



# **Imitation to Innovation in China**

**The Role of Patents in Biotechnology and  
Pharmaceutical Industries**

**Yahong Li**



New Horizons in **Intellectual Property**

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Pharmaceutical Industries

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NEW HORIZONS IN INTELLECTUAL PROPERTY

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To Professor John H. Barton, a Great Mentor

and

For Grace and Gloria

## Foreword

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Today, China is undertaking what is probably history's most spectacular investment in basic science, especially in biotechnology. Under its 2006 Science and Technology Plan, it has set out an ambitious goal of investing 2.5 per cent of GDP in research and development by 2020. This will require nearly a quadrupling of expenditure. Among the targeted areas are protein science, development and reproductive biology, transgenic plant breeding, and drug development.<sup>1</sup> China already has more researchers than any other nation except the United States.<sup>2</sup> And China is just developing new plans for bringing more equality to national health care.

It is not clear to me, however, whether this investment will be successful in benefiting the Chinese economy or the Chinese citizen in the street. As noted in a recent OECD report, China's 'capabilities for making productive use of accumulated investment in R&D, human resources for science and technology..., and the related infrastructure have developed much [more] slowly, especially in the business sector,' than has the nation's overall socioeconomic progress.<sup>3</sup> There are many steps in R&D from basic research to the development of products that matter for health care or for food production. At each stage, entrepreneurs and innovators, whether in the government or in the private sector, are needed to take basic ideas, visualize their application, and invest in the research and production facilities needed to turn those ideas into products. China will require an enormous infrastructure of institutions and legislation for this to happen.

Intellectual property may significantly help this process. In the United States, for example, research sponsored by the National Institutes of Health at major research universities is often patented and licensed to venture-capital funded biotechnology companies. These firms bring basic research ideas to the academic to some degree of commercial applicability and then either invest in the needed clinical trials and production processes or sell the ideas through joint ventures with existing larger pharmaceutical firms. Patents are important to the universities, to the venture capital process and to the strategic alliance process.

It is also possible that intellectual property could harm the process. Patents on research tools have complicated biotechnology research in the United

States. And in agricultural biotechnology, patents have led to industry conglomeration in ways that have slowed entry by new firms and may have slowed application to important crops such as wheat.

This is the background against which Professor Yahong Li is publishing this important and much needed book. It would be relatively easy to write a book that examines China's patent legislation and compares it with China's commitments under the 1995 Agreement for Trade Related Intellectual Property. It would also be relatively easy to describe criticisms of China's enforcement procedures, typically relying on critiques by foreign firms seeking stronger intellectual property rights. What is special about this book is that it goes well beyond such analysis.

First, Professor Li brings solid knowledge of the biotechnology sector. Therefore she is able to investigate the law to a much deeper degree – not just to note enforcement difficulties but also to examine whether the Chinese implementation of the law in different areas really serves the social policies of encouraging research and the application of that research. The United States is discovering, for example, that details of patent law – what kinds of inventions should receive protection, how broad that protection should be, what rights it provides – make an enormous difference in whether the law in fact helps innovation or hurts it. Professor Li applies this kind of thinking to China.

Second, Professor Li knows the Chinese language and has looked carefully at a variety of Chinese judicial material. Her reviews of specific controversies and decisions provide deep insight into how the Chinese patent granting and enforcement system really works, and allow consideration of the details of patent coverage – details that are crucial for evaluating the effectiveness of the law. I know of no other academic writing in English which has combined knowledge of the industry with knowledge of original Chinese sources.

Third, Professor Li brings understanding of the business matrix of biotechnology, including the working of the US venture capital and research communities. Hence, she is able to provide insight into the really difficult questions that will face China as it attempts to convert this massive research investment into products that benefit the Chinese people. These are not just questions of the scope of patent coverage in biotechnology; they are also questions of the applicability of antitrust law, of the appropriate government rights in government-funded inventions, and of the matrix of contract law and intellectual property law that affects licensing.

