An empirical study on the role of patents in fostering local pharmaceutical innovation in China

He, Rong

An empirical study on the role of patents in fostering local pharmaceutical innovation in China

by

Rong He

A thesis submitted for the Degree of Doctor of Philosophy
Centre for Commercial Law Studies, School of Law
Queen Mary, University of London

Declaration

I declare that the work presented in this thesis is the result of my own research, undertaken at the Centre for Commercial Law Studies, School of Law, Queen Mary, University of London

Rong He

May 23, 2012

Abstract

International analysts tend to view China as a major beneficiary of the TRIPS Agreement, particularly concerning the effects of the stronger patents of TRIPS on local innovation. Chinese policymakers were also motivated to adopt TRIPS IP reforms by the expectation that stronger patents would stimulate China's development and improve its ability to match the performance of developed countries more rapidly. Yet, due to the lack of empirical studies, these assumptions remain theoretical. This research investigates empirical evidence to test these assumptions and determine actual impacts on China's pharmaceutical innovation. It seeks to answer two main questions: (1) how has the TRIPS legal framework affected China's ability to formulate a pro-development patent policy for pharmaceuticals? (2) how has China's patent policy affected domestic pharmaceutical innovation? The investigation adopts a public health perspective, through comparative legal analysis and statistical study. The empirical assessment was built on country-level data collection.

The legal evaluation has revealed that China has adopted a pro-patent policy for pharmaceuticals, in implementing TRIPS, Chinese policy-makers did not balance intrinsic industry interests in strong patent protection against wider socio-economic interests and issues under Chinese law and legal practices. This research has found that China's pro-patent policy has had multifaceted economic effects on innovation. Whereas, positive effects of patent strengthening were indentified empirically through innovation indicators, including patent applications and grants, R&D expenditure and ITT inflow, the study also revealed various problems and challenges. Local innovation remains imitation-oriented, little R&D is devoted to researching cures for major

diseases, more MNC patents control leading and upstream technologies, and patent litigation has greatly increased. These developments do not augur well for China's ability to approach developed countries in pharmaceutical innovation. The Chinese experience revealed in this thesis contrasts with conventional expectations of the effects of TRIPS, at least in the Chinese pharmaceutical industry.

Contents

Acknowledgement

The research presented herein has been conducted at the Centre of Commercial Law Studies, School of Law, Queen Mary University of London. It has been sponsored by the Wellcome Trust. I would first like to convey my gratitude to these two organisations for their recognition of the value of this research topic, as well as their provision of excellent research environment and financial support respectively. I must also express my gratitude to the Development Studies Programme offered by the London School of Economic and Politics (LSE). This research topic was inspired by my educational experiences there.

The production of this research has drawn inspiration from many sources. Many people have contributed and assisted this study in various forms. First and foremost, I would like to express my gratitude to Professor Duncan Matthews and Professor Graham Dutfield for their supervision[1], advice and inspiration. Beside academic guidance, they have kindly offered many other means of support to me in every stage of this research project. Working with them in the past few years, I have not only developed my understanding of the subject, but also gained skills and experience as a researcher. Their influence and inspirations will be beyond this study.

I am also greatly indebted to many other individuals who have made a contribution to this research in various ways:

[1] Professor Graham Dutfield and Dr Duncan Matthews worked as my first supervisor and second supervisor respectively during the period from October 2005 to January 2007, their supervision roles in my studies switched as a result of Professor Graham Dutfield's move to another institution in January 2007. In September 2009, the formal supervisionship of Professor Graham Dutfield ended as the result of the expiry of his contract with the School of Law, Queen Mary University, but he has kindly offered to review the final draft of this thesis.

Dr Barbara Woodward has offered the greatest support for this thesis. She has not only provided thorough review and comment on the thesis, but also helped greatly with its written-English.

Mr Paul Wusteman has been an incredible mentor and a great support for me during my studies in London. His broad knowledge and great insights have very much broadened my horizons.

Dr Lauren M. Phillips and Ms Dawn Lardner reviewed the research proposal for this study and offered me their invaluable research suggestions.

.

Professor Peter Drahos reviewed the research outline of the thesis and gave his precious time to exchange views about this research topic.

Ms Viviana Munoz-Tellez and Dr Johanna von Braun contributed their precious time to discuss this research topic with me and provided invaluable information.

Professor Clemens Stubbe Ostergaard reviewed the research report about my research findings and offered very useful feedback.

Dr Wang Xian Bing reviewed the core parts of my thesis and offered me great advice on empirical assessment.

Ms Yang HongJu has contributed to this project through numerous discussions and debates with me about the political economy of IPRs in general, and Chinese IPR issues in particular.

Mr Malcolm Langley provided many research materials and information to this research, and helped me to find important research information. In addition, he kindly helped me with my written English in my early writing.

My special thanks go to my family. I own a huge debt of gratitude to my fiancé, Fredrik Lövkvist. His great support and love have lightened up my PhD journey like golden starts. I am also highly indebted to my sisters, He Mei and He Jing, for shouldering all my family duties in China while I have been away for all these years of overseas studies. Particularly, I would like to thank my parents for their great support for my dreams all the time.

Finally, I would like to thank everyone who has directly or indirectly contributed to my research and enriched my educational and life experience during my period of study in England. I apologise that I could not mention you all individually.

Abbreviations:

DFID	British Government's Department for International Development
PAAD	Patent Affairs Administration Department
UNCTD	United Nations Conference on Trade and Development
AIDS	Acquired Immune Deficiency Syndrome
ANDA	Abbreviated New Drug Application
APIs	Active Pharmaceutical Ingredient
CIPR	Commission on Intellectual Property Rights
CIPIH	Commission on Intellectual Property Rights, Innovation and Public Health
CPC	Chinese Communist Party
CPO	China Patent Office
DFID	Department for International Development
EU	European Union
FDA	US Food and Drug Administration
GMP	Good Manufacturing Practice
HIV	Human Immunodeficiency Virus
Hatch-Waxman Act	Drug Price Competition and Patent Term Restoration Act of 1984
ICTSD	International Centre for Trade and Sustainable Development
IFPMA	International Federation of Pharmaceutical Manufacturers Association
ITT	International Technology Transfer
IPRs	Intellectual Property Rights
IPC	International Patent Code

JPO	Japan Patent Office
MNCs	Multi-national Corporation
NCE	New Chemical Entity
OECD	Organization for Economic Cooperation and Development
Paris Convention	Paris Convention for the Protection of Industrial Property
PAAD	Patent Affairs Administration Department of the State
PEG	Patent Examination Guide
PRC	People's Republic of China
EPO	European Patent Office
PCT	Patent Cooperation Treaty
PEUs	Patent Examination Units of the SIPO
PRC	People's Republic of China (PRC),
PREB	Patent Re-examination Board of the SIPO
QHU	Qing Hao Su, a novel chemical drug developed by Chinese scientists in 1970s
R&D	Research and Development
SIPO	State Intellectual Property Office of the PRC
SFDA	State Food State Food and Drug Administration of the PRC
TRIPS	Trade-related aspects of intellectual property rights
US	The United States
UM	Utility model
USPTO	United State Patent and Trademark Office
EU	Europe Union
WHO	World Health Organization
WIPO	World Intellectual Property Organisation

Table of cases

Table of legislation

1. Domestic patent legislations:

Patent Law of the People's Republic of China (1984)

Patent Law of the People's Republic of China (1992)

Patent Law of the People's Republic of China (2001)

Patent Law of the People's Republic of China (2008)

Implementing Regulations of the Patent Law of the People's Republic of China (1992)

Implementing Regulations of the Patent Law of the People's Republic of China (2001)

Implementing Regulations of the Patent Law of the People's Republic of China (2010)

Patent Examination Guide of the SIPO (2006)

2. Judicial Interpretations

Interpretation by the Supreme People's Court and the Supreme People's Procuratorate of Several Issues Concerning the Specific Application of Law in Handling Criminal Cases Involving Violations of Intellectual Property Rights' (2004)

Interpretation by the Supreme People's Court and the Supreme People's Procuratorate of Several Issues Concerning the Specific Application of Law in Handling Criminal Cases Involving Violations of Intellectual Property Rights' (2007)

SPC Stipulations on Preliminary Injunctions against the Acts of Infringement of Patent (2001)

3. Domestic drug regulations

Drug Administration Law of the People's Republic of China (2001)

Regulations for Implementation of the Drug Administration Law of the People's Republic of China (2002)

Regulations on Administrative Protection for Pharmaceuticals (1992)

Measures of the Administration of Drug Registration of the People's Republic of China (2002)

Measures of the Administration of Drug Registration of the People's Republic of China (2007)

4. Other domestic laws

Administrative Procedural Law of the People's Republic of China (1989)

Anti Unfair Competition Law of the People's Republic of China

Constitution of the People's Republic of China (1982)

Constitution of the People's Republic of China (2004)

Criminal Law of the People's Republic of China (1997)

General Principle of Civil Law of the People's Republic of China (1986

5. International laws and other legal documents:

Agreement on Trade-Related Aspects of Intellectual Property Rights (1995)

Doha Declaration on the TRIPS agreement and public health (2001)

Drug Price Competition and Patent Term Restoration Act of 1984

Federal Food, Drug, and Cosmetic Act (1938)

Paris Convention for the Protection of Industrial Property (1979)

'Report of the Working Party on the Accession of China ', (WT/ACC/CHN/49,1 October 2001).

Accession of the People's Republic of China, (WT/L/432, 23 November 2001)

Transitional Review under Section 18 of the Protocol on the Accession of the People's Republic of China: Report to the General Council by the Chair, (WT/IP/C/39, 21 November 2005)

China — Measures Affecting the Protection and Enforcement of Intellectual Property Rights: Request for Consultations by the United States, (WT/DS363/1, 16 April 2007)

China – Measures Affecting the Protection and Enforcement of Intellectual Property Rights: Report of the Panel, (WT/DS363/R/Corr.1, 19 August 2009)

Major sources of empirical research data

The Statistic Year Books of the State Intellectual Property Office (SIPO) from 1987 to 2006

National bureau of Statistic of China database, the annual reports from 2000 to 2007

U.S. Patent and Trademark office, 'Patenting in Technology Classes, Breakout by Geographic Origin (State and Country), Count of 1963 - 2008 Utility Patent Grants

China Health Statistic Digest 2004

China patent database, SIPO

Interview information, Chengdu, Beijing, China, 2008

List of interviewee

1. Professor Zhang jianxin, Sino-British AIDS Prevention and Care Project Office of Sichuan
2. Prof Zhou Chang Hui, School of Public Health, Sichuan University.
3. Prof Liu Yi, School of Public Health, Sichuan University
4. Dr. Wu Rui, Deputy Director of Sichuan Food and Drug Administration.
5. Wang Cheng Pin, Head of the Department of Law and Regulation, Sichuan Food and Drug Administration
6. Yi Dan, Head of JiJian District of State Administration for Industry and commerce of Chengdu.
7. Huang You Ling, patent attorney, Ke Hai Patent Agency
8. Tang Li Rong ,patent attorney, Ke Hai Patent Agency
9. Xiong Hui, Deputy Director of Sichuan Industrial Institute of Antibiotics Ltd (SCIIA)
10. Zhong Xing Xiao, Director of R & D Management of Sichuan Industrial Institute of Antibiotics Ltd (SCIIA)
11. Qian Wei, Head of Department of Manufacture and Technology , Chengdu Diao Group (CDDA)
12. Scientist A[2], Chengdu Diao Group
13. Scientist B[3], Chengdu Diao Group
14. Yang Hongju, Legal Affairs Dept. State Intellectual Property Office
15. Wang Hong, Researcher, State Intellectual Property Office

[2] Scientist A has expressed her attention to remain anonymous
[3] Scientist B has expressed her attention to remain anonymous.

16. Wen Xi Kai, Emeritus Deputy Head of legal affairs Department of State Intellectual Property Office, China Intellectual Property Training Centre

List of tables, Charts and Appendices

Chapter 1 Introduction

1.1 Research themes

'Developing country members of the World Trade Organization (WTO) no longer have the policy options and flexibilities developed countries had in using IPRs to support their national development.'[4] This lamentation represents a core concern about the limitations imposed by a WTO agreement, the Trade-Related Aspects of Intellectual Property Rights (TRIPS or the TRIPS Agreement), on the developing members' legislative autonomy in framing national intellectual property rights (IPRs) systems. Economic history has proven that such legislative adaptability was instrumental in promoting indigenous technological and economic progress. It is argued that today's developed countries enjoyed and benefited from such legislative autonomy in their economic developmental stages.[5]

Some scholars contend that a harmonised IPRs system can bring in efficiency gains from an economic standpoint.[6] The United States has been active in convincing other nations to adopt a stronger IPRs regime since strengthening its own patent system in the 1980s. Over the course of a long campaign, the US has not only succeeded in the

[4] UNCTAD-ICTSD (2003), 'Intellectual Property Rights: Implications for Development', (Geneva: UNCTAD-ICTSD), pIV.
[5] For the review of the argument, see Chang, HJ (2002), *Kicking Away the Ladder: Development Strategy in Historical Perspective* (London: Anthem Press), Dutfield, G (2005), 'Is the World Ready for Substantive Patent Law Harmonisation? A Lesson from History', in Peter Drahos (ed.), *Death of Patents* (Witney: Lawtext).
[6] E.g., Abbot, F and Gurry, F (1999), *The International Intellectual Property System: Commentary and Materials* (1; The Hague: Kluwer Law International), p603; Maskus, K (2000), *Intellectual Property Rights in the Global Economy* (Washington DC: Institute of International Economics), p89 ('The strength of IPR is a significant and positive determinant of international business activity. Stronger global IPRs could enhance dynamic efficiency with which resources are allocated internationally, which should help mitigate any adverse distributional consequence.').

incorporation of the TRIPS Agreement into the charter of the WTO but also in pressuring more and more nations into bilateral free trade agreements (FTAs) with so-called 'TRIPS –plus' IPRs provisions.[7] The US arguments include that stronger patent protection would stimulate a higher level of local innovation, attract greater investments and market entry by innovative companies, and promote larger disclosure and circulation of technical information.[8] Concerning the health impacts of the Agreement, some economists express optimism about the dynamic benefits of strong patents in directing additional R&D research devoted to diseases prevalent in developing countries,[9] and they suggest such a dynamic benefit together with the others can provide long-term benefits offsetting the higher drug prices imposed by patents.[10]

Both of the above arguments are narrowly framed and do not reflect the multifaceted and diverse impacts the patent norms in the TRIPS Agreement have on development. They do, however, highlight two salient points often debated in the global IPRs discourse: the policy and economic effects of TRIPS implementation. The former concerns how the TRIPS' universal approach affects IPRs policy-making and legislative adaptability in developing countries; the latter stresses economic consequences resulting from IPRs laws and policies adopted under the TRIPS framework. The existing research on these subjects is either theoretical or based on countries' pre-TRIPS experience.

---

[7] These US arguments are well-documented in the academic literature. E.g., Ryan, M (1998), *Knowledge Diplomacy: global competition and the politics of intellectual property* (Washington, D.C.: The Brookings Institution); Drahos, P (2001), 'Bits and Bips: Bilateralism in Intellectual Property ', *The Journal of World Intellectual Property*, 4 (6), pp791-808; Matthews, D (2002), *Globalising the Intellectual Property Rights* (London: Routledge). Sell, S (2003), *Private Power, Public Law: The Globalization of Intellectual Property Rights* (Cambridge: Cambridge University Press).

[8] Abbot, F (2001), 'The TRIPS Agreement, Access to Medicines and the WTO Doha Ministerial Conference', (Quaker UN Office Occasional Paper No. 7), p5.

[9] Diwan, I and Dani, R (1991), 'Patents, Appropriate Technology, and North-South Trade', Policy Research Working Paper (Washington D.C.: The World Bank). Maskus, K (2000), *Intellectual Property Rights in the Global Economy* (Washington DC: Institute of International Economics)

[10] Maskus, K (2000), p164.

Consequently, there is a pressing need for a scholarly examination of the actual TRIPS implementation experience in developing countries. This empirical study aims to test the above arguments by examining China's early experience in implementing TRIPS patents rules in the pharmaceutical field. It is submitted that if the actual policy and economic effects of TRIPS implementation in China can be indentified empirically, imperfect as it may be, they can provide a valuable aid for developing governments to execute the Agreement on a better informed basis.

1.2 Research scope and background

The investigation of this empirical study focuses on the impacts of the implementation of the TRIPS Agreement in the pharmaceutical industry. This is an area in which scholars have perceived the TRIPS rules to have the most profound effects both on IPRs policy-making and on economic development involving the pharmaceutical industry in developing countries.

The TRIPS Agreement obliges members to provide patent protection to all fields of technology for twenty years' duration. This mandate has deprived member countries of their traditional legislative autonomy in the pharmaceutical field. Prior to the TRIPS Agreement, international treaties had recognized the members' freedom to tailor their national patent systems to their national interests and development level. Therefore, different legal standards for pharmaceutical patents had existed to greater or lesser extent among various jurisdictions, regarding areas of non-patentability, the rights conferred to patentees, the durations and terms of these rights, etc.[11] Countries with a stronger pharmaceutical industry like the US tend to grant strong patent protection as an

[11]Gad, M (2006), *Representational Fairness in WTO Rule-Making* (London: British Institute of International and Comparative Law), p52.

institutional advantage to support its 'national champion'. Some other developed countries allowed pharmaceuticals to be patented only when their technology achieved sophistication and competitiveness. France did so in 1960, Ireland in 1964, Germany in 1968, Japan in 1976, Switzerland in 1977, Italy and Sweden both in 1978, and Spain in 1992.[12] For developing countries, it has always been in their interests to exclude product patents for pharmaceuticals to meet their needs to improve public health in particular and to advance indigenous technical development in general. Prior to TRIPS, drugs were not patentable in about fifty developing countries.[13]

The TRIPS Agreement precludes such different legislative treatment on medicines and makes protection of product patents to new medicines mandatory. Article 27.1 stipulates that 'patents shall be available for any inventions, whether products or processes, in all fields of technology….. Patents shall be available and patent rights enjoyable without discrimination as to the field of technology and whether products are imported or locally produced'. This provision rules out the common practice of excluding pharmaceuticals and chemicals in developing countries' patent law.[14] Article 33 unifies the patent term as twenty-years at least from the filing date of application. As a result, the legal framework governing manufacturing, commercialisation of and access to medicines has been altered dramatically in developing countries.[15]

[12] Dutfield, G and Suthersanen, U (2004), 'Harmonisation or Differentiation in Intellectual Property Protection? The Lessons of History', (Geneva: Quaker United Nations Office).
[13] Lanjouw, J (1997), 'The Introduction of Pharmaceutical product patents in India: 'Heartless exploitation of the poor and suffering'? 'Discussion *Paper* (No. 775: Economic Growth Centre, Yale Univ.); WIPO (1988), 'Existence, Scope and Form of Generally Internationally Accepted and Applied Standards/Norms for the Protection of Intellectual Property', Negotiating Group on TRIPS, p33.
[14] Gad, M (2006), *Representational Fairness in WTO Rule-Making,* pp52-53.
[15] Ibid, p95.

The process of implementing the TRIPS Agreement has caused great concerns about the impact of patents on health welfare in developing countries. These concerns provoke intense political and legislative backlash against pharmaceutical patents, particularly in the context of the HIV/AIDs pandemic in developing countries.[16] To respond to the international concerns about access to medicine in developing countries, the WHO Ministerial Conference of 2001 adopted the Doha Declaration on the TRIPS Agreement and Public Health (Doha Declaration 2001). Doha Declaration 2001 recognizes the concerns about patents' effects on medicine prices[17] and reaffirms the legitimacy of the use of mechanisms under the Agreement, commonly called TRIPS flexibilities, in circumscribing patent monopoly for better access to essential medicines. Other reforms have addressed legal barriers to the utilisation of one of the key TRIPS flexibilities, compulsory licences. Initially, the Agreement only permitted the products manufactured under compulsory licensing to be used within the domestic market; this precluded many developing countries without manufacturing capability from participating in the compulsory license system. The WTO General Council passed a decision on August 30, 2003, which created a temporary mechanism to allow WTO member states to issue compulsory licenses to export generic substitutes to countries without sufficient or with no health manufacturing capability.[18] On December 6, 2005, WTO member states

[16]For example, South Africa adopted provisions allowing for parallel importation of medicine as well as the use of compulsory licences in certain circumstance. In 1998, 39 multinational pharmaceutical companies brought a legal suit against the South African government. After intense global NGO campaigns, the companies was finally compelled to withdraw the case, for detailed account, see Hoen, Ellen 't (2002), 'TRIPS, Pharmaceutical Patents, and Access to Essential Medicines: A Long Way From Seattle to Doha.' *Chicago Journal of International Law* 3(1).

[17] Article 3, WTO (2001), 'Declaration on the TRIPS Agreement and Public Health ', WT/MIN(01)/DEC/2.

[18] Matthews, D (2004), 'WTO Decision on Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health: a Solution to the Access to Essential Medicines Problem? 'Journal *of International Economic Law,* 7 (1).

reached an agreement to modify Article31 (f) of the TRIPS, thus legitimising such a mechanism.[19]

Conversely, a counter movement has emerged from beyond the TRIPS forum. New measures, either introducing a higher level of patent standards on medicines than those under the TRIPS Agreement or reducing the scope and effectiveness of TRIPS flexibilities, are increasingly negotiated under the free trade agreements (FTAs) between developed countries, especially the US, and developing countries.[20] These measures include a broadening of patent scope, patent term extension, compulsory license restrictions, parallel exportation prohibition, extensive data protection, patent registration linkage and so on.[21] These provisions are infamously termed as 'TRIPS-plus' provisions.[22]

This new movement under FTAs opens up new frontiers about the nature, state and effects of TRIPS implementation in developing countries. To sign up the IPRs provisions under the FTAs implies either abandoning the TRIPS flexibilities or agreeing to the higher level of patent standards on medicines and other technical products. The development of a mutually exclusive two-tiered global IPRs system raises more questions. It is broadly recognized by development agencies that it is in developing

[19] Matthews, D (2006 a), 'From the August 30, 2003 WTO Decision to the December 6, 2005 Agreement on an Amendment to TRIPS: Improving Access to Medicine in Developing Countries', *Intellectual Property Quarterly,* 2; WTO (2005), 'Members OK Amendment to Make Health Flexibility Permanent', (WTO press release), at http://www.wto.org/english/news_e/pres05_e/pr426_e.htm, accessed on June 8, 2007.
[20] Musungu, S and Dutfield, G (2003), 'Multilateral agreements and a TRIPS-plus world: The World Intellectual Property Organisation (WIPO)', (Geneva: Quaker UN Office Paper), p2 & Correa, C (2006), 'Implication of Bilateral Free Trade Agreement to Access to Medicines', *Bulletin of the World Health Organisation* 84 (5), p399.
[21] Correa, C (2006), 'Implication of Bilateral Free Trade Agreement to Access to Medicines'; Shadlen, K (2005), 'Policy Space for Development in the WTO and Beyond: The Case of Intellectual Property Rights', (Glocal Development and Environment Institute, Working Paper NO. 05-06),
[22] Musungu, S and Dutfield, G (2003). p2.

countries' interests to interpret TRIPS as a ceiling and to utilize its built-in flexibility mechanisms in full.[23] So, why have some developing members of the WTO opted out of the TRIPS minimum regime and adopted a TRIPS-plus approach in the process of TRIPS implementation? Do they really believe the higher level of patent protection is more conducive to their development, or have they agreed due to a misunderstanding of the likely effects or to political pressure and compromise? To answer these questions, it is necessary to examine the impacts of TRIPS and TRIPS-plus patent regimes on local innovation to determine whether the new patent regimes have induced a higher level of innovation and technology diffusion or raised roadblocks for local firms for acquiring and developing new technologies in developing countries. The next section discusses how these impacts may be explored through a case study on the Peoples' Republic of China (China).

1.3 The significance of a case study on China

A study on China's experience of TRIPS and TRIPS-plus implementation in the pharmaceutical area may provide the information and insights needed to answer the above questions.

First, China's early experience with the TRIPS' pharmaceutical patent regime makes an apt example for exploring the impacts of TRIPS on development. China appeared to show fewer qualms about the possible repercussions of TRIPS than many other developing countries. While developing countries, led by India and Brazil, opposed the wholesale imposition of western IPR standards by the US and EU countries during the

[23] Such as UNCTAD-ICTSD (2005), 'Resource book on TRIPS and Development', available at http://www.iprsonline.org/unctadictsd/ResourceBookIndex.htm, CIPR (2002), 'Integrating Intellectual Property Rights and Development Policy', in (London: UK International Development).

TRIPS negotiations, China introduced TRIPS-style patent rules for pharmaceuticals as early as 1992.[24] Now that more than fifteen years have passed, some early impacts of TRIPS on development perhaps can be observed and understood through this empirical study on China.

Secondly, China has also taken a different course from many other developing countries in response to the TRIPS-plus agenda. During the TRIPS implementation process, developing countries at China's comparable development position, such as India and Brazil, strongly resisted the IPRs overly protectionist tendencies and actively exploited the TRIPS flexibilities to promote public health and other development interests. In contrast, China introduced TRIPS-plus provisions for pharmaceutical patents under the first two Chinese patent reforms in 1992 and 2000, and these remain largely unaltered and unchallenged to date despite the recent adoption of key TRIPS flexibilities under the 2008 amendment of Chinese patent law.

Finally, China is one of the world's main suppliers of generic drugs, including anti-retroviral. Yet, in 2006, the per capita drug expenditure in China was less than US$20, among the lowest in the world, and the annual drug expenditure for the majority of rural people, who account for 80% of the population, was even lower, below US$5 per capita.[25] Thus, despite its recent success in economic growth and poverty reduction,

[24] According to Liu, XH, an Chinese law maker, the 1992 amendment of the Chinese patent law made a direct reference to the drafted TRIPS Agreement, see Liu, XH (2008), 'A Study on Patent Compulsory License System in China – With Particular Reference to the Drafted 3rd Amendment to the Patent Law of the P.R. of China ', in W Pyrmont, et al. (eds.), *Patents and Technological Progress in a Globalized World* (Springer Berlin Heidelberg), p116. In addition, chapter 4 will give a detailed account on the key patent provision relevant to pharmaceutical under the Chinese patent law 1992.

[25] OECD health data, cited in 'Chinese biogenerics and protection of IP', *Genetic Engineering & Biotechnology News,* Vol. 26 (15) (1 September 2006). <http://www.genengnews.com/articles/chitem_print.aspx?aid=1875&chid=0>

there were still some 135 million people living below the poverty line in 2009.[26] This clearly indicates that domestic medicine consumption greatly depends on the supply of low cost generic medicines.[27] Internationally, China is currently the largest producer of vaccines in the world.[28] Active pharmaceutical ingredients (APIs) produced by Chinese firms are dominant in the API import markets in the EU, the US, India and Japan.[29] Importantly, Chinese firms are increasingly important suppliers of certain products that target the diseases prevailing in poor countries. Many Indian and other developing countries purchase and are outsourcing ingredients for anti-retroviral from China.

Given China's unique policy towards pharmaceutical patents and its significant role in access to medicine at home and abroad, it is important to understand the rationales behind Chinese patent policy-making and the policy impacts on the local generic industry and its innovative capabilities. The lessons drawn from China's experience may provide useful information and insights for further policy experimentation in IPRs and other innovation strategies domestically and internationally.

1.4 The existing research and knowledge gap

The scope of current literature on China's experience in implementing the TRIPS Agreement mainly examines Chinese IPR legislation, its compliance and non-compliance with TRIPS obligations, or enforcement procedures and problems. A large volume of studies has also contributed knowledge of the strength or weakness of the

[26] World Bank (2009), 'China from poor areas to poor people', in Poverty Reduction and Economic Management Department (ed.), (Washington: World Bank), p3.
[27] Grace, C (2004), 'The Effect of Changing Intellectual Property on Pharmaceutical Industry Prospects in India and China: Considerations for Access to Medicines', (London: UK Department of International Development).
[28] BMI (2008), 'China Pharmaceuticals & Healthcare Report ', (Q2; London: Business Monitor International Ltd), p38.
[29] Luo,Y (2008), 'China: Current trends in pharmaceutical drug discovery', *IDrugs,* 11 (4), p279 & BMI (2008), 'China Pharmaceuticals & Healthcare Report ' , pp41-42.

Chinese pharmaceutical industry in terms of production and innovation. Yet, there is a shortage of empirical studies on the interplay between China's approach to TRIPS implementation and the potential for innovation in the Chinese pharmaceutical industry. There is also a need for empirical studies that are initiated from a public health policy perspective and based on data collected at the country-level. This research aims to add such new information and insights to academic knowledge.

Yet, the existing relevant literature does provide insightful observations and valuable empirical data for this research. Peter Yu has contributed a large volume of studies on the history and politics of the Chinese intellectual property system.[30] Maskus, Dougherty, and Mertha have examined how the inadequate enforcement of IPRs limits incentives to develop products and brand names, especially for small and medium-size enterprises.[31] Lixuan has offered a theoretical overview on the static and dynamic effects of the introduction of TRIPS product patent regimes to pharmaceutical patents in China.[32] Cheri Grace has contributed an early empirical report on the state of the Chinese pharmaceutical industry, its response to changes of the patent system, and its implications for access to medicine domestically and internationally.[33] In addition, a large amount of scholarship has shed light on the enforcement of IPRs in China.[34] A recent study assigned by the Commission on Intellectual Property Rights, Innovation and Public Health (CIPIH) has studied the state of health-related innovation in China.

[30] For example, Yu (2000),(2001),(2006), (2009) etc.
[31] Maskus, K , Dougherty, S, and Merth, A (2005), 'Intellectual Property Rights and Economic Development in China', in K Maskus C Fink (ed.), *Intellectual property and development: lessons from recent economic research* (Washington, DC: World Bank).
[32] Li, X (2008), 'The Impact of Higher Standards in Patent Protection for Pharmaceutical Industries under the TRIPS Agreement – A Comparative Study of China and India', *The World Economy,* 31 (10), 1367-82.
[33] Grace, C (2004), 'The Effect of Changing Intellectual Property on Pharmaceutical Industry Prospects in India and China: Considerations for Access to Medicines'; Grace, C (2005), 'A Briefing Paper for DFID: Update on China and India and Access to Medicines', in FDID (ed.), (London: DFID).
[34] E.g., Nie, JQ (2006), *The Enforcement of Intellectual Property Rights in China* (London: Cameron May Ltd).

However, the main focus of the analysis was to provide an overview of the input indicators of innovation whereas the output indicator 'patent' and the interplay of patent policy and innovation were not included in the scope of that project. This gap has been greatly filled by new published research from Li Yahong. However, her research perspective is more from an economic viewpoint and the research mainly relies on second hand data.[35]

1.5 Research objectives, questions and method

The existing theoretical and empirical studies widely view China as a major beneficiary of the TRIPS Agreement, particularly concerning the effects of the TRIPS stronger patent protection provisions on local innovation.[36] Nonetheless, there are also concerns that the TRIPS patent regime may hamper local innovation and disadvantage the development of the local generic industry.[37] Yet, there is little evidence one way or the other to confirm these views. This research is thus motivated to investigate information and evidence that may verify or disprove those theoretical assumptions.

The central concerns of this study are twofold: 1) how does the TRIPS' universalism affect China's legislative capability in utilizing IPRs for development? and 2) how have the perceived economic benefits and costs of the TRIPS' patent regime materialized in China? These questions fall between quantitative and qualitative assessments. The following are the designed research questions for this study:

[35] Li, YH (2010), *Imitation To Innovation In China: the Role of Patents in Biotechnology and Pharmaceutical Industries* (Cheltenham: Edward Elgar).
[36] For example, CIPR (2002), CIPHI (2006), Maskus (2005).
[37] Grace, C (2004), p7.

1. Has China been able to formulate a pro-development patent policy for pharmaceuticals under the TRIPS legal framework? To this end, it examines the following sub-questions in turn:

1.1 What are the current state and nature of pharmaceutical patent protections and enforcement in China? Have the relevant standards applied in China met its international obligation?

1.2 What is China's policy approach to TRIPS implementation in the pharmaceutical field? Has China made effective use of the TRIPS flexibilities to protect and promote public health interests?

1.3 What are the rationales behind Chinese particular pharmaceutical patent policy?

2. What effects has China's particular patent policy had on local innovation? This investigation is guided by the following two sub-questions:

2.1 What is the state of local pharmaceutical innovation using both quantitative and qualitative standards?

2.2 Have patent incentives contributed to more R&D activities allocated to the cure of diseases essentially important to Chinese patients?

3. How can the research findings be explained and what implications can be drawn from China's experience?

Comparative legal analysis is employed as the major approach in the legal evaluation. The comparison includes two orientations. The first type of comparative study analyses four versions of Chinese patent law. Chinese patent law has been revised three times since its initial promulgation in 1984. Each revision has embedded within it significant differences in some important substantive or procedural patent standards. This type of

comparison is used to investigate the changes to substantive patent standards applied for pharmaceuticals, the state of the accommodation of TRIPS flexibilities or TRIPS-plus standards under the Chinese patent system, the changes of threshold of enforcement measures etc. The second type of comparative study involves the international comparison between Chinese pharmaceutical legislation and foreign law or international IPRs treaties. The legal analysis applies the law of the Paris Convention for the Protection of Industrial Property (the Paris Convention), the TRIPS Agreement, and some relevant legal provisions under US patent law.

In addition, statistical analyses are employed to establish the correlation between stronger patents and the growth of local innovation. The major indicators include the number and type of pharmaceutical patent, pharmaceutical R&D expenditures, the number of patents granted to Chinese nationals by the USTR in the past twenty years, the composition of FDI from the leading multinational pharmaceutical companies (MNCs,) operating in China, comparative patent ratio quotient between the inventions for the cure of major diseases and the aggregate pharmaceutical patent filings. All the patent related data covers a span of two decades. The data is directly drawn from the official statistics.

IPRs-related political economy and development perspectives are employed in order to explain the rationales, nature and effects of each relevant reform of Chinese patent law, to describe policy related recommendations, and to draw useful lessons from the Chinese experience in TRIPS implementation.

1.6 Limitations of the research

This research project is limited by the complexity of the research project itself, the short history of TRIPS implementation in China, and various methodological and other practical constraints. Firstly, this research centres on the role of patents in innovation, but other factors, such as government policies and complex economic dynamics, also influence innovation together with the IPRs regime. It is difficult to distinguish the roles of patents from the effects of these other policies and factors on innovation so that appropriate attribution cannot always be given in the analysis. Secondly, China introduced product patent protection on pharmaceuticals in 1992 while TRIPS-compliant enforcement measures were not accommodated into law until 2000. It can be argued that TRIPS implementation in China is still in its preliminary stage. The research findings may be inconclusive and should be interpreted only as an indication of current trends in this field. Thirdly, the author's limited pharmaceutical knowledge could have restricted the methodology design and the interpretation of the research findings.

1.7 Structure of the thesis

This study is divided into nine chapters containing the content summarised as follows:

Chapter 1 presents the main research premises and the core research questions of the thesis.

Chapter 2 reviews the genesis and the history of the TRIPS Agreement.

Chapter 3 reviews the current knowledge existing and the gaps occurring in the two premised research themes. It first examines how the TRIPS Agreement affects national legislative capability in designing and enforcing national patent rules, then, studies the

diverse roles patents can play in the evolution of local innovation. The knowledge gaps in these two areas are also identified.

Following the opening chapters, the thesis commences the investigation on the policy effect of TRIPS implementation in China from chapter 4 to chapter 6.

Chapter 4 reviews the legal history of introducing the TRIPS standards into Chinese patent laws. The analysis places its emphasis on both the threshold for the pharmaceutical patent protection applied, and the rationales behind each law reform.

Chapter 5 evaluates whether public health interests have been incorporated into the current Chinese pharmaceutical patent system. The evaluation covers four areas: the patentability standard, TRIPS-flexibilities, TRIPS-plus provision, and the application of Utility Model protection for pharmaceuticals.

Chapter 6 explores the nature and state of pharmaceutical patent enforcement in China. The examination involves two questions: 1) Has the Chinese enforcement procedure provided a TRIPS-consistent patent enforcement for pharmaceutical patents? 2) Has the Chinese enforcement procedure been carried out in 'a balanced and pro-competitive way'?[38]

[38] This perspective is inspired by the CIPR report. It points out ''We agree that enforcement systems in developing countries need to address serious IPR infringements more effectively. This is important to protect the incentives that the system offers to IP rights holders. But it is also important that developing countries develop institutions capable of doing this in a balanced, pro-competitive way', CIPR (2002), 'Integrating Intellectual Property Rights and Development Policy', in UK International Development (ed.), (London), p147.

Chapter 7 explores the second research question concerning what effect of Chinese particular patent policy has had on the development of local pharmaceutical innovation. A statistical approach is used to in assessment**.**

Chapter 8 offers explanations for the research findings.

Chapter 9 concludes the investigations and draws implications from China's given experience.

.

Chapter 2 Advent of the TRIPS Agreement

To appreciate the relationship between patents and pharmaceutical innovations requires an understanding of the North-South conflict on this issue and the history of the TRIPS Agreement. Therefore, I shall start with a historical review of these subjects.

Patents have been the subject of controversy for at least two centuries.[39] The debate on pharmaceutical patents was central in at least two salient events in the recent history of the international IPRs system: the attempt to revise the Paris Convention in the earlier 1980s and the introduction of the TRIPS Agreement in 1995 under the auspices of the WIPO and WTO, respectively**.** While rights holders and their supporters upheld the merit of patent protection for promoting pharmaceutical innovations, scholar and activists challenged the professed fairness and justice concerning poor access to essential medicines for the poor. Developing countries' governments have increasingly challenged pharmaceutical patents through national legislation reforms or campaigns advocating public health reform and international patent rules favourable to development. Nevertheless, the past two decades have witnessed not only the aggressive reinforcement of a pro-patent international patent governance regime, but also a 'ratchet-up' of patent standards across countries regardless of their level of economic, social and technological development. What were the drivers behind this development? If such development was against the interests of developing countries, why did they accept the rules of the current international patent governance? This chapter aims to examine these questions through the history of IPRs from the 1960s towards the 1995.

[39] Pugatch, M (2006), 'Introduction: Debating IPRs', in M Pugatch (ed.), *The Intellectual Property Debate: Perspectives from Law, Economics Political Economy* (Cheltenham: Edward Elgar), p 2.

