醫法新論

由歐盟孤兒藥案件談競爭法與藥品超額定價問題

EU Orphan Drug Cases and Tackling Excessive Drug Pricing by the Enforcement of Competition Law

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摘 要

由於孤兒藥的市場特性以及法定銷售專屬權保護，使藥廠有超額定價誘因，傷害了消費者及國家利益。近年歐盟數會員國接續對同一孤兒藥藥廠以違反競爭法裁罰，是為Leadiant案；歐盟執委會也查處安沛（Aspen）藥廠的血癌用藥，是否有違法超額定價情事，此顯示歐盟以競爭法介入藥價管制的趨勢。在個案中歐盟採「UB測試」，即先「量」後「質」的分析模型，已具有通案性。歐盟競爭法設有禁止支配事業不公平定價的榨取式濫用條款，我國公平法亦有主旨相同的規範，歐盟的執法作為值得參考。

The unique characteristics of orphan drug market

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and the right of exclusivity provide the incentives for pharmaceuticals to adopt excessive pricing. In recent years, three EU member states' competition authorities had fined the same orphan drug company, Leadiant, due to illegal excessive prices. European Commission also sanctioned Aspen because the medicine manufacture had imposed unfair prices, abused its dominant position and violated the EU competition law. All these facts reflect the trend that EU competition law has been used as a tool to tackle the exorbitantly high drug prices. The "UB test", i.e., cumulatively quantitative and qualitative analyses, is applied in those cases. The rules for prohibiting abuse of dominance in both EU and Taiwan have the common purposes and principles, therefore the practices and enforcement experiences in EU are valuable for use to learn.

壹、前言

孤兒藥（orphan drugs, orphan medicinal products）係指主要用於治療、預防或診斷罕見疾病（rare diseases）的藥品。罕見疾病（下稱「罕病」）的定義，依據我國「罕見疾病防治及藥物法」（下稱「罕病法」）第3條第1項授權衛生主管機關公告之標準，係指年盛行率為萬分之一以下之疾病[1]；在美國是以境內病人數少於20萬人之疾病視為罕病[2]；歐盟法規則是

1 民國89年8月9日行政院衛生署衛署保字第080009924號函。
2 U.S. Food & Drug Aminstration, Office of Orphan Products Developmen, Dec. 13, 2022, https://www.fda.gov/about-fda/office-clinical-policy-and-programs/office-orphan-products-development

以每1萬人中病人數少於5人作為罕病之定義[3]。由於罕病的病例與病人數目甚少，既無市場規模，藥品的研發及臨床試驗相對複雜，藥廠基於成本效益的考量，認為開發治療罕病藥品的成本，不可能透過「正常」售價且數量有限的銷售得以回收，研發與製造孤兒藥無利可圖，欠缺經濟誘因導致市場失靈。這個特性說明了何以治療罕病的藥品稀缺，被名之為孤兒藥的原因。為滿足病人的醫療需求，保障基本人權，各國立法政策上無不以提供研發獎助及藥品銷售專屬權（market exclusivity）為誘因[4]，達到促進治療罕病藥品上市的目的。從競爭法的觀點，孤兒藥銷售專屬權實質上是以法規為藥廠創造了獨占地位，減少孤兒藥市場的競爭。此外，孤兒藥銷售專屬權與藥品專利是兩種平行而並存的排他權利，研究顯示，視原廠藥專利期間與銷售專屬權期間重疊的程度，孤兒藥銷售專屬權對藥廠提供保護的效果與價值將有所差異；如果專利權期間屆滿之後，孤兒藥銷售專屬權仍持續有效，銷售專屬權會有部分替代專利保護的功能[5]，有延長孤兒藥藥廠獨占期間的效果。就算專利與專賣兩項權利都已失效，由於市場規模實在太小，可預期利潤根本無法吸引學名藥廠進入市場參與競爭，使得孤兒藥市場呈現自然獨占的特質，即使在各種專屬權利都不復存在的情形下，原孤兒藥藥廠仍可能在未來相當期間內，持續維持獨占地位[6]。

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3 Article 3(1)(a), Regulation No 141/2000 of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products (hereinafter referred to as "Orphan Regulation").

4 罕病法第10條、第17條參照。

5 Nicholas Bagley, Benjamin Berger, Amitabh Chandra, Craig Garthwaite & Ariel D. Stern, *The Orphan Drug Act at 35: Observations and an Outlook for the Twenty-First Century*, 19 INNOVATION POLICY AND THE ECONOMY 103 (2019).

6 *Id*., at 103, 106, 114.