生技製藥產業技術授權與研發契約之研究

─兼論專利集管與強制授權制度

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摘　要

生物技術產業之產業結構複雜，涵蓋產品研發、製造、法規範之符合、行銷…等多方面，加以技術層次高、近代以來發展快速，縱係生物技術背景之專家亦無法熟知各領域之特有技術，是生技製藥產業專業分工細，常須跨領域地從事橫向及縱向的整合，並在產品研發及申請核准上市、行銷的接力過程中，各自發揮專長、完成階段性任務，以收最大實益。因此，生技製藥產業之結構自日趨於複雜化，而須透過合作或分工之模式(如併購、合資、聯盟或技術移轉…等方式)，以收商業最大獲利。

承上，生技製藥產業所牽涉的技術移轉，其技術標的大多是以法律手段所保護的一種法律上利益，亦即「智慧財產權」。智慧財產權係透過法律授與權利之擁有者的一項獨占、排他的特殊利益，而此獨占之本身，即有妨害競爭之虞。是生技製藥產業無論採取何種方式去解決「技術取得」之問題(如策略聯盟、單純授權契約、專利集管或強制授權…等)時，除以內部自行研發方式取得外，都無可避免地牽涉到「不當限制競爭」之反托辣斯(Antitrust)議題。

近年來，隨著少數的基因專利及許多等待法令批准的專利申請逐漸增加…等情況，專利權利因權利的獨占、排他本質及專利數量的激增，竟逐漸發展出權利無從充分利用的「反共有化的現象」，而此現象亦已開始威脅生技產業之發展。此外，隨著阻礙性專利及堆積性授權之不斷增加及逐漸高漲的權利金，生技產業亦遭受前所未有的挫折。嘗試研發技術及量產生技產品的業者深知─除非繞過該問題不管，否則只好試著有效率地去解決上開問題。

惟何者為有效率的可能解決之道(技術移轉)？在涉及反托辣斯(Antitrust)議題部分，目前各國之見解及處理方式為何？

按，因應生技製藥產業的「複雜性產業結構」及「國際技術分工」的趨勢，生技製藥產業的技術移轉契約可概分為研發聯盟契約(CRADAs)或外購契約(Outsourcing agreement)二種，契約的內容或有差異，惟契約之主要項目及運用的技巧則有其共通之處，本文乃就契約簽訂前之協商、議訂之內容…等，及技轉契約各別條款所可能涉及之反托辣斯議題，分就美國及歐盟之立場，概要說明之，俾得據為生技製藥產業研擬技術移轉契約時參酌之用；其次，鑒於生技製藥產業中關鍵性技術取得之重要性與困難度，有學者提出以組成專利網或專利集管(patent pool)之模式，來取得技術或形成商業上競爭障礙，惟格於該產業中之特殊屬性，其效果受有相當限制，縱然如此，探究專利集管適用之利弊得失後，仍可認定專利集管不失為生技製藥產業用以整合技術平台的有效工具之一，至其所引發的限制競爭之疑慮，美國及歐盟原則上均採肯定其有益競爭之效力，但同時亦設下相當審查基準，以避免「反競爭效果」之出現；另，生物技術產業間技術之取得，在與公益有關等議題的特定的情形下，亦可能以「強制授權」(non-voluntary licesne)之方式來達成目的，美國及歐盟就其「強制授權」實施的特定要件及可能引發的反效果，均設有相當的審查程序及標準，以確保技術移轉在公益與私益間的合理與平衡。

Technology Transfer and Research Contract of Biopharmaceutical Industry :Including the Use of Patent Pooling and Non-voluntary Licensing.

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Abstract

In recent years, as the few number of applications for the patent of gene and many other patents waiting for legal approval has increased, and due to patents' monopoly and exclusiveness benefits and to the soaring number of patent rights, we witness the continuous expansion of the anti-commons phenomenon - A phenomenon that has began to threaten the development of the Bio-Technology Industries.

In addition, the constant increase of "blocking patents" and "stacking licenses" and the surge of patents' payoff have brought a new and unknown discouragement to biotechnology industries. The companies that attempt to research and develop technologies and produce new products are well aware of the need to find a suitable solution to this problem.

What is, therefore, an effective method (to employ in the transfer of technologies) that is sufficient to solve this problem? What are the ideas and methods that are relevant to antitrust issues and that are put to practice abroad?

Biopharmaceutical Industries, in order to accord with "Complicated Industry structure" and the trend of "International

Technologies' Division of Labor" have employed two kinds of Agreements for Transfer of Technology: "Cooperative Research and Developments Agreements (CRADAs)" and "Outsourcing Agreements". Although the contents of these two agreements are different, the main issues and the mode of performance is commonplace for both kinds.

This study examines the discussions and negotiations prior to the contract's sign up; antitrust issues that are relevant for articles in agreements for transfer of technologies; It discusses the differences between the American approach and the European one; The study gives brief explanations and its main objective is to serve as reference for Biopharmaceutical Company, when drafting an agreement for Transfer of Technologies. In addition, in light of the importance and the level of difficulty that Biopharmaceutical companies faces amidst the acquisition of its main technologies, some scholars suggested the models of patent pools and patent net compositions in order to block competition from technologies' acquirers or developers and to limit it to distinctive attributes within the industry. Although the effectiveness of these methods is quite limited, after a thorough examination of the advantages and disadvantages of the Patent Pool model, I found that the method could serve the Bio-Technological Pharmaceutical Industry as an effective tool in the integration process of its technological platforms.

As for the doubts about the method's limitation of market competition, although in principle both the US and the European Union have affirmed the method's ability to enhance competition, but at the same time they also set up examination standards, in order to prevent the occurrence of any "uncompetitive" effects. In addition, in order to accord

with Public Welfare requirements, the acquisition of technologies within the Biopharmaceutical industry can reach its goals by using a “non-Voluntary License” mode of performance. The US and the European Union have set up appropriate examination procedures and standards for investigating the requirements and the negative effects involved with its implication, in order to balance between public welfare and private interest in the process of technologies’ transfer.