2.1 The north-south conflict in pharmaceutical patents in the era of the Paris Convention

2.1.1 The influence of Dependence Theory

When former European colonies started to gain their independence and acceptance as sovereign states after 1945, the predominant policy to enable their development was to nurture domestic technological capabilities.[40] This objective was particularly reinforced by the dominant development thinking known as 'Dependence Theory' from the mid-1960s to the 1970s. Despite variations, the dependency theorists generally viewed the underdevelopment of developing countries largely to be a result of their dependent relationship with developed countries. They were concerned that the development path of both economy and culture of the poor countries was largely conditioned by developed countries through trade, migration, and capital and technology flow. Consequently, they believed, developing countries were deprived of autonomy to adopt alternative policies to achieve desirable economic growth.[41]

Among the generally dependent relationships with rich countries, technology dependence is regarded as particularly detrimental and influential for the development prospects of developing countries. Stewart suggests that the dependence on advanced countries for technology could be the cause as well as a consequence of general dependence on them.[42] As the history of industrialisation demonstrates, technology played a crucial role in narrowing the economic gaps between the late- developing

[40] Allen, T and Thomas, A (2000), *Poverty and Development into the 21 Century* (Oxford University Press), p404.
[41]Todaro, M (1989), *Economic Development in The Third World* (London: Longman), p78; Stewart, F (1978), *Technology and Underdevelopment* (London: Macmillan), pp114-116.
[42]Stewart, F (1978), *Technology and Underdevelopment*, p116.

countries and the leading countries. Thus, Stewart argues that technology dependence is possibly the most critical feature to the break up of the dependent economic relationship with advanced industrialised countries.[43]

The dependence theory dominated development policy, particularly after the increasing dissatisfaction with the earlier import substitution industrialization (ISI) development strategy in the developing countries from the late 1960s to 1970s. Reducing technology dependence became a critical goal of the development agenda. Two opposing approaches were prescribed to accomplish this task prescribed by different schools of economic theory. The 'structuralists' emphasized the importance of building up local technological capabilities through 'learning- by-doing' while 'neo-liberal' theorists proposed the advantage of integration into international technology trade.[44] The former approach advocates domestic research and development efforts, such as imitation, reverse engineering, studying information available from patent applications, international exchange of technical personnel and the use of non-proprietary technology etc. The latter prefers trade in capital or technological goods, foreign direct investment, and purchase of technological licenses.[45]

Although it is debatable which approach works best, both approaches involved implementation of international technology transfer (ITT), i.e. the international flow of industrial technology from developed world to developing countries. At the time there was a huge gap in technological capability between developing and developed countries. According to studies by the United Nations, only 6 percent of the estimated 3.5 million

[43] Ibid.p116.
[44] Pearson,(1992), 'Technology and Industrialisation', in Tom Hewitt, Hazel Johnson, and Dave Wield (eds.), *Industrialisation and Development* (Oxford University Press).
[45] Maskus , K and Reichman, J (2005), 'The Globalisation of Private Knowledge Goods and the Privatization of Global Public Goods', in K Maskus and J Reichman (eds.), *International Public Goods and Transfer of Technology* (Cambridge: Cambridge University), p12.

patents granted in 1972 were to developing countries, of which less than one-sixth were owned by nationals of developing countries. The majority of advanced industrial technology was produced in developed countries.[46] It is generally considered to be less costly and faster to acquire technological capability through technology transfer than to develop it from the scratch with domestic resources. [47] Nonetheless, developing countries highly valued the ability to build indigenous scientific and innovative capabilities because it directly serves their aspirations to improve their autonomy in technology. Consequently, developing countries tended to apply a combination of these two approaches in their industrialization practice.

Governments of all countries, regardless of national wealth, focus particular attention and scrutiny on the pharmaceutical industry as it is a powerful, strategic industrial sector. Moreover, pharmaceutical products have greater relevance to general social welfare than any other industry. Thus, the economic and political implications of pharmaceuticals can influence government policy decision-making.[48] The relative strengths of the two interest groups shifted towards industry with the emergence of the modern pharmaceutical industry after the Second World War. Transforming into intensive research and advertising businesses, drug companies grew rapidly and concentrated on legal monopolies of specific products protected by patents and branded names in developed countries.[49] By the 1970s, this industry had become highly concentrated and a few multinational companies had established their dominance over

[46] See Table 7, 12 in UN Publication 'The Role of the Patent System in the Transfer to Developing Countries' cited in p119 in Stewart, F (1978), *Technology and Underdevelopment.*
[47]Maskus , K and Reichman, J (2005), 'The Globalisation of Private Knowledge Goods and the Privatization of Global Public Goods' p11.
[48] Gereffi, G (1983), *The Pharmaceutical Industry and Dependency in the Third World* (Princeton N J: Princeton University Press), p167.
[49] Ibid, p169 .

production, marketing, and research and development (R&D) in the world pharmaceutical market.[50] This trend was demonstrated in Lall's studies:

> The developing and southern European countries accounted, around 1971, for only 14 per cent of world pharmaceutical output… The three leading countries (United States, Japan, and the Federal Republic of Germany), accounted for nearly 70 per cent of pharmaceutical output in the developed market-economy countries….[51]

The imbalance of the world pharmaceutical market meant that developing countries were heavily dependent on foreign pharmaceutical products and technology whose value was often protected by patents or branded names.[52] This dependence had detrimental economic and social consequences in developing countries, such as high drug prices, inappropriate products or technology, structural constraints to developing their indigenous pharmaceutical industry and innovative capability and so on.[53] This unfavorable position prompted governments of developing countries to search for measures to gain greater autonomy over their pharmaceutical industries at economic institutions as both the national and international levels. Among other international legal arrangements existing prior to their independence and participation in the international legal system, developing countries found they were locked into the international patent system under the World Intellectual Property Organization (WIPO).

---

[50] Lall, S. (1975) 'Major issues in the Transfer of Technology to Developing Countries: a Case Study of the Pharmaceutical Industry ', in UNCTAD (ed.), (UNCTAD), p.4.
[51] Ibid. p4.
[52] Gereffi, G (1983), *The Pharmaceutical Industry and Dependency in the Third World, chapters* 6 &7.
[53] Lall, S. (1975), 'Major issues in the Transfer of Technology to Developing Countries: a Case Study of the Pharmaceutical Industry ', p4, p23.

2.1.2 Developed countries: motives for the internationalisation of patent protection

Competing with developing countries' needs to acquire indigenous technology capability, the interest of developed countries to re-regulate the trade in technological goods worldwide has ascended as a result of four recent developments.

Firstly, technology-intensive goods had become the most dynamic segment of production and trade in developed countries around the mid-1960s, and the economic structure of developed countries started to go through a change towards de-industrialisation. The key features of this trajectory were the decline of manufactured goods and the growth of knowledge-intensive goods.[54] Investment in research and development (R&D) had steadily increased in developed countries in the 1970s, particularly with private large firms playing an increasingly major role.[55] As a result, during this period, the number of high R&D manufactured products produced for international trade by the major developed countries, such as the United States, Japan, Germany and the United Kingdom, expanded rapidly.[56]

Secondly, since 1950, multinational companies (MNCs) had found developing countries to be increasingly desirable and popular locations for foreign direct investment (FDI). When developing countries adopted import substitution industrialisation (ISI) policies in the 1950s, which discouraged the import of competing manufactured goods from

[54] Reynolds, J (1990), 'UK Manufacturing Industry: Structural Change and Competitiveness - a Lesson for Other Countries? ' in A Webster and J Dunning (eds.), *Structural Change in the World Economy* (London: Routledge), p12; Gray, H (1990), 'The Role of Services in Global Structural Change', in A Webster and J Dunning (eds.), *Structural Change in the World Economy* (London: Routledge), p70.
[55] Correa, C (2000), *Intellectual Property Rights, the WTO and Developing Countries* (London: Zed Books Ltd) p3.
[56] See table 4.4,4.5,4.6 in Hughes, K (1990), 'Competition, innovation, and industrial performance', in A Webster and J Dunning (eds.), *Structural Change in the World Economy* (London: Routledge), pp52-53.

developed countries through tariff barriers[57] MNCs responded to such tariff measures by establishing manufacturing operations in the developing countries themselves. Meanwhile, free trade zones (FTZs) or export processing zones (EPZs) established by developing governments also attracted increasing numbers of MNCs to relocate their manufacturing operations in those countries.[58] In addition, other favourable economic conditions, including cheap labour and services, low costs of manufacturing operations, preferential treatment for foreign investment and abundant resources nearby also attracted FDI to developing countries. However, MNCs soon became dissatisfied by the legal systems of developing countries in which they could not enjoy the same institutional advantages as those in their home countries. The reasons will be discussed in the fourth factor below.

Thirdly, US competitiveness in manufacturing and technology had been challenged in certain high-tech areas. Japan first and later the Asian newly industrialising countries like Korea, Singapore, Hong Kong and Taiwan had emerged as aggressive competitors of the US firms' in consumer electronics, microelectronics, robotics, computers and various services such as in engineering and construction. US industries viewed this erosion of technology leadership as a consequence of lax IPR protection for US technology in those countries and regions.[59]

Fourthly, IPRs protection in their target foreign markets was not sufficient to protect MNCs technology assets and the associated profits. Historically, IPR laws have been 'introduced by nation states in response to economic demands and ideas of moral value

[57] Jenkins, R (1992), 'Industrialisation and the Global Economy ', in T Hewitt, H Johnson, and D Wield (eds.), *Industrialisation and Development* (Oxford: Oxford University Press), pp22-23.
[58] Ibid .
[59] Correa, C M (2000), *Intellectual Property Rights, the WTO and Developing Countries,* p4.

which have focused particularly on their own territories and nationals'.[60] Although there are a number of international treaties mandating standards, IPRs protection was fundamentally a national, territorial principle prior to the introduction of the TRIPS agreement.[61] Regarding patent rights, the Paris Convention of 1883 has been the major international arrangement governing the patent rights among member states. However, the Paris Convention did not try to level national laws or establish the reciprocity principle for national treatment. On the contrary, it stipulated vast legislative freedom for each country and only required the equal treatment of nationals and foreigners (national treatment principle).[62] This allowed member states the freedom to tailor national patent regulations to specific national interests. Even patent standards among developed countries were different from each other, such as the treatment of pharmaceutical patents,[63] the scope of the coverage of the patent allowed, the types of patent and quasi-patents; the inventions excluded from patenting, or some procedural variation as 'first –to –file' versus 'first to invent' system, and examination versus registration.[64]

IPR policy is traditionally a matter of national discretion. In accordance with their own technology levels and industrial development objectives, developing countries emphasize the social welfare function of exclusive rights. Their IPR legislation tends to be designed to facilitate production and access to innovation. As a consequence, the

---

[60] Cornish, W and Llewellyn, D (2007), *Intellectual Property: Patents, Copyrights, Trademarks and Allied Rights, 6th Edition* (London: Sweet & Maxwell), P26
[61] Drahos, P (1997), 'Thinking Strategically about Intellectual Property Rights ', *Telecommunications Policy,* 21 (3), p203
[62] Gontijo, C (2005), 'Changing the Patent System from Paris Convention to the TRIPS Agreement: the Position of Brazil', (2005; Berlin: Heinrich Böll Foundation). p7.
[63] 'For example, France only allowed pharmaceuticals to be patented in 1960, Ireland in 1964, Germany in 1968, Japan in 1976, Switzerland in 1977, Italy and Sweden
both in 1978, and Spain in 1992.' Dutfield, G and Suthersanen, U (2004), 'Harmonisation or Differentiation in Intellectual Property Protection? The Lessons of History', p6.
[64] Letterman, G (2001), *Basic of International Intellectual Property Law* (New York: Transnational Publishers Inc), p173-177.

level of protection on patents is generally weaker than the standard that MNCs can typically expect to enjoy in their home countries. This difference in patent protection level tends to result in the unintended rent transfer from MNCs to their local competitors through their 'free-riding' activities.

2.1.3 Conflicting interests on international patent governance

Divergence in IPR law and practice has always existed between technologically advanced countries and those in the process of industrialisation. The former countries emphasize the protection of IP rights while the latter focus on facilitating the diffusion of industrial technology. Historically, countries in catch-up positions preferred to adopt a patent policy which limited the scope of protection on foreign technological goods as part of their developmental strategies. For example, '….when the United States was still a relatively young and developing country,…. it refused to respect international property rights on the grounds that it was freely entitled to foreign works to further its social and economic development.'[65]

Developing countries logically choose to provide weaker and more flexible standards to protect foreign-patented technology in their domestic markets. They put emphasis on the provisions of local working requirements, parallel imports, and great scope for compulsory licensing in the absence of local working.[66] This kind of patent policy reflects a utilitarian approach toward patent laws, i.e. a patent system should be designed according to socio-economic conditions and primary development purposes in given countries.

[65] From the report by the office of Technology Assessment of the US Congress April 1986, cited by Yusuf, A (1998), 'TRIPS: Background, Principles and General Provisions', in C Correa (ed.), *Intellectual Property and International Trade* (London: Kluwer Law International Ltd), p4.
[66] ibid, p5.

Due to either colonial heritage or perceived interests, many developing countries obtained membership of the Paris Convention in 1960s and 1970s. The Paris Convention could bring benefits to developing countries if it facilitated the inflow of foreign industrial technology into their economy. Article 5 of the Convention may fulfil this expectation through its compulsory working provision and non-working sanctions. It implies that member states have the right to demand that foreign patentees explore their invention locally. These provisions were introduced based on the experience of the developed countries during in their industrialisation. However, the effectiveness of compulsory working provisions depends on substantive conditions. As Penrose indicates: 'Compulsory working provisions cannot compel foreigners to work their patents. ….if domestic producers cannot use his invention, he will not fear his competitors very much and certainly won't go to the trouble of producing under what are, to him, unprofitable conditions in order to maintain his patent.'[67] It is very likely that many developing countries do not have sufficient technological capacities to absorb and use foreign inventions. In addition, their markets are generally small and unprofitable, and thus unattractive to MNCs. These economic disadvantages have undermined the effectiveness of the local working requirement, in other words, it was most unlikely any developing members of the Paris Convention would benefit from the compulsory working provision. The economic reciprocities expected from complying with the obligations under the Paris Convention were not returned to developing member countries. On the contrary, developing states bore a significant socio-economic burden due to their compliance with the international patent rules. [68]

[67] Penrose, E (1951), *The Economics of the International Patent System* (Johns Hopkins).
[68] Anderfelt, U (1971), *International Patent-Legislation and Developing Countries* (Hague: Martinus Nijhoff), p277.

Since the early 1960s, there was growing awareness of the adverse effects of the international patent system on the socio-economic development of developing countries. Nationals from developed countries held the majority of patents filed in developing countries. The monopoly power and patent abuse exercised by foreign right holders worked against national interests of developing countries. For example, in the area of pharmaceuticals patents, in an empirical study Agarwal has indicated that leading transnational pharmaceuticals dominated 85-90% of patent ownership in developing countries; however, only 5-10% of these patents were actually exploited in the developing countries. The majority of the remaining ownerships exacted profits through their import monopoly power.[69] Lall in his report to the UNCTAD claimed that foreign pharmaceutical patents could be detrimental to health welfare of people in developing countries.

> The legal character of patents needs to be reformed in a manner that would permit local firms in developing countries to copy or adapt foreign technology for national interest. Furthermore, the restrictions on cheaper imports which are provided for by the existing system should be abolished.[70]

The Andean group, united through the Treaty of Cartegena, started to challenge the traditional principles of the Paris Convention. They argued that development should be prioritised as the objective of patent system.[71] In Brazil, its patent law of 1969 abolished all patent protection for pharmaceuticals. India passed its Patent Law Act No.39 in 1970 that treated medicine, food and agro-chemicals as specific subjects, and granted them only seven years of patent protection. Compulsory licensing could be granted after three

---

[69] Agarwal, A (1978), *Drugs and the Third World* (London: Earthscan), cited in Jucker, E (1980), *Patent and Pharmaceuticals* (Basle: E Jucker).
[70] Lall, S. (1975), 'Major issues in the Transfer of Technology to Developing Countries: a Case Study of the Pharmaceutical Industry'.
[71] Susan, S (1998), *Power and Ideas: North - South Politics of Intellectual property and Antitrust* (New York: State university of New York press), p112.

years of selling a pharmaceutical patent, and the maximum royalty was set at 4%[72]. This new law laid down a pivotal foundation, allowing India to build a successful generic industry.[73] Following these initiatives, India formally called for a revision of the Paris Conversion in a 1974 WIPO meeting.[74]

On the other side of the world, developed countries were coming to the opposite conclusion: that there should be even stronger international rules protecting patent rights. The economic structure of developed countries had been transformed by globalisation of production, technology progress in communication, transport and production, and declining costs of international trade and investment. The US, along with the EU and Japan, had developed into the net producers and the major suppliers of technology-intensive goods in the world market since1980s.[75] Industrial property had become developed countries' major source of assets, and they were increasingly dependent on patents, copyrights and trademarks to maintain their competitiveness in the world market. As a result, industrialised countries began to argue that the weak state of patent protection in developing countries threatened their economic interests, and they began to advocate strengthening intellectual property rights protections on a global basis.

2.1.4 Attempts to revise the Paris Convention

From 1980 to 1984, there were negotiations between the Group of 77 and the OECD countries for the Revision of the Paris Convention, launched under the Diplomatic

[72] Jucker, E (1980), *Patent and Pharmaceuticals,* ppl34-35.
[73] Drahos, P (2002), 'Developing Countries and International Intellectual Property Standard-setting', *Journal of World Intellectual Property,* 5, p768.
[74] Sell, S (1998), *Power and Ideas: North - South Politics of Intellectual property and Antitrust,* p111.
[75] Bently, L and Sherman, B (2004), *Intellectual Property Law, Second Edition* (Oxford: Oxford University Press), p6.

Conference for Protection of Industry property under the auspices of WIPO.[76] UNCTAD joined developing countries' campaign for the reform of the Paris Convention. It conducted two studies entitled 'The Role of the Patent System in the Transfer of Technology to Developing Countries' and 'International Patent System as an Instrument for National Development' in 1974 and 1975, respectively. These studies not only raised awareness among developing countries of the adverse impacts of patents on development, but also contributed to building a consensus among a group of developing countries on the terms and merits of demanded reforms of the Paris Convention.[77]

Two issues were ardently discussed in the negotiations. First, developing countries attempted to request the preferential treatment under Article 5 regarding the importation and process patents. The second major issue they sought was to gain more effective measures to Article 5 (A), such as the grant of an exclusive compulsory licence to address or relax the conditions to use the sanctions, etc. to address the non-working and insufficient working of patents.[78]

Non-discrimination and national treatment are longstanding traditional principles of Paris Convention, and OECD countries rejected developing countries' request for the adoption of preferential measures to Article 5.[79] Moreover, as the Paris Convention was devised to overcome hidden domestic barriers through reciprocal legislative arrangements in international industrial trade, OECD states argued that the adherence to this principle was essential to maintaining the balance between rights and obligations.

[76] Sell, S (1998), *Power and Ideas: North - South Politics of Intellectual Property and Antitrust*, p107.
[77] Ibid.
[78] Ibid, pp119-130.
[79] Ibid, p120.

The OECD countries also resisted the local working arguments, although they acknowledged the importance of technology transfer in assisting economic growth in developing countries[80] However, they argued that patent protection was the legal basis for the diffusion of technology and that attempts to weaken or abolish patent protection in developing countries would actually discourage foreign investment in production and technology transfer locally.[81] The OECD countries also produced empirical studies in the defence of those propositions. Sell and Mundkowski suggested in their empirical analysis that patent protection has played a positive role to some extent in the pharmaceutical industry in Latin America.[82] Hallstain's survey pointed out the significant negative effects of the Indian Patent Act 1970: 'Whereas 4,158 foreign patents were filed in India in 1969, only 3, 864 were filed in 1970, and no more than 2372 in 1973 – a decline of more than 40% in four years'.[83] These studies attempted to suggest that the movement in patent reform in developing countries was to their disadvantage. However, they cannot deny the link between the India 1970 Patent Act and the fact of the rapid growth of indigenous production and technical capability of the Indian pharmaceutical industry since the 1970s.

The clash of interests between the two groups was so significant that no agreement was reached at the end of negotiations in 1986. Still, the attempts to introduce a

[80] Hallstein, H (1975), 'Patent Protection, Transfer of Technology and Developing Countries - a Survey of the Present Situation', (ICC), p 432.
[81] Jucker, E (1980), *Patent and Pharmaceutical* pp91-100
[82] Sell, A and Mundkowski, M (1979) 'Patent Protection and Economic Development - Some Results of an Emprical Analysis in the Pharmaceutical Industry in Latin America', Cited in Sell,S (1998), *Power and Ideas: North - South Politics of Intellectual property and Antitrust*, p118.
[83] Hallstein, H (1975), 'Patent Protection, Transfer of Technology and Developing Countries - a Survey of the Present Situation', p439.

development-focused instrument into the patent system succeeded in the national legislation of developing countries even though it halted in the international system.

2.2 The advent of the TRIPS Agreement

Since the failure of the attempts to revise the Paris Convention, the disputes between the developing and developed countries on pharmaceutical patent rules have persisted and evolved. In 1994, a compromise was reached under an international legal framework, i.e. the TRIPS Agreement under the auspices of the WTO. The Agreement has been controversial since its beginning, because it is widely conceived as an outcome of an undemocratic negotiation process, in which developing countries were not only short of representation, knowledge, and full information of the IP issues, but also were subject to economic coercion from the US. This section reviews the political and economic factors that contributed to the establishment of TRIPS.

2.2.1 MNCs' defining role in the making of the TRIPS agreement

A. Pharmaceutical MNCs' interests in the internationalisation of IP protection

Conventionally, nation-states play the predominant role in international political relations, and only states create the law governing their relations, including international rules on intellectual property rights. Nonetheless, since the 1960s and particularly since the 1990s, the transnational forces of economic globalization have enabled non-state actors, including MNCs, to increase their influence in the international realm, and this has at times, undermined states' sovereign authority.[84] Much of the world's production, capital, and technology and market access are under the control of MNCs.[85] They play a

[84] Gilpin, R (1987), *The Political Economy of International Relation* (Princeton: Princeton University Press), p232
[85] Steger, M (2003), *Globalisation: A Very Short Introduction* (Oxford: Oxford University Press), pp48-51.

major role in determining the location of industries, the direction of trade flow and other economic activities. As a consequence, MNCs have become increasingly successful in their attempts to incorporate their self-interests in the economic and legislative regulation of many nations.

Worldwide international IP protection has been centred in such interests since the 1980s. MNCs economic supremacy has been building on their specialisation and competitiveness in the international trade and investment of high technology goods. For example, the ratio that high technology-intensive goods account for in the US exports rose from 25.8 percent in 1970 to 31.1 percent in 1982.[86] This implies the significance of the world market for MNCs' profitability and revenues. However, as discussed earlier, the IPR rules and practice in protection standards, limitation and enforcement vary between jurisdictions. MNCs can't enjoy the same level of protection generally in developing countries as in their home countries. Since the mid-1960s, developing countries have pursued the strategy of facilitating the production of and access to innovation. This policy has benefited indigenous technology capability building and enhanced the availability of affordable technological goods for consumers, but has lessened MNCs' profitability and returns from the investment in R&D.[87] Moreover, they have also perceived local generic drug companies as a competitive threat. These dual challenges have led MNCs to seek institutional means to safeguard their economic interests both nationally and internationally.

Pharmaceutical MNCs have been among the most active parties of this movement. Two main claims have been employed to justify their demands for internationalised IPRs

[86] See table 4.4 in Hughes, K (1990), 'Competition, innovation, and industrial performance', p52.
[87] Matthews, D (2002), *Globalising the Intellectual Property Rights* (London: Routledge) p9; Blakeney, M (1995), 'Intellectual Property in World Trade', *International Trade Law and Regulation,* 1 (3), p77.

protection. The first refers to the high expenditure on research and development of new drugs. It is cited that that it costs about US$350 million to develop a new drug on average and ten or twelve years to bring it to the market. 93 percent of new drug therapies are brought in by private R&D.[88] In addition, the pharmaceutical compounds are relatively easier to be duplicated. Therefore, the pharmaceutical industry has particularly viewed patent protection as the crucial means to recoup their investment and maintain their ability to develop new drugs. This argument finds its resonance in Arrow's proposition on the necessity of a rewarding mechanism for the R&D activities. Arrow suggests that innovative activities would diminish if the research results and its financial rewards are reaped by others. Patents have been credited with this incentive function to ensure the willingness of private companies to invest in innovation.[89] Secondly, pharmaceutical MNCs also contend that patent protection is the engine for pharmaceutical innovations, which in turn encourages pharmaceutical R& D to bring flourishing new products.[90] Therefore, developing countries would actually benefit from introducing the product patents to their legislation, since this would encourage more private R & D investment into the research on drugs for tropical diseases.[91]

B. Mobilising the reform of IP laws domestically and internationally

The above line of argument has been resorted by the pharmaceutical industry to push for the establishment of a universal IPRs standard globally since the late 1970s. An anti-counterfeiting coalition was established among 100 MNCs cross industries from automobiles, software, clothing, pharmaceuticals and food to luxuries and

[88] Ryan, M (1998), *Knowledge Diplomacy* (Washington, D.C.: The Brookings Institution), pp29-30.
[89] Arrow (1962), 'Economic Welfare and the Allocation of Resources for Invention', *The Rate and Direction of Inventive Activity: Economic and Social Factors* (National Bureau of Economic Research).
[90] Goren, David (2006), 'Pharmaceutical Innovation and Intellectual Property Right: a Global Public Good? ', in M. Pugatch (ed.), *The Intellectual Property Debate: Perspectives from Law, Economics Political Economy* (Cheltenham: Edward Elgar), pp159-69.
[91] Diwan, I and Dani, R (1991), 'Patents, Appropriate Technology, and North-South Trade', *Policy Research Working Paper* (Washington D.C.: The World Bank).

entertainment.[92] The campaigns of this coalition have whetted the appetites of protectionism in the trade negotiations under the auspices of General Agreement on Trade and Tariff (GATT). Although the initial negotiation on an anti-counterfeiting Code under the Tokyo Round between 1973 and 1979 bore no fruition, this experience enlightened more sophisticated preparation from the US industries to further their advocacy on intellectual property issues in the next GATT negotiations, the Uruguay Round.[93]

In Europe, the Publishers' Association from the United Kingdom started to exercise the strategy of coordinating IPRs protection internationally by lobbying the Deputy US Trade Representative to take action against copyright infringement in 1978.[94] In the US, the MNCs mobilized their influence even more directly and effectively, in their attempts to make intellectual property protection a trade issue at both bilateral and multilateral levels. The US President Advisory Committee on Trade and Policy and Negotiation (ACTPN) was one of the major forums for them to influence US trade policy. High-level executives from MNCs, such as Ed Pratt, Chief Executive Officer of the Pfizer, often worked as the advisors for ACTPN.[95] MNCs also took action to press the government to respond to the infringement of IPRs abroad by submitting reports of their annual revenue losses to the congressional hearings.[96]These actions persuaded the US government to address the demands from businesses for higher standards of IPR protection and enforcement through legislative action at both the domestic and international levels.

[92] Matthews, D (2002), *Globalising the Intellectual Property Rights,* p 9.
[93]Ibid, p 9, p13.
[94] Ibid, p13.
[95] Ibid, p18.
[96] Ibid, p13.

In the 1980s, strong lobbies from US multinational corporations successfully pressurise the government to tackle the comparatively lax IPRs standards in developing countries through unilateral trade sanctions. The amended Section 337 of the Tariff Act of 1930 was employed to enhance the enforcement of intellectual property rights domestically in order to protect US rights holders from unfair import competition, although the legitimacy of Section 337 had been challenged by the EC and Canada through NAFTA and GATT, and consequently this provision had to be amended in compliance with GATT.[97] Regarding the protection of US IPRs overseas, the Special 301 provision of the Trade Act of 1974 amended by Ominbus Trade and Competitiveness Act of 1988 (the Special 301 provision) was devised to strengthen the US leverage to improve IPRs enforcement in the world market. The Special 301 provision has provided effective measures for assessment, negotiation and sanctions to achieve the elimination of so-called 'unjustified and unreasonable' trading practices of US trading partners.[98]

The Special 301 provision quickly and effectively pressed the legislative changes desired by the US government on various rival markets. Korea, the first country targeted by the US, responded the threat of sanctions under the Special 301 provision by changing its national intellectual property laws in 1985.[99] In another example, in 1992, faced with the combined threat ('stick') of US trade sanctions and the promise ('carrot') of access to US markets, China amended its first Patent Law of 1984 to incorporate US-demanded IPRs standards on pharmaceuticals and chemicals.[100]

---

[97] Evans, G (1994), 'Intellectual Property as a Trade Issue: The Making of the Agreement on Trade-Related Aspect of Intellectual Property Rights', *World Competition,* 18 (2).
[98] Ibid, p151.
[99] Matthews, D (2002), *Globalising the Intellectual Property Rights,* pp15-16.
[100] Ostergard, R (2002), *Development Dilemma : The Political Economy of Intellectual Property Rights in the International System* (New York: LFB Scholarly Publishing LLC), pp119-139.

The success of such US bilateral negotiations encouraged MNCs to extend their strategy of linking trade to intellectual property into the global trade regime, the GATT. In 1988, three leading MNCs groups, the Union of Industrial and Employers Confederations of Europe (UNICE), the Japanese Federation of Economic Organization and the Intellectual Property Committee (IPC), submitted a joint report entitled Basic Framework of GATT Provisions on Intellectual Property to all participants in the Uruguay Round. The Basic Framework included features such as minimum standards in the major areas of IP, mechanisms to maintain the agreed IPRs standards, and incentive provisions such as preferential treatment and technical assistance etc. All these features were included in the final version of the TRIPS Agreement.[101]

As a result of their powerful, organized campaign beginning in the 1980s, MNCs succeeded in capturing the formulation of national and international rules governing IPRs through their intervention in the political process of making the international TRIPS Agreement. They devised a strategy for defining IPRs as a trade-related issue at both national and international levels. By projecting IP interests as a matter of national competitiveness,[102] they mobilized their national governments to take legislative actions at both national and international levels. It is rather clear that intellectual property business interests greatly influenced the creation of the TRIPS Agreement in its initiation, drafting and negotiation processes. Among the most prominent of the active lobbyists were major multinational pharmaceutical companies, including Pfizer, Merck, Bristol-Meyers and Johnson and Johnson.[103]

---

[101] Evans, G (1994), 'Intellectual Property as a Trade Issue: The Making of the Agreement on Trade-Related Aspect of Intellectual Property Rights'.
[102] Ryan, M (1998), *Knowledge Diplomacy* (Washington, D.C.: The Brookings Institution).
[103] Matthews, D. (2002) *Globalising the Intellectual Property Rights, chapters 1 & 2*. Sell, S. (2003) *Private Power, Public Law: The Globalization of Intellectual Property Rights*? Ryan, M. (1998) Chapter 4.

2.2.2 Structural vulnerability of developing countries

A. Low participation and low representation

It was observed above that developing countries had historically low levels of participation and engagement in the international IPRs system of the WIPO. When IP issues arose during the TRIPS negotiation process, many developing countries were unable to participate in an informed way in the WTO-TRIPS negotiation process. The Agreement was widely criticised by its perceived adverse impacts on undeveloped economies before and during its negotiation. Yet, it was clear that it is an agreement that would have far-reaching implication in their prospects for social and economic development. Only ten countries, India, Brazil, Argentina, Cuba, Egypt, Nicaragua, Nigeria, Peru, Tanzania and Yugoslavia, had the capabilities to enable them to be actively involved in opposing the US GATT agenda.[104] As the negotiations progressed, most of these countries eventually accepted the US position.[105] India was the only country to oppose the December 1991 text proposed by Chairman Anell and the GATT Secretariat. The outcome of the negotiation of this text was similar to the final, formal TRIPS text.[106]

Developing country inactivity has persisted in their domestic implementation of the TRIPS Agreement. For example, many have failed to take advantage of TRIPS flexibilities to promote public interests. Under Article 31 of the TRIPS Agreement the

---

[104] Bradley, J,(1987) '*Intellectual Property rights, Investment, and Trade in Services in the Uruguay Round: laying the foundation*' cited in Drahos, Peter (2002), 'Developing Countries and International Intellectual Property Standard-setting', *Journal of World Intellectual Property,* 5.
[105] Watal, J (2001), *Intellectual Property Rights in the WTO and Developing Countries* (London: Kluwer Law International), pp28-35.
[106] Ibid, p37.

governments of member states may authorise the use of compulsory licensing (CL) under certain conditions and procedures when faced with a public health emergency. The Doha Declaration on the TRIPS Agreement and Public Health (Doha Declaration), adopted by the WTO Ministerial Conference of 2001, affirmed this allowance; however, according to the recent survey by the Consumer Project on Technology, there is still little CL activity taking place in developing countries.[107]

Developing countries have traditionally been reluctant to participate in the multilateral trade system at all due to the sense of unequal bargaining power. In fact, many developing countries had viewed the GATT, which governed international trade before the WTO was established, as a club for developed countries. Under this forum, they believed that the initial proposals and the following rule-making processes were all dictated by wealthy countries, and issues of importance to developing countries were always left out of the negotiating rounds.[108]

Another factor that may have discouraged developing countries from engaging with the international trade regime was the trade policy most developing countries had adopted between the 1950s and the 1970s. Most developing countries had development policies that aimed to maximize GNP growth through capital accumulation and industrialisation. Their government leaders thought that liberal free trade would stifle the development of infant industries rather than promote industrialisation.[109] In 1964, a new multinational institution, the United Nations Conference on Trade and Development (UNCTAD), was

[107] See the table 1 in p25-26 in Drahos, P (2007), 'Four Lessons for Developing Countries from the Trade Negotiations over Access to Medicines '.
[108] Singh, J (2000), 'Weak Powers and Globalism: the Impact of Plurality on Weak-Strong Negotiations in the International Economy ', *International Negotiation* 5, pp452-453.
[109] Meier, G and Rauch, J (eds.) (2005), *Leading issues in economic development* (Oxford Oxford University Press), p144. See UNCTAD website: <http://unctad.org>.

established to deal specifically with the concerns of developing countries in respect to their problems relating to trade and development.[110]During the 1960s and 1970s, the developing countries mainly pursued their international trade agenda through this new institution. Through UNCTAD, developing countries attempted to establish a system of preference facilitating their manufactured exports to industrialized markets and stabilizing commodity prices.[111]

Since the 1980s, developing countries' participation in the GATT, and subsequently in the WTO, has increased significantly. During the Uruguay Round, the number of developing country memberships in the GATT increased to 96.[112] Notwithstanding membership growth, the number of votes attributable to developing countries was not sufficient alone to overturn their weak bargaining power in the WTO negotiations.[113] Besides lacking experience in previous GATT negotiations rounds, they also had the other disadvantages of lacking human resources, information, and negotiating strategies in contrast to their counterparts in the Uruguay Round.

B. Divergent interests among developing countries

During the 1960s and 1970s, developing countries generally achieved overall economic growth.[114] What followed was a period of contrasts in economic performance in the

[110] Haggard, S (1995), *Developing Nations and the Politics of Global Integration* (Washington, D.C Brookings Institution). p 39.
[111] Barry, T (2001), 'WTO in Focus – new series on policy briefs and policy on trade'. <http://www.fpif.org/wto/contents.html>.
[112] Drahos, P (2003), 'When the Weak Bargain with the Strong: Negotiations in the World Trade Orgnisation', *International Negotiation,* 8, p85.
[113] Ibid, p 79.
[114] Easterly, W (2001), 'The lost Decades : Developing Countries' Stagnation in Spite of Policy Reform 1980-1998', in G Meier and J Rauch (eds.), *Leading Issues in Economic Development* (Oxford: Oxford University Press), p35 Figure 1a.

developing world, with economic stagnation in Latin America and Africa on the one hand, and rapid economic growth achieved by the newly industrialised countries in East Asia.[115] Some of them, including the 'Four tigers', enjoyed some of the highest growth rates in the world in the thirty-year period between 1960 and 1990 and managed to catch up with the developed nations in per capita terms. [116]

The diverse developmental trajectories among developing countries have caused their economic interests under the GATT to move apart. At the earlier stages, developing countries engaged under the auspices of two distinctive groups, labelled G10 and G20. The former, led by Brazil and India, was concerned about the issues related to safeguarding textile manufacturing and agriculture, and to contesting the potentially undesirable linking of services and intellectual properties with the new Round of negotiations. The G20 group, which was mainly made up of East Asian, South Asian and several Latin American countries, increasingly valued the advantages of working within the framework of the international trade system. They were already prepared to accept an extension of GATT rules into areas such as service, IPRs and other deep integration agendas.[117] The increasing departure of the interests among developing countries led to the splintering of trade policy unity among developing countries. With added bilateral pressures from more powerful countries, more and more developing countries began, to accept the western concepts of IPRs and trade policy promoted through the multilateral or bilateral forums. [118]

---

[115] Ibid, pp34-40.
[116] Rodrik, D (1995), 'Getting Interventions Right: How South Korea and Taiwan Grew Rich', *Economy Policy* 20.
[117] Haggard, S (1995), Developing Nations and the Politics of Global Integration.
[118] Michalopoulos (2001), *Developing countries in the WTO* (New York: Palgrave).

C. The collapse of the coalition between Brazil and India

The 1960s and early 1970s were viewed as the ideal moment for developing countries to press their demand for a new international economic order. One of the important conditions was the political unity under the leadership of Brazil and India among developing countries. However, this favourable condition started to dissipate in the run-up to the 1980s. The coalition between Brazil and India began to waver. One major internal reason leading to this change was the departure in developmental policies between these two countries.[119] From the 1960s up to1985, India had consistently implemented a heavily import-substitution oriented policy. Brazil had pursued a similarly protectionist industrial policy following the end of the Second World War. However, since the mid-1960s, Brazil had adapted to the export –oriented growth industrialisation policy[120] after confronting difficulties and dissatisfaction with the import substitution industrialisation policy.[121] The departure of economic policies between these two countries made their political alliance fragile in facing the external pressures and threats.

On the other side, the US started to pursue bilateral or unilateral approaches more strongly to further its IP objectives, following the failure of negotiations in the Paris Convention of 1986. Since this point the coalition between Brazil and India had played the leading role in the opposition to the US's IPR agenda under the framework of the

[119] Haggard, S (1995), Developing Nations and the Politics of Global Integration.
[120] World Bank (1987) 'World Development Report' cited in Todaro, M (1989), *Economic Development in The Third World* (London: Longman), pp 428-429.
[121] Jenkins, R (1992), 'Theoretical perspectives', in T Hewitt, H Johnson, and D Wield (eds.), *Industrialisation and Development* p133.

GATT.[122] Thus, for the US to succeed with its agenda, 'the Brazil- India axis was one that had to be broken'.[123] This was to be achieved without much difficulty by the pressure of trade sanctions exercised by the US. The US acted in July 1987, when the USTR launched an investigation into the Brazilian patent provisions for pharmaceutical products under Section 301of Trade Act of 1974 [124] The investigation led to the imposition of a100 percent tariff ad valorem on exports of more than 20 pharmaceutical products from Brazil to the US, affecting trade worth US$39 million.[125] Thereafter, further tariff penalties were continually imposed on other Brazilian goods. In June 1990, the Brazilian President announced a legislative action in response to the US's demand. Soon after, in Geneva, India found little support from Brazil in the negotiations.[126] Through similar approaches, the US broke down the resistance of other developing countries and effectively isolated India by deploying the same tool of trade sanctions.[127]

D. Market dependence

Another cause of developing countries' vulnerabilities in international economic relations derives from their asymmetric dependence upon US markets for international trade. The ability to access US markets is highly attractive for international exports due to its huge size and affluence; however, historical policy influences could affect developing countries trade orientation and dependence on the US quite differently. For example, Brazil and other Latin American countries that had espoused protectionist

[122] Singh, J (2000), 'Weak Powers and Globalism: the Impact of Plurality on Weak-Strong Negotiations in the International Economy ', p7.
[123] Drahos, P (2002), 'Negotiating Intellectual Property Rights: Between Coercion and Dialogue', in P Drahos and R Mayne (eds.), *Global Intellectual Property Right: Knowledge, Access and Development* (Hamphshire: Palgrave Macmillan), p171.
[124] Drahos, (2002), 'Negotiating Intellectual Property Rights: Between Coercion and Dialogue' p171; Bello, J (1989/1990), 'Section 301: The United States' Response to Latin American Trade Barriers Involving Intellectual Property', The University of Miami Inter-American Law Review, 21 (2), 495-505
[125] Watal, J (2001), *Intellectual Property Rights in the WTO and Developing Countries*, p25.
[126] Drahos, P (2002), 'Negotiating Intellectual Property Rights: Between Coercion and Dialogue'.
[127] Watal, J (2001), *Intellectual Property Rights in the WTO and Developing Countries*, p36.

import-substitution industrialization policies. This became problematic when Brazil needed new markets. It found opportunities with its Latin America trade partners from the 1950s and the early 1960s to be limited because the strong influence of the doctrine of the import-substitution industrialisation in Latin America led to inward-orientated economies. Consequently, the open economies in North America and Europe became the most important markets for Brazilian exports. Another factor that separated Brazil from other developing countries was that until 1970 it produced primary and semi-processed products, and demand by developed countries provided important markets for Brazilian exports. So, it had already long relied on the US and Europe as its major export markets for coffee, sugar, soybeans and iron ore.[128]

Korea provides another example of dependency on US markets. The foundations of economic ties between Korea and the United States were laid in the Korean War. The US had provided about US$6 billion between 1945 and 1978 in aid of Korea's economic reconstruction and development.[129] Because of its internal constraints (narrow domestic market, rare resources) and favorable external conditions (the historical link with Japan and political and economic support from the US), the Korean government adopted an export-oriented development policy, and the US and Japan naturally became its major trading partners.[130] Korea exported 75.6 percent of all trading goods to the US and Japan in 1970. Following this, there was a governmental effort to reduce the dependence on the US and Japan's market through diversifying export markets, but the level of Korean export going to these two countries was still as high as at 55.6 percent

---

[129] Bell, M. (1990), *Brave New Third World: Strategies for Survival in the Global Economy* (London: Earthscan), cited in Edwards, C (1992), 'Industrialisation in South Korea ', in T Hewitt, H Johnson, and D Wield (eds.), *Industrialisation and Development* (London: Oxford University Press in association with the Open University Press), p106.
[130] Edwards, C (1992), 'Industrialisation in South Korea ', pp106-107.

in 1986.[131]

In the world economy, all countries are unavoidably dependent on each other; however, the dependence among countries varies in kind and in degree.[132] Interdependence of certain forms and degrees could integrate countries in a competitive and coordinated way. It tends to produce mutual benefits and positive development for all the partners. However, this dependence, either in an unfavorable form or of an asymmetric degree, would bring about vulnerability and undesirable consequences for the partners who are more greatly reliant on the others in the international economic relations. The latter circumstance was the case with Brazil and Korea when they confronted US demands to reform their national intellectual property laws in the mid and the later 1980s. Given wealth and technological asymmetries, the majority of developing countries are subject to the whims of the countries they rely on; with their economic prowess, rich capital source and technological advancement, the US and Western European countries have enjoyed powerful bargaining positions in international economic relations.