In short, Professor Li is publishing a highly valuable book at an optimal time. It will, of course, be valuable to practitioners. But its value is deeper.

China will face new tasks in the next decades in ensuring that its expanded scientific research investment genuinely benefits its society, especially in a time of likely economic slowdown. I very much doubt that China's system for harnessing innovation will look much like that of the United States university licensing and venture capital system; it will almost certainly involve different kinds of mechanisms designed for China's society. I am absolutely confident, however, that China's decision-making in this area will benefit from the analysis in this book.

I am privileged to have been Professor Li's dissertation supervisor at Stanford and to provide this Foreword. Her book goes way beyond that dissertation and is a valuable contribution to our understanding of China's patent law and its innovation system.

John Barton  
Stanford Law School

## NOTES

1. H. Xin and G. Yidong, China Bets Big on Big Science; *Science* 311: 1548-9 (17 March 2006)
2. OECD Reviews of Innovation Policy, OECD 2008.
3. *Id.*

# Preface and Acknowledgments

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Patents played, and may be still playing, an indispensable role in promoting innovation in developed countries such as the United Kingdom, the United States, Germany and Japan. Yet they have become a target of increasing criticism in these countries for blocking innovation and access to medicine due to broad, extended and overlapping protection. What role, then, do patents play in China, the world's largest developing country with a relatively high technological capacity but still in transition from imitation to innovation? How can China use patents to stimulate innovation while avoiding adverse effects that they have had in developed countries? Those issues are the focus of this book as it explores China's biotechnology and pharmaceutical patenting.

Seven years ago when I started this project, I had a rather simple goal in mind, that is, to ascertain how China's patent law governs biotechnology and pharmaceutical inventions. I planned to focus on legislation only, to compare Chinese law on biotechnology and pharmaceutical patenting with the laws of other countries. However, as the research progressed I became less satisfied than I had been with the existing literature and my original goal. I found that analyzing law without understanding the industries and technology that it governs is like building a skyscraper on sand. My research therefore expanded to include industries, markets and R&D capacity, all of which proved more challenging than I expected. There is a sea of materials and statistics that lack authority and consistency, in need of constant verification and updating. Understanding the science of biotechnology and pharmacology was another fascinating but tremendous challenge. I was humbled by the long and painful process of learning, and grateful for all the help and insight I received from some distinguished scientists at the University of Hong Kong (HKU): Professors C.M. Che of the Department of Chemistry and Professor William Mak of the former Director of Genome Research Center. I was also very fortunate to have had a 'private tutor' to consult with on a daily basis. My husband, Professor X.Y. Guan, a cancer geneticist at HKU Faculty of Medicine, constantly rescued me from the frustration of understanding the difficult concepts of biotechnology. The project would not have moved as smoothly without him.



I met an even greater challenge when trying to understand the implications of business statistics and the scientific literature on patent law, and how patent law influences business and scientific activities. In these areas I was guided by the late Professor John Barton of Stanford Law School, with his enlightening and often provocative questions, comments and suggestions. An ongoing exchange of ideas with him helped to deepen my analyses and arguments, particularly in relation to how patents help to commercialize biotechnology and pharmaceutical inventions, the role of private funding and government support for scientific research, the differences between the commercialization processes of the United States and China, and whether antitrust law has any place in solving the problem of monopoly in China's biotech patenting. I also benefited significantly from the suggestions and comments of Professors Mark Lemley and Henry Greely of Stanford Law School, who were instrumental in shaping my research direction and questions, particularly with respect to the relationship between patent law and the diversification of technologies, and ethical issues in China's biotechnology and pharmaceutical research. The discussion on the interplay between patents and business, science and ethics was further enriched by insights and information from the following scholars and professionals of various disciplines: Professor Paul Cheung, Director of HKU Technology Transfer Office, Professor Tao Zhigang of HKU School of Business, Professor Dan Yang of HKU Department of Chemistry, Professor Edwin Hui of HKU Faculty of Medicine, Mr Alan Fan of Huawei Technologies Co. Ltd, Ms Lin He of Wyeth, and Dr Minyue Zhang of Nanjing University.

