Pharmaceutical Patent Valuation Based on Technology Innovation and Applications in the Industry

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DISSERTATION ACCEPTANCE CERTIFICATE

The undersigned, appointed by the

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Contents

Abstract

Patent valuation has raised tremendous concern from the research-based pharmaceutical industry for a long time. Questions about the valuation of drug patent portfolios, determinants of success of pharmaceuticals launches, assessment of research and development (R&D) performance or innovation output, and competitive position of different firms in the industry all tend to revolve around the basic question on pharmaceutical patent valuation. Over the past decades, a considerable number of studies on patent valuation were conducted, which mainly focused on general and multi-industry patents and do not usually factor in the technological parameters in order to ensure wide validity for various industries. However, as far as the research-based pharmaceutical industry is concerned, technology factors are critically essential for evaluating patents. In general, there has so far no been effective patent valuation method specifically designed for pharmaceuticals.

This research aims to establish a patent valuation model specifically focusing on drugs based on established patent valuation methods and comprehensive considerations on pharmaceutical technology factors and to explore its potential applications to the industry. Our model comprehensively involves various variables, including number of citations received, patent challenge, number of claims, number of citations made, blockbuster drug, patent portfolio, new dosing schedule, new indication, new combination, new chemical entity (NCE), new dosage form, new product, new strength, orphan drug, pediatric drug, and grant year. In this model, all indicators of patent value could be available early in a patent's life at little cost from public patent data banks. In order to cover a wide range of pharmaceutical patents and ensure the validity of the research outcome, the research sample is composed of all patents listed in the 21st edition Orange Book, which has a total of 913 patents granted by U.S. Patent and Trademark Office (USPTO). The data come from four sources: patent database of National Bureau of Economic Research (NBER), Orange Book of Food and Drug Administration (FDA), legal status database from International Patent Documentation Center (INPADOC), and global blockbuster drug database from Pharmaceutical Digital Library (PHARMADL).

Through multiple regression analysis, it is found that Pharmaceutical Technology Details Indicators (PTDI) significantly influence pharmaceutical patent value and, more importantly enhance the quality of existing valuation methods. Moreover, the marginal effect of individual predictor on patent value is quantitatively measured as follows, respectively: (1) the expected value for an opposed patent is about 34% higher than for a non-opposed patent, holding other factors constant; (2) a one-unit increase in the number of claims increases the value by 2%; (3) a one-unit increase in the number of citations made increases the value by 1%; (4) the expected value for a patent of blockbuster drug is about 17% higher than for a patent of common drug, holding other factors constant; (5) a one-unit increase in the size of patent portfolio increases the value by 3%; (6) new indication increases the expected patent value by 25%; (7) new combination decreases the value by 26%; (8) NCE increases the value by 62%; (9) new dosage form increases the value by 60%; (10) new product increases the value by 57%; (11) new strength decreases the value by 12%; (12) orphan drug decreases the value by 7%; (13) pediatric drug decreases the value by 10%; and (14) a one-year increase in the patent age decreases the value by 16%.

These results are basically consistent with theoretical predictions and further demonstrate the validity of new value indicators and this model. As is well known, NCE is all along the darling of the pharmaceutical industry because it generally represents original research and innovative technique which drive the development of the research-based industry. In this model, NCE actually plays the role of the strongest positive factor influencing the expected patent value. On the contrary, orphan drug and pediatric drug show significantly negative effect, which could be rationally interpreted by small patient population of these drugs. In addition, based on a consideration on 20-year patent term, the residual value of a patent in the model after 20 years roughly equals 3% coincident with the fact that the value of patent rights decays to zero when they expire. In this sense, .16 could be roughly considered the yearly depreciation rate of patent value.

In addition to set up this pharmaceutical patent valuation model, potential commercial application of this model is explored in the following context: technology innovation and intellectual property valuation of Chinese Medicine, pharmaceutical patent valuation in China, the assessment of innovation output and firm performance, and blockbuster methodology and pharmaceutical valuation. Firstly, this method is explored to assess technology innovation and

intellectual property of Chinese Medicine through the analysis on two potential patent technologies on Chinese Medicine. Secondly, it could be clearly showed that commercial transactions involving pharmaceutical patent valuation, for example, technology innovation and transfer, as well as patent protection and licensing have been becoming more and more frequent, when China's pharmaceutical market is growing rapidly and shifting greatly. Patent valuation model specifically focusing on drugs could be widely applied to the evolving pharmaceutical market in China. Thirdly, in view of the wide implications of pharmaceutical patent value, this method shows the wide and potential application to assess innovation output and firm value in the pharmaceutical industry. Finally, on a basis of empirical study, this method is applied to evaluate pipeline drugs and to identify blockbuster drugs at an early stage in terms of the close ties between pharmaceutical patent value and pharmaceutical product value.