E. Domestic 'regulatory capture'

At the domestic level, the relative backwardness of economies and rigid political systems add another level of vulnerability to developing countries in the international system.[133] For instance, India has traditionally demonstrated great determination and abilities in its utilization of IPRs for development. Its pioneering reform of its patent law in 1970 not only promoted its indigenous pharmaceutical industry, but also showcased an efficient technology-learning path for technologically undeveloped

[131] 'Korean foreign economic relation'. <http://www.country-studies.com/south-korea/foreign-economic-relations.html>, accessed on April 17, 2008.
[132] Hettne, B (1990), *Development Theory and the Three Worlds* (Hong Kong: British Library Cataloguing in Publication Data), p114.
[133] Krasner, S. (1985), *Structural Conflict: The Third World Against Global Liberalism* (University of California Press), Chapters1-3.

countries. Also, internationally, India has always stood at the forefront of defending developing countries' interests. For example, during the TRIPS negotiations, it fought for various dilutions of restrictive conditions proposed by the US on Article 31 of TRIPS and argued for provisions that maintained some useful policy space for developing countries to utilise the CL provision.[134]

Nevertheless, since the 1990s, the industry groups, the Confederation of India Industry (CII) and the Associated Chambers of Commerce and Industry (ASSOCHAM), together with the newly emerged technology-based industries, have risen as the most influential economic powers in India. They started to favour strengthening intellectual property protection in India, in order to safeguard their growing trade interests in the US market.[135] India undertook a dramatic IP policy shift from one of opposition to one of favouring stronger IP protection, especially after the political party Bhartiya Janata Party (BJP) came to power. This policy change by the Indian government did not mean that they had been persuaded of the value of a strong IP regime,[136] but is rather more likely to have been a policy strategy to reduce the uncertainty and risk associated with being confronted with powerful domestic and international forces.

2.3 Concluding remarks

The TRIPS rules can be shown to be the result of a long period of North-South conflicts over IPRs since the 1970s. During their early industrialization period, developing countries began to find that the international convention governing patents, the Paris Convention, contained standards contrary to their interests in industrialisation and

[134] Watal, J (2001), *Intellectual Property Rights in the WTO and Developing Countries*, p34.
[135] Ramanna, A (2005), 'Shifts in India's Policy on Intellectual Property: The Role of Ideas, Coercion and Changing Interests', pp160-161.
[136] Ibid, p159.

technology acquisition. As a consequence, many restructured their national legislation in the 1970s to fit their particular levels of development and in the early1980s, some launched initiatives to reform the Convention. Their efforts failed, however, due to the irreconcilable conflict of interests and insurmountable power imbalances between developing and developed states.

Contrary to the original intentions of the developing countries, a new international IPRs legal framework with higher standards was initiated and negotiated under the GATT Uruguay Round of trade negotiations in the late 1980s and concluded as a result of the TRIPS Agreement in 1994. Some scholars have suggested that the TRIPS Agreement was a bad deal for the developing member countries because it was a product of developed countries' superior and coercive bargaining power and developing countries' economic dependence and their ignorance of IP matters. On the other hand, it is also argued that the TRIPS Agreement was the result of a trade-off between developed countries' interests in safeguarding their IP assets in developing countries' markets and developing countries' interests in accessing developed countries' markets, FDI and technology. The history of the TRIPS negotiation has provided well-document evidence for the former argument. Within the latter argument, certainly developed countries' IPRs agenda was largely satisfied by the adoption of the TRIPS Agreement. Nevertheless, the economic benefits that developing countries expected through their concessions on IP have largely not materialized. This raises the question whether those promises were simply theoretical assumptions or purely rhetoric used by those promoting stronger IP protection rules to persuade recalcitrant developing countries not to oppose the TRIPS Agreement. The next chapter provides a critical review of these

theoretical assumptions and discusses the impacts of the TRIPS Agreement on development in developing countries.

Chapter 3 TRIPS and pharmaceutical innovations in developing countries: existing knowledge and gaps

This chapter reviews the possible impact of the stronger patents of TRIPS on indigenous innovation in developing countries. The focus of examination concerns both the policy-effect and economic-effect of such provisions. Therefore, it examines the following two questions in turn:

1) Whether or not TRIPS implementation affects a member country's adaptability in designing and executing its own IPR law and policy;

2) Whether TRIPS implementation can promote indigenous innovation, international technology transfer (ITT), and additional global R&D responding to the local major health needs of developing countries.

3.1 Policy effects of TRIPS implementation

Does TRIPS implementation impede the legislative adaptability of developing countries in making a pro-health patent system? A good understanding of this question may be found through a comparative study of the patent rules prior to and after the TRIPS Agreement as well as a study of the complementary institutional factors. Thus, this section first reviews patent standard setting under the Paris Convention, followed by a study of the new pharmaceutical patent regime under the TRIPS framework, involving TRIPS compulsory standards, TRIPS-plus standards and TRIPS flexibilities. Then, it also analyses the relationship between institutional capabilities and the use of TRIPS

flexibility. It concludes by reviewing answers and knowledge gaps with respect to the two thematic questions posed.

3.1.1 Pharmaceutical patent policy making prior to TRIPS

Prior to TRIPS, patent policies in pharmaceuticals have traditionally varied greatly over space and time. Fundamentally, patent rights, like other forms of intellectual property rights, are national and territorial in nature.[137] It is a matter that should be left within a state's decision-making process. Any sovereign state is entitled to its autonomy in formulating and enforcing its patent laws in respect to national interests. Nevertheless, as a contracting party for any international agreements, the country is obliged to comply with the commitments it has undertaken.

As mentioned earlier, the main international convention governing patents before the entry of the TRIPS Agreement was the Paris Convention. Although contracting countries of the Convention are allowed the autonomy to develop and enforce their own patent legislation, they must abide by the standards and obligations established under the Convention, and the scope of their national patent policies and the flexibilities in their administrative practice have to conform to the standards of the Convention. Nonetheless, the Paris Convention did not have a broad membership until the 1970s. The number of original signatory contracting countries was 14, increased to 47 by 1958 and to 80 by 1973. Many major developing countries including India, Malaysia, Pakistan, the Republic of Korea, Sudan and Thailand were yet to become members of

[137] Bently, L and Sherman, B (2004), *Intellectual Property Law, Second Edition* (Oxford: Oxford University Press), p5.

the Paris Convention by that time. In the Soviet Union and other socialist countries, a system of honourable reward for inventions applied. Not bound by international rules, these countries formulated and enforced a national patent system according to their respective interests. In addition, the patent standards for pharmaceuticals among developed countries also varied according to their industrial strength and competitiveness. Hence, the following review will discuss not only the major provisions of the Paris Conventions but also the patent standard-setting for pharmaceuticals in various groups of countries, namely developing countries, socialist countries and developed countries, in the pre-TRIPS period..

A. Major provisions of the Paris Convention in relation to pharmaceutical patents

The Paris Convention is constituted by a straightforward mission that is to protect industrial property and to safeguard the interests of rights holders.[138] Consequently, the privileges for rights holders are stated in considerable detail in the Convention. On the other hand, there is little recognition or consideration of the public interest that the system is expected to serve, nor do the rights afforded to countries granting these privileges and the remedial measures to deal with possible abuses of the system receive the same level of safeguard.[139] Thus, its developing country members have long criticised the patent protection maximalist approach adopted by the Convention.

Nevertheless, the Paris Convention, unlike its later rival the TRIPS Agreement, does not mandate a universal minimum standard. Instead, it adopts ‘a mechanism of international

[138] Article 1, the Paris Convention.
[139] Balasubramaniam, K (1987), 'Pharmaceutical Patents in Developing Countries: Policy Options', p103.

protection without harmonisation'[140] It does not attempt to level national laws and, despite six modifications since its inception, it leaves significant legislative freedom in substantive matters such as patentability criteria, exclusion of patentability and duration of patents, for example.[141]

National treatment

Article 2.1 of the Convention requires that whatever rights and obligations are provided for a country's nationals under national patent law should also be applicable to foreigners. This provision appears to permit formal differences in rules provided that the level of protection granted to local and foreign nationals is equivalent. Commentators credit this principle as being a rule of non-discrimination between nationals and foreigners in protection while allowing legislative freedom for members to develop and enforce their own laws in certain important areas: non-patentability, the rights conferred to patentees and the duration and terms of these rights. [142]

Independence of patent

Unlike Article 27.1 under TRIPS, the Convention does not establish any patentability criteria and allows exclusions from patentability.[143] Under Article 4 bis, the Convention stipulates the rule about the 'independence of patents obtained for the same invention in different countries'. It does not intend to lay down unified standards but instead 'patents applied for in the various countries of the Union by nationals of countries of the Union shall be independent of patents obtained for the same invention in other countries,

[140] Bently, L and Sherman, B (2004), *Intellectual Property Law,* p5.
[141] Correa, C (2005), 'Implementing the TRIPS Agreement in the Patents Field: Options for Developing Countries', *The Journal of World Intellectual Property,* 1 (1), p76, UNCTAD-ITCSD (2004), 'Resource book on TRIPS and Development'. <http://www.iprsonline.org/unctadictsd/ResourceBookIndex.htm>, p354; Gontijo, C (2005), 'Changing the Patent System from Paris Convention to the TRIPS Agreement: the Position of Brazil', <http://www.boell.de/alt/de/02_public/4930.html>, accessed on August 5,2008.
[142] Bently, L and Sherman, B (2004),, p5; Gontijo, C (2005), p7.
[143] UNCTAD-ITCSD (2005), 'Resource book on TRIPS and Development'. p354.

whether members of the Union or not' The independence of such patents is also applied as regards the grounds for nullity and forfeit, and as regards their normal duration. These provisions can be interpreted to mean that member states remain free to make their own decisions on substantive matters such as patentability, exclusion of patentability, and duration of patent protection, for example.[144]

Compulsory licensing

The term 'compulsory licensing' or non-voluntary use 'refers to the practice by a government to authorise itself or third parties to use the subject matter of a patent without the authorisation of the right holder for reasons of public policy.'[145] As mentioned earlier, the Paris Convention recognises the rights of its members to grant compulsory licensing to prevent abuses of patent rights, and failure to work the patent is explicitly recognised as such an example (Article 5 A.2). This provision has been the most controversial in the history of the Paris Convention, [146] for it directly touches on the issues that create 'the conflict between the interest of the national economy as a whole and the interest of the individual patentee in obtaining the maximum return from his patent'.[147] After five revisions since its inception, its final text lost much of its flexibility and became more rigid than the original.[148] This rendered Article 5 of the Convention virtually unable to promote technology transfer or prevent patent abuse in developing countries.[149]

---

[144] Balasubramaniam, K (1987), 'Pharmaceutical Patents in Developing Countries: Policy Options', p104.
[145] Reichman, J and Hasenzahl, C (2003), 'Non-voluntary Licensing of Patented Inventions: Historical Perspective, Legal Framework under TRIPS, and an Overview of the Practice in Canada and the USA', UNCTAD-ICTSD working paper, p1.
[146] Roffe, P and Vea, G (2009), 'The WIPO Development Agenda in a Historical and Political Context', in W Netanel (ed.), *The Development Agenda: Global Intellectual Property and Developing Countries* (Oxford Scholarship Online).
[147] Penrose, E (1951), *The Economics of the International Patent System* (Johns Hopkins), cited by Roffe, P and Vea, G (2009), p 85.
[148] 'For example the original text allowed countries to determine freely the rules under which local exploitation could take place. 'Roffe, P and Vea, G (2009), p92, p97.
[149] UN (1975) "The Role of the Patent System in the Transfer of Technology to Developing

Nevertheless, the limitations laid down under the Convention are less restrictive compared to the new modalities added to this provision under TRIPS. It only sets a minimum period of time before compulsory licensing may be applied for 'before the expiration of a period of four years from the date of filing of the patent application or three years from the date of the grant of the patent,' (Article 5 A.4); it does not provide a right to compensation for patent holders, but otherwise does not restrict the granting of such licenses.[150] The term 'working' is not defined in the 1883 Convention and members are free to make their own determination of the rules under which local exploitation can take place.[151] Consequently, both developed and developing countries have interpreted 'working' as local production and not importation in accordance with Article 5.A.4 of the Convention.[152]

The above three provisions of national treatment, independence of patent and compulsory licensing lay down the primary principles and procedures for safeguarding the rights of patent holders, especially in foreign jurisdictions. However, it also keeps open considerable policy options in areas such as patentability criteria, exclusion of patentability, duration of patentable criteria and the rules for local exploitation. Such legislative leeway allows member countries flexibility in adopting patent rules adapted to their national conditions.

Countries" cited in Balasubramaniam, K (1987), 'Pharmaceutical Patents in Developing Countries: Policy Options ', p105; Roffe, P and Vea, G (2009).

[150] Abbott, F, Cottier, T, and Gurry, F (1998), *The International Intellectual Property System: Commentary and Materials* (Kluwer), pp717-718.

[151] Ladas, S (1975), *Patents, trademarks, and related rights : national and international protection* (2; Cambridge: Harvard University Press), p523.

[152] UNCTAD-ITCSD (2005) , 'Resource Book on TRIPS and Development', p369.

B. Developed countries

The patent system was a legislative creation by medieval European countries. The first patent law was probably established by the Republic of Venice in 1747 aimed at regulating inventors' protection through statutory law. This system evolved and was established widely in other European countries and the rest of the world over the next four hundred years.[153] However, various standards were established under different national patent systems to fit with national interests. With respect to the patent rules on pharmaceuticals, the design of legislation, such as the scope of patentability, the types of patents and quasi-patents, the inventions excluded from patentability, and the duration of rights, all become deeply defined by the strengths of the respective pharmaceutical industries.[154]

In the US, chemical products have always been patentable and pharmaceutical products followed.[155] As the US pharmaceutical industry has grown to become the leader in the world market, it has successfully lobbied for longer and more frequent extensions for drug patents. However, in most European countries, only the processes by which drugs are produced have been patentable until recently. In France, pharmaceutical inventions were not subject matter under 1844 patent law. Patents for processes were allowed with the evolution of legislation, but the inclusion of product patents was forbidden until the 1966 law, in which limited product patent protection was allowed. The ban on drug patenting was only completely removed in 1978.[156] In Germany, patents for both

[153] See Machlup, F (1958), 'An Economic Review of the Patent System', (Study of No 15 of the Subcommittee on Patents, Trademarks, and Copyrights of the Committee on the Judiciary, US Senate,) pp 2-4.
[154] Dufield, G (2003), *Intellectual Property Rights & the Life Science Industries: A Twentieth Century History* (Aldershot: Ashgate).
[155] Boldrin, M and Levine, D (2008), *Against Intellectual Monopoly* (New York: Cambridge Univ. Press), p215.
[156] Boldrin, M and Levine, D (2008), *Against Intellectual Monopoly, p216.*

chemical and pharmaceutical processes were adopted under the 1877 law. Product patenting was prohibited until the extension of patent protection to products obtained through a patented process under the 1891 law. General patentability for chemical and pharmaceutical products was finally established in 1967.[157] In Switzerland, patents for chemical processes were only introduced in 1907 as a result of constant political and legal pressure from Germany; nevertheless the rules were applied restrictively.[158] Patents for products were only introduced into Swiss patent law in 1977. In addition, Ireland allowed pharmaceuticals to be patented in 1964, Japan in 1976, Switzerland in 1977 and Italy and Sweden both in 1978, and Spain in 1992.[159]

C. Developing countries

Given the weak industrial base and resource constraints, developing countries have naturally emphasised the social welfare function of exclusive rights. Their IPR legislation tends to be designed to facilitate local production and access to innovation. Pharmaceutical products have greater relevance to social welfare than any other industrial products. It is in the interest of developing countries to adopt a patent system which encourages the transfer of technology and the entry of generic competition. Thus, the strength of patent protection for pharmaceuticals in developing countries has been weaker than that adopted by developed countries in terms of patentability, the duration of patents, the working requirements and the compulsory licensing system. In addition, some of major developing countries, including China, India, Malaysia, Pakistan, the Republic of Korea, Sudan and Thailand, have only relatively recently acceded to the Paris Convention. Their adherence to the Convention began in the 1980s. China, for

[157] Boldrin, M and Levine, D (2008), *Against Intellectual Monopoly* , p216.
[158] Ibid, p216.
[159] Dutfield, G and Suthersanen, U (2005), 'Harmonisation or Differentiation in Intellectual Property Protection? The Lessons of History', p135.

example, became a member in July 1992, India in December 1998 and Pakistan as recently as 2004.[160] It seems only natural that there was great distance between the pharmaceutical patent standard settings of developed and developing countries.[161] India's Patent Law of 1970 laid down a pivotal foundation allowing India to build a successful generic industry.[162]

D. Socialist countries:

Many socialist countries provided another model of legal protection for inventions. This was termed as Author's or Inventor's Certificate. This system was first introduced in the Soviet Union under its first legislation 'Decree on Inventions' on June 30, 1919; it was then taken up by many other socialist countries, with certain changes.[163] The Inventor's Certificate granted the right of exploitation of inventions to the state and the inventors were rewarded with remuneration or a prize from the state. The inventors had no rights to transfer or license their inventions to third parties.[164] Medical substances obtained by non-chemical processes and inventions relating to methods of treating disease were subject matters rewarded by the Certificate. The general nature of this model was to encourage invention through non-monetary and honourable rewards.[165] The incentive mechanism under the Inventor's Certificate is obviously in contrast to the exclusivity rights provided by the patent system.

---

[160] The main information is referred to Roffe, P and Vea, G (2009), China's accession information is referred to at <http://www.wipo.int/treaties/en/Remarks.jsp?cnty_id=931C>, accessed on October 19, 2008

[161] Jucker (1980), *Patent and Pharmaceuticals* (Basle: E Jucker), p34-35.

[162] Drahos, P (2002), 'Developing Countries and International Intellectual Property Standard-setting', *Journal of World Intellectual Property,* 5, p768.

[163] Ladas, S (1975), *Patents, Trademarks, and Related rights : National and International Protection* (2; Cambridge: Harvard University Press), p380.

[164] Ibid, p381.

[165] Ben,K (1985/86), 'The Patent Law of the People's Republic China in Perspective ', *University of California Los Angeles Law Review,* 33.

The above account of the historical and complex international patent regimes is inevitably simplified. It is important to note that many alternatives may exist simultaneously, such as patent protection being, in theory, an option for inventors in some socialist countries;[166] the harmonisation movement around the world, and the inception and operation of the Patent Cooperation Treaty in 1970 under the World Intellectual Property Office (WIPO).

In brief, prior to the TRIPS Agreement, the patent standard setting for pharmaceuticals was a matter for sovereign decisions. The Paris Convention, the primary international patent governing treaty before the TRIPS Agreement, has operated under 'a mechanism of international protection without harmonisation', allowing the autonomy of member countries to design their respective patent systems according to the level of economic development and to product concerns. Therefore, differences in pharmaceutical patent laws had existed to a greater or lesser degree between various jurisdictions regarding areas of non-patentability, the rights conferred to patentees and the duration and terms of these rights, for example.[167] The historical records demonstrate that the development of branded pharmaceutical industries and generic industries both benefitted from the existence of this variation in the patent policies adopted in each jurisdiction.

3.1.2 New legal framework for pharmaceutical patents after TRIPS

The TRIPS Agreement has provoked dramatic changes in the legal framework of pharmaceutical patents both nationally and internationally. It closes significant policy options provided under the Paris Convention through a universal IPRs mandate. It significantly increases the level of patent protection beyond the standard previously

[166] Ladas, S (1975), *Patents, Trademarks, and Related rights : National and International Protection*, p381.
[167] Gad, M (2006), *Representational Fairness in WTO Rule-Making,* p52.

established under the Paris Convention and other international treaties.[168] The following section reviews a number of key TRIPS provisions to illustrate the changes TRIPS has brought to the legal framework of pharmaceutical patents.

A. Key TRIPS obligations to pharmaceuticals

National treatment and most favoured nation (MFN) are two fundamental principles of the TRIPS Agreement. The national treatment principle basically requires that each member of the WTO treats nationals of other member states at least as well as it treats its own nationals in the matter of IP protection. This is incorporated by reference to the national principle provisions under the WIPO conventions. [169]

The MFN principle is one of the additional principles set up under TRIPS which are absent from the Paris Convention. It provides that the members of the WTO shall immediately and unconditionally extend to all other members 'any advantage, favour, privilege or immunity' granted with respect to the protection of intellectual property to nationals of any country including a non-member of the WTO.[170]

The impact of TRIPS principles on pharmaceutical patent protection is profound in developing countries. Under the MFN principle, any strengthening of patent protection through FTAs in one WTO member is unconditionally and automatically accorded to the benefit of all other members.[171] On the other hand, the formal equality required by the national treatment and MFN may not be an 'unalloyed benefit' to developing

[168] Harris, D (2004/2005), 'TRIPS' Rebound: How the Agreement on Trade-Related Aspects of Intellectual Property Rights ("TRIPS") Can Ricochet Back Against the United States: An Historical Analysis ', *Northwestern Journal of International Law & Business,* 25 (99), p105.
[169] UNCTAD-ITCSD (2004), 'Resource book on TRIPS and Development', p63.
[170] Article 4, the TRIPS Agreement.
[171] Correa, C (2007), *Trade Related Aspects of Intellectual Property Rights: A Commentary on the TRIPS Agreement* (New York: Oxford University Press Inc.), p5.

countries. Given the tremendous gap in technical capabilities between developed and developing countries, these two principles which require developing countries to treat local and foreign economic parties on the same basis may in effect place developing countries at a disadvantage in their international trade with developed countries[172]

Non-discrimination

TRIPS Article 27 requires WTO members to provide patent protection without discrimination in terms of the place, the field of technology, whether products are imported or locally produced, while permitting certain exceptions.[173] Discrimination is neither allowed between different fields of technology in national patent laws nor is it permitted between the places of inventions whether they are imported or locally produced. [174] This provision has evoked intense protest for it is perceived as the most rigorous limitation on national autonomy over IP matters among TRIPS rules.[175]

The non-discrimination principle of TRIPS rules out the policy option of allowing the exclusion of inventions in fields such as food, medicines and agricultural goods under the previous international treaties.[176] Secondly, it creates an inconsistency between Article 5(A) of the Paris Convention and Article 27.1 of TRIPS. Article 5(A) states that importation does not equate to local working, whereas TRIPS Article 27.1 provides that patents should be enjoyed without discrimination as to whether products are imported or locally produced. [177] This discrepancy has led to controversy about which provision

[172] UNCTAD-ITCSD (2004), 'Resource Book on TRIPS and Development', p89.
[173] Such as the exceptions defined under Articles 7, 8, .27.2, 27.3a, 27.3b, .30, 31, 40 etc. of the TRIPS Agreement.
[174] Article 27.1, the TRIPS Agreement.
[175] Harris, D (2004/2005), 'TRIPS' Rebound: A Historical Analysis of How the TRIPS Agreement Can Can Ricochet Back Against the United States', *Northwestern Journal of International Law & Business,* 25 (99), p106.
[176] Gad, M (2006), *Representational Fairness in WTO Rule-Making*, pp53-53.
[177] Correa, C (1994), 'The GATT Agreement on Trade-Related Aspects of Intellectual Property Rights: new standards for patent protection', *European Intellectual Property Review,* 16 (8), p331.

prevails, and whether Article 27.1 of TRIPS was intended to supersede the rule under Article 5(A) of the Paris Convention, thereby prohibiting a member from issuing compulsory licenses for lack of local working. Some scholars have argued that this provision does not incorporate a direct ban on the working requirement. Others have contended that Article 27.1 requires equal treatment for both imported and locally produced goods, and the imposition of the local working requirement is therefore not allowed. They then consider that the working of a patent can be satisfied by importation for the purposes of compulsory licences.[178] Such conflicting interpretations were manifested in the WTO US-Brazil case in which the US challenged the local working requirement provided under Brazilian 1996 IP law. Although the case was not decided on the merits as the US withdrew its complaint, this case demonstrated that states interpret Article 27.1 rather differently for the purpose of compulsory licensing. Such differences in interpretation may reduce the scope of the application of compulsory licensing.

Patent term:

Article 33 of TRIPS provides that patent protection has to last at least a period of 20 years from the filing date. This provision attempts to harmonise the patent term by providing a minimum standard. The term of protection under TRIPS is longer than in many countries,[179] including China, which provided a 15-year term from the filing date.[180] Moreover, TRIPS non-discrimination clause also rules out the practice of varying the length of patent terms according to the type of invention.[181] For example,

[178] UNCTAD-ITCSD (2005), p374, p482-483.
[179] Harris, D (2004/2005), 'TRIPS' Rebound: A Historical Analysis of How the TRIPS Agreement Can Can Ricochet Back Against the United States', p106.
[180] Article 45, Chinese Patent Law of 1984.
[181] Harris, D (2004/2005), 'TRIPS' Rebound: A Historical Analysis of How the TRIPS Agreement Can Can Ricochet Back Against the United States', p107.

the 1970 Indian patent law provided a 5-year term for patent processes for pharmaceuticals and longer terms for other inventions.

Pharmaceutical test data protection

Pharmaceutical registration data refers to data results from preclinical and clinical studies on the efficacy and non-toxicity of pharmaceutical products. Such data is required as the justification for national health authorities in their decisions on the granting of manufacturing or marketing licences for pharmaceutical products containing new chemical entities.[182]

Prior to TRIPS, countries had full discretion to determine whether or not to confer protection on such data. The TRIPS Agreement established the first international standard on this subject under Article 39.3.[183] It requires members to protect 'undisclosed' pharmaceutical registration data from 'unfair commercial use'. However, the rule provides broad parameters for members to interpret the rule in their national laws, thereby allowing different models for such protection to be applied in various jurisdictions under the WTO.[184]

Enforcement mechanism:

The enforcement mechanism is another major innovation of the TRIPS Agreement in relation to other existing IP treaties. Part III lays down the minimum substantive standards for the enforcement of IPRs. The scope of the enforcement procedure is broad, including measures to prevent IPR infringement domestically and at borders, civil and

[182] See the concept from the CPTECH, at <http://www.cptech.org/ip/health/data/>, last accessed on May 28, 2010.
[183] See Correa, C (2004), 'Protecting Test Data for Pharmaceutical and Agrochemical Products under Free Trade Agreements', (UNCTAD-ICTSD UNCTAD Dialogue (Bellagio)), p4.
[184] See, e.g. Arrivillaga, L (2005), 'An International Standard of Protection for Test Data Submitted to Authorities to Obtain Marketing Authorization for Drugs', *The Journal of World Intellectual Property,* 6 (1), cited in Correa, C M (2004), p4.

administrative procedures, remedies, provisional measures, and other special requirements related to border measures and criminal procedures.[185] These enforcement rules are in place at both national and international levels.[186] Nationally, many members, in particular developing countries, are required to adopt higher enforcement procedures despite a lack of infrastructure and resources. Internationally, TRIPS Article 64 establishes a punitive dispute settlement procedure to resolve IP disputes. This rule provides a mechanism by which members can threaten to invoke this WTO remedy of withdrawing trade concession when the accused party fails to comply with a WTO ruling.[187]

B. TRIPS flexibility

Although the TRIPS Agreement's universal approach significantly reduces the policy leeway of member countries, in its defence the Agreement incorporates a number of flexible provisions designed to facilitate development and to protect the public interest. To mitigate the problematic TRIPS constraints, it is crucial for developing countries to utilise TRIPS safeguarding mechanisms effectively in the process of TRIPS implementation. This objective calls for a good understanding of the scope of flexibilities and active initiatives in the process of TRIPS interpretation and implementation. For a reference for future proposals, this section reviews the key operative flexibilities and some useful implementation precedents.

Key operative flexibilities:

The guiding rules for TRIPS interpretation and implementation

[185] Article 41-60 of the TRIPS Agreement.
[186] Harris, D (2004/2005), 'TRIPS' Rebound: A Historical Analysis of How the TRIPS Agreement Can Ricochet Back Against the United States', p116.
[187] Shaffer, G (2003), 'How to Make the WTO Dispute Settlement System Work for Developing Countries', (ICTSD Resource Paper No. 5), p9.

Articles 1.1, 7 and 8 of the TRIPS Agreement are considered to be the 'guiding principles' for its interpretation and implementation.[188] Thus, the clarification of these guiding principles may be considered the first and principal task for member countries to undertake. These provisions clearly state that WTO member states should balance the private interests in IPRs against a variety of wider socio-economic interests in the course of their implementation of the TRIPS Agreement.

It is a well-established in international law, that states are bound by the agreements they make with other states, known as *pacta sunt servanda* and enshrined in Article 26 of the Vienna Convention on the Law of Treaties (Vienna Convention).[189] Thus, clearly WTO members must abide by their TRIPS obligations; however, this obligation does not dictate how TRIPS should be observed domestically.[190] The guiding principles are provided as guidance. Under the first, Article 1.1 of the TRIPS Agreement endorses freedom in its implementation method. While obliging conformity, it states that '…..[m]embers shall be free to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice'. This implies that TRIPS obligations may have no 'direct effect' in member countries and that each member may determine the relationship between TRIPS and domestic legal systems constitutionally for itself; it also provides authorisation for members to implement TRIPS-compatible rules in a manner most appropriate for their national conditions.[191]

[188] UNCTAD-ITCSD (2005), 'Resource book on TRIPS and Development'. Yu, P (2009),
[189] 'Every treaty in force is binding upon the parties to it and must be performed by them in good faith.' Article 26, the Vienna Convention (1969).
[190] Cottier, T and Schefer, K (1999), 'The Relationship between World Trade Organisation Law, National and Regional Law', in F Abbot, T Cottier, and F Gurry (eds.), *The International Intellectual Property System: Commentary and Materials* (1; The Hague: Kluwer Law International), p558.
[191] UNCTAD-ITCSD (2005), 'Resource book on TRIPS and Development'. pp17-18.

In the second guiding principle, Article 7 delineates five objectives that TRIPS implementation aims to achieve in developing countries. It provides:

> The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.

This article clearly indicates that the Agreement is intended to promote not only the interests of individual rights holders but also the socio-economic welfare interests of the wider society. Thus, a reasonable interpretation of this provision is that the Agreement requires member states to strike a balance between these interests in the process of implementing TRIPS under national IPRs laws.

In the third set of guiding principles, Article 8.1 recognises that member countries are reasonably expected to adopt TRIPS-consistent internal measures to protect public health and promote certain sectors important to their socio-economic objectives, while Article 8.2 endorses the TRIPS-compliant domestic measures against patent abuse and anti-competition acts. [192]

Despite the existence of limitations in Articles 7 and 8 of 'various procedural and compensatory encumbrances',[193] these Articles may enable developing countries to explore TRIPS flexibilities more effectively. For example, a broad interpretation of

[192] UNCTAD-ITCSD (2005), 'Resource book on TRIPS and Development', pp126-127, also Article 8 of the TRIPS Agreement reads as: '1. Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement. '
'2. Appropriate measures, provided that they are consistent with the provisions of this Agreement, may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology.'
[193] UNCTAD-ITCSD (2005), p134.

these Articles was referred to favourably in the WTO dispute, *Canada – Patent Protection of Pharmaceutical Products* (Canada – Generics disputes).[194] In its final report, the WTO panel declared that: '[b]oth the goals and the limitations stated in Articles 7 and 8.1 must obviously be borne in mind when [examining the words of the limiting conditions in Article 30] as well as those of other provisions of the TRIPS Agreement which indicate its object and purposes'.[195]Moreover, Articles 7 and 8 were considered to be important guidelines in the Doha negotiations.[196] The Ministerial Declaration, in Paragraph 19, explicitly requires that Council in its work 'shall be guided by the objectives and principles set out in Articles 7 and 8 of the TRIPS Agreement and shall take fully into account the development dimension.'[197] Building on this, Professor Yu has recommended five ways in which Articles 7 and 8 could facilitate a more flexible TRIPS interpretation and implementation:

> (1) as a guiding light for interpretation and implementation; (2) as a shield against aggressive demands for increased intellectual property protection; (3) as a sword to challenge provisions that overprotect intellectual property rights or tolerate their abuse; (4) as a bridge to connect the TRIPS regime with other intellectual property or related international regimes; and (5) as a seed for the development of future international intellectual property norms.[198]

It is worth noting that the inherent ambiguities in Articles 7 and 8 are a result of the compromises reached among the disparate state views during the negotiation of the Agreement, leading to the possibility of different interpretations.[199] As a consequence, exploiting the policy space opened by this ambiguity under Articles 7 and 8 may

---

[194] WTO (2000) Canada – Patent Protection of Pharmaceutical Products, Report of the Panel, WT/DS114/R, March 17, 2000.
[195] Ibid.
[196] Gervais, D (2003), *The TRIPS Agreement, Drafting History and Analysis (Second Edition).* (London: Sweet and Maxwell), p120.
[197] WTO (20 November 2001), 'Ministerial Conference Fourth Session Doha, Ministerial Declaration ', (WT/MIN(01)/DEC/1).
[198] Yu, P. K. (2009), 'The Objectives and Principles of the TRIPs Agreement ', 46 *Houston L. Rev.* 797-1046., available at <SSRN: http://ssrn.com/abstract=1398746>.
[199] Frankel, S (2005), 'The WTO's Application of 'The Customary Rules of Interpretation of Public International Law' to Intellectual Property', Virginia Journal of International Law, 46..

provide an important starting point for developing countries to advance their interests under the TRIPS framework.

Flexibilities relevant to pharmaceutical patents

There are a number of 'flexibilities' available in the TRIPS Agreement that can be useful to promote public health and access to medicines in developing countries. The main relevant provisions include: compulsory licensing (Article 31), parallel importation (Article 6), provisions relating to exceptions to patent rights (Article 30), provisions relating to patentable subject matter (Article 27.2 & 27.3), provisions relating to data protection (Article 39) and provisions relating to the abuse of rights, competition and the control of anti-competitive practices (Articles 40).[200]

Compulsory licensing provision could be used as a policy mechanism to address problems such as the high price of medicines, anti-competitive practices and the under-supply of essential medicines. Parallel importation provision could be used as a measure to enable the importation of lower-priced patented pharmaceuticals and thus promote access to affordable medicines. This flexibility is reaffirmed by the Doha Declaration. Articles 27.2 and 27.3 permit the refusal to grant patents in some areas related to public health. Article 30 allows member countries to provide experimentation and early working exceptions. In addition, Article 39 provides the limitation on the extent of test data protection while Article 40 allows safeguarding measures against patent abuse. Both of these provisions could be very useful to facilitate the early entry of generic medicines and the healthy development of the local pharmaceutical industry

[200] Musungu, S, Villanueva, S, and Blasetti, R (2004), 'Utilizing TRIPS Flexibilities for Public Health Protection Through South-South Regional Frameworks', (South Centre), pp11-12.

in developing countries. A detailed discussion of patent-specific flexibilities will be provided in the context of China's experience in TRIPS implementation in Chapter 5.

Political scope of TRIPS flexibilities

The mere existence of TRIPS flexibilities, although essential, does little to ensure protection of public interests and in particular, their interest in access to medicines. More essential, perhaps, are the political will and abilities of states in their implementation of the TRIPS Agreement. In past decades, various developing countries demonstrated great determination and were proactive in exploring policies to meet their national development priorities. In this regard, Brazil and India perhaps stand out.[201] Both countries have played pioneering roles in initiating appropriate IP policies beneficial to their domestic economic development for several decades. For example, both countries' pre-TRIPS patent laws contained a similar local working clause which requires patent-holding companies to work their inventions locally in order to maintain exclusive rights, and this requirement continues after their adoption of TRIPS.[202] Also, India has traditionally provided a pre-grant opposition system which ensures that patents are not granted unnecessarily or to inventions not up to their particular standards for patentability. Despite pressures to eliminate this system, this pre-grant mechanism has been retained under section 3(d) of the revised Indian Patent Law (2005).[203] In Brazil, the health authority has used its domestic law provisions on compulsory licensing (CL) to negotiate price discounts for HIV/AID medicines from pharmaceutical

[201] Deere, C (2009), The Implementation Game:The TRIPS Agreement and the Global Politics of Intellectual Property Reform in Developing Countries (Oxford Scholarship Online), p312.
[202] Shadlen, K (2005), 'Policy Space for Development in the WTO and Beyond: the Case of Intellectual Property Rights', (Global Development and Environment Institute), p22.
[203] Referring to Section 3 (d), a patent application for a patent on Combivir from GSK was opposed by a coalition of public-interest group in 2006. They argued that Combivir is a combination of two know drugs and is not considered as a new invention under the law. Following the filing of this pre-grant apposition and public protest, GSK withdrew the given pending patent application in India as well as Thailand. See WHO (2008), 'Country Experiences in Using TRIPS Safeguards', (WHO Regional Office for South-East Asian).

MNCs. The 2001 President Directive and 2003 reform have made the CL provision easier to issue and less vulnerable to appeal.[204] In May 2007, a CL for public non-commercial use of Efavirens was actually issued after the price negotiation with the patent owner Merck failed.[205]

In addition, international civil society pressure has on occasion proved to be an effective means of defending developing member countries' use of TRIPS flexibilities. For example, to make medicine more affordable, in 1997 the South African government passed the Medicine and Related Substances Control Amendment Act, which allowed parallel imports, enforcing generic substitution, and implementing price controls. When thirty-nine multinational pharmaceutical companies filed a lawsuit to block the legislation under the claims that the law was unconstitutional and that it violated the TRIPS rules, there was an intense backlash from international media and civil society organizations. In the end, the companies were pressured to withdraw the case.[206] .In another example, an active and well-organized international campaign by NGOs and international media organizations helped developing countries gain the WTO's Declaration on the TRIPS Agreement and Public Health (the Doha Declaration). This reaffirmed and clarified the existence of flexibilities within the TRIPS Agreement.[207]

In brief, this section has demonstrated that political and judicial processes are interactive and complementary in the international IP forums. Just as WTO judicial processes shape bilateral negotiations, political processes inform and influence judicial

[204] Shadlen, K (2009), 'The Politics of Patents and Drugs in Brazil and Mexico: the Industrial Bases of Health Policies', *Comparative Politics*, 42 (1), 41-58, available at <http://eprints.lse.ac.uk/27051/>.
[205] Ibid.
[206] MSF (2001), 'South Africa: Big Pharma Backs Down'. <http://www.doctorswithoutborders.org/publications/ar/report.cfm?id=1204>.
[207] Matthews, Duncan (2006 b), 'NGOs, Intellectual Property Rights and Multilateral Institutions', (ESRC); Deere, C (2009).

decisions [208]If developing countries want to be more effective in advancing their national interests in international IP negotiations, they will need to identify common interests. Then, through cooperation and political mobilisation, they may have more successes.