The most difficult part of the project, however, was that there had been three drafts and one final amendment to the Chinese patent law since I undertook my research, necessitating constant changes to my manuscript. Another difficulty lay in finding the statistics of patent filings for the biotech and pharmaceutical industries because they were recorded based on patent categories, patent applicants, or by country rather than by industry. In addition to reading the scattered reports and articles on China's biotech and pharmaceutical industries, I enlisted Ms Shan Chi's help in finding the patent applications for biotechnology and pharmaceutical inventions and the subsequent decisions made by China's patent office. In assessing the difficulties and problems embedded in the country's biotechnology and pharmaceutical patenting, I benefited from discussions with Dr Yonghong Li of China's State Intellectual Property Office, Professor Naigen Zhang of Fudan University, Professor Xi Wang of Shanghai Jiaotong University, and Mr Xun Xu of Shanghai Patent and Trademarks Office LLC.

I owe a debt of gratitude to Professor Dr Heinz Goddar of Boehmert & Boehmert for reading my manuscript and providing me with many insightful comments that helped me to rethink some of the issues. I am very thankful that Professor Jon M. Garon of Hamline University Law School and Professor Peter Yu of Drake University Law School read my manuscript and pointed out several places that required improvement. My appreciation also goes to Dr Jasmine Chambers of the US Patent and Trademarks Office, for suggesting that the latest US biotechnology patenting case, *In re Kubin*, should be discussed in Chapter 7 of this book.

The completion of this book would not have been possible without understanding and support from the Dean of HKU Faculty of Law, Professor Johannes Chan, and the former and current Heads of HKU Department of Law, Mr Michael Jackson and Professor Hualing Fu. I am also grateful for the opportunity provided by HKU to participate in two university strategic research themes – Drug Discovery and Synthesis, and Ethical and Legal Issues for Genomics, Proteomics and Bioinformatics – from which I learned more than I contributed. I was also fortunate to receive a significant grant from the Research Grant Committee of Hong Kong government which was very important in helping me carry out my research.

I would like to express my appreciation to Edward Elgar Publishing (EE) for its vision and commitment in promoting the understanding of IPRs around the world, and for publishing my book. My special thanks go to EE staffs Mr Ben Booth, Ms Jenny Wilcox and Ms Sylvia Trevis for patiently and efficiently working with me from the beginning of the book project.

This book is dedicated to the late Professor John Barton, my JSD supervisor at Stanford Law School, who passed away shortly before the manuscript was completed. I am saddened by the fact that he will never see the book in print, and feel profoundly honored to have his Foreword published in the book, displaying his deep concern about the conflict between patents and social development, his tireless search for a better solution, and his wholehearted support for the endeavors of a younger generation of intellectual property law scholars. The publication of this book now has a new meaning – it is a living testimony of Professor Barton's life-long dedication and contribution to legal education and to the scholarship of intellectual property law, particularly on the interplay between law, science and social development. —

Yahong Li  
Hong Kong

## List of Abbreviations and Acronyms

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'863' Program	National High-Tech Development Program
'973' program	National Basic Research Program
1035 Project	Medical and Pharmaceutical Innovation Project
Bt	Bacillus thuringiensis
CAFC	Court of Appeals for the Federal Circuit
CAS	Chinese Academy of Sciences
CAS-MPG	CAS and the Max Planck Society
CAU	China Agriculture University
CBD	Convention on Biodiversity
CIPR	Commission on Intellectual Property Rights
CNCBD	China National Center for Biotech Development
CTD	Committee on Trade and Development
EC	European Commission
ED	erectile dysfunction
EPC	European Patent Convention
EPO	Erythropoietin
EPO	European Patent Office
ESCRO	Embryos Stem Cell Research Oversight
ESCs	embryonic stem cells
EU	European Union
FDI	foreign direct investment

