Agreement, in various regional trade

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agreements and free trade agreements to serve for the benefits of their pharmaceuticals industries. This paper will review the regulations of patent linkage to examine whether it would limit the effects of compulsory licensing, and to check if it will be different if the Member issuing compulsory licensing is in a situation that is able or unable to manufacture pharmaceuticals.

Key words: Patent Linkage, Compulsory License, TRIPS Agreement