C.TRIPS-plus provisions

While the TRIPS mandate created obstacles for access to medicines for developing countries, the recent adoption of TRIPS-plus patent regimes in a growing number of developing countries has added to this problem.[209] This trend could be the result of international power pressures, economic dependence and weak institutional capabilities within developing countries.[210] Having failed to achieve all they demanded in TRIPS negotiations and implementation, developed countries and their IP industries have sought other means to either limit the use of TRIPS flexibilities or to press for higher IP standards than the TRIPS minimum requirements for developing countries. Free trade agreements, trade investment deals, WTO DSU and WIPO negotiations are the typical means used to push TRIPS-plus standards.[211] In addition, the 'ideational tool' has also been deployed to reinforce an international policy environment advocating TRIPS-plus standards. Through technical assistance programmes, published research and WTO trade policy review processes, the pro-IP discourses sustain the spread of their argument that IP and development are mutually supportive. Currently, TRIPS-plus IP rules have

[208] Shaffer, G (2004), 'Recognizing Public Goods in WTO Disputes Settlement: Who Participates? Who Decides? The Case of TRIPS and Pharmaceutical Patent Protection', Journal of International Economic Law, 7 (2), pp. 459-82.
[209] Correa, C (2006), 'Implication of Bilateral Free Trade Agreement to Access to Medicines', *Bulletin of the World Health Organisation* 84 (5), p399.
[210] Deere, C (2009), 'The Implementation Game:The TRIPS Agreement and the Global Politics of Intellectual Property Reform in Developing Countries' (Oxford Scholarship Online)
[211] There are well-documents discussion about this movement towards 'a TRIPS-plus world;, for example: Drahos, P (2001), 'Bits and Bips : Bilateralism in Intellectual Property'; Musungu, S and Dutfield, G (2003), 'Multilateral Agreements and a TRIPS-plus World: The World Intellectual Property'; Shadlen, K (2005), 'Policy Space for Development in the WTO and Beyond: the Case of Intellectual Property Rights', Mercurio, B (2006), 'TRIPS-Plus Provisions in FTAs: Recent Trends'; Deere, C (2009),

been imposed as the new basis for trade negotiations between developed and developing countries.[212] Moreover, they are gradually becoming accepted as the new norm even among developing countries for various reasons.

There are several reasons developing countries are acquiescing to TRIPS-plus rules. Firstly, as explained in Chapter 2, developing country economic dependence on the US and EU markets and technologies has always undermined their capacity to resist pressures from the more powerful states. This increases the likelihood of their accepting the more demanding IP rules. Secondly, their lack of IP expertise and experience in IP matters has made developing countries susceptible to the strong influence of pro-IP capability-building discourse. Consequently, their policy makers and IP experts may have become gradually accustomed to viewing the TRIPS-plus approach toward TRIPS implementation as the only reasonable alternative.[213] Finally, the growing competitiveness of domestic industries in the more rapidly developing countries as their interests approach those of developed countries may be inclined to support the TRIPS-plus policy options.[214]

The submission of increasing numbers of developing states to TRIPS-plus norms poses serious problems for the development, health and well-being of developing countries with weaker economies. This is because TRIPS-plus provisions not only impede generic competition but also have the potential to impact future global IPR development. It is important for policy makers in developing countries to understand the impacts of TRIPS-plus provisions on development in general and public health in particular. For

[212] Deere, C (2009), pp306-307.
[213] Drahos, P (2007), '"Trust me": Patent Offices in Developing Countries', (ANU working paper).
[214] Ramanna, A (2005), 'Shifts in India's Policy on Intellectual Property: The Role of Ideas, Coercion and Changing Interests', Deere, C (2009),

this purpose, this section reviews some key TRIPS-plus provisions that are a particular threat to the health welfare of people in developing countries.

Patent term extension

Free trade agreements (FTAs) often oblige signatory countries to extend the terms of patents to compensate for unreasonable loss of the effective patent term as a result of a lengthy regulatory approval or patent application process.[215] Some FTAs even require an automatic patent term extension on the basis of the extension granted in other countries at the request of the rights holder.[216] Since such obligations under FTAs are 'independent, cumulative and with no maximum period', a patent may be extended for an indefinite period due to the delays in the granting of patent and drug registration. Presumably, this could lead to a drug patent lasting for several months or years beyond the 20-year term established under the TRIPS Agreement.[217]

Allowing such patent term extensions for regulatory procedures could have unfortunate unintended consequences.[218] For example, the patent regulatory offices in many developing countries are generally understaffed, and pending application backlogs are not uncommon.[219] As a result, imposing the patent term extension obligation may put pressure on staff to rush their assessments on the validity of patents or the efficacy and safety of drugs. This could result in ineffectual or unsafe products being granted patents and unqualified or even dangerous medicines being marketed to customers.[220]

---

[215] Correa, C (2006), 'Implication of Bilateral Free Trade Agreement to Access to Medicines', p400.
[216] Musungu, S and Oh, C (2005), 'The use of flexibilities in TRIPS by developing countries: can they promote access to medicines?', (Commission on Intellectual Property Rights, Innovation and Public Health (CIPIH)), p60.
[217] Correa, C (2006), 'Implication of Bilateral Free Trade Agreement to Access to Medicines', p401.
[218] Smith, S (2006), "TRIPS Plus' Bilateral Agreements - a Threat to Public Health', *Third World Resurgence* (196), p17.
[219] Correa, C (2006), 'Implication of Bilateral Free Trade Agreement to Access to Medicines', p401.
[220] Smith, S (2006), "TRIPS Plus' Bilateral Agreements - a Threat to Public Health', p17.

Pharmaceutical test data exclusivity

The US has sought to create another TRIPS-plus obligation beyond the TRIPS requirements on the provision concerning the protection of pharmaceutical data. The broad scope of TRIPS Article 39.3, on protection of pharmaceutical data has enabled WTO members to adopt diverse modes of protecting pharmaceutical test data under their national laws while remaining within the regulatory constraints of TRIPS and the other relevant international treaties.[221] For example, the US and the EU have implemented their Article 39.3 obligations in an anti-competitive way that grants a period of 'marketing exclusivity' on pharmaceutical test data under their current legislation.[222] On the other hand, it has been argued that TRIPS requires the protection of pharmaceutical test data under the established WTO fundamental principle prohibiting unfair competition, and therefore, market exclusivity should be viewed as a kind of implied TRIPS-plus standard.[223] This argument was raised by Argentina in a WTO case that remains unresolved because the US withdrew its complaint against Argentina for non-recognition of data exclusivity under its national law after the WTO consultation.[224] The argument, however, remains viable and worthy of further consideration.

---

221 Weissman, Robert (2006), 'Public Health-friendly Options for Protecting Pharmaceutical Registration Data', International Journal of Intellectual Property Management, 1 (1/2), p114.

[222] Sanjuan, R, Love, J, and Weissman, R (2006), 'Protection of Pharmaceutical Test Data: A Policy Proposal', (Knowledge Ecology International), p8, p13.

[223] Correa, C M (2004), 'Protecting Test Data for Pharmaceutical and Agrochemical Products under Free Trade Agreements', (UNCTAD-ICTSD UNCTAD Dialogue (Bellagio),p4.

[224] 'The US government initiated a case under WTO rules complaining about Argentina's alleged failure to appropriately protect test data. The dispute was settled at the consultation stage after two years of discussions. Argentina did not accept the US claim that exclusive rights should be granted for test data and maintained unchanged its law. No further action in the framework of the WTO has been taken by the USA against Argentina, or any other country that does not recognize data exclusivity. However, the USTR has listed, under the Special Section 301 of the Trade Act, a large number of countries that, according to the USTR, do not confer adequate (that is, exclusive) protection for test data.' see Correa, C M (2004), Ibid, p5.

All the same, the US has actively sought to have this TRIPS-plus standard recognized in other jurisdictions through trade negotiations and particularly by including it in its free trade agreements.[225] The US model of data exclusivity was first incorporated under Article 1711 of the North American Free Trade Agreement of 1992 (NAFTA).[226] Since then, the US has succeeded in including this provision in its FTAs with many other countries, including Australia and the developing countries, Bahrain, Jordan, Panama, Singapore, Morocco, Chile and the Dominican Republic and Central American countries (CAFTA). These FTAs established a *sui generis* data exclusivity regime in which the period of protection is generally five years for pharmaceuticals and ten years for agrochemicals. [227]

The argument supporting this approach is that since drug development is expensive and risky, the data exclusivity approach can provide an economic incentive for originator companies to undertake R&D and to ensure their huge investments are protected against the 'free-ride' of generic companies.[228] However, the application of data exclusivity creates major barriers to the early entry of generic competition. Generic companies must wait to enter into the market until they are allowed to use the data for regulatory registration, for it is too expensive and wasteful for generic companies to repeat the tests conducted by originator companies. Thus, data exclusivity in effect confers a marketing monopoly on the term of exclusivity provided.[229]

---

[225] Ibid, p5.
[226] Reichman, J.H. (2004), 'Undisclosed Clinical Trial Data under the TRIPS Agreement and its Progeny: a Broader Perspective ', *CTSD-UNCTAD Dialogue on Ensuring Policy Options for Affordable Access to Essential Medicines* (Bellagio), p4.
[227] Correa, C M (2004), 'Protecting Test Data for Pharmaceutical and Agrochemical Products under Free Trade Agreements', p 5.
[228] Gorlin, J (2000), 'Encouragement of New Clinical Drug Development: The Role of Data Exclusivity,' (Geneva: IFPMA,), p7.
[229] Weissman, R (2006), 'Public health-friendly options for protecting pharmaceutical registration data', p114-115.

Patent linkage

Patent linkage or patent-registration linkage refers to the practise of linking the regulatory authorisation of a generic medicine to the patent status of the referred originator medicine.[230] The concept of 'patent linkage' is statutorily provided in the US under the Drug Price Competition and Patent Term Restoration Act of 1984 (the Hatch-Waxman Act). [231] This Act requires that the Food and Drug Administration (FDA) maintain a publication of pharmaceutical products and their uses currently under patent, which is commonly known as the Orange Book. The FDA may not authorise the marketing approval of a generic copy of a brand name product that is protected by a patent listed in the Orange Book.[232]

The patent linkage scheme under FTAs is not deemed as an obligation under TRIPS by most commentators.[233] In reality, whether or not to adopt such a practice is subject to national jurisdictions. While some countries, such as the US, China, Canada and Australia, have incorporated patent linkages into their national laws, many others, including the EU, have not accepted it; [234] instead, a Bolar-exception provision was recently introduced by Directive 2004/27/EC amending Directive 2001/83/EC on the EU code relating to medicinal products for human use.[235] The Bolar-exception provision is named after the case Roche products Inc vs. Bolar Pharmaceutical Co, in which the

[230] EGA (2008), 'Patent-related Barriers to Market Entry for Generic Medicines in the European Union', (Brussels: European Generic medicines Association), p23.
[231] 21 U.S.C. § 355 (j)(5)(B)(iii)(2004).
[232] See the judgement of 'Bayer vs DCGI and Cipla and UOI ', (The High Court of Delhi), p10
[233] Sinha, S 'Storm over Drug-Patent-Registration Linkage after Court Rejects Bayer Petition', *Livemint.com* and *The Wall Street Journal* (11 October 2009): <http://www.livemint.com/2009/10/11205401/Storm-over-drugpatent-linkage.html>, also Correa, C (2006), 'Implication of Bilateral Free Trade Agreement to Access to Medicines', *Bulletin of the World Health Organisation* 84 (5), p401.
[234] Sinha, S 'Storm over Drug-Patent-Registration Linkage after Court Rejects Bayer Petition', *Livemint.com* and *The Wall Street Journal* (11 October 2009).
[235] EGA (2008), 'Patent-related Barriers to Market Entry for Generic Medicines in the European Union', p23.

Court of Appeals for the Federal Circuit denied Bolar's right to use Roche's patented invention in experiments conducted for the purpose of regulatory approval. Right after the court's decision, however, the congress passed a law permitting such use of patented products in experiments for the purpose of obtaining FDA approval rights. This provision allows the use of patented products to conduct tests and obtain regulatory approval from the health authority before the expiry of a patent. This can facilitate the commercialisation of the generic alternative right after the patented pharmaceutical product expires.[236] This Bolar-exception provision proved to be consistent with Article 30 of TRIPS under a WTO case initiated by the European Communities and their members against Canada.[237]

In comparison, patent linkage creates a higher level of rights protection for pharmaceutical patents than the TRIPS provision. This system requires the health authority to refuse to register a generic version of medicine if the related patent is still in force. Legally, only a court can decide the validity of a patent or whether there is infringement or not. Yet, with the imposition of a patent linkage system, such responsibilities are shifted to the health authorities which normally do not have the sufficient expertise. [238] In addition, it is well-documented that pharmaceutical patents with sub-patentability have been used strategically to encumber or block potential

[236] Correa, C (2007), Trade Related Aspects of Intellectual Property Rights: A Commentary on the TRIPS Agreement (New York: Oxford University Press Inc.), p305.
[237] WT/DS114/R, Para 8.1, p174, The panel concluded that Canada was not in violation of its obligations under Articles 27.1& 28.1 of TRIPS in terms of its practice of allowing the development and submission of information required to obtain the regulatory approval for pharmaceutical products without the content of the patent holders (Section 55.2.(1) of Canada Patent law).
[238] Correa, C (2006), 'Implication of Bilateral Free Trade Agreement to Access to Medicines', p402.

competitors.[239] Such patents, in many cases subject to the validity challenge, can impose legal hazards to delay the entry of generic competition.[240]

In short, three measures promoted under the FTAs from the US impose higher levels of patent protection to pharmaceutical products than those mandated by the TRIPS Agreement. They may erect formidable legislative or administrative barriers to the early entry of generic competition, particularly needed in developing countries. Moreover, these TRIPS-plus standards of the FTAs enacted by a WTO member apply to other WTO members under the principle of most favoured nation. One of the major consequences of the application of the TRIPS-plus standard is that WTO members are then limited in their ability to use the exceptions and flexibilities preserved under the Agreement. This can significantly constrain national discretion of WTO members in designing their own pharmaceutical patent legislation suitable for their national conditions.

3.1.3 Institutional challenges for the use of TRIPS flexibility

For developing countries to exploit the TRIPS flexibilities and to ward off external pressures against their internal policies, they need to develop sufficient institutional capabilities to enable policy makers to clarify their domestic public goods priorities, coordinate their strategies and formulate effective pro-development IPR policy. However, many developing countries are generally not well equipped with these capabilities. The following section highlights several institutional weaknesses:

[239] Correa, C (2004), 'Ownership of knowledge- the Role of Patents in Pharmaceutical R&D ', Bulletin of the World Health Organisation, 82 (10). p785.
[240] EGA (2008), 'Patent-related Barriers to Market Entry for Generic Medicines in the European Union', p23; Correa, C (2006), 'Implication of Bilateral Free Trade Agreement to Access to Medicine', p402.

A. Institutional factors important for the translation of TRIPS flexibilities into national law and practices

Local technical expertise

It is well-recognised that one of the major obstacles to the effective use of TRIPS flexibilities is a lack of technical expertise. [241] In a report commissioned by the UK Government,[242] the commissioners found that developing countries are generally lacking, although to different degrees, legal professionals, IP expertise, and policy development capability in the area of IPRs.[243] The limited domestic capacity makes the majority of developing countries strongly dependent on technical assistance from international agencies like WIPO, the European Patent Office (EPO) or the international cooperation agencies of developed countries for drafting and modernizing their national IP systems.[244] These external aids have emphasised the strengthening of IP protection and thus largely facilitate the business interests of foreign IP rights holders.[245] For example, the model laws developed by the WIPO for developing countries were drafted 'either at the behest of or closely aligned with the positions of the US and Europe'.[246] Consequently there is a focus on promoting universal IP rights without sufficient regard

[241] Musungu, S, Villanueva, S, and Blasetti, R (2004), 'Utilizing TRIPS Flexibilities for Public Health Protection Through South-South Regional Frameworks', p24.
[242] Leesti, M and Pengelly, T 'Institutional Issues for Developing Countries in Intellectual Property Policymaking, Administration & Enforcement', (CIPR, Study Paper 9),
[243] Leesti, M and Pengelly, T 'Institutional Issues for Developing Countries in Intellectual Property Policymaking, Administration & Enforcement',, p6; Chapter 7, CIPR (2002), 'Integrating Intellectual Property Rights and Development Policy'.
[244] Correa, C (2002), 'Formulating Effective Pro-development National Intellectual Property Policies ', (ICTSD-UNCTAD Dialogue, Bellagio), p5 &6; CIPR (2002), 'Integrating Intellectual Property Rights and Development Policy', p138.
[245] Leesti, M and Pengelly, T 'Institutional Issues for Developing Countries in Intellectual Property Policymaking, Administration & Enforcement', p44.
[246] Netanel, N (2009), 'The Development Agenda', in N Netanel (ed.), *The Development Agenda: Global Intellectual Property and Developing Countries* (Oxford Scholarship Online), p9.

for their social cost, so that they have generally failed to provide guidance for members in utilising the TRIPS flexibilities for their development priorities.[247]

Moreover, it is apparent that domestic agencies are in better positions to understand national needs and concerns, whereas foreign agencies have much lower understanding of local norms, cultures and conditions. Given the profound influence of patent policy on access to medicines and medical technology, it is too important issue to leave it to foreign agencies dictate the orientation of pharmaceutical patent policy.

Coordination between relevant government departments

Patent policy for pharmaceuticals is more than just a legal issue. The implication of patent rights will also affect the interests of industry competitors and customers. Thus, policy making for pharmaceuticals can be a complex mixture of economic, social and legal standards. Conflicts of interests are often apparent in the law-making process. Typically, industry groups and health departments might lobby for different positions. To reconcile such differences, the formulation of patent policies related to pharmaceuticals should ideally proceed with comprehensive coordination between relevant agencies, such as law making agencies, patent offices, drug registration bureaus, health authorities, and special courts, for example.

However, the ability of developing countries to co-ordinate policies across governments remains low and insufficient. Some countries have established intra-government mechanisms to improve the coordination of policies and advice. However, the evidence found by the CIPR study suggests that such coordination consultations have not

[247] Correa, C (2002), 'Formulating Effective Pro-development National Intellectual Property Policies ', pp5-6.

generated effective results, and in many cases they are not able to readily provide technical advice and expertise.[248]

Public participation:

The decision-making process in many developing counties is largely based on a top-down approach. Intellectual property offices and trade departments often dominate the standards setting process for pharmaceutical patents, and there is often limited participation of representatives from the industry and consumers in the process of patent policy formulation.[249] Although some developing countries are exceptional in this aspect, for instance India has preserved a broad-based, extensive system for public consultation and debates, [250] in most cases the process of IP policy making in developing countries lacks any real interactions with domestic stakeholders.[251]

B. Institutions facilitating the effective use of TRIPS flexibilities:

Drug regulation

A competent drug registration authority (DRA) and appropriate drug legislation have to be in place in order to realise the benefits of TRIPS flexibilities. Compulsory licensing is one of the vital provisions enabling a WTO developing member to improve access to essential medicines. However, a competent DRA is required to carry out the tasks involved in the standard regulation of the safety, efficacy and quality of the drugs in question in case a compulsory licence is successfully issued and a product manufactured.[252] In reality, many developing countries do not have sufficient technical

[248] Correa, C (2002), 'Formulating Effective Pro-development National Intellectual Property Policies ', p139.
[249] Ibid, p2.
[250] CIPR (2002), 'Integrating Intellectual Property Rights and Development Policy', p140.
[251] Correa, C (2002), 'Formulating Effective Pro-development National Intellectual Property Policies', p2.
[252] Hill, S and Johnson, K (2004), 'Emerging Challenges and Opportunities in Drug Registration and Regulation in Developing Countries', (DFID Health Systems Resource Centre), p34.

and infrastructural capacities for the registration and regulation of medicines.[253] One WHO project surveyed 36 African countries and found that only three had a limited drug regulatory capability and that none had a 'comprehensive drug regulatory capacity.'[254]

This regulatory incompetence is also found in the aspect of making drug registration and regulation rules. The survey from Hill and Johnson revealed that regulatory systems in developing countries are yet to be able to respond effectively to the changes imposed by TRIPS and FTAs. In particular, there is lack of effective legislation to allow the utilisation of TRIPS flexibilities.[255] Instead, some TRIPS-plus provisions, particularly patent linkage and data exclusivity, are increasingly translated into the regulatory regime of developing countries via bilateral trade agreements with developed countries, especially the US.[256]

The role of the court

Certain TRIPS flexibility provisions aim to facilitate the availability of generic medicines or the early entry of generic competition. However, these provisions are often undermined by rights holders through tactical litigation, in particular, preliminary injunctions in court. This highlights the role of courts in facilitating the effective use of TRIPS flexibilities.

A preliminary injunction refers to a temporary injunction issued before or during the trial to prevent an irreparable injury from occurring before the court has a chance to

[253] Musungu, S, Villanueva, S, and Blasetti, R (2004), 'Utilizing TRIPS Flexibilities for Public Health Protection Through South-South Regional Frameworks',p28.
[254] WHO (1999) Status of Drug Regulation and Drug Quality Assurance in WHO African Region and Selected Countries, WHO, March, cited in Musungu, S, Villanueva, S, and Blasetti, R (2004).
[255] Hill, S and Johnson, K (2004), p 6.
[256] See the analysis in 2.2.2 B for the detailed account of TRIPS-plus issues.

decide the case. Article 50 of TRIPS empowers the court to issue a preliminary injunction against infringements that are taking place or are imminent. It also requires the court to exercise its authority to impose a number of conditions on the application of a preliminary injunction. To fulfil such a 'check and balance' approach requires a competent court, which is often absent in developing countries.

3.1.4 Summary: the known and unknown

The TRIPS Agreement places new and significant restrictions on the legal options available to developing countries to create domestic policies and law to promote and protect public health, even though some of the built-in flexibility mechanisms may be useful to help them to mitigate some of the possible effects of such lost adaptability. In addition, many developing countries lack the institutional capabilities to make effective use of TRIPS' flexibilities for their national development purposes.

It is not clear whether the national capabilities of particular developing states, such as growing economic power and political independence, can help in mitigating the loss of legislative adaptability in IPR matters, or whether they can be helpful in alleviating aggressive attempts to limit the use of TRIPS flexibilities through FTAs or other protectionist approaches. It is notable that China is one of a small group of developing countries whose economic and political competitiveness is growing rapidly. This thesis is interested to explore whether China possesses or is developing capabilities to exploit the TRIPS flexibilities more effectively, ward off the pressures of more powerful states acting through the international IPR regime, and thus, improve its autonomy in domestic IP policy making.

3.2 Economic effects of TRIPS implementation

This section explores the range of economic benefits TRIPS can be expected to deliver to developing countries. It seeks to determine whether it can promote a higher level of local innovation, international technology transfer (ITT) and additional global R&D, particularly in areas devoted to the prevention and cure of diseases relevant to developing countries. To find answers to these questions it examines current scholarship.

3.2.1 Theory: a trade-off between static loss and dynamic gains

Economists have detected an inherent conflict between public and private interests in the context of IPRs. On the one hand, static efficiency requires the satisfaction of public interests in having wide access to inventions at an affordable price, which may be quite low. On the other hand, dynamic efficiency necessitates meeting private interests in profit generation, which may be substantial but necessary for providing an incentive to invest in new inventions.[257]

A. Static effects

This basic innovation trade off in IPRs is demonstrated below in Figure 1. The Figure illustrates the linear demand and marginal revenue for a newly invented product that can be supplied to the market at constant marginal costs.[258] In the absence of patent protection, many firms could compete in the market with imitative substitutes of the product. The 'ex-post optimality' requires firms to sell their products at a competitive

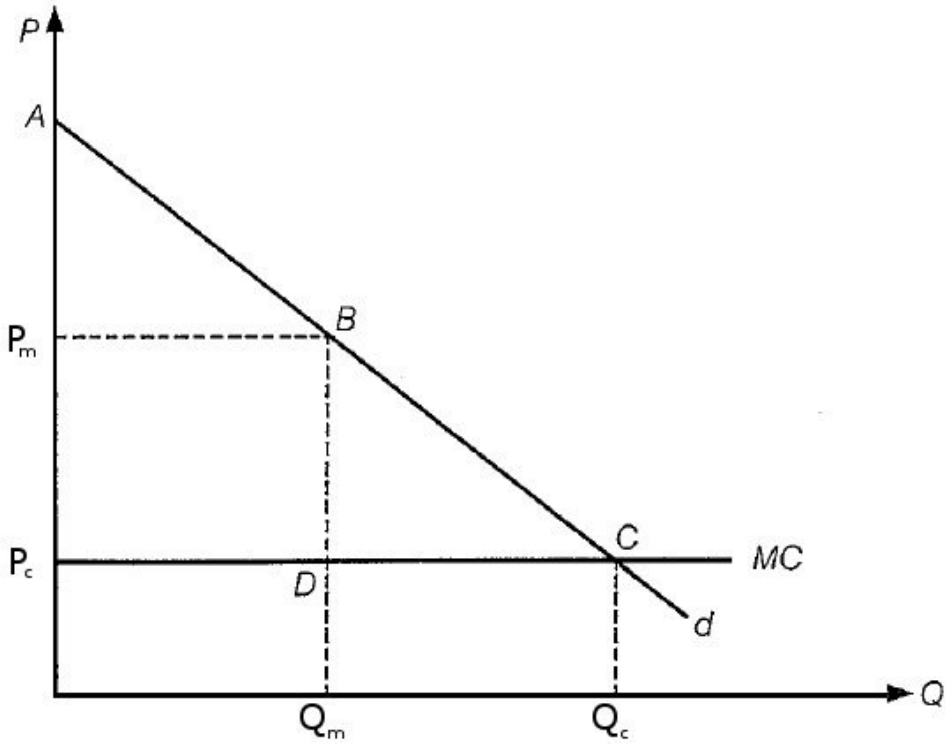
[257] Maskus, K (2000), Maskus, K (2000), *Intellectual Property Rights in the Global Economy,* p29.
[258] The figure is drawn by referring to the work of Lanjouw, J.O. (1997), 'The Introduction of Pharmaceutical product patents in India: 'Heartless exploitation of the poor and suffering?'; Nogues, J (1993), 'Social Costs and Benefits of Introducing Patent Protection for Pharmaceutical Drugs in Developing Countries' and Maskus, K (2000), Maskus, K (2000), *Intellectual Property Rights in the Global Economy*.

price, which is assumed to be equal to the marginal cost Pc and output Qc.[259] Then, the area of APcC is the generated customer benefits; the introduction of patent protection transforms the competitive market into a monopolistic place. When a firm has a monopoly over a product it can sell this product at a much higher level than in a competitive market, at Pm, given the high cost of R&D, and the output would fall to Qm as a consequence of less demand. The monopoly rents earned by the patentee firm are in the area PcPmBD. This area represents a rent transfer from the customers to the firm, which constitutes a welfare loss or, as is termed in economics, a deadweight loss to consumers, with the introduction of patent protection to a product.[260]

In the open economy, for a country in the position of importing or producing imitative substitutes the decision to reward patent protection facilitates the transfer of monopoly rents to foreign rights holders. This implies the static loss of the area PcPm BC, in addition to a reduction of output from local firms. Subsequently, a country newly introducing patent protection may suffer higher static costs than that it would pay in a closed economy.[261] A country would suffer a straightforward welfare loss if its market were too small for such a transfer to induce more foreign R&D investment in products that meet local needs.[262]

[259] Competitive price here refers to the price lower than that offered by the originator.
[260] For a detailed economic elaboration, see Nogues, J (1993) 'Social Costs and Benefits of Introducing Patent Protection for Pharmaceutical Drugs in Developing Countries', pp28-40.
[261] Lanjouw, J.O. (1997), 'The Introduction of Pharmaceutical product patents in India: 'Heartless exploitation of the poor and suffering?', p7.
[262] Maskus, K (2000), *Intellectual Property Rights in the Global Economy,* p33.

Figure 1: Innovation trade-off in IPRs



B. Dynamic effects

Economists also have noted the sources of dynamic gains from such a basic trade-off. The granting IP monopoly rights can generate sufficient payoffs to foster dynamic innovation, which in turn increases long-term customer welfare by producing more new and diverse products. Maskus has argued that free limitations and selling cannot generate sufficient profits to cover the financial demand for original R&D projects. Such an inadequacy would result in no investment in research and development of a product, and the entire customer benefit would disappear.[263]

[263] Maskus, K (2000), Maskus, K (2000), *Intellectual Property Rights in the Global*, pp29-30.

This model finds its support from other theoretical studies. Diwan and Rodrik have suggested that the patent protection provided by developing countries can work as an incentive to attract additional R&D activities from developed countries to meet their local needs. Tayor's theoretical study on the linkage between IPRs and R&D shows that the insufficient patent protection not only discourages foreign innovators to engage in R&D activities in a desirable mode, but also makes them unwillingly to transfer their technology in the given jurisdiction.[264]

.

Nevertheless, many economists have also raised doubts about the possible effects of the role of patents on innovation. Maskus warns that IPRs should be understood as the second best solution.[265] Intellectual property rights are expected to foster investment in R&D and knowledge creation, but they impose constraints on the current consumption of knowledge by enhancing the market power of rights holders, which necessitates government policy mediation to strike a balance between the producers of knowledge and society.[266] Moreover, other theoretical arguments also predicted that the strengthening of patent protection may slow down technology progress in the long run. Takalo and Kanniainen's model suggested that enhanced patent protection may encourage firms to delay the commercialisation of innovation. Under strong patent protection, firms find it more profitable to exploit current technologies. They tend to opt to slow down the development or exploitation of new technology or products.[267]

---

[264] Taylor, M (1994), 'Trips, Trade, and Growth', *International Economic Review,* 35 (2).
[265] Ibid, p31.
[266] Braga, C and Fink, C (1999), 'The Economic Justification for the Grant of Intellectual Property Rights: Patterns of Convergence and Conflicts', in F Abbot, T Cottier, and F Gurry (eds.), *The International Intellectual Property System: Commentary and Materials* (1; The Hague: Kluwer Law International), p267.
[267] Takalo, T and Kanniainen, V (2000), 'Do Patents Slow down Technological Progress?: Real Options in Research, Patenting, and Market Introduction ', *International Journal of Industrial Organization,* 18 (7).

In brief, there seems to be a consensus among the economists studied about the static effects of patents, but they maintain more contentious views about the dynamic gains of the role of patents in innovation. Still, it is not enough to rely on theoretical arguments to understand the relationship between patents and innovation. The following section turns to an examination of actual practices to obtain empirical evidence that should enable a more reliable determination to be made.

3.2.2 Empirical analyses

The section reviews empirical studies of actual practice to help determine whether the supposed advantages of strong patents have materialised in terms of fostering local innovation, strengthening patents and technology transfer and advancing global research on diseases relevant to developing countries.

A. The role of patents in fostering local innovation

A principle argument advanced by advocates of strong IP protection is that it promotes higher levels of innovation by local companies.[268] Lanjouw (1997) was optimistic about these benefits and indentified supporting evidence from her 1996 and 1997 surveys on the impacts of introducing product patents for pharmaceutical industries in India. She confirmed that large firms in India are already responding to TRIPS by increasing their total R&D expenditure and by moving away from the sole development of new processes towards new molecular discoveries.[269] In contrast, the literature review by Maskus, including experiences from countries such as South Korea (Kawaura and LaCroix,1995), Argentina (Nougues, 1990) and Lebanon (Maskus 1997b), suggested that the preponderance of evidence indicates that limited financial capital tends to

[268] Branstetter, L G (2005), 'Do Stronger Patent Induce More Local Innovation? ' in Keith E Maskus (ed.), *International Public Goods and Transfer of Technology* (Cambridge: Cambridge University Press), p309.
[269] Lanjouw, J (1997), 'The Introduction of Pharmaceutical product patents in India: 'Heartless exploitation of the poor and suffering?', p33.

prevent local pharmaceutical firms in developing countries from undertaking R&D.[270] Lerner used the patent application as a measure to assess the impact of strengthening patent standards in local innovation. His results on sixty countries over a 150-year period also confirmed that strengthening patent protection did not appear to have positive effects on domestic patent application.[271] Branstertter et al. looked at R&D input and output in Japan following two waves of patent strengthening reforms in 1988 and the mid-1990s. They found no evidence of increased R&D spending and patenting activities. In fact, the 1990s witnessed a wide decline of R&D investment associated with the general economic downturn in Japan.[272]

Conversely, recent empirical studies support Lanjouw's optimism on the role of strong patents in reducing local innovation. Maskus, Dougherty and Metha (2005) indentified rapid growth of patenting and R&D expenditure from Chinese enterprises and suggested that the strengthening of IPR is one of important factors contributing to such positive effects in local technological development.[273] Chadha's (2009) micro-econometric studies on 65 Indian pharmaceutical firms revealed a significant increase in patent activities for the period 1991 to 2004. He argued that this result proved the positive impact of introducing stronger patents in India.[274] Meanwhile, Chaudhuri (2009) also reported that R&D expenditure dramatically increased whilst the structure of R&D activities shifted towards more involvement with the development of new chemical entities (NCEs) and new formulations and compositions, but he suggested that the

[270] Maskus, K (2000), *Intellectual Property Rights in the Global Economy*, p165.
[271] Lerner, Josh (2002), 'Patent Protection and Innovation Over 150 Years', *NBER Working Papers 8977* (National Bureau of Economic Research), p30.
[272] Branstetter, L G (2005), 'Do Stronger Patent Induce More Local Innovation? '.
[273] Maskus, K , Dougherty, S, and Merth, A (2005), 'Intellectual Property Rights and Economic Development in China', in K Maskus C Fink (ed.), *Intellectual property and development: lessons from recent economic research* (Washington, DC World Bank), p319, p323.
[274] Chadha, A (2009), 'TRIPS and Patenting Activity: Evidence from the Indian Pharmaceutical Industry', *Economic Modelling,* 26, p504.

primary motivation for this was not the TRIPS-compliant product patent regime in India but the patent regime in developed countries, given their market orientation focusing on the larger and more lucrative markets in developed countries.[275]

The scholarship examined shows the empirical studies conducted after the TRIPS regime was established have detected some positive effects of strengthened patents on innovation, whereas the studies examining pre-TRIPS experience of stronger patents under national legal reforms found little such evidence. This indicates that the legal changes produced by TRIPS compliance may have had stronger impacts on the national economy than on internal patent reform. But what is of most interest to this thesis is that these positive effects seem to be indentified in only a few of the larger developing countries, such as India and China. This suggests that local conditions, such as market size, local imitative and innovative capabilities, level of development and growth, also play a part in fostering the growth of R&D spending and patenting activities in a country. This proposition is evident in a recent empirical study. Qian studied 26 sample countries which had newly introduced the pharmaceutical patent law during the period of 1978 to 2002. He found that the establishment of patent laws does not 'promptly stimulate local innovation' by itself, but that other additional conditions, such as higher levels of economic development, education attainment, and economic freedom, play more influential roles in accelerating local innovation.[276]

---

[275] Chaudhuri (2009), 'Is Product Patent Protection Necessary to Spur Innovation in Developing Countries?' in N Netanel (ed.), *The Development Agenda: Global Intellectual Property and Developing Countries* (Oxford Scholarship Online), p288.

[276] Qian, Y (August 2007), 'Do National Patent Laws Stimulate Domestic Innovation in a Global Patenting Environment? a Cross-Country Analysis of Pharmaceutical Patent Protection, 1978–2002', *The Review of Economics and Statistics,* 89 (3), p436.

While this evidence may suggest that TRIPS rules may induce more local innovation at least to middle income developing countries, this claim has to be weighed against the potential negative impacts of strong patents on innovation. Technological development essentially involves learning about existing advanced technology. However, patents restrict access to that technology by imposing high costs on copying and imitating them. This causes problems for developing countries because imitation by reverse-engineering is a common means for their innovation.[277] Moreover, the legal framework under TRIPS or TRIPS-plus regimes enhances the power of rights holders in technology transactions, consequently, the costs of obtaining technology through licensing are likely to increase which would exclude imitation via reverse engineering even more. [278]A strong patent system which limits access to existing technology can make both 'catch-up' efforts and campaigns against poverty and disease more costly or difficult for developing countries.

The above review has found mixed evidence about the role of patents in fostering local innovation. While earlier empirical studies established that patent strengthening had no significant effects in inducing local innovation, the post-TRIPS empirical studies have indentified some positive impacts of TRIPS implementation but principally in larger developing countries such as India and China.

B. Patent strengthening and international technology transfer

[277] Odagiri, H, et al. (2010), Intellectual Property Rights, Development, and Catch-up (Oxford University Press), p426..
[278] Correa, C (2005), 'Can the TRIPS Agreement Foster Technology Transfer to Developing Countries?' in K Maskus and J Reichman (eds.), *International Public Goods and Transfer of Technology under a Globalized Intellectual Property Regime* (Cambridge University Press), p254.

International technology transfer (ITT), in the form of licensing, capital goods and technical assistance, constitutes a crucial source of innovation in developing countries.[279] During the TRIPS negotiations, developed countries argued that strengthening the IPRs protection was a prerequisite for fostering increased technology transfer flows to developing countries.[280] In theory, the existence of an effective IPR protection is assumed to be a logical precondition for the international transfer of certain new technologies, especially those such as pharmaceutical inventions which can be easily copied. The offer of sufficient IPR protection enables firms to take control of their proprietary technology and charge sufficient prices that reflect the cost of innovation in the technology transfer deals. This position can encourage firms to transfer their technology property either through licensing or direct foreign investment (FDI). [281]

Does an increased flow of foreign technology into developing countries after they adopt a stronger IPR regime really occur? The preponderance of econometric studies confirms that market-mediated forms of technology transfer, such as trade flow, FDI and licensing, respond positively to patent strengthening in advanced and larger developing countries.[282] Branstetter et al. examined the response of US multinational companies to patent reform in 16 middle income developing countries during the period of 1982 to 1999 and found that royalty payments for technology licensing to affiliates or third parties had significantly increased. The same was true with the deployment of R&D

[279]Correa, C (2005), 'Can the TRIPS Agreement Foster Technology Transfer to Developing Countries?', p229.
[280] Ibid, p227.
[281] Roffe, P (2005), 'Comment: Technology Transfer on the International Agenda', in K Maskus and J Reichman (eds.), *International Public Goods and Transfer of Technology Under a Globalized Intellectual Property Regime* (Cambridge University Press), p26.
[282] Maskus, Keith E and Reichman, Jerome H (2005), 'The Globalisation of Private Knowledge Goods and the Privatization of Global Public Goods', in Keith E Maskus and Jerome H Reichman (eds.), *International Public Goods and Transfer of Technology Under a Globalized Intellectual Property Regime.*

expenditure and patent applications.[283] Smith's statistical analysis suggested that patent strengthening had positive effects on the market expansion of US affiliate sales and technology licensing, and that this was particularly effective across countries with strong imitative abilities.[284] Lerner did not find positive links between patent strengthening and increased domestic patenting activities in his survey on 60 countries over a 150-year period, but he did indentify a positive correlation between foreign patenting and reforming countries.[285] This result also suggested a positive link between technology transfer and patent strength.

Again, it is also important to note the fact that the main beneficiaries of increased levels of ITT induced by patent strengthening are middle income countries, despite the wide membership of TRIPS, including economies at all levels. This implies that patents may not be the main determining factor for attracting foreign technology transfer; other factors, such as infrastructure, market size, and economic level, for example, all matter.