FDZJ	Fudan-Zhangjiang Bio-Pharmaceutical Co. Ltd.
GBHI	Guangzhou Bio-Medicine and Health Institute
G-CSF	granulocyte colony-stimulating factor
GDP	gross domestic product
GLP	good laboratory practice
GM	genetically modified
GM-CSF	granulocyte-macrophage colony-stimulating factor
GMP	good manufacture practice
GSK	GlaxoSmithKline
HAU	Huanan Agriculture University
HBV	hepatitis B virus
HCRFs	homologous complement restriction factors
HCV	hepatitis C virus
HESC	human embryonic stem cell
HGP	Human Genome Project
HLPP	Human Liver Proteome Project
HUGO	Human Genome Organization
HUPO	Human Proteome Organization
IL-2	Interleukin 2
IPR	intellectual property right
IUPGR	The International Undertaking on Plant Genetic Resources
IVF	<i>in vitro</i> fertilization
LDC	least developed country
LDL	low-density lipoprotein
MCP Gene	methyleyclopropene gene
DAF Gene	decay accelerating factor gene
MOST	Ministry of Science and Technology

MPCs	multinational pharmaceutical companies
MSD	Merck Sharp & Dohme
NCE	new chemical entity
NIH	National Institute of Health
NPC	National People's Congress
NPCSC	National People's Congress Standing Committee
PAA	patent administrative agencies
PCR	polymerase chain reaction
PCT	Patent Cooperation Treaty
PRC	People's Republic of China
PREB	Patent Re-Examination Board
PVR	plant variety right
QSAR	quantitative structure-activity relationship
S&T	Science and Technology
SARS	Severe Acute Respiratory Syndrome
SCI	Science Citation Impact
SETC	State Economic and Trade Commission
SFDA	State Food and Drug Administration
SIMM	Shanghai Institute of Materia Medica
SIPO	State Intellectual Property Office
SMEs	small and medium-sized enterprises
SNP	single nucleotide polymorphism
SPC	Supreme People's Court
TCM	traditional Chinese medicines
TPA	Tissue Plasminogen Activator
TRIPS	Trade-Related Aspects of IPRs Agreement

UNESCO	UN Educational, Scientific and Cultural Organization
UPOV	International Union for the Protection of New Varieties of Plants
USPTO	United State Patent and Trademark Office
WARF	Wisconsin Alumni Research Foundation
WIPO	World Intellectual Property Organization
WWBP	Worldwide Biotech & Pharmaceutical Company
YUT	Yunnan University Technology Ltd

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# 1. The Role of Patents in Innovation: Introduction

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The topic of the role of patents in innovation is not new, rather, it is an old topic which has been debated for centuries by many scholars in many books and articles. This book does not intend to repeat what had been said in the existing literature, but attempts to add new findings to the existing stock of knowledge, and use these new findings to correlate or verify some of the existing conclusions. The new findings contain a central question which needs to be answered, that is: do patents promote innovation in biotechnology and pharmaceutical industries in China? This is a country which is largely different from most countries in the world as it is the largest developing country; a transitional economy with a strong public element, and the world's fourth-largest economy with relatively high technological capacity. Phrasing this question in another way: how do patents' role in China's biotechnology and pharmaceutical industries differ from their role in those industries in industrialized and other developing countries? The new findings will be derived from a thorough research into biotechnology and pharmaceutical patenting in China in later chapters: its technological background, legal standards, and empirical data analyses of patent applications and litigations, and so on. However, these findings will be of little meaning unless compared with the existing literature on the topic. Therefore, an introduction of existing debates in this chapter on the role of patents in innovation, including the debates about patent's role in industrialized countries and in developing countries, will serve as a theoretical foundation for the discussions of the new findings about the patent's role in China later on. In the meantime, to help readers understand the justifications and significances of some events, facts and legal issues discussed in later chapters, this chapter also provides background information on how the issue of patents and innovation was raised and what are the laws and policies concerning patents and innovation in China.