摘要

隨著醫療科技的進展，人類對於疾病的成因、機轉、病程、及治療，在不斷地研究突破下，有著持續的進步而對人類的健康有著不可或缺的貢獻。其中藥品，正是人類對抗疾病最關鍵、也最普遍的方式之一，對公共衛生的重要性自不待言。

其中，由於生命科學的本質使然，開發新的藥品對於研究發展的倚賴，遠勝於其他產業，因此，創新研發藥廠對於開發一項新藥的平均投資，已達十三億美元之譜；此外，由於藥物對人體的生理功能、體內恆定能造成極大的影響，因此世界各國的醫藥衛生主管機關無不對於藥品的上市加以嚴格的管制，使得現今開發一項藥品平均約耗時十至十五年。藥品開發的巨大投入與耗時極長的開發期間，使得製藥產業亟需經由智慧財產權的制度來提供其投入研發創新之誘因。然而，因為智慧財產之保護，也使得新藥往往售價高昂而造成公眾近用之阻礙。而學名藥正是解決這樣的問題的關鍵之一，亦為世界各國所大力推動。在推動學名藥產業上，實驗實施免責為制度上極為重要的考量之一。本文及希望藉由對製藥產業特質之探究，美國普通法上以及成文法上實驗實施免責的探討，我國實驗實施免責之規定與判決之研究，來找出我國當下實驗實施免責的規定於製藥產業中適用時所可能發生的問題，以及相對應的可能改進方案。

本文第二章本章先行探討製藥產業之特質；第三章討論美國普通法上實驗實施免責之概念，並歸結出美國普通法上實驗實施免責的三項適用要件；第四章探討美國成文法上實驗實施免責之立法背景、相關判決以及對生物科技領域各層面的影響；第五章則先行探討世界貿易組織於「與貿易相關智慧財產權協定」中對於專利權之限制基礎。其後探討我國專利法中之一般實驗實施免責以及藥事法中針對製藥產業之實驗實施免責之相關規定，並由學者論述以及相關判決中，探討我國實驗實施免責之相關規定於製藥產業實務上所可能面臨之問題，並提出可能之解決方案。

Abstract

With the progress of medical technology, humans have been furthering the understanding of the etiologies, mechanisms, courses, and treatments of diseases. Such continued progresses have contributed significantly to improving human health. Among all the treatments, the pharmaceutical is one of the key and common ways with which humanity fight diseases. Its importance to public health is beyond doubt.

Due to the nature of the life sciences, the pharmaceutical industry depends more on research and development than other industries do. Therefore, on average, it costs innovative pharmaceutical companies 1.3 billion U.S. dollars to develop a new drug. Furthermore, countries around the world pose strict regulations on new drugs' entering the market since drugs cause huge impacts on the physiological functions and internal balances of the human body. Hence, it generally takes ten to fifteen years for a new drug to be fully developed. The enormous investment and lengthy developing period makes the pharmaceutical companies extremely dependant on the intellectual property system to provide them with the incentive for research and development. However, it is also because of the intellectual property protection that makes new drugs expensive and difficult for the public to access. The Generic drug, however, is one of the key solutions to solve this problem and is intensively promoted by countries all over the world. Regarding the promotion of the generic drug industry, the experimental use exemption is one of the vital systemic considerations. There are discussions on the characters of the pharmaceutical industry, on the common law and statutory experimental use exemptions of the United States, and on the related regulations and precedents of the experimental use exemption in Taiwan. Through the above discussions, the thesis is aimed at identifying the possible problems the regulations on experimental use exemption might cause when applied to the practice of the pharmaceutical industry and at proposing possible solutions to such problems.

The characters of the pharmaceutical industry are discussed in Chapter two. The concepts and the criteria of the common law experimental use exemptions are discussed in Chapter three. The legislation background, related precedents, and impacts on the field of biotechnology of the statutory experimental use exemptions in the United States are illustrated in Chapter four. Lastly, in chapter five, the restrictions on patent right in the Agreement on Trade-Related Aspects of Intellectual Property Rights of the World Trade Organization is first discussed. The related regulations on experimental use exemptions in Taiwan are later discussed. Lastly, through the scholars' opinions and related precedents, the possible problems of application of the experimental use exemption in Taiwan are illustrated and the probable solutions are proposed.