C. The interface of patent strengthening and additional global research on the diseases of poorer nations

The most controversial issue about the impact of patents is that they impose high drug prices and decrease the choice of sources of medicines.[286] However, the industry emphasises the indispensable role of patent incentives for drug development and

[283] Branstetter, L, Fisman, R, and Foley, C (2005), 'Do Stronger Intellectual Property Rights Induce More Technology Transfer? Empirical Evidence from U.S. Firm-Level Panel Data', (Harvard Business School Working Paper).
[284] Smith, P (2001), 'How do Foreign Patent Rights Affect U.S. Exports, Affiliate Sales, and Licences', *Journal of International Economics* 55 (2), pp430-432.
[285] Lerner, Josh (2002), 'Patent Protection and Innovation over 150 Years ', p21.
[286] CIPR, 2002, 'Integrating Intellectual Property Rights and Development Policy', Chapter 2, p1.

justifies the potential impacts of patents on drugs via compensation through new and additional research devoted to the cure of particular diseases found in the poorer nations.

The creation of new drugs is highly capital and technology intensive but the number of products finally introduced to the market is very low.[287] Surveys conducted by Levin and Scherer et al. suggested that the pharmaceutical industry is more dependent on the patent system than many other sectors for recouping its R&D investment costs and for generating profit to fund further R&D activities.[288] Research-based pharmaceutical MNCs have strong interests in the establishment of a globalised strong patent-protection regime.[289] They can expect to profit greatly from the global application of TRIPS patent standards, which they played an influential role in creating by pressing for the incorporation of IPRs into the legal framework of the world's trading system.[290]

On the other hand, TRIPS implementation also obligates States to balance these private interests against interests that touch wider economic and social issues. In the pharmaceutical field this refers to the interests of patients and the users of patented technologies, as provided under Articles 7 and 8 of TRIPS. The Doha Declaration on the TRIPS Agreement and Public Health (Doha Declaration on Health) supports this proposition, It stresses that TRIPS should be implemented and interpreted in a way that supports public health 'by promoting both access to existing medicines and the creation of new medicines.' Thus, it reaffirms the governments' rights to use the TRIPS

[287] CIPIH (2006), 'Public Health, Innovation and Intellectual Property Right'.
[288] Levin, R. C., et al. (1987), 'Appropriating the Returns from Industrial Research and Development ', *Brookings Papers on Economic Activity,* (Special Issue 3); Scherer, F. (2001) "The Patent System and Innovation in Pharmaceuticals", *Revue Internationale de Droit Economique*, (Special Edition, 'Pharmaceutical Patents, Innovations and Public Health').
[289] CIPR, 2002, 'Integrating Intellectual Property Rights and Development Policy', Chapter2.
[290] For the review of the pharmaceutical MNCs' great influence in the making of the TRIPS Agreement , see Drahos, P (2002), 'Negotiating Intellectual Property Rights: Between Coercion and Dialogue',), Matthews, D (2002), *Globalising the Intellectual Property Rights* ,and Sell, S (2003), *Private Power, Public Law: The Globalization of Intellectual Property Rights* etc.

flexibilities in circumventing patent rights for the improvement of access to essential medicines.[291]

The final empirical analysis in this section 3.2.2 examines the likelihood of TRIPS' commitments promoting better access to medicine. Research by the WHO provides some disappointing empirical evidence. In its 1996 study, the WHO surveyed the global allocation of R&D funds to research on two of the prevailing diseases in developing countries and found that only a few R&D investments and inventions had been devoted to the diseases particularly relevant to developing countries. The survey reported that of an overall global US$56 billion in R&D investment annually, R&D spending was only US$32 million on diarrhoea per year and between US$48 to US$68 million on pneumonia per year. Moreover, much of this spending was targeted on inventions that mainly benefit people living in *developed* countries, such as those travelling to developing countries.[292] According to another report by Pecoul et al., of the 1,233 drugs licensed worldwide between 1975 and 1997, only 13 were for tropical diseases. Among these, five were from veterinary research and two were versions of existing medicines; only four were developed by private investments specialising in tropical human diseases.[293] Finally, in one of the most recent studies, the Commission on Intellectual Property Rights, Innovation and Public Health (CIPIH) also confirmed the continuation of this problem. The CIPIH explained that 'because the market demand for diagnostics, vaccines and medicines needed to address health problems mainly affecting developing

[291] See Article 4, 5, Doha Declaration on Health , WTO, 'The Doha Declaration explained', at http://www.wto.org/english/tratop_e/dda_e/dohaexplained_e.htm, last accessed on June 20, 2010.
[292] WHO (1996), 'Ad Hoc Committee on Health Research Relating to Future Intervention Options: Investing in health research and development ', (WHO, TDR/Gen/96.1), pXXV.
[293] Pécoul B, et al. (1999), 'Access to Essential Drugs in Poor Countries: a Lost Battle? 'Journal *of the American Medical Association* 281(4) (4).

countries is small and uncertain, the incentive effect of intellectual property rights may be limited or non-existent'[294].

3.2.3 Summary: the known and unknown

The examination of the economic effects of TRIPS implementation in this section 3.2 has found that economists suggest that TRIPS may bring a trade-off effect to developing countries, resulting in a short-term welfare loss associated with monopoly pricing on the one hand but on the other, long-term economic benefits associated with innovation. Nevertheless, the existing empirical evidence cannot verify this trade-off effect as yet, but it does suggest that TRIPS has delivered some positive innovation benefits to the larger developing countries. However, insufficient time has passed to draw a conclusive judgement on the role of TRIPS in fostering innovation in developing countries, and uncertainties lie even for the larger developing countries if innovation there is still incremental and cumulative in nature. This raises another question for further empirical studies: how can a strong patent system that limits access to the existing technology affect the technological 'catch-up' efforts in the large developing countries? It is hoped that this new empirical study on Chinese experience will contribute to an answer to this question.

3.3 Concluding remarks

This literature review explored two questions. Firstly, it attempted to understand how TRIPS implementation affects national legislative adaptability in making and enforcing patent rules in developing countries. The prevailing view is that the universal strong patent protection approach of the Agreement may restrict developing countries' ability

[294] CIPIH (2006), 'Public Health, Innovation and Intellectual Property Right', (Geneva: World Health Organisation).

to adapt their domestic laws to enable the designing of a patent system that works for its public health interests, despite the TRIPS built-in flexible safeguarding mechanisms. The challenges are twofold: developing countries face formidable institutional challenges in utilising and exploiting TRIPS' flexibilities for their development interests, and they are also confronted with increasing IPRs protectionism beyond TRIPS, such as the harmonisation movement under the WIPO and higher IPRs standards under FTAs and other international agreements.

The second question examined whether the stronger patent of TRIPS has fostered local innovation in developing countries. Economists seem to share a consensus about the welfare loss that developing countries will suffer in the short term,[295] but they diverge concerning the roles of the stronger patents in innovation. Some studies suggested that the harmonised patent regime would bring in certain long-term benefits, such as a higher level of local innovation and greater inflow of ITT, but others argued that patents impose barriers to access the existing technology and hence give rise to the under-provision of essential medicines and the delay of technology learning and catch-up. Nevertheless, the existing empirical evidence is too mixed and inconclusive to verify the theoretical propositions.

What is fascinating in this research is that certain positive effects of TRIPS implementation have so far been found only in middle income countries. This finding suggests two further empirical topics for this research: (a) Are middle-income countries with relatively stronger economies and institutional capabilities likely to do better in mitigating the loss of legislative adaptability under the TRIPS framework? and (b) Is a

[295] Li, X (2008), 'The Impact of Higher Standards in Patent Protection for Pharmaceutical Industries under the TRIPS Agreement – A Comparative Study of China and India'.

strong patent system more beneficial for middle- income developing countries?[296] In the following chapters these two topics will be explored in a case study of China's TRIPS implementation experience in the pharmaceutical field.

[296] A strong patent system refers to a national patent system in which the standards of patent protection and enforcement are structured at a higher level than the TRIPS minimum standard. In particular, it may abandon some key TRIPS flexible provisions or opt for higher standards.

Chapter 4 Evolution of pharmaceutical patent rules in China

This chapter is set to provide the political and legal background for the analysis on the relationship between TRIPS implementation and the development of local pharmaceutical innovation in China. It reviews the legal history that led to the incorporation of TRIPS standards into the Chinese patent laws. It focuses on both the threshold for pharmaceutical patent protection and the rationales behind each law reform. The first section examines the background, adaptive efforts and policy effects of the passage of the first patent law in the People's Republic China (PRC or China). Section two then analyses why and how China adopted product patents for medicines as early as in 1992. Finally, the third section evaluates the major pharmaceutical patent provisions under the 2000 Chinese patent law to determine whether China has fulfilled its WTO accession commitments.

4.1 The establishment of the 1984 Chinese patent law

As with much of the body of law promulgated during the 1980s, the 1984 Chinese patent law[297] was the result of the tentative efforts of the PRC government to adapt foreign legal and policy ideas to its own political and economic circumstances.[298]

[297] The 1984 Chinese patent law refers to the first patent law introduced by the PRC in 1984; it is titled as 'Patent Law of the People's Republic of China' in full.
[298] Potter, P (2001), *The Chinese Legal System: Globalization and Local Legal Culture* (London: Routledge), p1, also see Alford, W (1995), pp 67-69 (examining the intense debates concerning the drafting of the 1984 patent law in China).

Consequently, its standard setting was experimental,[299] and its implementation marked with deficiencies when compared with its designated major objectives.

4.1.1 Background

In the end of the 1980s, when the PRC commenced efforts to be more receptive to the world outside its borders, it found itself to have fallen far behind the West in terms of productivity and technological competence. To fulfil its catch up ambitions, the government introduced a policy known as the 'four modernisations' programme as a blueprint for development policy.[300] This programme was aimed at building the four sectors of agriculture, industry, national defence and science and technology through advanced science and technology.[301] This meant that accelerating access to foreign technology became an essential policy objective.

The PRC found the United States to a particularly attractive trading partner, given its advanced industrial and technological economy and its new, friendly diplomatic policy towards China.[302] However, the US demanded the protection of the IPR assets of its citizens as a condition from the start of negotiations of the bilateral science and technology (S&T) agreements, such as the 'U.S.-China Agreement on Cooperation in Science and Technology' and 'the Understanding on Cooperation in Space Technology'.[303] When the 'Agreement on Trade Relations between the United States of America and the People's Republic of China' was concluded, the two parties agreed to

[299] A 'trial and error' approach has been one of leading guidelines for national policy reforms under Deng's leadership in China, see Lo, C (1992), 'Deng Xiaoping's Ideas on Law: China on the Threshold of a Legal Order', *Asian Survey,* 32 (7), p654.
[300] Mason, D (1984), 'China four modernizations: Blueprint for Development or Preclude to Turmoil ', *Asian Affairs* 11 (3), p47.
[301] The communiqué of the Third Plenum of the 11th Central Committee of the Communist Party of China.
[302] The US normalised its diplomatic relationship with China in 1979.
[303] Yang, DL (2003), Intellectual Property and Doing Business in China (London: Pergamon).

provide equivalent IPR protection to each other's citizens.[304] Pursuant to this agreement, China joined the World Intellectual Property Organization ("WIPO") in 1980 and the Paris Convention for the Protection of Industrial Property 1984.[305] To implement these agreements, in 1984 the PRC government enacted the Patent Law of the People's Republic of China, China's first patent law.

The PRC found itself in a major dilemma of a clash of legal cultures. The notion of private ownership rights was completely new to the PRC and potentially conflicted hugely with the existing legal culture based on socialist principles.[306] This resulted in intense debates concerning the validity of the introduction of a patent system in China. Proponents primarily stressed the desirable economic benefits purportedly associated with a patent system. They argued that a patent system would introduce not only meaningful material incentives to spur domestic innovation but also offer systematic way of obtaining new technological information. These benefits could promote growth and help make up for developmental losses due to the Cultural Revolution.[307] They also emphasised that a patent system would yield benefits to China in its international economic relations. They believed that the establishment of a modern patent system would promote greater foreign investment and international technology transfer to China.[308] On the other side, the opponents contended that the patent system could lead to foreign control of technology given the discrepancy in the levels of economic and technological development between China and the West. This then could hinder the

[304] Yu, P (2002), 'The Second Coming of Intellectual Property Rights in China', *Benjamin N. Cardozo School of Law Occasional Paper No 11, p8.*
[305] Ibid, p8.
[306] Alford, W (1995), *Steel a Book is a Elegant Offence* (Stanford University Press), p70.
[307] Zhao, YG (2003), *The History of the Formulation of the First Patent Law in the PRC* (Beijing Intellectual Property Rights Press), in Chinese. Alford, W (1995), *Steel a Book is a Elegant Offence*
[308] Zhao, YG (2003) & Alford, W (1995).

healthy development of domestic technology and national industries.[309] They also argued that the concepts of private ownership and profit-oriented goals associated with a patent system were antithetical to the socialist principles of collectivism and service-minded attitudes toward work.[310] Some of the opponents even condemned the establishment of a patent system as a treasonous act against national interests because they believed this system would only benefit foreign interests.[311]

The line of the debates was sharply drawn between representatives from the legal and economic communities. The legal experts, who favoured adoption of a patent system, was initially supported by officials from the National Science and Technology Department and were later joined by officials from the national patent office.[312] From the start they had strong support from the new political and state leader, Deng Xiao Pin, and. Deng instructed the formation of committee to draft the text of the first modern Chinese patent law following China's execution of the bilateral trade agreement with the US in July 1979.[313] The opponents came from the economic bureaus. The economic experts submitted written arguments against adopting a patent system to Deng and other leaders of the State Council in August 1980. Two subsequent meetings among experts were organised to consider both arguments on the issue.[314] The views of the proponents prevailed, and the drafting work continued. Nonetheless, due to the consistent

---

[309] Liu, DM (2006), 'The Transplant Effect of the Chinese Patent Law', *Chinese Journal of International Law* 5(3), p740.
[310] Alford, W (1995), *Steel a Book is a Elegant Offence* (Stanford: Stanford University Press), p68.
[311] An, L and Xu, Y (2009), 'The Turbulent History of the State Intellectual Property Office in the Past Three Decades', SIPO online publications. in Chinese, available http://www.sipo.gov.cn/ztzl/qtzt/qzjj30/dtbd/201001/t20100111_487451.html, accessed on Feburary 1 2012.
[312] The drafting of the Chinese Patent Law 1984 was organised by the National Science and Technology Department was organiser in 1978. The national patent office was found in 1980. See Zhao, YG (2005), 'A major founder of the Chinese Patent System: Wu Heng', SIPO online publications. <http://www.sipo.gov.cn/sipo/bgs/lzp/200605/t20060517_100006.htm>.
[313] Zhao, YG (2005), 'A major founder of the Chinese Patent System: Wu Heng'.
[314] Ibid.

objections and criticism from economic officials, the draft was amended twenty-five times before its final submission to the National People's Congress (NPC).[315] In the end, it was Deng's instruction to the NPC , of 'the earlier the establishment of a patent system, the more advantageous to China' that finally paved the way for the ultimate approval of the Chinese patent law in March 1984.[316]

4.1.2 Bifurcated adaptive efforts under the 1984 Chinese patent law

Given the political concerns and the economic expectations prevailing in the passing of the 1984 patent law, the PRC strive to fulfil two key objectives through the careful design of the new rights under its first patent law. These aims were to introduce private rights-based incentives to promote innovation and yet restrict such rights to an extent that would enable the government to safeguard important state interests.

The 1984 law designed the new rights were within careful boundaries to aimed to avoid compromising the state's basic interests and socialist legal principles.[317] The new patent law granted private property rights to individuals or entities for their inventions, but the scope of private ownership was limited to prevent the extraction of monopoly rents. [318] For example, Article 6 provided that only enterprises were entitled to apply for patents in 'service invention-creations'.[319] Rule 10 of the implementation regulation defines 'a service invention or creation' broadly to include anything made during or in relation to one's job, using materials or data from one's work unit, or within a year of leaving

[315] An, L and Xu, Y (2009), 'The Turbulent History of the State Intellectual Property Office in the Past Three Decades'.
[316] Ibid.
[317] Alford, W (1995), *Steel a Book is a Elegant Offence*, p70, p76.
[318] Alford, W (1995), *Steel a Book is a Elegant Offence,* p70.
[319] The 1984 Chinese Patent Law.

work.[320] Given the dependence of Chinese individuals on jobs, capital and equipment provided by state-owned work units in the 1980s, this provision posed sufficient limitations on private ownership in favour of state interests.

A similar bias was also structured under the provision of compulsory licensing. Article 14.1 empowered the state council and other competent governmental units to compel the licensing of patents held by state entities, subject only to the condition that such action is taken 'in accordance with the state plan', with a payment decided by the state. Article 14.2 authorised competent governmental units to order the licensing of patents held by either individuals or entities under collective ownership as long as they could be considered of 'great significance to the interests of the State or to public interest, and is in need of dissemination and application.' [321]

Besides these ideological-oriented adaptations, other cautions and limitations were adopted to promote national interests in advancement of domestic innovative capabilities under the law. For example, Article 25 excludes seven categories from patentability. The fifth one was 'pharmaceutical products and substances obtained by means of chemical process'.[322] This exclusion included new pharmaceutical compounds and compositions or mixtures of pharmaceutical products.[323] This provision disadvantaged pharmaceutical patents given that inventive steps were easy to discern and copy.[324] On the other hand, such provision was conducive for the production of low

[320] Alford, W (1995), *Steel a Book is a Elegant Offence,* p71.
[321] Article 14, the 1984 Chinese Patent Law.
[322] Article 25, the 1984 Chinese Patent Law.
[323] Li L(1989) *'Answers to Questions Concerning Patent Protection for Chemical Inventions in China'*, China Patent & Trademarks, April, p23-24.
[324] Alford,W (1995), *Steel a Book is a Elegant Offence,* p72.

cost generic medicine. This provision also allowed the option to develop domestic pharmaceutical technology though imitative innovation or learning.

A similar logic was applied in Article 11, which states that 'no entity or individual may, without the authorization of the patentee, exploit the patent, that is, make, use of or sell the patented product, or use the patented process, for production or business purposes' and does not prevent the importation of the products made by the third country (which do not protect process),[325] and in Article 45 which limits patent duration to a maximum of fifteen year.[326]

4.1.3 Policy effect

In the 1984 Chinese patent law, the political motive of maintaining state control of new rights was incompatible with the concept of exclusivity inherent in a patent system. This State policy objective implemented in the new patent system was disadvantageous to private rights holders. On the other hand, from a public health policy perspective, the 1984 patent law was effective in enhancing protection of public health because prohibiting the patenting of pharmaceutical products in China contributed to the rapid growth of domestic production and spread of cheaper generic medications in the 1990s. Prior to 1949, the provision of traditional medicines was very limited, and there were effectively no Western medicines available in China.[327] Table 4.1 illustrates the output of raw medicine production in China. In 1980, there were 3964.5 tons, and this soared to 330000 tons in 1995, increasing production by a multiple of 83. By 1995, China had already exported its medicines to over 100 countries, and China ranked first in the world

[325] Article 11, the 1984 Chinese Patent Law; Alford,W (1995), *Steel a Book is a Elegant Offence Steel a Book is a Elegant Offence,* p72.
[326] Alford,W (1995), *Steel a Book is a Elegant Offence Steel a Book is a Elegant Offence* .
[327] West,A (1997), 'The pharmaceutical and healthcare industries of China ', (London: FT Pharmaceuticals & Healthcare Publishing, p 41.

production and export of penicillin and second for Vitamin C. Since then, the Chinese pharmaceutical industry has increasingly developed into the main supplier of low-cost medicine to large populations nationally and internationally.[328] It must be noted that other national policies and economic factors had also contributed to this progress, including national funding schemes, fiscal initiatives, market advantages, talent and education policies etc. The role of these complementary factors in fostering domestic innovation will be discussed in Chapter 7.

Table 4.1: Output of raw medicine production in China (1980 -1995)

Years	Output (Ton)	Growth Rate
1980	3964.5	
1985	147832.8	3729%
1990	209300	142%
1995	330000	158%

Source: China pharmaceutical industry overview, available at http://www.chinadetail.com/Business/IndustryReviewsPharmaceuticalIndustry.php

[328] Grace,C (2004), 'The Effect of Changing Intellectual Property on Pharmaceutical Industry Prospects in India and China: Considerations for Access to Medicines', in British Government's Department for International Development (DFID) (ed.), (London: FDID).

4.2 The 1992 reform of Chinese patent law

The development of the IPRs system entered into another phase in the 1990s in China. Chinese IPR protection standards were rapidly ratcheted up largely due to requirements to conform to the IPRs norms demanded by its major trading partners, particularly the US. Another contributing factor was that the PRC's increasing dependence upon US markets and technology made it more vulnerable to US pressure for IPR reforms following the US model. Also, China's economic development-centred policy may have rendered it more likely to adopting IPR norms advocated by its other major trading partners. In addition, the political aspiration of resuming WTO membership also obliged China to harmonise its IPRs regime in line with the legal framework of the TRIPS Agreement.

4.2.1 Sino-US bilateral agreement on IPRs

China has emerged as one of the fastest growing economies in the world since the 1980s. According the World Bank, China enjoyed average GDP growth rates of around 10% during the 1980s to 2000.[329] However, a large proportion of Chinese economic growth has been driven by international trade and investment.[330] Among others, the US and China have become most significant trade partners to each other. The bilateral trade between the US and China has substantially expanded from $8 billion to $121 billion, and China ascended from the US' 18th to its 4th trading partner in the period of 1986 to

[329] World Bank (2002), 'World Development Indicators', (Washington D. C.: World Bank).
[330] Ostergard, R(2002), *Development Dilemma : The Political Economy of Intellectual Property Rights in the International System* (New York: LFB Scholarly Publishing LLC), p120.

2001.[331] Sino-US trade relations proved to be the catalyst to shaping China's IPR policy.[332]

The comparative advantage for the US in trade depends upon IP-intensive goods. Sufficient IPR protection is vital for securing US economic interests in the Chinese market. China, on the other hand, was at the stage of developing domestic industrial capability through imitative innovation and learning. Chinese interests were attained through national industry policy including a more lenient patent regime on intellectual properties than those of developed countries.

The different levels of IPR protection in the US and China increasingly resulted in infringements or piracy of American goods in the Chinese market. The industries claimed that losses due to Chinese patent infringement, copyright piracy and trademark counterfeiting were estimated at $1billion by 1994 and that they were escalating rapidly.[333] Several US industries, such as pharmaceuticals, music and software, started lobbying the US government intensively to take actions to protect their IPR assets in China. The US government responded repeatedly with unilateral trade sanctions to press IPR legal reform in China.[334] The Special 301 provision of the US Trade Act of 1974, amended by the Omnibus Trade and Competitiveness Act of 1988 (the Trade Act) was devised to strengthen US leverage to improve the enforcement of IPR protection in the targeted countries like China.[335] Section 301 permits the United State Trade

[331] USTR (2006), 'U.S.-China Trade Relations: Entering a New Phase of Greater Accountability and Enforcement', in United States Trade Representative (ed.), p8.
[332] Ostergard, R (2002), *Development Dilemma: The Political Economy of Intellectual Property Rights in the International System* (New York: LFB Scholarly Publishing LLC), p130.
[333] Ryan, M (1998), *Knowledge Diplomacy* (Washington, D.C.: The Brookings Institution), p80.
[334] Yu, P (2000), 'From Pirates to Partners: Protecting Intellectual Property in China in the Twenty-first Century', *American University Law Review,* 50 (34).
[335] Ibid, p151.

Representative (USTR) to investigate unfair practices concerning IPRs, to initiate plans of action, and to impose sanctions against US trading partners for 'unjustified and unreasonable' trading practices.[336]

The USTR placed China on the "Priority Watch List" in 1989. In response, China adopted a new copyright law and new implementing regulations in 1990, followed by a set of computer software regulations in 1991;[337] however, these Chinese legislative efforts failed to satisfy US expectations. The USTR soon initiated another Special 301 investigation of China's IPR practices in May 1991.[338] Meanwhile, market access bilateral negotiations were also underway in June and August in Beijing and Washington, respectively. The negotiations were not constructive, and the US government threatened to impose prohibitive tariffs on 3.9 billion Chinese exports to the US market in August 1991.[339] China reacted with counter-sanctions of a similar amount on US goods.[340] The two countries reached a compromise to avert a trade war, by signing the Memorandum of Understanding between China (PRC) and the United States on the Protection of Intellectual Property (1992 MOU) on January 17 1992.[341]

The 1992 MOU significantly changed the substantive rules of Chinese patent law. In its Article 1(a), the Chinese government commits to provide patent protection to all chemical inventions, including pharmaceuticals and agricultural chemicals, whether

[336] See Section 301 of the 1974 Trade Act at http://www.osec.doc.ov/ogc/occic/301.html.
[337] Yu, P (2000), 'From Pirates to Partners: Protecting Intellectual Property in China in the Twenty-first Century',, pp 140-141.
[338] Ibid, p142.
[339] Lardy, N (1994), p 81.
[340] Ibid, p142.
[341] Yu, P (2000), 'From Pirates to Partners: Protecting Intellectual Property in China in the Twenty-first Century'.

products or processes.[342] Article 1(3) assures the term of protection for a patent of invention will be extended to 20 years from the original 15 years. Article 1 (D:i) pledges to extend patent rights to the imported products.[343] Moreover, the 1992 MOU endorsed strict TRIPS criteria on the provisions on Compulsory Licence.[344] As a result, significant limitations were imposed on the use of compulsory license in the follow-on revision of Chinese patent law.

4.2.2 Major changes to China' patent law in 1992: a pioneering move towards the TRIPS pharmaceutical patent regime

Pursuant to the agreements made in the 1992 MOU, China revised its patent law and implementation regulation. The major amendments to the Chinese patent law relevant to pharmaceutical patents are listed below:

1. To expand the patent protection for pharmaceutical and chemical products, by omitting the Clause (5) 'Pharmaceutical products and substances' from the Article 25 which stipulates the fields excluded from patentability.
2. To prolong the duration of the patent protection for the invention from 15 years to 20 years (Article 45) the utility model 5 years to 10 years
3. To modify the provision on compulsory licences and place more restrictions on its use, such as, limitation of the use of compulsory license for the supply of domestic market[345] a request for authorisation from the patentee on reasonable

[342] The 1992 MOU, available at http://tcc.export.gov/Trade_Agreements/All_Trade_Agreements/exp_005362.asp.,Acessed on March 6, 2009.
[343] The 1992 MOU.
[344] Article 1(D) in the 1992 MOU.
[345] Rule 68.5, the 1992 Implementation Regulation of Chinese Patent Law.

terms (Article 51), non-exclusive and non- assignable (Article 54), and a reasonable fee decided by both parties through consultation (Article 57) etc.

4. To add on the right of import to the exclusive rights granted to the patentee and thus treat inventions equally whether they are imported or locally produced (Article 11).[346]

The 1992 Chinese patent law had already incorporated TRIPS-level patent standards for pharmaceuticals, including changes to substantive obligations particularly significant for pharmaceuticals. Such standards included expanding patent protection from processes to all product substances, non-discrimination on the patent whether or not the product was imported or locally produced, and a 20-year patent duration, and restraints on the use of compulsory licensing. Thus, China adopted a much stronger form of patent protection for pharmaceuticals much earlier than many other developing countries at comparable developmental positions. A notable example is India, which only adopted product patent protection rules in 2005.

4.2.3 Chinese administrative protection for pharmaceuticals: TRIPS-plus standards

Like China's early move relative to other developing countries toward adopting strong patent protection rules, it also adopted TRIP-plus standards in its legislation governing pharmaceuticals earlier. This was first evident when it signed a 1992 Memorandum of Understanding (MOU) with the United States establishing retroactive patent protection to existing foreign pharmaceutical patents. This was initiated by a concession China

[346] The following summary is based on the article by Shen, Jl (1993), 'Some Important Amendments to the Chinese Patent Law', *World Patent Information,* 15 (4).

made in the 1992 MOU in which China agreed to offer specific patent administrative protection to existing US patents on drugs and agricultural chemical products if they:

(i) were not subject to protection by exclusive rights prior to the amendment of current Chinese laws;

(ii) are subject to an exclusive right to prohibit others from making, using or selling it in the United States which was granted after January 1, 1986 and before January 1, 1993;

(iii) have not been marketed in China; [347]

This advantage was then extended to *all* foreign pharmaceutical patent holders in the new legislation**, '**Regulations on Administrative Protection for Pharmaceuticals' promulgated by the State Pharmaceutical Administration on December 19, 1992.[348] Its Article 1 states that the purpose of 'Administrative Protection' is 'expanding economic and technological cooperation and exchange with foreign countries, providing Administrative Protection to the lawful rights and interests of the owners of the exclusive right of foreign pharmaceuticals.'

Table 4.2 below presents the Chinese administrative standards in relation to those under the TRIPS Agreement. Compared to similar measures (widely called 'the mailbox system') provided by Article 70.8 of the Agreement, the 1992 MOU together with the **'**Regulations on Administrative Protection for Pharmaceuticals' provided even greater protection for existing foreign pharmaceutical and agricultural chemical patents. First, the Chinese rules were retroactive to January 1 1986, providing protection six years before both the signing of the 1992 MOU and the patent protection on pharmaceutical

[347] Article 2, The 1992 MOU.
[348] **'**Regulations on Administrative Protection for Pharmaceuticals', available at http://former.sfda.gov.cn/cmsweb/webportal/W45649038/A47484015.html. accessed on April 16, 2009.

products permitted under the revised 1992 Chinese patent law.[349] Meanwhile, similar protection under TRIPS was only made available from January 1 1995, when it entered into force.[350] Secondly, regarding the terms of duration, the TRIPS mailbox system only requires protection 'for a period of five years after obtaining marketing approval in that Member or until a product patent is granted or rejected in that Member….';[351] whereas the Chinese 'Administrative Protection' grants seven years and six months.[352]

It is important to note that Chinese administrative protection is not only a TRIPS-plus standard, but it is also another example of the unequal treatment between domestic and foreign inventions. Only existing foreign pharmaceutical patents can enjoy such protection; domestic pharmaceutical inventions are excluded.[353] There are a lot of interests at stake with such an arrangement. Foreign companies demonstrate strong incentives for using this system to extend their patent monopoly rights in China, even though their products are not the subject matter of protection.[354] On other hand, it is not in Chinese national interest to extend patent monopoly in terms of its needs to access low cost medicines and technology.

[349] UNCTAD-ICTSD (2005) 'Resource Book on TRIPS and Development', p766.
[350] UNCTAD-ICTSD (2005) 'Resource Book on TRIPS and Development', p766.
[351] Article 70.9, the TRIPS Agreement.
[352] Article 13, **'**Regulations on Administrative Protection for Pharmaceuticals'.
[353] Article 1&3, Ibid.
[354] Zhang, QK,(2008), *Intellectual Property Strategy and Practice in Pharmaceutical and Biotechnology* (Beijing Intellectual Property Press), pp186-189.

Table 4.2: Comparative administrative protection standards under TRIPS and Chinese laws

	TRIPS	China
Duration (yrs)	5	7.5
Retroactive protection date	1/1/1995	1/1/1986

Sources:
1) Article 70.9, the TRIPS Agreement
2) Article 13, 'Regulations on Administrative Protection for Pharmaceuticals'.

4.3 The 2000 amendment of Chinese patent law

In 2000 Chinese patent law was amended a second time. The principle aim of the second amendment was to ensure that Chinese law conformed with TRIPS requirements in order to honour the commitments China made for its accession to the WTO.[355] Fulfilling such commitments is an enormous task for China given the comprehensiveness of TRIPS norms, the Chinese experience with IPRs, and the rapid time frames for implementation and compliance. Opinions are divided on the extent of conformity of the 2000 Chinese patent law with TRIPS. Some scholars have suggested that the 2001 patent law principally offers consistent protection in line with the requirements of TRIPS.[356] While many others have insisted that significant gaps still remain, even though the changes to China's patent law in 2000 represents a step closer

[355] Para 67 & 68, WTO (1 October 2001), 'Report of the Working Party on the Accession of China', (WT/ACC/CHN/49).
[356] Guo, SK and Zuo, XG (2007), 'Are Chinese Intellectual Property Laws Consistent with the TRIPS Agreements? ' in P Torremans, HL Shan, and J Erauw (eds.), *Intellectual Property and TRIPS Compliance In China: Chinese and European Perspectives* (Cheltenham: Edward Elgar Publishing Limited); Gao, LL (2008), ' China's Patent System and Globalization ', *Research Technology Management,* 56 (6). It is noted that Gao was the Commissioner of the Chinese Patent Office and the Founding Commissioner of the State Intellectual Property Office.

to TRIPS compliance.[357] This examines the degree of conformity of the 2000 amendment of Chinese patent law with the TRIPS Agreement. It focuses on the provisions particularly relevant to pharmaceutical patents.

4.3.1 WTO entry and the 2000 amendment of Chinese patent law

Beginning in 1986, China sought to resume its GATT (later updated to the WTO) membership.[358] It perceived that the WTO's trade liberalisation agenda offered a favourable trade environment and could facilitate its export-led growth strategy. More importantly, in seeking WTO membership, China expected to gain leverage to counterbalance the pressure from bilateral trade conflicts through WTO equality principles. Governing principles of the WTO oblige member states to treat their trading partners equally, to give them 'Most-favoured-nation' (MFN) Status equally, and to grant national treatment to foreign products, services and nationals.[359] It is vital for China's exports and its economic growth to access the US market, as the largest and most advanced world market; however, China has been entangled in annual battles with the US Congress regarding review of its MFN trade status in the US. Securing a permanent MFN through the WTO could help China to avoid the political

---

[357] Chert, J (2001), 'The Amended PRC Patent Law', *China Business Review,* 28 (4);Thomas, M and Raiti, J (Nov/Dec2002), 'The TRIPS Agreement and China', *China Business Review,* 29 (6); Yu, X (2001), 'The Second Amendment of the Chinese Patent Law and the Comparison between the New Patent Law and TRIPS ', *The Journal of World Intellectual Property,* 4 (1); Moga, T (Nov/Dec 2002), 'The TRIPS Agreement and China', *The China Business Review*.

[358] 'China was one of the 23 original signatories of the General Agreement on Tariffs and Trade (GATT) in 1948. After China's revolution in 1949, the government in Taiwan announced that China would leave the GATT system. Although the government in Beijing never recognized this withdrawal decision, nearly 40 years later, in 1986, China notified the GATT of its wish to resume its status as a GATT contracting party.' WTO inf., **'**WTO successfully concludes negotiations on China's entry', http://www.wto.org/english/news_e/pres01_e/pr243_e.htm, last visit on May 6 2009.

[359] WTO inf. at http://www.wto.org/english/thewto_e/whatis_e/tif_e/fact2_e.htm, accessed on May 6, 2009.

embarrassment over US Congress's annual scrutiny on its human rights, labour standards, and environmental record.[360]

One of the key subjects in China's WTO accession negotiations was the issue of intellectual property protection in China. The final Working Party Report on China's WTO accession devoted 55 paragraphs out of a total of 343 to China's commitments under the TRIPS regime.[361] Accession to the WTO required China to negotiate bilateral trade agreements with its major trading partners.[362] The most difficult negotiation rounds were with the US and the European Union (EU).[363] China finally reached agreements with the US in November 15 1999 and with EU on May 19 2000. Among other concessions, China agreed to implement the TRIPS Agreement in full from the date of its accession.[364]

Against the foregoing background, China launched work on a second amendment of its patent law. The Chinese State Intellectual Property Office (SIPO) began drafting this amendment in 1998.[365] The amendment was approved by the National People's Congress on August 25, 2000 and entered in to force on July 1, 2001.[366] Thirty-six out of the sixty-nine Articles of 1992 Patent Law were substantively modified. This included changes to twenty-seven Articles and the deletion of four Articles.[367]

---

[360] Nolt, J (1999), 'China in the WTO: The Debate', *Interhemispheric Resource Centre and Institute for Policy Studies* 4(38).
[361] Long, YT (2002), 'Implications of China's Entry into the WTO in the Field of Intellectual Property Rights ', in C Magainos, Long YT, and S Francisco (eds.), *China in the WTO : the Birth of a New Catching-up Strategy* (New York: Palgrave Macmillan), p165.
[362] WTO website, 'How to become a member of the WTO', see http://www.wto.org/english/thewto_e/acc_e/acces_e.htm, accessed on May 6 2009.
[363] Nolt, J (1999), 'China in the WTO: The Debate .
[364] WTO (2001), 'Accession of the People's Republic of China', (WT/L/432, 23 November 2001). Para 1.3.
[365] Chert, J (2001), 'The amendment PRC Patent Law', *China Business Review,* 28 (4) p38.
[366] Patent Law of People's Republic of China (2001), available at http://www.sipo.cn/sipo_English /lawsregulations/200203/t20020327_33872.
[367] Yu, X (2001), 'The Second Amendment of the Chinese Patent Law and the Comparison between the New Patent Law and Trips', *The Journal of World Intellectual Property,* 4 (1), p137.

4.3.2 Comparison of the 2000 Chinese patent law and TRIPS

As examined in the previous section, the 1992 amendment incorporated the principal TRIPS-compliant rules relevant to pharmaceuticals. Nevertheless, differences still exist between the Chinese patent law and the TRIPS Agreement. Before the 2000 amendment, the Chinese patent law contains both provisions having lower thresholds of protection, i.e. TRIPS-minus provisions, and those with higher standards when compared to the TRIPS minimum standards. But the 2000 amendment only upgraded those provisions with TRIPS-minus standards without downward adjustment on those TRIPS-plus provisions. This final section of Chapter 4 reviews the former upward changes in relation to TRIPS, while the remaining TRIPS-plus provisions are examined in Chapter 5.

A. Exclusivity rights:

Article 11 of the Chinese patent law defines the scope and content of exclusivity rights conferred on the patentees. Under the 1992 law, the exclusivity rights granted to the patentee only included the rights to make, use and sell the patented products. In comparison, Article 28 of TRIPS provides a broader scope; 'offering for sale' defined under the TRIPS provision was not included in Article 11 of the 1992 Chinese patent law. The aim of making 'offering for sale' illegal without prior authorisation was to enable a patentee to stop infringement prior to the transaction so that any associated damage can be prevented. At present, most countries have defined unauthorised 'Offer for sale' as a violation of a patentee's rights by law. According to the TRIPS provision, the 2001 amendment granted the right to prohibit the unauthorised 'offering for sale' of patented products to the patentees. Consequently,

the content and scope of the exclusivity rights of patentees in the 2000 Chinese patent law were updated in compliance with TRIPS. [368]

B. Compulsory licence

The 2000 Chinese patent law increased the conditions required for the use of compulsory licences. The major changes covered the following aspects:

1) Article 53 of the Law of 1992 only required the dependent invention to be 'technically more advanced' in relation to the earlier invention to be qualified for the application of compulsory licence to exploit the earlier invention. Article 50 of 2001 patent law enhances the standard for such use and transplants in the exact same wording 'an important technical advance of considerable economic significance' from the TRIPS Article 31(l)(i).

2) 1992 Patent Law had no similar rules as defined in Article 31 (g) of TRIPS relating to the provisions on the duration, scope and determination of the compulsory licence.[369] Paragraph 2 of Article 52 of 2001 patent law defines these elements and provides that the decision of a compulsory-licence shall specify the scope and duration of the licence as well as the grounds for the decision. When these reasons cease to exist or are likely to expire, the patent holder may appeal to the patent administration department of the State Council to terminate the compulsory licence.

3) The limitation in TRIPS on the use of compulsory licences predominantly for the supply of the domestic market was not directly written into the 2001 patent law, but it was adopted under paragraph 4 of Article 72 in the Implementing Regulations of the

[368] Yu, X (2001), 'The Second Amendment of the Chinese Patent Law and the Comparison between the New Patent Law and TRIPS', p146; Chert, J (2001), 'The Amended PRC Patent Law', p38.
[369] Guo, SK and Zuo, XG (2007), 'Are Chinese Intellectual Property Laws Consistent with the TRIPS Agreements? ', p14.