Key Words: Pharmaceutical; Patent valuation; Chinese Medicine; Technology innovation

中文摘要

專利價值評估很早以前就引起了以研究爲基礎的制藥產業的高度關注。藥品專利組合的價值，新藥上市成功的影響因素，研發績效或創新產出的評估，以及產業中不同企業的競爭地位等等問題都涉及到藥品專利價值評估這個基本問題。過去幾十年已有大量關於專利價值評估的研究，但是這些研究爲了確保對多種產業的適應性，大都廣泛地以多種產業專利爲研究樣本，並很少考察技術性指標。 然而，對以研究爲基礎的制藥業而言，技術性指標顯然對評估其專利價值具有非常重要的作用。總體來說，到目前爲止還沒有一種有效的專門針對藥品的專利估價方法。

該研究目的爲：在充分借鑒現有專利估價方法和全面考慮藥品技術性指標的基礎上，建立一種專門針對藥品的專利價值評估模型，並探討其在產業中的潛在應用。該研究共涉及到如下16個變量：被引次數、專利挑戰、權利請求項數、引用次數、暢銷藥品、專利組合、新療程、新適應症、新複方、新化學單體、新劑型、新產品、新劑量、孤兒藥、兒科藥和授權年份。模型中所有專利價值評價指標的資料均能在專利早期從公共專利資料庫中以較低成本獲得。爲了盡可能廣泛的覆蓋藥品專利以保證研究結果的效度，本研究樣本由第21版美國食品與藥品管理局《藥品橙皮書》中的所有專利構成，總共涉及913項美國專利。資料主要來源於美國國家經濟研究局專利資料庫、美國食品與藥品管理局《藥品橙皮書》、國際專利文獻中心法律狀態資料庫和藥物數位圖書館的全球暢銷藥物資料庫。

多元回歸結果表明藥品技術性指標顯著影響著藥品專利價值並能優化目前的專利價值評估方法。該研究進一步量化了每個指標對專利價值的邊際效果，具體如下：（1）在其他條件不變的情況下，異議專利的預期價值比非異議專利高34%；（2）權利請求項數每增加一項，專利價值增加2%；（3）引用次數每增加一次，專利價值增加1%；（4）在其他條件不變的情況下，暢銷藥物專利的預期價值比普通藥物專利高17%；（5）專利組合每增加一個單位，專利價值增加3%；（6）新適應症增加預期專利價值25%；（7）新複方減少預期專利價值26%；（8）新化學單體增加預期專利價值

62%；（9）新劑型增加預期專利價值60%；（10）新產品增加預期專利價值57%；（11）新劑量減少預期專利價值12%；（12）孤兒藥減少預期專利價值7%；（13）兒科藥物減少預期專利價值10%；（14）專利年齡每增加一年，其價值減少16%。

以上結果基本上與理論假設一致，並進一步說明了新價值指標和模型的有效性。眾所周知，新化學單體通常代表了推動以研究爲基礎的制藥產業發展的原創研究和創新技術，因而它一直是制藥產業中競相追逐的目標。在該模型中，新化學單體確實是影響預期專利價值最顯著和積極的因素。與之相反，孤兒藥和兒科藥在模型中顯示出顯著消極的效果，這主要是由於這些藥物的用藥人群規模較小。此外，專利保護期一般爲20年，該模型顯示20年後專利殘值約爲原值的3%，這也與現實中專利到期後價值衰減爲零的事實基本一致。從這種意義上說，16%能被粗略地看作專利價值的年貶值率。

該研究除了建立藥品專利價值評估模型外，還從如下角度探討了模型潛在的應用價值：中藥技術創新與知識產權評估、中國的藥品專利價值評估、創新產出和公司績效評估、以及暢銷藥與藥品價值。首先，通過對兩項潛在的中藥專利技術的分析，探討了該模型在評估中藥技術創新和知識產權中的應用。其次，在當前中國藥品市場高速成長和巨大轉型的時期，涉及到藥品專利估價的商業交易，比如技術創新與轉移，專利保護與許可等，正變得越來越頻繁。特別針對藥品的專利價值評估模型能夠廣泛應用於中國藥品市場。第三，考慮到藥品專利價值的廣泛意義，該方法也能廣泛應用於評估制藥產業中的創新產出和公司價值。最後，考慮到藥品專利價值與藥品價值的緊密聯繫，在實證分析的基礎上，該方法也能應用於在研藥物的評估和暢銷藥物的早期識別等領域。

關鍵詞：藥品；專利價值評估；中藥；技術創新

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Awards and Honors

1 Scholarship from the Austrian Federal Ministry for Science and Research, from August 2008 to March 2009
2 Distinguished Speaker, China Pharmaceutical University, April 2009
3 Listed in Annual Report 2008 of Eurasia Pacific Uninet (EPU) in Austria as Excellent Student Representative, 2009.
4 Scholarship from the University of Macau, 2004-2009
5 Excellent Student Award, 43rd Annual Meeting of U.S. Drug Information Association, June 2007.
6 Conference Grant from European Business School INSEAD, March 2007.
7 The Third Award, 9th Challenge Cup of China, October 2005.
8 Excellence Award, Conference for the Propagation and Innovation of Chinese Traditional Culture, July 2005.

List of Figures

List of Tables

Abbreviations

ANDAs	Abbreviated New Drug Applications
CM	Chinese Medicine
CAM	Complementary/Alternative Medicine
EPVI	Established Patent Value Indicators
EPO	European Patent Office
FDA	Food and Drug Administration
GERD	Gastroesophageal Reflux Disease
HPLC	High Performance Liquid Chromatography
IP	Intellectual Property
INPADOC	International Patent Documentation Center
LDL	Low Density Lipoprotein
ML	Maximum Likelihood
NBER	National Bureau of Economic Research
NCE	New Chemical Entity
NDF	New Dosage Form
NDAs	New Drug Applications
NME	New Molecular Entity
PUD	Peptic Ulcer Disease
PHARMADL	Pharmaceutical Digital Library
PTDI	Pharmaceutical Technology Details Indicators
QML	Quasi Maximum Likelihood
R&D	Research and Development
SSRI	Selective Serotonin Reuptake Inhibitor
TI	Technology Innovation
TM	Traditional Medicine
USPTO	U.S. Patent and Trademark Office
WHO	World Health Organization