Patent Law of the People's Republic of China, which state that: 'The decision of the Patent Administration Department under the State Council granting a compulsory license for exploitation shall limit the exploitation of the compulsory license to be dominantly for the supply of the domestic market.'[370]

4) Significant gaps and non-compliance still exist between the 2000 Chinese patent law and TRIPS. These include:

(i) a lack of any provision for the use of compulsory licences as an anti-competitive remedy and its conditions in line with TRIPS Article 31(K), in which it states that when the government uses compulsory licences to remedy anti-competitive practices, it is not required for prior negotiation or notification of the patentee as required under Article 31 (b) & (f); and

(ii) in the 2001 patent law there is no specification that the patentee should be paid 'adequate remuneration in the circumstances', as provided under TRIPS Article 31 (h).

C. Enforcement measures

1) Preliminary injunction made available. The 1992 patent law did not have any injunctive provisions similar to the rule provided under the TRIPS Article 50 that permits ordering the staying of infringement pre-litigation proceedings.[371] Moreover, the 2001 Patent Law added rules on provisional measures concerning this issue in Article 61. It provides that the court may adopt provisional measures to order the suspension of the reported infringing action or preserve the related property upon the

370 Article 72, Implementing Regulations of the Patent Law of the People's Republic of China (2001) , available at http://www.sipo.gov.cn/sipo_English/laws/lawsregulations/200203/t20020327_33871.htm.
371 Yu, X (2001), 'The Second Amendment of the Chinese Patent Law and the Comparison between the New Patent Law and TRIPS'', p150; Guo, S.K.& Zuo,X.D.(2007), Guo, SK and Zuo, XG (2007), 'Are Chinese Intellectual Property Laws Consistent with the TRIPS Agreements? ', pp14-15.

plea of the right holder on the conditions that he or she provides evidence that the patent right is being infringed or such infringement is imminent, or any delay is likely to lead to irreparable damage to the legitimate interest.[372]

2) The determination of damages codified. The 1992 Patent Law did not set a standard for the determination of infringement damages. In practice, courts usually use the general tort standard of infringement remedies.[373] The 2001 patent law adds a provision concerning the determination of damages in Article 60. It provides that the calculation of the amount of infringement damages for a patent right shall be based on the patentee's loss caused by the infringement or the infringer's profits derived from the infringing act. If it is difficult to assess the damages based on the patentee's losses or the infringer's profits, the amount may be determined according to the appropriate multiple of the patent's licence fee under exploitation contract.[374] This provision makes it is possible for the rights holder of the patent to obtain compensation beyond the actual economic losses.[375]

3) Burden of proof. Under the 1992 Patent Law, the second paragraph of Article 60 provided that the reverse of the burden of proof is applied in the infringing disputes for process patents. Any entity or individual manufacturing the identical product needs only to furnish the proof of the process used in the manufacture of its or his product.[376] In conformity with Article 34 of the TRIPS Agreement, Article 57 of the amended 2000 Patent Law provides that any entity or individual manufacturing the identical product must prove that a different process was used in the manufacture of its or his product.

---

[372] Article 61, the 2000 Chinese Patent Law
[373] Chert, JW (2001), Chert, J (2001), 'The Amended PRC Patent Law'.
[374] Article 60, the 2000 Chinese Patent Law.
[375] Shen, YZ (Dec 2002/Jan 2003), 'China Sweeps Away Outdated IP'', *Managing Intellectual Property*, pp31-36.
[376] Article 60, Chinese patent law 1992;.

4) Some important lacunas remain regarding enforcement measures under the 2001 patent law, particularly when compared to Article 41.1 of TRIPS:

Firstly, some observers have suggested that the damages provided by Chinese law are inadequate and fall short of the requirements of, 'expeditious remedies which constitute a deterrent to further infringements,' as envisioned by TRIPS Article 41.1,[377] although it is debatable how to interpret this ambiguous TRIPS requirement about the threshold of damages rewards.[378] This argument is generally grounded in the fact TRIPS implementation in China did not result in a reduction in the level of counterfeit goods in China.[379]

Secondly, Article 41.1 also requires the establishment of safeguards against the malicious use of enforcement procedures to prevent legitimate competition and other lawful acts. Article 48 specifies that measures should be taken to ensure against economic injury of a defendant due to abuse of the enforcement measures. A similar concern was also found in the TRIPS Preamble, in which it pronounces that measures and procedures to enforce intellectual property rights should not themselves become barriers to legitimate trade. Article 8.2 also specifies the need to prevent the abuse of IPRs by rights holders. The abusive use of enforcement measures is of particular concern in the pharmaceutical field, and this has been proven to be a conventional method by which brand-name companies employ strategic litigations to exclude

[377] Article 57, Chinese patent law, 2000; Moga, T (Nov/Dec 2002), 'The TRIPS Agreement and China', *The China Business Review*, p15. Miller, E and Miller, H (2007), 'A Review of TRIPS and TRIMs Enforcement Issues in the People's Republic of China: Background and Analysis of the Intellectual Property Protection and Enforcement Crisis Facing U.S. Industry', (the U.S. Small Business Administration).
[378] Correa, C (2007), *Trade Related Aspects of Intellectual Property Rights: A Commentary on the TRIPS Agreement* (New York: Oxford University Press Inc.), p412.
[379] Moga, T (Nov/Dec 2002) 'The TRIPS Agreement and China',; Miller, E and Miller, H (2007), 'A Review of TRIPS and TRIMs Enforcement Issues In the People's Republic of China: Background and Analysis of the Intellectual Property Protection and Enforcement Crisis Facing U.S. Industry'.

competitors from the market.[380] These provisions emphasize the concept of abuse of enforcement procedures, indicating 'the Agreement's search for a balance between the protection of IPRs and the interests of third parties'.[381]

In the 2000 Chinese patent law, there is no provision concerning restrictions on the abuse of patent rights. This is an important inconsistency when compared to the TRIPS Agreement.

4.4 Concluding remarks

China's particular political and economic environment makes it unique in the way it developed its national pharmaceutical patent system. In its first patent law adopted in 1984, China demonstrated its willingness and ability to transplant foreign laws within its legal system. Subsequently, even though bound by new obligations of an alien nature to its legal culture by virtue of its membership of the Paris Convention, China maintained a large degree of legal autonomy to design its own national patent law, however cautiously it did this. As a result, the 1984 Chinese patent law managed to integrate two national development agendas: to promote 'socialist legality with Chinese characteristics' and to support national interests in access to pharmaceutical products and technology. The political agenda that sought to maintain some state control over the rules concerning the new, alien rights to protect these national interests, however, created legal barriers to legitimising the new property rights interests of patent rights holders provided under the patent law.

[380] Correa, C (2007), *Trade Related Aspects of Intellectual Property Rights: A Commentary on the TRIPS Agreement*, p412.
[381] UNCTAD-ITCSD (2005), 'Resource Book on TRIPS and Development', p597.

Furthermore, a growing dependence upon US markets and technology increased China's vulnerability in its negotiations of the Sino-US bilateral economic relationship prior to its WTO membership. Instead of the cautious approach to adopting new and alien legal concepts on private property rights taken under the 1984 Chinese patent law, China was pressurized into adopting a pro-patent approach under both the Sino-US bilateral IPRs agreement (1992 MOU) and the 1992 law amendment. Consequently, Chinese patent rules governing pharmaceuticals were 'ratcheted up' to TRIPS-compliant standards ten year before China joined the WTO.

In addition, the prevailing economic-centred ideology directing national economic reform contributed to the evolution of the Chinese patent system. This ideology prioritises economic interests over others and encourages the institutionalisation of any policy instruments which facilitate economic growth. The objective of the Chinese patent system was dedicated to promote mainly economic interests without considering how this might affect wider social issues. The adoption of such a narrow functionalist approach may well have caused China to have fewer qualms over adopting a pro-patent regime on pharmaceuticals than other developing countries.

Lastly, a comparative study of the 2000 Chinese patent law with the related provisions in the TRIPS Agreement has revealed that the Chinese harmonisation efforts were focused on the strengthening of patent rights in accordance with the TRIPS Agreement, although significant discrepancies remain in terms of compulsory licensing and enforcement measures. By far the most remarkable gaps, perhaps, lie in the lack of measures to prevent both abuses of IPR rights and anti-competitive practices.

Chapter 5 Evaluation of pharmaceutical patent standards in China from a public health perspective

This chapter examines how China has exercised its limited legislative authority and the policy it has adopted in formulating its national pharmaceutical legislation under the TRIPS framework. The investigation seeks to answer four questions. Firstly, has China defined appropriate standards for patenting pharmaceuticals in its law or applied them in legal practice to ensure the patent system works for its dual national objectives of promoting access to medicine while also encouraging the R&D of new drugs? The second question asks whether China has made effective use of the safeguard mechanisms available in the TRIPS Agreement to protect public health interests. If the findings indicate it has not, then a third query is: has China opted to adopt TRIPS-plus patent provisions emerging from the FTAs that either restrict the use of TRIPS flexibilities or impose higher levels of patent protection? Finally, given the predominant use of the Utility Model (UM) form of protection for pharmaceuticals in China, subsection 5.4 below responds to the question and attempts to open a debate about whether UM protection is an appropriate form of IP protection for pharmaceutical products for China.

5.1 The relevant legislative framework

The legal assessment will examine the following legislation:

1. Patent laws of the PRC:

The first patent law of the PRC was promulgated in 1984 and then amended three times in 1992, 2000, and 2008, respectively. The 1984 patent law was structured with significant limitations on patents and drugs that were excluded from patentability. The changes and new rules introduced under the 1992 and 2000 patent laws focused to a large extent on strengthening the state's control of rights. The most recent amendment may demonstrate the growth of Chinese legislative discretion in balancing the interests between the patentees and users.

2. Implementing Regulations of the Patent Law of the PRC (Implementing Regulations of the CPL)

Chinese laws have traditionally been drafted in general and broad terms. Their implementation then requires the effective interpretations from various authorities. These various interpretations therefore form important sources of law. Chinese laws would be unusual, if not meaningless, without these interpretations.[382] The Implementing Regulations of the CPL were formulated to guide the effective interpretation of patent laws. So far four versions have been published.

3. Drug administrative law:

The first comprehensive Drug Administrative Law was promulgated in 1985; it stipulates the responsibilities and obligations of drug manufacturers, distributors and medical research institutions. It requires the premarket testing of safety and efficacy for the approval of new drug products. This law was revised in 2001 and remains in force and unchanged.[383]

[382] Chen, Jf (1999), *Chinese Law: Towards an Understanding of Chinese Law, its Nature and Development* (The Hague: Kluwer Law International), p106.
[383]Ibid, p30.

4. Implementation Regulations for the Drug Administration Law

These regulations were promulgated on September 15, 2002. It was under these regulations that China first incorporated data exclusivity for pharmaceutical registration data. This regulation remains unchanged since its enactment.

5. Measures of the Administration of Drug Registration

The Chinese modern regulatory system for pharmaceuticals has a very short history. In 1979, the Ministry of Health and the State Pharmaceutical Administration of China jointly promulgated the New Drug Management Regulation. Under this regulation there were no requirements for systematic scientific proof of safety and efficacy for the approval of new drugs. Thus, the national marketing of a drug by local companies was easily authorised through the provincial regulatory department. Then, in 2002, China promulgated a its first law regulating the registration of drugs used in China. After a few years of experience, it enacted new and better informed rules called Measures on the Administration of Drug Registration, in 2005 and updated in 2007.

5.2 The patentability of pharmaceutical inventions in China: laws and practices

5.2.1 Patentability criteria for pharmaceuticals

Promoting access to medicine and healthcare has become a major public issue in China. A 2004 study by the PRC Ministry of Health, The Third National Healthcare Survey, indicated that 48.9% of people on average (73% in rural areas) who should have sought medical treatment chose not do so because of the high cost of health treatment and

medicines.[384] Current discourses commonly blame this problem on the poor coverage of health insurance, the government's reluctance to invest in health, and misconduct within the medical services.[385] Yet, there has been little discussion of or attention paid to the impact of current laws on patent protection on the access to medicine in China in the post-TRIPS era.

The TRIPS Agreement rules out the traditional legal approach[386] and requires higher patent protection standards to be applied to pharmaceuticals in China.[387] The strengthened patent protection can provide strong economic incentives to stimulate more pharmaceutical R&D activities, but this legal change can also close off traditional revenue options and redirect firms' production, marketing and R&D activities. Consequently, this can affect the price of medicines and decrease the choice of sources of medicines.[388] The standards of patentability and the quality of patent examination also matter for access to medicine. Low standards of patentability and poor examination of pharmaceutical inventions can not only lead to the proliferation of patents, which erect a 'patent wall' blocking the introduction of more useful health products,[389] but also delay the entry of generic competition.

---

[384] MOH (2004-12-03), 'Press Release Brief of the Third National HealthCare Survey from the Ministry of Health (MOH)', (MOU Press Office) http://www.china.com.cn/zhuanti2005/txt/2004-12/03/content_5719473.htm, accessed on October 6, 2008, in Chinese.

[385] Wang, SG (2005), 'State Extractive Capacity, Policy Orientation, and Inequity in the Financing and Delivery of Health Care in Urban China', in Asian Research Centre (ed.), (London School of Economic and Political Science).

[386] Such as the 'Inventor's certificate', 'new drug certificate', and 'Administrative protection'.

[387] The first Chinese patent law, promulgated in 1984, only provided process patent and 15 years patent term for the pharmaceutical inventions.

[388] Grace, C (2004), 'The Effect of Changing Intellectual Property on Pharmaceutical Industry Prospects in India and China: Considerations for Access to Medicines', (London: UK Department of International Development), p8, p30.

[389] Heller, M and Eisenberg, R (May 1998), 'Can Patents Deter Innovation? The Anticommons in Biomedical Research ', *Science,* 280 (5364), available at http://www.sciencemag.org/cgi/content/full/280/5364/698; accessed on August 28, 2009; Correa, C (2007), *Trade Related Aspects of Intellectual Property Rights: A Commentary on the TRIPS Agreement* (New York: Oxford University Press Inc.), p97.

Given the efffect of patents on drug prices and availability, the criteria that are applied to examine and grant pharmaceutical patents are directly relevant to public health policies.[390] Article 27 of the TRIPS Agreement states that an invention, in order to be patentable, has to be new, involve an inventive step and be capable of industrial applicability. But the Agreement does not dictate the definitions of these three criteria, leaving member countries free to adopt their particular standards of patentability adapted to the characteristics of their legal systems and developmental needs, as long as the minimum legal mandate is met.[391] It can be debated what constitutes the desirable patentability criteria for developing members in TRIPS implementation. However, a basic guideline is that policymakers and patent examiners are obliged to design or execute the patent system in a health-sensitive manner, since their decisions have direct implications on the health and life of humanity. In addition, a well-recognised general rule is advocated by Carlos Correa as below:

> Obviously, the narrower the novelty standard, the lower the bar to assess inventive steps, and the broader the concept of industrial applicability or utility, the greater the number of applications that may be granted in a particular country. A greater number of grants made on the basis of low standards of patentability may lead to unnecessary limitations on competition without any significant trade-off in terms of more innovation to address society's needs.[392]

In this sense, given its public health needs, industry structure and low technical competitiveness, it may suit China to adopt the standard of patentability which only admits pharmaceutical inventions that are truly new, having taken substantive inventive steps, with immediate industrial applicability,

---

[390] Correa, (2007), 'Guidelines for he examination of pharmaceutical patents: developing a public health perspective', (Geneva: ICTSD, WHO, and UNCTAD).
[391] Correa, C (2000), 'Integrating Public Health Concerns into Patent Legislation in Developing Countries', (Geneva: South Centre), p3.
[392] Correa, C (2007), 'Guidelines for the Examination of Pharmaceutical Patents: Developing a Public Health Perspective', (Geneva: ICTSD, WHO, and UNCTAD), p3.

5.2.2 Novelty

China had applied a 'relative' novelty standard for patentability until 2009 when its amended patent law changed this to an 'absolute' novelty standard.[393] Table 5.1 below shows the various definitions of the 'novelty' requirement under the four versions of the Chinese patent laws. Under the 1984, 1992 and 2001 laws, China provided a 'relative' novelty standard for patentability. This meant that an invention was deemed to be 'new' if it was both (1) not publicly disclosed in publications from anywhere in the world before the date of filing; and (2) not used or made by any other means within China. This two-pronged approach to novelty applied a universal novelty standard to publication and a local novelty standard for prior public use. This implied that the use of inventions outside China did not destroy its novelty within China. As such, China's novelty standard was long structured more narrowly than the single absolute novelty standard widely adopted in other jurisdictions.

The 2008 amendment replaced the relative novelty standard with absolute novelty. It introduced and defined the concept of 'prior art' under Article 22.4. It defines 'prior art' as any technology known to the public anywhere in the world before the filing date of the patent application in China or abroad. The new provision raises the threshold on public use and knowledge from 'in China only' to any part of the world. This means that if an invention is accessible to the public or known to the public anywhere in the world before its Chinese filing date, it loses its novelty and is therefore no longer patentable in China.[394]

[393] Correa, C (2007), p4.
[394] Sutherland (2009), 'The Third Amendment to the Chinese Patent Law', *IP Legal Alert.*

Nevertheless, Chinese practitioners appear to have doubts about the practical effects of this change. In legal practice, the application of the novelty standard depends on the interpretation of the concept of 'known to the public' by the Chinese Patent Office (CPO), the Patent Examination Units (PEUs) and the courts. In China, the CPO, the Patent Re-examination Board (PRBs) and the courts have tended to construe novelty to be lost only when the 'art' or invention is freely available to any individual. Accordingly, the novelty of an invention is not necessarily destroyed if its essence is only disclosed to a number of people without placing them under an obligation of confidentiality.[395] For example, when technology that embodies a particular invention is the subject of a direct sale in another country then such a sale may be regarded as a private sale in China; hence, its novelty may not be destroyed in Chinese jurisdiction.[396] It is anticipated that the concept of 'known to the public' will continue to be applied by the Chinese patent offices. Such a practice is susceptible to manoeuvring by experienced patent applicants in order to overcome novelty barriers.

[395] Chan, G (21/12/09), 'The Third Amendment to China's Patent Law Introduces 'Absolute novelty' - Some Practical Implications',(Rouse) <http://www.lexology.com/library/detail.aspx?g=ae99e313-ef6c-4715-8a6e-6d837250e9f6>.,accessed on February 2,2010.
[396] Ibid.

Table 5.1: Novelty standards under Chinese patent laws

	Provisions (Article 22.1)	**Nature**
1984	"Novelty" means that, before the date of filing, no identical invention or utility model has been publicly disclosed in publications in the country or abroad or has been publicly used or made known to the public by any other means in the country, nor has any other person filed previously with the Patent Office an application which described the identical invention or utility model and was published after the said date of filing.	Relative Novelty (RN)
1992	The same as the above	RN
2000	The same as the above, except replacing 'the Patent Office' with 'the Patent Administration Department' in the last sentence.	RN
2008	"Novelty" means that the invention or utility model shall neither belong to the prior art, nor has any entity or individual previously filed before the date of filing with the patent administrative department under the State Council an application on an identical invention or utility model which was recorded in patent application documents or other gazetted patent documents published after the said date of filing.	Absolute Novelty

Source: Chinese patent laws of 1984, 1992, 2000, and 2008

5.2.3 Non-obviousness or inventiveness

It is widely recognised that the application of a strict standard of inventiveness would be the best policy from the perspective of public health,[397] as a strict requirement for 'non-obviousness' or 'inventiveness' can promote genuine innovation, avoid unnecessary limitations to generic competition,[398] and prevent the granting of patents on variants of existing drugs or minor development with no medical significance.[399]

[397] Correa, C (2007), 'Guidelines for the Examination of Pharmaceutical Patents: Developing a Public Health Perspective', p5.
[398] Ibid.
[399] Correa, C (2000), 'Integrating Public Health Concerns into Patent Legislation in Developing Countries', (Geneva: South Centre), p44.

As Table 5.2 below shows, before the 2008 Chinese patent law, the legal definition of 'non-obviousness' or 'inventiveness' had remained the same. The provision sets very general and vague criteria in which an invention has to embody 'prominent substantive features' and to 'represent notable progress'. The legal explanations for these criteria are not provided under either patent laws or the related implementation regulation but are specified under the Patent Examination Guide (PEG). However, according to the CPOs examiners, the explanations under the PEG are overly broad and confusing. The examiners have had difficulties in applying the standard in their examinations. This could result in an arbitrary patent grant or patent denial.[400] A recent study of the examination practice of the CPO also suggests that the determinations of 'non-obviousness' or 'inventiveness' are largely subject to the patent examiners' subjective decisions. Examination methods applied by the office are not as sophisticated as those in the United States and Europe.[401]

To ensure a strict assessment of inventiveness, it is critical to have a clear criterion for defining who constitutes the 'person skilled in the art'. Correa has suggested that 'person skilled in the art' should not be simply someone with a very general or ordinary knowledge but an expert in his technical field.[402] In chapter 4 of the Examination Guideline of the SIPO, 'The person skilled in the art' is defined as:

> …a fictional 'person' who is presumed to be aware of all the common technical knowledge and have access to all the technologies existing before the filing date or the priority date in the technical field to which the invention pertains, and have capacity to apply all the routine experimental measures before that date…[403]

[400] Gong, JH (April 2007), 'Bewilderment in Judging Inventiveness', *China Intellectual Property* (17). The author is an examiner of Material Engineering Examination Department, State Intellectual Property Office; Li, YH (2010), *Imitation To Innovation In China: the Role of Patents in Biotechnology and Pharmaceutical Industries, p120.*
[401] Li, YH (2010), *Imitation To Innovation In China: the Role of Patents in Biotechnology and Pharmaceutical Industries*,(Cheltenham: Edward Elgar), p120.
[402] Correa, C (2007), 'Guidelines for the Examination of Pharmaceutical Patents: Developing a Public Health Perspective', p5.
[403] Rule 2.4, Patent Examination Guide of the SIPO, 2006.

Chinese criterion defines 'the person skilled in art' as a technician with 'common technological knowledge' rather an expert. This definition confers a lower standard than that under the interpretation recommended from a public health perspective. In reality, the application of this standard among the courts or the office is various wide ranging. Some scholars have suggested that professional experts with superior knowledge are frequently appointed by the courts to assess their inventiveness.[404] Others have claimed that 'the person skilled in the art' is, in many cases, sourced through personal contacts rather than selected based upon their professional skills in some local courts.[405] These problems may undermine the inventiveness standard in the patent law in practice and thus lead to a proliferation of patents for trivial developments.

[404] Li, YH (2010), p130.
[405] Communication with Huang You Li and Tian Li Rong, patent attorneys, Ke Hai Patent Office.

Table 5.2: Standards for Inventiveness under Chinese patent laws

	Patent provisions (Article 22.2)	**Implementation provisions**
1984	"Inventiveness" means that, as compared with the technology existing before the date of filing, the invention has prominent substantive features and represents notable progress and that the utility model has substantive features and represents progress.	None definition about the ‘ existing technology’[406]
1992	The same as the above	The existing technology referred to in Article 22, paragraph three of the Patent Law means any technology which has been publicly disclosed in publications in the country or abroad, or has been publicly used or made known to the public by any other means in the country, before the date of filing (or the priority date where priority is claimed), that is, prior art.
2000	The same as the above,	The same definition with a minor difference in wording.
2008	The same as the above, but add: The “prior art” referred to in this Law refers to any technology known to the public before the filing date of the patent application in China or abroad.	

Sources:
1. Chinese patent laws of 1984, 1992, 2000, and 2008
2. Implementing Regulations of the Patent Law of the People's Republic of China PRC of 1984, 1992, 2000, 2008

[406] ‘Existing technology’ instead of ‘Prior art’ was officially used in the Chinese patent laws before the 2008 Chinese patent law.

5.2.4 Utility or Practical Application

It is a general principle of patent law that it should protect a technical solution to a given problem rather than abstract knowledge. Hence, a patent claim should contain a viable technical solution rather than a speculative or intended result.[407] Utility under the Chinese patent law is termed a 'practical application' rather than industrial application. The definition of 'practical application' remains the same under all four versions of the Chinese patent laws. The provision provides that 'practical application' implies that the inventions can be made or used and can produce 'effective results'. The guideline for patent examination elaborates this standard as follows: (1) To be patentable an invention has to be able to solve a technical problem and be put into practice. In other words, if the application relates to a product, this product shall be able to be made industrially and solve a technical problem; if it relates to a process, the process shall be able to be used industrially and solve a technical problem.[408] (2) The 'effective results' means that the economic, technical or social effects of the subject matter of a patent application for invention or utility model shall be positive and advantageous and can be considered likely to be achieved by a person skilled in the art.[409] The wording of these definitions suggests a narrow concept of industrial application.

In practice, however, there are inconsistencies between the law and the procedure applied in the process of patent examination in terms of the interpretation of the concepts of 'effective results' or 'positive and advantageous results' among the various patent offices and courts. For example, SIPO patent examination tends to interpret

[407] Correa, C (2007), 'Guidelines for the Examination of Pharmaceutical Patents: Developing a Public Health Perspective', p5.
[408] Rule 2, Chapter 5, Patent Examination Guide of the SIPO.
[409] Ibid.

'positive result' or 'effective result' as 'not negative or non-harmful effect'. The latter are much lower standards, for any invention whose effect is neither negative nor harmful can fall into this requirement.[410] The 2008 amendment did not make any changes or provide clarification to the criteria of 'practical application' either in the patent law or the implementation rules. If the particular interpretation with the SIPO patent examination procedure continues, the standard of utility in China will remain broad in legal practice.

In summary, the above evaluation has found that the Chinese patent system had a relative novelty standard until recently and that the rather lenient examination procedure tended to result in a low threshold for findings of inventiveness and industrial application. Some commentators have suggested that the low standards for patentability may be a deliberate Chinese government policy to promote domestic patenting activities.[411] However, such a policy is not necessarily helpful for China's technology catch-up agenda, and it inevitably enables the patenting of a large number of inventions associated with variants of existing drugs or minor modification of existing drugs.

5.3 TRIPS implementation approach: TRIPS minimum or TRIPS-plus?

The TRIPS flexibilities are built-in mechanisms for enabling WTO member countries to balance private IP interests against a variety of wider national socio-economic interests. The effective use of these flexibilities requires governments to clarify their own national interests and then to adopt the new IPR rules to fit within those interests as best as possible. The problem is that the institutional capabilities are often insufficient in many

[410] Li, YH (2010), *Imitation To Innovation In China: the Role of Patents in Biotechnology and Pharmaceutical Industries.p132.*
[411] Chow, KB, et al. (2007), 'China and Taiwan', in S Uma, G Dutfield, and KB Chow (eds.), *Innovation without patents: harnessing the creative spirit in a diverse world* (Cheltenham: Edward Elgar Publishing Ltd), p156.

developing countries, particularly as the property concepts being adopted are usually alien to the nations' legal cultures.[412] This section 5.3 investigates whether China has manifested competent institutional capacities in its use of TRIPS flexibilities in seeking to achieve its objectives for its public health interests. The legal evaluation centres on the evolution of key exceptions and limitations relevant to pharmaceuticals under the four versions of Chinese patent law in relation to TRIPS. The review also draws on some implementation practices from other developing countries.

5.3.1 Transitional period

China was required to implement its TRIPS obligations from the start of its accession, while other middle-income developing countries, like Brazil and India, have benefited from the transitional periods.[413] It may be debated whether China could have taken advantage of transitional periods before it was committed to full compliance with the TRIPS Agreement. The answer may depend on two factors: (1) whether the legal option was available to China when it was negotiating the terms for its WTO accession; and (2) what terms were reached through the bargaining between China and the incumbent WTO members?

Article 65 of the TRIPS Agreement provides a number of transitional periods on particular conditions for WTO members to utilise in bringing their IPR legal framework into full conformity with the TRIPS obligations. The benefits provided by Article 65 are explicitly applicable to the founding members of the WTO; however, China was not a founding member when the TRIPS Agreement entered into force. Thus, Article 65 is

[412] CIPR (2002), 'Integrating Intellectual Property Rights and Development Policy'.
[413] Yu (2009) 'Sino Trade Agreements and China's Global Intellectual Property Strategy', p21.

not directly applicable to China. Nevertheless, this does not rule out the possibility of China enjoying the benefits of a transitional period based on three grounds. Firstly, the notion of transitional period is deemed to be a recognition that the WTO shall grant a new member the time necessary to bring itself into full conformity with the obligations required by the Agreement.[414] China acquired a conditional status as a developing country when it joined the WTO as it was then a developing economy in the process of transforming from a centrally-planned to a market economy.[415] The global IPR system was a major new institutional mechanism for China, and there was a little IP experience and expertise at its disposal. Up to the present it has found implementation and enforcement to be problematic. It may be argued that China requires a transitional period to bring its domestic IPR system fully in line with the TRIPS rules.

Secondly, the particular accession terms for each new WTO member are the result of separate negotiation processes,[416] although each state must comply with all obligations of all WTO agreements when they join.[417] TRIPS is silent about whether or not a new member benefits from transitional periods. China therefore may have had an opportunity to negotiate over the terms of benefits of transitional periods enjoyed by other members at comparable levels of development. Thirdly, as a one-time applicant country with one of the largest negotiating powers of any applicant to the WTO',[418]

---

[414] UNCTAD-ITCSD (2005), 'Resource Book on TRIPS and Development'. p706.
[415] 'As is true for nearly all countries, China's protocol does not contain any explicit mention that China is to be treated as a developing country, The only known exception was Mexico's accession..'. But China asserted its position as such when it joined the WTO. The US and EU accepted this status on the condition that China waived certain rights. See Gao, LL (2008), 'China's Patent System and Globalization ', *Research Technology Management,* 56 (6) and Stewart, T. (2002), 'Accession of the People's Republic China to the World Trade Organisation: Baseline of Commitments, Initial Implementation and Implication for US- PRC Trade Relation and US Security Interests ', (USCC Research Paper).
[416] WTO 'How to join the WTO: the Accession Process '. <http://www.wto.org/english/thewto_e/whatis_e/tif_e/org3_e.htm>.
[417] Jones, K (2009), 'The Political Economy of WTO Accession: the Unfinished Business of Universal membership', World Trade Review, 8 (2), p290.
[418] Neumayer, E (2011), 'Strategic Delaying and Concessions Extraction in Accession: Negotiations to the World Trade Organization', (London: LSE Working Paper), p12.

China would presumably have had a good opportunity to use this strength to bargain for transitional periods if China valued this benefit highly.

Little is publicly known about the details of WTO accession negotiations.[419] It is therefore not clear whether a transitional arrangement was included or what the positions of the parties were on this issue in China's WTO accession negotiations. However, China seemed neither to recognise the need for transitional periods nor to value the benefit of transitional periods highly. In fact, political statements made at the time heralded the commitment to full compliance as an achievement in itself. This view can be observed from the following explanation of Guo Li Lin, the then Commissioner of the SIPO: '…following the 1993 Amendment, China's Patent Law was, at least in principle, in compliance with the TRIPS Agreement. There is no need for China, as a developing country or a country in transition from a central planning economy to a market economy, to have a four-year transitional period…'.[420] What is unclear is whether this was an isolated or at least a minority view, whether the Chinese negotiators were somehow misdirected in arriving at this conclusion.

5.3.2 Compulsory licences

The term compulsory licence refers to a license granted by a government authority enabling the use of a patented invention without the rights holders' consent under the justification of a public interest. The TRIPS Agreement recognises such licences under

[419] Kennett, M., S.J. Evenett, and J. Gage. 2005. Evaluating WTO Accessions: Legal and Economic Perspectives. Geneva: Ideas Centre.
[420] Gao, LL (2008), 'China's Patent System and Globalization ', *Research Technology Management,* 56 (6), p36.

its Article 31. However, the clause sets forth certain conditions for issuing such licences, but it does not limit the grounds that might be used to justify compulsory licensing.[421] This gives WTO states flexibility to define their own nationally appropriate grounds. Such legal flexibility was reaffirmed by Rule 5 (b) of the Doha Declaration on the TRIPS Agreement and Public Health, which provides that '[e]ach Member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted'.

Under current Chinese patent law, there are six possible grounds for granting compulsory licences:

- Article 48.1 reintroduces the working requirement which was specified under the 1984 Chinese patent law but deleted in the 1992 and 2001 patent laws. This ground is explicitly permissible under Article 5 A (2) of the Paris Convention. The clause indentifies the failure to exploit the patent or insufficient exploitation after expiration of three years from the grant of the patent rights, or four years from the date of application, as the first ground for granting compulsory licensing. Rule 73 of the Implementing Regulations further states that insufficient exploitation implies that the scale and method of exploitation by either the patentee or the licensee does not meet the domestic demand for the patented products.
- Article 48.2 provides a ground for granting a compulsory licence to reduce or eliminate the negative impact of anti-competitive acts determined by law. This ground is also specified under Article 31(k) of TRIPS.

[421] WTO , Fact Sheet:TRIPSs and Pharmaceutical patents, Obligations and exceptions' available at http://www.wto.org/english/tratop_e/trips_e/factsheet_pharm02_e.htm, accessed on 09/07/10; Correa, C (2007), *Trade Related Aspects of Intellectual Property Rights: A Commentary on the TRIPS Agreement*, p314.

- Article 49 defines a national emergency or any extraordinary state of affairs as the third ground. Combined with Article 54, the requirement of prior negotiation is not required for such grounds. In addition, the ground of public interest is also provided under this provision, although the patent law and its implementation regulations do not provide specifications about what constitutes public interest.
- Article 50 states that the patent administrative authority under the State Council may grant a compulsory licence for the production of a patented drug and its subsequent exportation to countries or regions allowed under the international treaties China is under contract with if required by the interests of public health. This provision adapts to the Chinese role as a major world generic drug supplier and has thus established a useful mechanism for the promotion of access to medicines domestically and internationally.
- Article 51 states that a compulsory licence may be granted if a new invention requires the use of pre-existing inventions to working, on the condition that the new invention has both economic significance and important technical features. This ground is specifically provided under Article 31 (l) of TRIPS.

Compulsory licensing was recognised under the 1984 Chinese patent law since its first establishment in the PRC. The legal terms of the clause have been substantially changed when compared to the provisions under the first version and those under the most recent version. Table 5.1 summarises the grounds and conditions under the four versions of the Chinese patent law. Several useful observations are highlighted below:

First: the provision on ‘working requirement’ was first introduced under the 1984 Chinese patent law and was then removed by the 1992 amendment. This change was

made pursuant to with the requirements of the bilateral IP agreement with the US (the MOU) in 1992. [422] In the 2008 revision, it was reintroduced as the first ground for issuing a compulsory licence.

Second: the contrast between the breadth of conditions and the narrow scope of grounds for issuing compulsory licences under the 1992 and 2001 laws provides useful evidence about the contraction of legislative capability as policy effects of the TRIPS implementation.

Third: new rules on compulsory licences under the 2008 Chinese patent law and Implementation Regulations present a more balanced compromise between conditions and grounds for granting a compulsory licence. Although so far no compulsory licences have been issued[423] or attempted in China to the best of the author's knowledge: the advancement of these rules may increase the feasibility and likelihood of compulsory licences being employed in China when the need occurs.[424]

[422] See chapter 4 for the details about the MOU.
[423] Liu, XH (2008), 'A Study on Patent Compulsory License System in China – With Particular Reference to the Drafted 3rd Amendment to the Patent Law of the P.R. of China ', in W Pyrmont, et al. (eds.), *Patents and Technological Progress in a Globalized World* (Springer Berlin Heidelberg), p115.
[424] Chen, T and Chen, A 'What Does The Third Amendment To China´s Patent Law Mean To Pharmaceutical Companies?' <http://www.mondaq.com/article.asp?articleid=65218>, accessed on July 9,2010.

Table 5.3: The conditions & grounds for the issuance of compulsory licences under four versions of Chinese patent laws

	1984	1992	2001	2008
Grounds	- Working requirement (Art 51 &52) - Dependent patents (Art 53)	- Refusal to licence (Art51) - National emergency & extraordinary state of affairs (Art 52) - Public interest (Art 52) - Dependent patents (Art 53)	- Refusal to licence (Art 48) - National emergency & extraordinary state of affairs - Public interest (Art 49) - Dependent patents Art 50	- Failure to exploit or insufficient working (Art.48.1) - Remedy for anticompetitive practices (Art.48.2) - National emergency & extraordinary state of affairs occurs (Art.49) - Public interest (Art.49) - Public health (Art.50) - Dependent patents (Art.51)
Conditions	-Prior negotiation for all grounds - Reasonable commercial terms - Notification -Non exclusivity -Non-assignment -Remuneration, -Judicial review -	-Prior negotiation for all grounds - Reasonable commercial terms - Notification -Non exclusivity -Non-assignment -Remuneration, - Judicial review	-Prior negotiation for all grounds - Reasonable commercial terms - Notification - Scope and duration - Termination -Non exclusivity -Non-assignment - Remuneration, - Judicial review	- Predominantly for the domestic market with exceptions of the uses under Art 48.2 & Art 50 - Prior negotiation & Reasonable commercial terms and period of time for the uses under Art.48.2 &Art.51 - Notification - Scope and duration - Termination -Non exclusivity -Non-assignment - Remuneration, - Judicial review

Sources: 1984, 1992, 2001 and 2008 versions of Chinese patent laws,
1984, 1992, 2001 and 2008 versions of Implementing Regulations of the Patent Law of the PRC

5.3.3 The exhaustion doctrine and parallel importation

The exhaustion doctrine is a concept under IP laws whereby IP rights holders can lose their exclusivity rights after selling their patented products on the market. This principle is provided under Article 6 of TRIPS and confirmed by the Doha Declaration. The Doha Declaration provides that WTO members are free to establish their own regime of exhaustion of rights without challenge.[425]

The exhaustion doctrine is an important mechanism for improving access to medicines, especially for low income countries. The application of the exhaustion doctrine enables parallel importation in which health providers can purchase drugs from the cheapest international sources.[426] Parallel importation has other price-reducing impacts, such as working as a negotiation tool with the original manufacturers, and it is also a means of technology transfer.[427] These benefits are practically relevant to Chinese health providers.

The 1984 Chinese patent law had established a form of national exhaustion rule. Its Article 62.1 provided that the '[u]se or sale of a patented product after it has been made by the patentee or with the authorization of the patentee and subsequently sold' shall not be deemed an infringement. This provision did not include 'import' of a patented product in its conditions. Given the territorial nature of IPRs laws, this provision

[425] Para. 5(d) of the Doha Declaration on Health.
[426] Parallel importations (PI) refers to the practice in which goods, produced genuinely under protection of a trademark, patent, or copyright, are placed into circulation in one market, and then imported into a second market without the authorization of the local owner of the intellectual property right. This owner is typically a licensed local dealer.' Maskus, K (2001), 'Parallel Imports in Pharmaceuticals: Implications for Competition and Prices in Developing Countries', p42.
[427] Maskus, K (2001), 'Parallel Imports in Pharmaceuticals: Implications for Competition and Prices in Developing Countries', p41.

provided national coverage of the exhaustion doctrine. This rendered parallel importation impermissible.

The amended provision under the 2001 Chinese patent laws may still be deemed to establish a national patent exhaustion regime. It provides in Article 63.1 that acts such as non-infringement, '[w]here, after the sale of a patented product that was made or imported by the patentee or with the authorization of the patentee, or of a product that was directly obtained by using the patented process, any other person uses, offers to sell or sells that product'. This provision may be interpreted to mean that the exhaustion principle can only be applied to a sold product which has been made or imported by the rights holders. There is no specification in regard to the importation of a product sold outside China into the domestic market by the rights holder.

The new exhaustion provision under the 2008 revision clearly establishes both national and international exhaustion regimes. It specifies that it is not deemed an infringement when 'any person uses, offers to sell, sells or imports a patented product or a product directly made from a patented process, which was sold by the patentee or an entity and individual with the authorization of the patentee.'[428] Under the current rule, parallel importation can be used as a drug price containment mechanism in China.

5.3.4 Exceptions to patent rights

States conventionally provide a variety of patent exceptions in areas where public interests are superior to those of the patentees, with the scope and content adapted

[428] Article 69.1, the 2008 Chinese Patent Law.

differently to national conditions. Some of these exceptions are particularly relevant to public healthcare.[429]

Article 30 of TRIPS allows members to make limited exceptions to patent rights, provided certain conditions are met: they should not unreasonably conflict with the normal exploitation of the patent, they should not unreasonably prejudice the legitimate interests of the patent owner, and they should take into account the legitimate interests of third parties. This provision does not specify the nature and extent of exceptions to the exclusive rights of the patentee and it leaves considerable policy space for members in this matter.[430] Note that, in practice, however, the existing scope of flexibilities is under pressure to be narrowed down from bilateral and multilateral treaties. I will elaborate on this point further in the next section.

In reality, there are counter factors limiting the national scope of exceptions to patent rights. Under the FTAs negotiated with the US, the parties are obliged to ban the export of any product made for testing and to provide a patent term extension under a Regulatory Review exception. Also, the parties adopting the exhaustion doctrine are also limited in adapting to the US-restricted international exhaustion principle. Finally, efforts under the WIPO to harmonise members' IPR regimes may also result in narrowing down the available scope in this area.[431]

[429] Correa, C (2000), 'Integrating Public Health Concerns into Patent Legislation in Developing Countries', (Geneva: South Centre), p65.
[430] Ibid, p65.
[431] Garrison, C (2006), 'Exceptions to Patent Rights in Developing Countries', (UNCTAD - ICTSD), pp72-73.

Surveys on the existing practice indicate that the following exceptions are most commonly provided under national legislation and which are deemed to be TRIPS-compliant:[432]

1. The early working exception: This device permits the use of a pharmaceutical invention to conduct tests and to obtain the regulatory approval of a generic alternative before the expiry of the patent. This exception may facilitate the more rapid commercialisation of a generic medicine upon patent expiration of the original drug.

2. Experimental and scientific use exception: This exception allows third parties to conduct experimental or scientific activities associated with the subject matter of a patent. It is widely adopted in many countries based on the principle that patent protection should not hamper the progress of science and technology.[433]

3. Individual prescription exception: This permits the use of pharmaceutical patents in preparing individual prescriptions by medical professionals. The exception, adopted under the EU's Community Patent Agreement in 1989, may be used as a reference.

The Chinese patent law permits experimental and scientific use of a patented invention from its initial establishment. But the early working exception was not codified in the law until the recent 2008 amendment. This revision introduced a new provision stating that: 'it is not deemed as an act of infringement if a patented drug or medical equipment is manufactured, used or imported solely for the purposes of providing information for

[432] Musungu, S and Oh, C (2005), 'The Use of Flexibilities in TRIPS by Developing Countries: Can They Promote Access to Medicines?', pp31-32.
[433] Garrison, C (2006), 'Exceptions to Patent Rights in Developing Countries'.

administrative approval.'[434] China is a major producer of generic medicines for both the domestic and international markets. This new exception has important implications for the development of generic products in China.

The individual prescription exception has not been incorporated into Chinese law so far. It seems that the utility of this exception has not become an issue in China, where generic drugs are the dominant medicinal supply, and pharmacies and doctors are generally not in a position to have comparable technologies and resources to make generic medicines.

It is noteworthy that China does not provide patent term extensions, although it affords patent linkage measures for the registration data of originator companies. Both measures are not deemed as obligations under TRIPS,[435] but critics point out that the introduction of the early working exception undermines the utility of patent linkages measure,[436] and they insist that measures like patent term extension should be incorporated as balancing provisions to the new exception.[437]

5.3.5 Exceptions from patentability

Exception from patentability refers to the exclusion of certain subject matters from protection to prevent the grant of patents from certain areas.[438] The implementation of this exception is in the interest of a country for public health purposes, for this

[434] Article 69.5, Chinese Patent Law 2008.
[435] UNCTAD-ITCSD (2005), 'Resource Book on TRIPS and Development'.
[436] Cohen, M, et al. (2009-12-07), 'New patent law amendment codifies some IP protections', *China Daily*.
[437] ICC (2006), 'Comments on the Draft Third Amendment of the Patent Law in China', (Paris: International Chamber of Commerce (ICC)), 65.
[438] Musungu, S and Oh, C (2005), 'The Use of Flexibilities in TRIPS by Developing Countries: Can They Promote Access to Medicines?', p33.

mechanism may prevent too many secondary patents granted to new uses, especially second uses of previously known medicines.

However, there are sharp disagreements over the validity of the patentability of new uses, especially second medical uses of known products. The proponents of the new uses patent justify this on the basis that a second medical use is also of importance for public health,[439] and in addition, that the discovery of a new use of known medicine may require the same level of R&D as for the original use of a new product.[440] The opponents of new use patents contend that the amount of work and investment claimed in making such inventions are applied to a very limited number of cases, if any. In fact, the protection of new uses, especially second medical indications, has been routinely employed as a business strategy enabling the originator company to extend the patent period and block the entry of generic drugs.[441]

The TRIPS Agreement does not specify the patentability of new uses of known products. Article 27.1 defines the patentable subject matter. It states that a patent should be provided for any inventions, whether they are products or processes, in all fields of technology. This mandate rules out the practice of excluding the patentability of pharmaceutical products commonly provided in many countries prior to TRIPS. Thus, it only explicitly obliges protection on products and processes. This leaves flexible policy space for member countries to determine whether or not new uses or second medical

[439] Grubb, P (2004), *Patents for Chemicals, Pharmaceuticals and Biotechnology* (Oxford Oxford University Press), p240. These are also the grounds used by the German Super Court in its ruling on the eligibility of the second medical use for a Utility Model protection, see Uekkull, A and Holder, N (June 2006), 'A Clever Move: Utility Models for Second Medical Use Inventions in Germany', (183: Patent World).
[440] Musungu, S, Villanueva, S, and Blasetti, R (2004), 'Utilizing TRIPS Flexibilities for Public Health Protection Through South-South Regional Frameworks', p15.
[441] Ibid, p16; Hoen, Ellen 't (2009), *The Global Politics of Pharmaceutical Monopoly Power* (Diemen: AMB Publishers); Boldrin, M and Levine, D (2008), *Against Intellectual Monopoly*.

uses are eligible subject matter under their own national laws.[442] In the US, the patenting of new uses is limited to 'method to use' and does not provide protection for products as such,[443] for example, claims of medical treatment for humans and surgical procedures are both patentable.[444] In contrast, the patentability of a new use of a known product is allowed under Article 54(5) of the European Patent Convention. [445]

Article 25 of the Chinese patent law defines the subject matter excluded from patentability by law. When comparing the most recent version of the Chinese patent law with its 1984 revision, the only major change was the removal of 25(5) pharmaceutical products and substances obtained by means of a chemical process in the 1992 revision. The subject matters excluded from Chinese patent law included: 1) scientific discoveries, 2) rules and methods for mental activities, 3) methods for diagnosis and for the treatment of diseases, 4) animal and plant varieties, 5) and substances obtained by means of nuclear transformation.

The exception of methods for diagnosis and for the treatment of diseases implies that no patents shall be granted to new uses of inventions or known pharmaceutical compounds in China if they are claimed as new methods for the treatment of diseases.[446] In practice, the patentability of the new uses of pharmaceuticals lies in the proper wording of the claims in China.[447] The second medical use can be patentable under Chinese patent law

[442] UNCTAD-ITCSD (2005), 'Resource Book on TRIPS and Development', p537.
[443] Musungu, S and Oh, C (2005), Musungu, S and Oh, C (2005), 'The Use of Flexibilities in TRIPS by Developing Countries: Can They Promote Access to Medicines?', p35.
[444] Grubb, P (2004), *Patents for Chemicals, Pharmaceuticals and Biotechnology, p240.*
[445] UNCTAD-ITCSD (2005), 'Resource book on TRIPS and Development', p356.
[446] Li,LT and Tai, TH. (01/04/2009), 'Features of Swiss-type Claims', *Managing Intellectual Property &* Feng, A (01/06/08), 'Take Local Practice into Account - Managing Intellectual Property ', *Managing Intellectual Property.*
[447] See the patentability information about Chinese patents provided by the Zhongzhi Law office http://www.zz-iplaw.com.cn/english/faq/faq_1.html.

as long the claim is presented in the form of 'Swiss-type' claims.[448] In fact, the current application guidelines provide information on how to patent a second medical use in China. The exemplified form of these claims reads as 'use of compound X in the preparation of a medicament for the treatment of disease Y'. [449]

5.3.6 Pharmaceutical registration data protection

Pharmaceutical registration data refers to data results from preclinical and clinical studies on the efficacy and non-toxicity of original pharmaceutical products. Such data is required as the justification for national health authorities in their decisions on the granting of manufacturing or marketing licences for pharmaceutical products containing new chemical entities (NCEs).[450]

National drug authorities conventionally do not require generic companies to repeat the same safety and efficacy testing as conducted by the originators, but they do require 'bioequivalence testing' from generic companies to show their products are chemically identical to the original products and possess the equivalent safety and efficacy. Most health authorities relied on pharmaceutical registration data submitted by originator companies or foreign approval or commercialisation to approve subsequent applications of generic alternatives prior to TRIPS.[451]

[448]Li,LT and Tai, TH. (01/04/2009), 'Features of Swiss-type Claims', Managing Intellectual Property'; Feng, A (01/06/08), 'Take local practice into account - Managing Intellectual Property ', Managing Intellectual Property.
[449] Feng, A (01/06/08), 'Take local practice into account - Managing Intellectual Property '.
[450] Correa, C (2004), 'Protecting Test Data for Pharmaceutical and Agrochemical Products under Free Trade Agreements'.
[451] Correa, C (June 2002), 'Protection of Data Submitted for the Registration of Pharmaceuticals: Implementing the Standards of the TRIPS Agreement ', (South Centre & WHO), p11.

A. Data exclusivity, a TRIPS-compliant or TRIPS-plus standard?

The international agreement about the standard of protection of such data is essentially provided under TRIPS Articles 39.1 and 39.3. The wording of the provisions specifies that pharmaceutical registration data submitted for market approval shall be protected against 'unfair commercial use'.[452] There is considerable debate and controversy about how to interpret this provision within national laws.[453] Research-based pharmaceutical companies and their supporters argue that since clinical test data is expensive, risky and time-consuming to produce, they should be protected under a fixed period of exclusivity rights. It is 'unfair commercial use' if the marketing approval of generic copies is allowed to use these data.[454]

Under strong lobbying from the industry, the US and the European Union are urging other members of the TRIPS Agreement to implement the Article 39.3 obligation through a system of exclusivity rights on pharmaceutical registration data in their national laws. The US/EU system is sometimes referred to as 'marketing exclusivity' or 'data exclusivity', rather than 'data protection', due to its high threshold, which is considerably beyond the minimum obligations under TRIPS.[455] The US model provides 5 years of data exclusivity to new drugs containing new chemical entities (NCEs) and 3 years of data exclusivity to new indications of already approved drugs.[456] The EU data

[452] Article 39.3, the TRIPS Agreement.
[453] Weissman, R (2006), 'Public Health-friendly Options for Protecting Pharmaceutical Registration Data', *International Journal of Intellectual Property Management,* 1 (1/2), p114.
[454] IFPMA (2000), 'Encouragement of new clinical drug development: the role of data exclusivity', (International Federation of Pharmaceutical Manufacturers (IFPMA)),at http://www.eldis.org/assets/Docs/29224.html, pp2-3, accessed on March 6,2010.
[455] Sanjuan, Judit Rius (2006), 'US and EU Protection of Pharmaceutical Test Data. 1', *CPTech Discussion Paper*. www.cptech.org, p2.
[456] Ibid, pp5-6; Pugatch, M. (2004), 'Intellectual Property and Pharmaceutical Data Exclusivity in the Context of Innovation and Market Access', *ICTSD-UNCTAD Dialogue on ensuring policy options for affordable access to essential medicines* (Bellagio), p9.

exclusivity protection is based on a system of the 8+2+1 formula: [457] 8 years of data exclusivity for new pharmaceutical products; 2 years of marketing exclusivity during which generic companies are allowed to submit bio-equivalence tests referring to the data of the original product but they are not yet allowed to market their generic substitute; 1 year of a 'non-cumulative' period of data exclusivity for new indications of an existing substance.

The alternative interpretation contends that Article 39.1 makes it clear that the obligation of the protection on pharmaceutical registration data under Article 39.3 is to be conferred under the principle of unfair competition as provided in Article 10bis of the Paris Convention.[458] Article 39.3 does not sustain the requirement of data exclusivity, and members have to meet their obligation under Article 39.1 when their national laws protect the data by prohibiting 'dishonest' uses of data, such as in situations when a competitor obtains data through fraud or breach of confidence, for example, and uses it to apply for market approval of their own products. [459]

Nevertheless, a review of the national legislation of 49 countries has revealed that 43% of them have not provided a data protection provision.[460] Under the national legislations adopting the provision related to data protection, the majority do not provide data

[457] ibid, p9; Amendments 8) 1and 8) 5 in EC (2004), 'Directive 2004/27/EC of the European Parliament and the Council of 31 March 2004 Amending Directive 2001/83/EC on the Community Code relating to Medicinal Products for Human use', available at eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2004:136:0034, accessed April 18,2010.
[458] UNCTAD-ITCSD (2005), 'Resource Book on TRIPS and Development', p521.
Article 39.1 reads as: In the course of ensuring effective protection against unfair competition as provided in Article 10bis of the Paris Convention (1967), Members shall protect undisclosed information in accordance with paragraph 2 and data submitted to governments or governmental agencies in accordance with paragraph 3.
[459] Correa, C (June 2002), 'Protection of Data Submitted for the Registration of Pharmaceuticals: Implementing the Standards of the TRIPS Agreement ', pp39-40.
[460] Musungu, S and Oh, C (2005), 'The Use of Flexibilities in TRIPS by Developing Countries: Can They Promote Access to Medicines?', p37,p70.

exclusivity approaches, although this situation may change with the increasing numbers of FTAs negotiated outside the WTO, which require data exclusivity to be incorporated within national laws.[461]

B. Evaluation of Chinese pharmaceutical registration data protection

The modern regulatory system on pharmaceuticals has a very short history in China. In 1979, the New Drug Management Regulation was jointly promulgated by the Ministry of Health and the State Pharmaceutical Administration of China. Under this regulation, there were no requirements for systematic scientific proof of safety and efficacy for the approval of new drugs. [462] National marketing of a drug by local companies was easily authorised through the provincial regulatory department.[463] The first comprehensive Drug Administrative Law was promulgated in 1985 and amended in 2001. It required the premarket testing of safety and efficacy and the approval of new drug products. However, no provisions on protection of the submitted testing data were provided under drug regulation laws during this period.

Nevertheless, it has been suggested that pharmaceutical registration data could be protected under the anti-competition law passed during the pre-TRIPS period in China.[464] Article 10 of this law requires that a business operator must not infringe upon trade secrets. Article 10.2 specifies that obtaining, using or disclosing the trade secrets of others by a business operator is deemed an infringement upon the trade secrets. 'trade

[461] Musungu, S and Oh, C (2005), 'The Use of Flexibilities in TRIPS by Developing Countries: Can They Promote Access to Medicines?', p38.
[462] Deng, RL and Kaitin, K (2004), 'The Regulation and Approval of New drugs in China', *Drug Information Journal,* p29.
[463]Ibid.
[464] Para 283, WTO (1 October 2001), 'Report of the Working Party on the Accession of China', (WT/ACC/CHN/49: WTO), accessed on July 13, 2010.

secrecy' is defined as utilised technical information and business information which is unknown by the public, which may create business interests or profit for its legal owners, and which is also is maintained in secrecy by its legal owners.[465] In addition, Article 219 of the Chinese criminal law code has similar definitions and also criminalises such acts of infringements on trade secrets.[466] Therefore, pharmaceutical registration data may be protected through the law on trade secrecy during the pre-TRIPS period, in theory.

In compliance with Article 39.3 of the TRIPS Agreement, China first incorporated a six-year data exclusivity rule on pharmaceutical registration data in September 2002 in Article 35 of the Regulations for Implementation of the Drug Administration Law of the People's Republic of China. The rule was also included in Article 14 of the Administrative Measures for Drug Registration (2002). Under the 2002 drug registration law, generic applicants are permitted to submit their applications two years before the expiry of patents.[467]

China's approach toward pharmaceutical data protection is deemed to be exceptional in comparison with other developing countries.[468] China and Vietnam exceptionally provide six-year and five-year data exclusivity, respectively.[469] It is reported that many developing countries have not provided a specific provision for data protection under their drug laws. For example, India has not yet incorporated a legal provision for

[465] Article 10, Anti Unfair Competition Law of the People's Republic of China, available at http://en.chinacourt.org/public/detail.php?id=3306, accessed on December 3,2009.
[466] Article 219, Criminal Law (1997), http://www.cecc.gov/pages/newLaws/criminalLawENG.php.
[467] Article 13, Administrative Measures for Drug Registration (2002)
[468] Musungu, S and Oh, C (2005), 'The Use of Flexibilities in TRIPS by Developing Countries: Can They Promote Access to Medicines?', p37.
[469] Musungu, S and Oh, C (2005), 'The Use of Flexibilities in TRIPS by Developing Countries: Can They Promote Access to Medicines?', p37.

pharmaceutical data protection.[470] Countries which do provide such protection mainly adopt a form of protection from unfair commercial use, using language similar to that provided in the TRIPS Agreement. Thus, China has adopted a much stronger standard of pharmaceutical registration data protection than other developing countries at comparative levels of development.

Nevertheless, China's implementation of of its data exclusivity provision has created great confusion and uncertainty. Chinese drug registration law provides a very ambiguous procedure for registration of data for protection. One of the key concerns here is the definition of 'new chemical entities' under Chinese data exclusivity law. The law does not define the term, 'new chemical entities', but provides that 'Application for new drugs refers to application for registration of drugs that have not been marketed within the territory of People's Republic of China.'[471] This creates great confusion about what qualifies as a new chemical entity and thus to data exclusivity protection under the Chinese registration law. In 2005, in the US-China Joint Commission on Commerce and Trade Medical Device and pharmaceutical Subgroup Pharmaceutical Task Force Meeting (JCCT), the US delegation requested clarification of this point. The PRC SFDA representative acknowledged that 'the definitions of fundamental terms have yet to be adopted' and 'more information on data protection is needed'. He also noted that there were three existing interpretations.

> There has been the suggestion that any chemical entity within two years of marketing should be considered a NCE [new chemical entity]. It has also been suggested that if a chemical entity has not been marketed in a country, it should be considered a NCE to that country. Then there is the opposite thought that DE [data exclusivity]. should

[470] PhRMA (2009), 'Pharmaceutical Research and Manufacture of American (PhRMA) Special 301 Submission ', p55.
[471] Article 12, 'Provisions for Drug Registration', SFDA Order No. 28 (PRC: SFDA).

apply to product first marketed in any market in the world, rather than first marketed in China.[472]

Based on the available information, the answer to this question remains uncertain. Since the US WTO delegation has repeatedly requested clarification at the JCCT meetings held in at least in 2005, 2006 and 2008,[473] and the powerful US lobbying group, the Pharmaceutical Research and Manufacturers of America (PhRMA), has continued to complain about the ambiguity of this term, including in its 2012 PhRMA Special 301 submission.[474]

The issue of what qualifies as a NCE has a profound impact on the scope and term of data exclusivity. If any chemical drug not previously been marketed in China can be registered as a NEC, this could lead to the extension of the scope of data exclusivity to non-NCEs. In fact, new indications of known drugs have been patentable as long as the claim is presented in the form of 'Swiss-type' claims in China.[475] Presumably, this type of drug can easily claim data exclusivity. In this sense, it would be possible for patent originators to enjoy between six to twelve years of data exclusivities. If data exclusivity is further employed to extend the protection of NCEs or even non-NCEs in China, the suppliers of cheaper generic alternatives from Chinese local firms will be serious affected, and as a direct consequence, public health.

[472] Ibid.
[473] These are three years when JCCT meeting reports were available to this research.
[474] PhRMA alleged that 'the current law is ambiguous as to how data protection is implemented. For example, certain key concepts such as "new chemical ingredient" and "unfair commercial use" are undefined', PhRMA (2012), 'PhRMA Special 301 Submission 2012', p28.
[475] Li, LT and Tai, TH (01/04/2009), 'Features of Swiss-type Claims', Managing Intellectual Property;

5.3.7 Patent registration linkage

A. A TRIPS-compliant or TRIPS-plus requirement linkage?

Patent registration linkage is seen as a mechanism to ensure that marketing approval of generic drugs will not be granted until the expiry of the relevant originator's patent.[476] The legal status of this mechanism is controversial. There are ongoing debates on the validity of patent registration linkage as a measure to enforce patent rights, particularly relating to pharmaceuticals. Research-based companies and their supporters have argued that Article 28 and Article 41 (1) of the TRIPS Agreement imply the concept of patent linkage.[477] They interpret these provisions as obligating national drug regulatory and patent offices to communicate with each other in order to ensure that applications for approval to market generic drugs are only authorised upon the expiration of relevant patents.[478]

In contrast, opponents have rejected the argument that the TRIPS provisions mandate the establishment of such patent registration linkage measures under national laws. Instead, they have viewed this patent linkage system as another TRIPS-plus measure and an additional barrier used to delay generic competition.[479] They have also warned

[476] Finston Consulting LLC (2006), *Overview on Patent Linkage*, www.finstonconsulting.com/version03/files/Overview.pdf, PhRMA Special 301 Submission 2007, p53, accessed on November 3, 2009

[477] 'What is the Patent registration linkage in Pharmaceuticals?' <http://www.lehmanlaw.com/resource-centre/faqs/health-sciences/what-is-the-patent-linkage-in-pharmaceuticals.html, accessed on November 3,2009.

[478] Finston Consulting (2006).

[479] Correa, C (2006), 'Implication of Bilateral Free Trade Agreement to Access to Medicines', Bulletin of the World Health Organisation 84 (5).

that the viability of compulsory licences would be undermined if national health regulatory bodies withheld the generic registration until the related patents expired.[480]

In reality, the obligation to link regulatory approval to patents varies in national jurisdictions. While some countries, like the US, China, Canada and Australia, have incorporated patent linkages into their national law, many others, including the EU, have not accepted it, without violating their obligations under the TRIPS. In fact, it is well-known that the EU has made use of the 'Bolar' provision to patent rights provided under Article 30 of the TRIPS. [481] The EU Directorate General for Competition (DGC) recently stated that: [482]

> Patent registration linkage refers to the practice of linking the granting of MA [marketing approval], the pricing and reimbursement status or any regulatory approval for a generic medicinal product, to the status of a patent (application) for the originator reference product. Under the EU law, it is not allowed to link marketing authorisation to the patent status of the originator reference product…. …Since the status of a patent (application) is not included in the grounds set out in the Regulation and in the Directive, it cannot be used as an argument for refusing, suspending or revoking …MA. ....patent-linkage is considered unlawful under Regulation (EC) No 726/2004 and Directive (EC) No. 2001/83.

Nevertheless, the patent registration linkage requirement, along with other TRIPS-plus measures, such as 'pharmaceutical data exclusivity' and 'patent term extension', has increasingly spread to more countries by means of terms imposed by entry into free trade agreements with the US.[483]

---

[480] Ermert, M (25/02/ 2009), 'Drug Patent Linkage Is Subject Of Court Case, Dispute In India', *IP Watch*. <http://www.ip-watch.org/weblog/2009/02/25/drug-patent-linkage-is-subject-of-court-case-dispute-in-india/> ,accessed on November 4,2009

[481] Sinha, S (11/10/ 2009), 'Storm over Drug-Patent Linkage after Court Rejects Bayer Petition', *Livemint.com & the Wall Street Journal*. http://www.livemint.com/2009/10/11205401/Storm-over-drugpatent-linkage.html, accessed on November 4, 2009.

482 Anonymous (2008), 'Pharmaceutical Sector Inquiry Preliminary Report', in EU DG Competition (ed.), p113,http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/preliminary_report.pdf, accessed on November 4, 2009.

[483] Correa, C (2006), 'Implication of Bilateral Free Trade Agreement to Access to Medicines'; Ermert, M (25/02/ 2009), 'Drug Patent Linkage Is Subject Of Court Case, Dispute In India';

B. The practice in other jurisdictions: Bayer v. UOI and Cipla

Recently, the divide between opponents and proponents of patent registration linkage was highlighted in the case of *Bayer* v. *UOI and Cipla*.[484] Bayer Corporation (Bayer) had filed a writ before the High Court of India in Delhi against Cipla ltd, the Drug Controller of India (DGCI) and the Union of India, seeking an order to restrain marketing approval of Cipla's generic version of Bayer's patented cancer drug Sorefanib (sold as 'Nexavar'). Initially, the court ordered an injunction to stop the DGCI from proceeding with Cipla's application for marketing approval. On appeal by Cipla, the appeal court reversed the decision and dismissed Bayer's petition, on 28 August 2009, on the grounds that there was no 'parliament-mandated' patent registration linkage system established in Indian law and that the DCGI had no authority or nor was it obliged to use patent policing powers in the process of marketing authorisation. The appeal court also criticised Bayer for trying to 'tweak public policies through court mandated regimes'.[485] This case could contribute significantly to the jurisprudence on patent registration linkage in India if no further appeal is pursued or won by Bayer and Bayer does not seek a decision by the WTO Dispute tribunal.

C. Evaluation of the Chinese Patent registration linkage provision in relation to the Hatch-Waxman Act

Revisiting the Hatch Waxman Act

[484] The main content of the case brief is drawn from the Judgement, *Bayer* v. *UOI and Cipla,* , provided by an online article at http://www.ip-watch.org/weblog/2009/08/21/indian-high-court-rejects-bayer-complaint-for-patent-linkage. Further information concerning the case history is drawn from the press and will be referred to below.
[485] Judgement, *Bayer* v. *UOI and Cipla, p31*

Under US law, patent registration linkage is provided statutorily in the Drug Price Competition and Patent Term Restoration Act of 1984 (the Hatch-Waxman Act).[486] The Hatch Waxman Act requires that the FDA make publicly available a list of approved drug products with monthly supplements, titled 'Approved Drug Products with Therapeutic Equivalence Evaluations' and widely referred as 'the Orange Book'.[487] The two main aspects of this mechanism are highlighted below:

- **Assertion of non-infringement or invalidation:** Once a right holder of a New Drug Application (NDA) lists its patent in the database of the Orange Book, a generic company applying for marketing authorisation of the same drug is required to assert that the relevant patent listed in the Orange Book is somehow invalid or will not be infringed by its ANDA application.[488]
- **Automatic 30-month stay of FDA approval:** Once the generic applicant makes the said assertion, the patent holder should be notified and given 45 days to file an infringement suit. During the litigation, the relevant generic application, the ANDA, has to be frozen for 30 months with the FDA. [489]

The US application patent registration linkage system has generated a great deal of litigation in the US.[490] This is mainly because the system of automatic 30-month stay has been used as a scheme for brand-name companies to delay the entry of generic competition of their much more expensive, blockbuster drugs. When an ANDA from a

[486] *See* 21 U.S.C. § 355(j)(7)(A)(iii), available at http://www.law.cornell.edu/uscode/21/usc_sec_21_00000355----000-.html, accessed on December 7, 2009.
[487] See Orange Book Preface, at http://www.fda.gov/Drugs/DevelopmentApprovalProcess/ucm079068.htm, accessed on December 7, 2009.
[488] 21 U.S.C. § 355 (j)(5)(B)(iii), http://www.law.cornell.edu/uscode/21/usc_sec_21_00000355----000-.html, accessed on December 7, 2009.
[489] Ibid.
[490] Borecki, T (2001), 'The Hatch-Waxman Act and Abbreviated New Drug Applications '. www.law.washington.edu/casrip/symposium/.../1-Borecki.pdf; accessed on December 7, 2009; Finston Consulting (2006).

generic company is filed, the original drug company almost always sues the generic company for patent infringement.[491] This action triggers a 30-month stay of the ANDA application with the FDA without further proceedings. Moreover, a pioneer drug patent holder could list several patents in the Orange Book, including invalid patents,[492] or additional patents with minor modifications, in many cases, without regard for safety or efficiency.[493]

Much of the problem may be that the Hatch Waxman Act does not contain a mechanism for ascertaining the accuracy of the listing. While the Act allows all NDA applicants to list all patents that are part of their products reviewed by the FDA in the Orange Book; the FDA has no authority to check the validity of the listed patents.[494] Consequently, the brand-name company is free to choose any one or all of its multiple patents listed to file numerous lawsuits to delay the entry of the generic ANDA application through multiple 30-month stays.

To stop the abuse of the 30-month stay system, the Medicare Act of 2003 limits the use of the automatic 30-month stays to one. While this amendment improves the certainty for generic entry and minimises costly and wasteful litigation, it does not prevent brand-name companies from seeking other strategies to delay or block generic competition. For instance, it has been reported that some brand-name pharmaceutical companies have

[491] Maureen, R (2002), 'Beyond Hatch_Waxman: Legislative Action Seeks to Close Loopholes in U.S. Law that Delay Entry of Generics into the Market', *Cenear,* 80 (38), pp53-59.
[492] Finston Consulting (2006), p11.
[493] Maureen, R (2002), 'Beyond Hatch_Waxman: Legislative Action Seeks to Close Loopholes in U.S. Law that Delay Entry of Generics into the Market'.
[494] 'Hatch Waxman: A Work in Progress'.supra note 77.

even offered payments to generic companies to postpone the launch of their products for a certain period or until the patents expire.[495]

The Chinese system of patent registration linkage

There has been a great deal of harmonisation between the US and Chinese regulatory systems governing drug registration. As reviewed in Chapter 4, US-based pharmaceutical companies had vigorously lobbied the US government to press China to reform its pharmaceutical legislation to conform with the US model in the 1990s. The introduction of the patent registration linkage mechanism was one feature included in such Chinese reforms. A Chinese SFDA representative has suggested that Chinese legislators were following the recommendations of PhRMA when they first introduced a patent registration linkage system in 2002 under Articles 11 of the newly promulgated Administrative Measures of Drug Registration as well as when it was updated in 2007 in Article 18.[496] The following are its main elements:

- **Assertion of non-infringement**: the law requires that all generic applicants have to issue a statement of non-infringement of any existing patents.

- **SFDA database:** the SFDA is obliged to publish the information of all reviewed and approved registrations and the statements of non-infringement from generic applications.

- **Injunction procedure for patent disputes**: the law provides that any patent disputes occurring relating to drug registrations should be settled in accordance with relevant

[495] Maureen, R (2002), 'Beyond Hatch_Waxman: Legislative Action Seeks to Close Loopholes in U.S. Law that Delay Entry of Generics into the Market'.

[496] This was suggested by Zhang Wei, a representative of SFDA to the US-China Joint Commission on Commerce and Trade Pharmaceutical and Medical Device Subgroup: pharmaceutical Task Force, see the minutes of the meeting dated on April 8-9, 2008, available at www.trade.gov/td/health/jcctpharma04-08summary.pdf, accessed on December 8, 2009.

patent laws or regulations. Article 66 of Chinese patent law (2008) provides a pre-litigation injunction procedure for patent disputes.

Table 5.4: Comparison of features of patent registration linkage under the US and Chinese systems

	US	China
Relevant statute(s)	Hatch Waxman Act	-Regulation on Drug Registration (Article 18) - Provisions under the patent law (Article 66)
Methods of linking generic approval to patents	Orange Book Accession of non-infringement or invalidation (Paragraph IV Certification)	SFDA database Accession of non-infringement
Procedure in case of patent disputes	Automatic 30-month stay of FDA approval	Resorting to the procedure under the patent law: pre-litigation injunction

Table 5.4 above summarises the main features of patent registration linkage in the US and China. The two systems have similarities as well as differences. The Chinese system shares a framework similar to that established under the US Hatch Waxman Act, and both systems maintain two similar tracks of patent registration linkage measures, i.e., publication of drug registration information and ownership declarations. The differences are outstanding and significant, particularly concerning procedures to resolve patent disputes occurring during the process of drug registration. In the US system, the FDA directly applies an automatic 30-month stay in response to allegations of infringement. As mentioned above, this mechanism is now only allowed to be used once against the alleged infringing act, and the rights holder involved must file the case within 45 days.

Under the Chinese system, the drug administration law does not establish a direct legal solution for the patent dispute occurring during the drug registration. Instead, it directs claimants to the special process provided under the patent laws. Article 66 of Chinese patent law provides a pre-litigation injunction for right holders to prevent possible and unrecoverable damages caused by infringements that are occurring or imminent. The provision orders the suspension of the alleged infringement acts upon the filing of a complaint detailing the allegations and requesting an injunction.[497] However, in contrast with the stricter US rules, there is no time limit on the suspension period or on the injunction applicant's pursuit of its case in the courts. Nor are there measures to prevent repetitive litigation relating to the same act. Furthermore, Chinese patent law allows two-years for initiating legal proceedings against an alleged infringement.[498] Thus, Chinese law gives originators several legal advantages that help them gain more time to prevent generic rivals from entering the market, whether their patents are valid or not.

Finally, Table 5.5 below summarizes the development of the special patent provisions most relevant to medicines under the four versions of Chinese patent law in relation to the TRIPS standards. It is observed that China opted to exceed the TRIPS minimum standards in implementing TRIPS in its 1992 and 2000 patent reforms. This TRIPS-plus approach toward pharmaceutical patents was very problematic from a public health policy perspective. Yet, the 2008 Chinese patent reforms revealed a policy shift in favour of utilizing TRIPS flexibilities. China's experience may reflect its inexperience with IPR matters as well as a traditional trial and error approach towards new law and policy.

[497] Article 66, Chinese Patent Law (2008).
[498] Article 68, Chinese Patent Law (2008).

Table 5.5: The use of TRIPS flexibilities in Chinese legislations in relation to TRIPS provision

Mechanism	Applicable Chinese legal sources	Chinese provisions	TRIPS provisions
Local working requirement, see table 3 for other elements under compulsory license	1984 Chinese patent law Art 51 &52 1992 Chinese patent law 2001 Chinese patent law 2008 Chinese patent law Art.48.1	Yes, 3 yrs from grant No No Yes, 3 yrs from grant, 4 yrs from application	To be authorised by Paris Convention (Art5 A (1) No direct prohibition in TRIPS Jurisprudence from EC-Canada, WTO case indicates member is free to adopt such provision [499]
Exhaustion doctrine	1984 Chinese patent law ,Art.62.1 1992 Chinese patent law, Art.62.1 2001 Chinese patent law, Art.63.1 2008 Chinese patent law, Art.69.1	National exhaustion National exhaustion National exhaustion International exhaustion	Article 6 of TRIPS Para 5 (d) of Doha Declaration.
Selected Exceptions from patent rights	1984 Chinese patent law, Art 62.5 1992 Chinese patent law, Art 62.5 2001 Chinese patent law, Art 63.4 2008 Chinese patent law Art 69.4 &5	Experiment exception Experimental exception Experimental exception Experimental exception + early working exception	Art. 30,
Selected exceptions from patentability	1984 Chinese patent law, Art.25.3 &5 1992 Chinese patent law, Art.25.3	Pharmaceutical products + methods for diagnosis and for the treatment of diseases, but **new medical uses** can be patentable if claimed by 'Swiss formula' approach	No specification, members are free to decide the patentability for new medical uses invention Free to adopt Swiss-formula approach [500]

[499] UNCTAD-ITCSD (2005), 'Resource Book on TRIPS and Development', p482.
[500] UNCTAD-ITCSD (2005), 'Resource Book on TRIPS and Development', p357.

	2001 Chinese patent law, Art.25.3 2008 Chinese patent law, Art.25.3	methods for diagnosis and for the treatment of diseases, **but new medical uses** can be patentable if claimed by 'Swiss formula' approach Same as the above Same as the above	
Data protection	Regulations for Implementation of the Drug Administration Law(2002), Art 35 'Measures on the Administration of Drug Registration Provisions for Drug Registration' (2007), Art.20	6 yrs data exclusivity for NECs 6 yrs data exclusivity for new medical uses	Data protection against unfair competitive practices, no specification about the duration of protection

5.4 Special issues: utility models for pharmaceutical inventions?

A Utility Model (UM) is a form of IP that is not covered by the TRIPS Agreement. It is a flexible mechanism lying outside the Agreement.[501] WTO Member countries, therefore, have legislative freedom to decide whether to provide such models of protection. Those who do recognise this model do not need to conform to the disciplines contained in the TRIPS Agreement[502] and enjoy considerable autonomy to design and execute this form of protection.[503]

Therefore, UM is one of only a few areas of IP subject matter where developing countries might be able to exercise meaningful legislative discretion in the TRIPS era. China has adopted UM in its patent law. In fact, UM has been intensively used by domestic innovators. Since 1985, of the three forms of Chinese patents, most domestic applications filed and granted were for UM patents.[504] This trend is also reflected in the pharmaceutical technical field. The survey conducted for this thesis has found that the number of domestic applications and grants for UM patents far exceeded that for invention patents since the introduction of the patent system. During the period from 1987 to 2006, Chinese inventors filed 75,912 applications for 'invention' patents with only 15,590 granted and 93,173 applications for 'UMs' with 66,962 granted, a much greater percentage of successful submissions.[505]

---

[501] WIPO 'Advice on Flexibilities under the TRIPS Agreement', <http://www.wipo.int/ip-development/en/legislative_assistance/advice_trips.html>, accessed on May 31, 2010.
[502] Correa, C (2007), *Trade Related Aspects of Intellectual Property Rights: A Commentary on the TRIPS Agreement* (New York: Oxford University Press Inc.), p36.
[503] UM is recognised under the Paris Convention, but this treaty allows the members considerable flexibility to develop and enforce their own national patent law.
[504] Yang, HJ (2008), 'Examination And Approval Of Patent Applications', in JC Wang, et al. (eds.), *Guide to the Newly Amended Patent Law* (Beijing: State Intellectual Property Office Press),. p258,in Chinese.
[505] See the survey presented by the empirical studies in Chapter 7.

For the Chinese government to realize its policy of promoting and protecting public health, it is important for it to consider the potential impacts of the existence of 66, 962 UM pharmaceutical patents on access to medicine in China. This section evaluates the appropriateness of applying this model of IP protection to pharmaceuticals in China.

5.4.1 Main characteristics of the UM system

The UM is a patent-like exclusivity right that allows a rights holder to prevent others from commercialising the protected invention without the rights holder's consent for a limited period of time. However, a right under the UM system differs from a patent in the following significant aspects: (1) The requirement for acquiring a UM is less stringent than for a patent, for UM applications the bar for 'inventive step' or 'non-obvious' is always lower; (2) The term of protection for UM is considerably shorter than that for patents; (3) The registration of UM is not only cheaper but faster than patents due to low costs and no requirement for examination in most countries where UM protection is available; (4) UM is considered particularly useful for SMEs that make minor and adaptive innovations to mechanical products.[506]

The TRIPS Agreement neither obliges nor limits the legislation of UM in member states, the provision of UM protection is subject only to the national treatment obligation established by the Paris Convention (Article 1 (2)).[507] In practice, UM is not provided as a standard feature within the intellectual property regime in many countries. It is currently available in approximately 70 countries. While countries such as the United

[506] WIPO, 'Protecting Innovations by Utility Models', <http://www.wipo.int/sme/en/ip_business/utility_models/utility_models.htm>, accessed on September 2, 2009; Correa, C (2007), *Trade Related Aspects of Intellectual Property Rights: A Commentary on the TRIPS Agreement, p36.*

[507] Correa, C (2002 d), 'Protection and Promotion of Traditional Medicine - Implications for Public Health in Developing Countries ', (Geneva: South Centre), p36.

States, the United Kingdom and Canada do not provide 'UM' protection; it is available in other equally significant countries like Germany, France, Italy and Japan etc.[508]

UM has been adopted under the Chinese patent law since 1984. The law does not specify patentable subject matters but stipulates in a general manner: 'this law is enacted to protect patent rights for inventions-creations….,' and 'In this law, inventions-creations means inventions, UM and designs.'[509] However, the implementation rule defines that 'UM' refers to any new technical solution relating to the shape, the structure, or their combination, of a product which is fit for practical use. The duration of a UM patent is 10 years from the date of filing or the priority date.[510] UM applications are subject to only a preliminary examination which simply requires compliance with formalities.[511]

5.4.2 The benefits of the UM system

UM is perceived as a cheaper and faster alternative to protect IP rights than patent, given its advantages in terms of registration cost and procedure.[512] It is also suggested that UM is of particular interest to developing countries, given that the innovation taking place there tends to be small, incremental and cumulative in nature.[513]

---

[508] Suthersanen, U, Dutfield, G, and Chow, K (2007), *Innovation without Patents: Harnessing the Creative Spirit in a Diverse World* (Cheltenham: Edward Elgar Publishing Ltd.),p19; WIPO, 'Where can UMs be Acquired?',http://www.wipo.int/sme/en/ip_business/utility_models/where.htm, accessed on September 8,2009.
[509] Articles 1.2 of the 2008 Chinese Patent Law. http://www.sipo.gov.cn/sipo2008/zcfg/flfg/zl/fljxzfg/200812/t20081230_435796.html, accessed on September 9, 2009,in Chinese
[510] Article 42 of the 2008 Chinese Patent Law.
[511] Article 40 of the 2008 Chinese Patent Law.
[512] Königer, K (2009), 'Registration without Examination: the Utility Model - a Useful Model? ' in W Pyrmont, et al. (eds.), *Patents and Technological Progress in a Globalized World: Liber Amicorum Joseph Straus* (Berlin: Springer).
[513] Suthersanen, U. (2006), 'Utility Models and Innovation in Developing Countries', *UNCTAD-ICTSD Project on IPRs and Sustainable Development*, p8.

The Chinese pharmaceutical industry has become one of the world's largest producers of active pharmaceutical ingredients (APIs).[514] However, its capability to innovate is still very limited. Few drugs are discovered and developed by domestic industry despite the recent boom of patenting activities. More than 95% of the drugs produced by the domestic industry are generic and me-too versions of drugs.[515] A lack of financial resources is one of the major obstacles to the new drug discovery in China. Considering financial constraints and the general low technical level of the domestic industry, it is expected that the majority of its R&D activities will fall into the types of minor and incremental innovation. In this context, UM might provide a useful economic incentive for individual businesses to engage in more incremental innovation. The successful commercialisation of UM patents can help the industry to expand revenue that can potentially improve the funding capability for the higher level of R&D in the further. From a public health perspective, minor or incremental therapeutic advances may also increase the value of a drug and hence yield health benefits to customers or patients.[516]

5.4.3 Uncertainties of UM system

Once granted, UMs benefit from the same exclusivity rights as invention patents. The existence of such large numbers of pharmaceutical UMs in China is certain to affect the costs of medicines and competition. Consequently, there is a need to examine the validity of the application of UMs to pharmaceuticals in China. This subsection investigates several policy issues relating to the operation of Chinese pharmaceutical UMs.

---

[514] Grace, C. (2005), 'A briefing paper for DFID: Update on China and India and access to medicines', in FDID (ed.), (London: DFID), p10.
[515] Luo, Y (2008), 'China: Current trends in pharmaceutical drug discovery', *IDrugs*,11 (4), p279.
[516] Palit, P and Bhattacharya, B (2008), 'Does intellectual property law in India and China encourage innovation?' *Journal of Japan Intellectual Property Association* 4(3), p83.

A. Is UM sufficiently low-priced in China?

The UM system is generally conceived as offering an inexpensive and manageable model of IPRs to protect the 'petty innovations' of individual researchers and Small Medium Enterprises (SMEs). A recent study reveals that a UM patent is not necessarily much less costly than an 'invention' patent in Germany where a UM system is well-established.[517] Is this also the case in China? Table 5.6 sets forth the fees charged by the SIPO applicable to both invention and UM patents. It shows that there is not a significant difference in the administration fees for UM and invention patents. In addition, the application for UM requires the same structure as that for an invention patent, which suggests that drafting and preparation burdens will not significantly influence an inventor's decision between applying for a UM or an invention patent.

Table 5.6 Charges for application for Invention and UM patents

(Currency: Chinese Yuan)

Items	**Invention**	**UM**
Application fee	900	500
Renew fee: 1-3 months	900	600
4-6 months	1200	900
7-9 months	2000	1200
10-12 months	4000	2000
Registration, printing & stamp duty	255	205
Each claim additional to the 10th claim	150	150

Source: SIPO patent fee check list, available at
http://www.sipo.gov.cn/sipo2008/zlsqzn/sqq/zlfy/200905/t20090515_460473.html

[517] Königer, K (2009), 'Registration without Examination: the Utility Model - a Useful Model?' pp25-26.

B. What is the quality of the pharmaceutical UM in China?

Under the Chinese UM protection process, inventions are not substantively examined, hence they tend to be very vulnerable to invalidation challenges.[518] A revision of Chinese patent law in 2000 introduced a provision by which UM rights holders may request SIPO to issue 'a search report' relating to the validity of a UM if they are involved in infringement disputes in a court or administrative agency.[519] Nevertheless, this procedure cannot guarantee the quality or the level of inventiveness of the UM.[520] It is reported that a major cause of the high patent invalidation rates relates to UMs and that 95% of revocation requests have been filed against UM patents, and more than 60% of cases have resulted in the nullification of the UM right.[521]The poor quality and endurance rate of many UM patents indicates that this model may not be an appropriate form of IP protection for pharmaceutical products to help China realize its policy of promoting and protecting public health.

C. Is the UM system an appropriate form of protection for pharmaceutical inventions?

Since a 'Utility model' right applies to a minor technical improvement relating to the shape, structure, or their combination, of a product patented under the Chinese patent law,[522] it is unlikely that a pharmaceutical UM will greatly benefit patients. In practice, the management and regulators interviewed for this thesis testified that it is not difficult to obtain a Chinese UM protection for the improvement of the shape of the

[518] Law360 (June 10, 2009), 'Real and Present Danger: Patent Litigation In China'. www.law360.com, accessed on August 8, 2010.
[519] Article 57, the 2000 Chinese Patent Law
[520] Chow, KB, et al. (2007), 'China and Taiwan', p162.
[521] Ibid, p163.
[522] Rule 2.2 of Implementing Regulations of the Patent Law of the People's Republic of China

pharmaceuticals.[523] In these cases, the therapeutic contributions of UM rights to the state of the art are rather limited.

From a public health perspective, therefore, UM rights do not confer any real benefits. They can raise the prices of medicines in the same way invention patents do in China. As one form of Chinese patent rights, the UM enjoys the exclusive rights that allow the rights holders to prevent others from commercially using the protected invention, without their authorisation, for ten years.[524] This enables the rights holders to adopt monopoly prices over the products commercialised successfully from UM inventions. In China, despite the adoption of a national price-containing policy since 1996 aimed at controlling expenditures on healthcare products,[525] patented medicines, produced domestically or imported, are excluded from the drug price list issued by the National Planning Commission.[526] Under the market principle, it is reasonable to assume that UM-based healthcare products can be priced as high as their monopoly position will support. Thus, the UM system may function as an additional obstacle for access to medicine in China.

A final issue surrounding UMs is the problem of infringement. There is a general consensus among IP practitioners that the Chinese UM system is heavily abused.[527] UM rights are allegedly granted to local 'inventors' for inventions imported from

523 Interview with Xiong Hui, Deputy Director of Sichuan Industrial Institute of Antibiotics Ltd, and Wang Cheng Pin, Head of the Department of Law and Regulation, Sichuan Food and Drug Administration.
524 Articles 11 & 42, the 2000 Chinese Patent Law.
525 Zhang, QQ (2008), *Intellectual Property Strategy and Practice in the Pharmaceutical and Biotechnological Fields* (Beijing Intellectual Property Rights Press), p261.
526 Zhang, QQ (2008), *Intellectual Property Strategy and Practice in the Pharmaceutical and Biotechnological Fields* , p263.
527 Mak, T (2011), 'Utility model and invalidation in China', The Journal of the Chartered Institute of Patent Attorneys, April.

overseas.[528] It is also alleged that the UM rights are frequently used as a guise of counterfeiting activities in China.[529] It is reported that 8% of over-the-counter medicines sold in China are counterfeit.[530] China is now regarded as a production centre of counterfeit medicines.[531] It is claimed that 'counterfeiters are now employing the UM and design patent system to claim protection for their modified versions of goods and products which are protected under foreign patents'.[532]

This subsection has addressed special issues concerning the suitability of the use of utility models rights for pharmaceutical inventions from a public health policy perspective. The issues addressed raised questions regarding the excessive use of the Chinese UM system in the pharmaceutical field. The investigation has found that the current procedures for pharmaceutical UM registration are not sensitive or tied to health issues in China. The UM is a flexible IP tool outside of the TRIPS Agreement and hence not confined by the principles of the TRIPS Agreement, and it is submitted that state policy makers could make better use of the legislative freedom available and adapt the UM system to balance both public health and other development interests.

[528] Chow, KB, et al. (2007), 'China and Taiwan', p162.
[529] 'While the terms "counterfeiting" and "piracy" do not follow a single agreed definition and are used in different ways, generally "counterfeiting" relates to the infringement of trademarks whereas "piracy" is associated with infringements of copyright or related rights.' Under the Article 51 of the TRIPS Agreement, counterfeiting only refers to trademark infringement, not patent infringement. See Matthews, D (2008), *The fight against counterfeiting and piracy in the Bilateral Trade Agreements of the EU* (Brussels: European Parliament), pp4-5.
[530] Matthews, D (2008), *The fight against counterfeiting and piracy in the Bilateral Trade Agreements of the EU*, p24.
[531] Morris, J and Stevens, P (2006), *Counterfeit medicines in less developed countries: Problem and solutions* (London: International Policy Network).
[532] Chow, KB, et al. (2007), 'China and Taiwan', p162.

5.5 Concluding remarks

The above evaluation of pharmaceutical patent standards in China has found that, until very recently, China had not exhibited sufficient legislative adaptability in developing its patent system to conform to government policies. It found that the design and application of the three criteria governing patentability may not be suitable for implementing China's policies of promoting both public health and local innovation. This was because the system provided a narrow novelty standard until recently, it also offered inventors an undemanding, low bar to cross to satisfy criteria required for 'inventiveness' and 'industrial application', and patent examination procedures were often lax.

Secondly, China's TRIPS implementation approach has limited its ability to implement its national public health policies. China has opted to interpret the TRIPS Agreement to provide a high level of protection for patents on pharmaceuticals. It has also implemented key TRIPS-plus patent provisions providing even stronger patent protections under bilateral trade agreements, and it abandoned or dismissed TRIPS flexibilities available to it under the TRIPS Agreement in its 1992 and 2001 versions of the patent law. Key TRIPS flexibilities have only been introduced in the recent patent reforms in 2008. It is uncertain whether or not these newly adopted TRIPS flexibilities can be effectively utilised for safeguarding public interests, given that various TRIPS-plus provisions are already established in the Chinese patent system. There will be a need to examine and reconcile any conflicting provisions.

Finally, China has not made maximum beneficial use of the utility model (UM), a system of creating flexible IP rights not covered by the TRIPS Agreement, in seeking to

achieve its policy goals. China has applied TRIPS' non-discrimination principle in designing and executing this IP subject matter. This policy has resulted in the patenting of remarkable numbers of pharmaceutical inventions either with trivial medical benefits or borrowed technology in China. Considering the therapeutic insignificance, negative impacts on drug prices, substantial legal uncertainties and costs associated with UM pharmaceutical inventions, this thesis suggests that policy-makers should check the application procedure and the validity of the UM system in the pharmaceutical technology field.

Chapter 6 Evaluation of pharmaceutical patent enforcement in China

International users of the Chinese patent system have widely criticized it for the inadequacy of legal enforcement of IPRs.[533] While the debate has centred on claims that Chinese enforcement procedures are not severe enough to deter violations, this chapter argues that the Chinese enforcement system has actually undertaken standards for pharmaceuticals beyond the minimum required by TRIPS and the system has also been hampered by loopholes facilitating abuse and over-enforcement. This section employs a legal assessment and a case study to illustrate this argument.

The first section of this chapter provides an overview of Chinese obligations in implementing TRIPS enforcement procedures; the second section engages in a legal assessment of the Chinese patent enforcement procedures regarding its compliance and inconsistency with the TRIPS Agreement. The assessment is based on the 'under-enforcement' allegations made by Pharmaceutical Research and Manufacturers of America (PhRMA), a major representative of US users of the Chinese pharmaceutical patent system. [534] In light of the allegations in question, a legal evaluation is carried out

[533] The US and the EU member countries allege that the inadequate enforcement system provides a safe harbour for a high level of counterfeiting and piracy in China. See the Council for Trade-Related Aspects of Intellectual Property Rights, Report to the General Council by the Chair: 'Transitional Review Under Section 18 of the Protocol on the Accession of the People's Republic of China, ' (IP/C/39 (Nov. 21, 2005)) & IP/C/50 18 November 2008).

[534] 'Under-enforcement' refers to failure resulting from either ineffective enforcement remedies or from the problematic execution of law with respect to deterring the infringement of conferred rights. This failure has often been deemed as the main cause for the prevalence of counterfeit medical products originating from China in both domestic and international markets .See Matthews, D (2008), 'The Fight Against Counterfeiting and Piracy in the Bilateral Trade Agreements of the EU', (Brussels: European Parliament), p24 & Morris, J and Stevens, P (2006), 'Counterfeit Medicines in Less Developed Countries: problem and solutions', (London: International Policy Network); PhRMA (2007), 'PhRMA Special 301 Submission 2007'; PhRMA (2009) , 'PhRMA Special 301 Submission 2009'.

on the legal provisions relating to administrative enforcement, criminal liabilities and their applicability to these claims. The third section looks at the Chinese enforcement procedure from the anti-abuse of patents' perspective. It focuses on the legal deficiencies of the newly introduced injunction remedy. Then, a case study on Eli Lilly's strategic litigation against Chinese generic competitors is provided to illustrate the point.

6.1 China's international obligations regarding the enforcement of pharmaceutical patents

In legal practice, the effectiveness of enforcement may be subject to different interpretations. In terms of the objective of the TRIPS implementation, however, national enforcement remedies are deemed to be 'effective' and 'adequate' if they are consistent with the Agreement's obligations.[535] Therefore, to assess the sufficiency of Chinese enforcement measures, the fundamental question is: what are China's obligations under the TRIPS framework?

Paragraph 1.2 of China's accession to the WTO Protocol [536] states that

> [t]he WTO Agreement to which China accedes shall be the WTO Agreement as rectified, amended or otherwise modified by such legal instruments as may have entered into force before the date of accession. This Protocol, which shall include the commitments referred to in paragraph 342 of the Working Party Report, shall be an integral part of the WTO Agreement.

[535] Correa, C (2007), *Trade Related Aspects of Intellectual Property Rights: A Commentary on the TRIPS Agreement* (New York: Oxford University Press Inc.), p1-2.
[536] WTO (2001), 'Accession of the People's Republic of China', (WT/L/432, 23 November 2001) (China WTO Accession Protocol).

Accordingly, China's international obligations concerning IPRs enforcement, including pharmaceutical patents, come from both the TRIPS Agreement and China's WTO Accession Protocol (including the Working Party report[537]). It is interesting to note that only a one-way set of commitments on the part of China was provided under both China's WTO Accession Protocol and the Working Party Report. This feature is in contrast with other international treaties which are presumed to provide a mutual balance between rights and obligations.[538]

- **TRIPS enforcement obligations:**

Part III of the TRIPS Agreement sets out detailed procedural standards of a civil, administrative and criminal nature, with aims to improve the adequacy and effectiveness of IPRs enforcement.[539] It provides provisions covering the general obligation (Article 41), the requirements concerning civil, administrative procedure and remedies (Articles 42-49), provisional measures (Article 50), and border measures (Articles 51-60), criminal procedures (Article 61), and transparency requirements (Article 63). These provisions are primary benchmarks to assess the adequacy and effectiveness of IPR protection in China.

- **Chinese commitments under the report of the working party**

Under the working party report, China has committed itself to broad, specific and detailed IPR enforcement obligations which are also under the WTO Accession

[537] WTO (2001), 'Report of the Working Party on the Accession of China ', (WT/ACC/CHN/49,1 October 2001) (The Report of the Working Party).
[538] Lei , JQ (2006), *The Enforcement of Intellectual Property Rights in China*, (London: Cameron May), p154.
[539] Dreier, T (1999), 'TRIPS and the Enforcement of Intellectual property Rights', in F Abbott, T Cottier, and F Gurry (eds.), *The International Intellectual Property System: Commentary and Materials* (The Hague: Kluwer Law International).

Protocol and the TRIPS Agreement.[540] In Section D, China confirmed it would effectively implement Articles 42 and 43 under judicial rules of civil procedure;[541] China promised to amend relevant rules to ensure full compliance with Articles 45 and 46 of TRIPS, and to ensure that damages paid by the infringer to the rights holder would be adequate to compensate for the injury suffered.[542] As far as provisional measures are concerned, China confirmed that its relevant provision under the Chinese patent law would be implemented and fully consistent with TRIPS Article 50.1-4.[543]

Most IPR enforcement measures have been introduced through administrative actions in China.[544] To respond to concerns expressed by members of the Working Party about the inadequacy of administrative sanctions, China committed to enhance its enforcement efforts, including through: (1) more effective administrative sanctions; (2) empowering the relevant the authorities to confiscate and seize evidence of infringement, such as equipment used for making infringed products, inventories and documents; (3) empowering the relevant authorities to impose sufficient sanctions to prevent or deter further infringement; and (4) transferring appropriate cases, including those involving repeat offenders and wilful piracy and counterfeiting, to the relevant authorities for prosecution under criminal law provisions.[545] China is also obliged to update its existing border measures to be fully consistent with Article 51-60 of TRIPS. Lastly, China confirmed that the relevant administrative authority would recommend the judicial authority to make the necessary adjustments to lower the thresholds so as to address the concerns of the Working Party.

---

[540] Lei , JQ (2006), *The Enforcement of Intellectual Property Rights in China,* p158.
[541] Para.291, The Report of the Working Party.
[542] Para, 292, The Report of the Working Party.
[543] Para, 296, The Report of the Working Party.
[544] Para, 297, The Report of the Working Party.
[545] Para, 299, The Report of the Working Party.

- **Chinese commitments under China's WTO Accession Protocol**

Under China' WTO Accession Protocol, China is required to provide information about the implementation of all of its commitments under the WTO Agreement and the Protocol.[546] In terms of its TRIPS obligations, China must first provide all amendments of its IPR laws in full compliance and with a full application of the TRIPS Agreement, and the protection of undisclosed information;[547] secondly, China must provide *'enhanced IPR enforcement efforts through the application of more effective administrative sanctions as described in the Report'* (italics added). [548]

The second provision explicitly states that China's commitment in enforcing IPRs is to establish stronger administrative remedies rather than criminal sanctions. This casts doubt over the US position concerning what constitutes China's full compliance in enforcement procedures. This has been a contentious issue between the US and China; while the former presses the need for stronger criminal and civil penalties regarding infringements in China, China responds that it has complied with TRIPS requirements through stronger administrative penalties.[549]

Upon its accession, China became bound by all of the TRIPS commitments that it confirmed under its Accession to the WTO Protocol and the Report of the Working Party. Numerous existing studies have demonstrated that the current IPR enforcement

[546] Article 18.1, China WTO Accession Protocol.
[547] Annex 1, VI (a), p17, China WTO Accession Protocol.
[548] Ibid.
[549] Annex 1A Pt. VI(b), in WTO (2001), 'Accession of the People's Republic of China', (WT/L/432, 23 November 2001).

procedures and remedies under Chinese IPR law have been harmonised in accordance with the requirements of the TRIPS Agreement and the Protocol.[550]

Yet, Chinese IPR enforcement continues to be criticised as inadequate and weak. In the context of pharmaceutical patents, PhRMA has been a prominent critic of the Chinese enforcement system. The following section examines the legal nature of Chinese enforcement process and remedies in light of PhRMA's allegations.

6.2 The enforcement problems with pharmaceutical patents: rights holders' perspectives

6.2.1 PhRMA's allegation

As the major representative of the US leading pharmaceutical research and biotechnology companies, PhRMA, has played a leading role in monitoring IP laws and practices as well as lobbying for legislative changes in China. The PhRMA submits annual reports, known as PhRMA Special 301 Submission Reports, to the US Trade Representative (USTR) with the list of its allegations and demands for legal changes concerning the Chinese IPRs and pharmaceutical regulatory systems. In its recent Special 301 submissions, while it acknowledges the efforts of the Chinese government in reforming the IPR system as well as the improvement of Chinese IPR operating environment,[551] PhRMA continually emphasizes its dissatisfaction with IP enforcement practice and some regulatory problems.

[550] Lei , JQ (2006), *The Enforcement of Intellectual Property Rights in China*, (2006), p217 & Guo, SK and Zuo, XG (2007), 'Are Chinese Intellectual Property Laws Consistent with the TRIPS Agreements?'. '

[551] PhRMA (2007), 'Pharmaceutical Research and Manufacture of American (PhRMA) Special 301 Submission 2007', p52, available at http://members.phrma.org/international/, accessed on 10 November 10, 2009.

The prevalence of counterfeit pharmaceuticals within and originating from China is one of the major concerns raised in the PhRMA Special 301 submission reports. It is claimed that PhRMA members lose approximately 10 to 15 % of their annual revenue to counterfeit products made in China.[552] Despite a series of actions to combat drug counterfeiting by the Chinese government, PhRMA believes that China is 'the world's leading exporter of counterfeit drugs and bulk chemicals'.[553] The 2009 report alleges that 'China is the country of origin for 80% of all counterfeit goods seized while entering the US.'[554]

The Pharmaceutical Research and Manufacturers of America identified the following major deficiencies with the Chinese IPRs enforcement system: [555]

- Administrative penalties lack deterrent effects.
- There is an imperative need for the administrative authorities to transfer more cases to the courts for the initiation of criminal liabilities.
- Excessive criminal thresholds are perhaps the most significant barrier to effective trademark enforcement.

Counterfeit drugs are a very serious threat to public health, and China is obliged to improve its enforcement measures if the problems have their roots there. In light of these allegations by PhRMA, the following section reviews relevant Chinese enforcement remedies, i.e. administrative enforcement and criminal liabilities, their

[552] PhRMA Special 301 Submissions 2004', available at http://members.phrma.org/international/resources/13.02.2004.586.cfm, accessed on November 10, 2009.
[553] PhRMA Special 301 Submissions 2007, p54. available at http://members.phrma.org/international/, accessed on November 10, 2009.
[554] PhRMA Special 301 Submissions 2009, p9 & p10.
[555] PhRMA Special 301 Submissions 2007, p54; PhRMA Special 301 Submissions 2009, p 42.

relationship to TRIPS obligations, and their applicability with respect to the IPR claims made by PhRMA.

6.2.2 Administrative enforcement and its deterrent effect

A. The prevalence of the administrative model of enforcement in China

Under Chinese patent law, there are two enforcement avenues provided for a patentee to enforce his patent rights .He may resort to judicial enforcement by filing a complaint to the People's Court, which has jurisdiction over the case. Alternatively, he may seek administrative enforcement by filing a complaint to the governing administrative authority for patent affairs. [556]

In legal practice, administrative enforcement is the first and most common form of enforcement in China.[557] Throughout most of the 1990s, infringement disputes were almost exclusively handled by the competent administrative authorities.[558] Despite the recent greater use of judicial enforcement, the administrative model of enforcement is still commonly used by both foreign and domestic patentees when enforcing their rights in China. Table 6.1 shows that the numbers of cases dealt with through administrative enforcement were seven times greater than those through judicial enforcement in 2004.

---

[556] Article 57, the 2001 Chinese Patent Law (2001); Implementation Regulations of the PLC (2001)
[557] 'Protect Your IPR in China: a practical guide for the US companies ', U.S. Department of Commerce International Trade Administration, available at http://www.mac.doc.gov/China/Docs/BusinessGuides/IntellectualPropertyRights.htm#CHINAS_IPR_ENFORCEMENT_SYSTEM, last accessed on July 28, 2010; Thomas, K (2007), 'The Fight against Piracy: working with the administrative enforcement system in China', in P Torremans, J Erauw, and HL Shan (eds.), *Intellectual Property And Trips Compliance In China: Chinese and European perspectives* (Cheltenham: Edward Elgar Publishing Limited). p86.
[558] Browning, T and Wang, C (2004), 'Ten years of enforcement in China ', *Managing Intellectual Property,* China IP Focus 2004, available at http://www.managingip.com/Article.aspx?ArticleID=1321688, accessed on July 29, 2010.

The use of juridical enforcement significantly increased in 2008, but the scale was still much smaller in comparison to that of administrative enforcement, although there are no available statistics relating to copyright administrative enforcement.

Table 6.1 Numbers of cases filed for administrative and judicial enforcement in 2004 and 2008

	Trademark Administrative enforcement	**Patent administrative enforcement**	**Copyright Administrative enforcement**	**Judicial enforcement**
2004	51851	1455	9691	8717
2008	56634	1126	not available	24406

Sources:
1) The 2004 data were taken from Table 4 in Thomas, Kristie (2007), 'The Fight against Piracy: working with the administrative enforcement system in China', p88.
2) The 2008 data were taken from 'White Papers on China's Intellectual Property Rights Protection', SIPO

B. The level of administrative sanctions

Given the prevalence of administrative enforcement in China, an adequate weight of administrative sanctions is essential for patent enforcement to be effective. Table 6.2 summarises the administrative sanctions established under the four versions of the Chinese patent law. Several observations can be made from a review of these statutes.

First, the early Chinese patent law only gave a vague outline of administrative sanctions on patent infringements. No detailed relevant procedural and remedial rules were provided under patent law and its Implementation Regulations in either the 1984 or 1992 patent laws. Considering the general inexperience of Chinese IP institutions, it is not hard to envisage the difficulties encountered when trying to use administrative enforcement in China under the early Chinese patent enforcement system.

Secondly, the legal reforms in 2001 and 2008 have arguably brought Chinese enforcement measures into conformity with the TRIPS requirements. In the 2001 Chinese patent law, the scope of infringing acts was more clarified; the amount of administrative penalties was specifically provided. However, the mild level of penalties may not bear a deterrent effect as required under Article 41 of TRIPS,[559] considering the consistent and rampant infringements in China. As far as patent infringement is concerned, the administrative penalty provided under the 2001 and 2008 Chinese patent laws only orders the infringer to stop the infringing act.

In the case of patent counterfeiting,[560] numerous penalties are provided under both the 2001 and 2008 revisions of the Chinese patent law. With respect to administrative penalties, Article 58 of the 2001 Chinese patent law authorised the confiscation of illegal earnings and an option to pay a fine on the illegal earnings of no more than three times the amount of these earnings; a fine of no more than RMB 50.000 was specified in cases where no illegal monies were earned. The level of administrative sanctions under the 2001 Chinese patent law was widely viewed as providing insufficient deterrence, considering the huge investment made in developing the products and the great potential for obtaining profits from the patented technology. [561] However, Article 63 of the 2008 Chinese patent law updated the amounts of the fine on illegal earnings from three times to four times the amount of the earnings. It also increased the amount of monetary penalties imposed in cases of non-existent illegal earnings of up to no more than RMB 200.000 Yuan. The deterrent effects of these new measures remain to be seen in the coming years.

---

[559] Article 41 of the TRIPS Agreement specifies that enforcement remedies shall provide a deterrent to further infringements.
[560]. Chinese patent law distinguishes patent infringement from patent counterfeiting while the TRIPS Agreement does not use the terminology of counterfeiting.
[561] Browning, T and Wang, C (2004), 'Ten years of enforcement in China '.

Thirdly, foreign users of Chinese enforcement systems, like PhRMA, have called for a greater use of criminal procedures and sanctions for patent infringements in China. Yet, China has insisted that addressing its enforcement problems through greater administrative or civil sanctions is consistent with its commitments made under its WTO Accession Protocol.[562] Moreover, the TRIPS agreement only requires the application of criminal sanctions to trademark and copyright infringements.[563] It can therefore argue that the PhRMA's pressure for a greater use of criminal enforcement in the patent area is a TRIPS-plus demand.

[562] Annex 1A, § VI(b). The Report of the Working Party.
[563] Article 61, the TRIPS Agreement.

Table 6.2: Administrative penalties under Chinese patent laws (CPL) in 1984, 1992, 2001 & 2008

CPL	Act of infringements	Acts of passing off patented products or process on one's own	Acts of passing off any non-patented products or process as patented products or process
1984	-To order the infringer to stop the infringing act -To compensate for the damage .(Art 60)		
1992	-To order the infringer to stop the infringing act -To compensate for the damage		
2001	- Order the infringer to stop the infringing act immediately - Civil action is provided. (Art 57)	-To order the rectification of the infringing act and the order is to be published -To confiscate the illegal earrings - To impose a fine of not more than **3** times his illegal earnings -To fine not more than RMB **50.000** Yuan , in case of no illegal earnings - To initiate criminal liabilities in case a counterfeiting act constitutes a crime, (Art 58)	- To order the rectification of the infringing act and the order is to be published -To fine not more than RMB 50.000 Yuan (Art. 59)
2008	- Order the infringer to stop the infringing act immediately - Civil action is provided. (Art60)	-To order the rectification of the infringing act and the order is to be published -To confiscate the illegal earrings (To be continued on next page)	(see the note below)

		-To impose a fine of not more than **4** times his illegal earnings -To fine not more than RMB **200.000** Yuan, in case of no illegal earnings -To initiate criminal liabilities in case a counterfeiting act constitutes a crime, (Art 64)	

Note: In the 2001 Chinese patent law, patent counterfeiting is categorized as 1) acts of passing off patented products or processes as on one's own, and 2) acts of passing off any non-patented products or processes as patented products or processes. However, the newly-updated 2008 patent law combines the above two types of act under a patent counterfeiting act. Chinese patent law distinguishes patent infringement from patent counterfeiting while the TRIPS Agreement does not use the terminology of counterfeiting.

6.2.3 Criminal liability and its deterrent effect

The PhRMA has objected to the threshold for Chinese criminal law to apply to patent violations. It has complained that China's threshold of criminal penalties is set too high to constitute a deterrent for infringing activities.[564] This section examines the legal sources of China's criminal law relating to the infringement of IPRs law and issues relating to threshold for the applicability of Chinese criminal liability.

A. Legal sources

Initially, criminal procedures and penalties for infringement of IPR rules were introduced under Article 127 of the Criminal Law of the People's Republic of China in 1979. The provisions were later updated in more detail under the revised Criminal Law of the People's Republic of China in 1997 (Criminal Law 1997).[565]

To facilitate better applicability of these legal provisions, China's Supreme People's Court and the Supreme People's Procuratorate jointly issued two legal interpretations in 2004 and 2007. They included: the 'Interpretation by the Supreme People's Court and the Supreme People's Procuratorate of Several Issues Concerning the Specific Application of Law in Handling Criminal Cases Involving Violations of Intellectual Property Rights' (2004 Interpretations on violating IPRs), and the 'Interpretation by the Supreme People's Court and the Supreme People's Procuratorate of Several Issues Concerning the Specific Application of Law in Handling Criminal Cases of violating Intellectual Property Rights (II)' (2007 Interpretation on violating IPRs). [566] The acts of

[564] PhRMA Special 301 Submission 2007.
[565] Lei, JQ (2006), The Enforcement of Intellectual Property Rights in China, p214.
566 Annex A-1, Executive Summary of the First Written Submission of the United States, WTO (2009), 'China – Measures Affecting the Protection and Enforcement of Intellectual Property Rights: Report of the Panel ', (WTO: Dispute Settlement Body).

violating IPRs are defined in Chapter III, Section 7, and are entitled 'Crimes of Violating Intellectual Property Rights'. According to Chinese legal practice, the legal interpretations from the Supreme People's Court (SPC) and the Supreme People's Procuratorate (SPP) have direct effects on the implementation of the law.

B. The threshold of Chinese criminal liabilities in relation to TRIPS

Criminal remedies against IP crimes have been at the centre of the criticisms about the inadequacy of Chinese enforcement provisions. Paradoxically, comprehensive criminal measures have already been provided under Chinese law. This section provides an overview of criminal measures in terms of the scope, content and standards in relation to TRIPS.

1. Scope:

Article 61 of TRIPS details obligations to provide for criminal procedures and penalties in some areas of the infringement of IPRs. The scope under this provision only includes cases involving infringement acts in the specific areas of trademark and copyright, i.e. trademark counterfeit and copyright piracy. Patents and other IPRs are not covered. Members are free to decide whether or not the same rule can be applied to other areas of intellectual property law.

Chinese Criminal Law 1997 specifies criminal offences against IPR and their punishment. [567] They include three types of trademark offences (passing off another's registered trademark, selling products bearing the counterfeit trademark, and illegally producing and/or illegally selling produced representations of a registered trademark)

[567] Criminal Law of the People's Republic of China was promulgated in 1979 and revised in 1997, available at http://www.cecc.gov/pages/newLaws/criminalLawENG.php.

(Articles 213–215), counterfeiting patents (Article 216), copyright infringement (Articles 217–218), and infringing on business secrets (Article 219). Thus, the scope of Chinese criminal procedure or penalties exceeds that required under TRIPS, i.e. for copyright and trademark, and it covers the areas of patents and business secrets as well.

It is important to note that China adopted criminal liability rules applicable to patents in its revised patent law of 2000. Article 58 provides that where any person passes off the patent of another person as his own and his infringement constitutes a crime, he shall be prosecuted for his criminal liability.

2. Content:

Under TRIPS Article 61:

(a) The second and third sentences of the provision specify that remedies must include imprisonment or monetary fines, while members may provide either measures or other criminal penalties to their own discretion.

(b) The judicial authority in 'appropriate cases', as stipulated in Articles 46 and 59, should be empowered to order the seizure, forfeiture and destruction of the infringing goods and of any materials.[568] It should be noted that the measure 'destruction of the infringing goods' is a quite strong sanction. It may lead to significant economic waste and might be socially unacceptable, especially in developing countries.[569]

Chinese criminal remedies are provided under both the Chinese Criminal Law and the Chinese patent law, including:

[568] Lei,JQ (2006), *The Enforcement of Intellectual Property Rights in China*, P213.
[569] UNCTAD-ITCSD (2005), 'Resource book on TRIPS and Development', p620.

(a) There are three types of sanctions provided under Article 216 of the Chinese Criminal Law: a fine, alone or in combination with criminal detention, or imprisonment for up to three years;

(b) Other forms of criminal procedures under TRIPS Article 61, such as the seizure, forfeiture and destruction of the infringing goods and other related subjects, are provided under the Chinese Criminal Law and other IPRs laws. In addition, Article 134 of the General Principles of Civil Law of the People's Republic of China also stipulates a variety of forms of civil remedies. Among others, it specifies that the people's court has the power to confiscate or forfeit the property used in carrying out illegal activities and the illegal income obtained thereby.[570]

(c) The 2008 amendment of Chinese patent law has added more forms of criminal procedure and penalties required by TRIPS Article 61. Specifically, Article 64 introduces measures such as evidence preservation, seizure or forfeiture, which may be applied to the proved counterfeit patent products.[571]

On the other hand, the remedy of the destruction of infringing goods is not provided in either the Chinese civil law or the Chinese patent law to date. Nor has such power been authorised under Chinese trademark law (2001).[572] Such omissions may suggest that China considers this measure to be wasteful and unacceptable socially and politically.

---

[570] General Principle of Civil Law of the People's Republic of China (1986), available at http://www.law-bridge.net/english/LAW/20065/1322572053247.html.

[571] The 2001 amendment of the Chinese patent law spelled out two types of patent infringing acts, namely 1) 'passes off the patent of another person', and 2) 'passes any non-patented product off as patented product or passes any non-patented process off as patented process'. However, under the 2008 amendment, these two types of patent infringements were combined as one termed as 'counterfeiting patent of another person'.

[572] In term of administrative sanction, China's copyright administrative authorities are empowered to order the destruction of the infringed copyright work by law. Article 39 of the Measures for

It is interesting to note that the recent US formal complaints against China under the WTO dispute settlement procedure were related to the measure of 'destruction of infringing goods', but only in terms of certain acts of trademark counterfeiting and copyright piracy. [573] The US alleged that the 'compulsory sequence' set under Chinese Customs provisions took away the authority of China's Customs to order the destruction or disposal of seized goods.[574] However, The WTO panel concluded that 'the United States has not established that the Customs measures are inconsistent with Article 59 of the TRIPS Agreement, as it incorporates the principles set out in the first sentence in Article 46 of the TRIPS Agreement'.[575] It also upheld some of the Chinese border measures, like the use of donations and sales,[576] noting that WTO members are allowed the flexibility to introduce additional measures beyond TRIPS.[577] However, the panel ruled that the measure of auction was insufficient for WTO requirements;[578] furthermore, the WTO panel recognised that China had extended protection to all forms of infringement, which is beyond the scope of the TRIPS agreement which only covers piracy and counterfeiting.[579]

3. Standard:

The TRIPS Agreement requires remedies to be sufficient as a 'deterrent' to infringement as well as consistent with 'the level of penalties applied for crimes of a

---

Implementation of Administrative Penalties Concerning copyright (2003), See note 41, Lei , JQ (2006), *The Enforcement of Intellectual Property Rights in China* , p202.

[573] WTO (2009), 'China – Measures Affecting the Protection and Enforcement of Intellectual Property Rights: Report of the Panel ', (Dispute Settlement Body). Note that this complaint only targeted on trademark and copyright areas.

[574] Para 3.1 (b), WTO (2009), 'China – Measures Affecting the Protection and Enforcement of Intellectual Property Rights: Report of the Panel '

[575] Para8.1(b) II, Ibid.

[576] The existing Chinese customs provisions allow border measures such as, to donate confiscated goods to charities, to sell them back to rights holders, or to auction them once the trademark infringing features have been removed, as alternatives to the destruction of confiscated goods. See Yu, Peter (2009), 'The US-China WTO cases explained', *Managing Intellectual Property.*

[577] Paragraphs 7, 323, 7.324 and 7.326, WTO (2009), 'China – Measures Affecting the Protection and Enforcement of Intellectual Property Rights: Report of the Panel ', pp68-69.

[578] Paragraphs 7.393, 7.394, Ibid, p81.

579 Yu, Peter (2009), ' The US-China WTO Cases Explained'.

corresponding gravity'. It does not specify the level of threshold of criminal liabilities that members have to meet in their national law. In practice, the establishment of criminal sanctions among members varies in their strength and scope. [580] For example, the US federal law applies criminal penalties and stiff civil remedies to acts of intentional counterfeiting.[581] Federal criminal penalties include:[582]

> (a) fines for individuals up to $2,000,000 ($5,000,000 for subsequent offences), or imprisonment not exceeding ten years (twenty years for subsequent offences),or both; and fines for corporations or partnership up to $5,000,000 ($15,000,000 for subsequent Offences); and (b) destruction of articles bearing the counterfeit mark.

The thresholds for criminal prosecution in China are provided under Article 216 of Chinese Criminal Law (1997), and 2004 Interpretations on violating IPRs and 2007 Interpretations on violating of IPRs from the Supreme People's Court and the Supreme People's Procuratorate. Article 216 reads as:

> 'Whoever counterfeits the patent of another shall,[583] if the circumstances are serious, be sentenced to fixed-term imprisonment of not more than three years or criminal detention and shall also, or shall only, be fined'.

Article 10 of the '2004 Interpretations on violating IPRs' further specifies the acts of patent counterfeit that are subject to criminal penalties in China as the below: [584]

> Any of the following acts falls under the definition of "counterfeiting patent of another person" stipulated in Article 216 of the Criminal Law: (1) Citing patent number on the commodities or the packing of the commodities one produces or sells without permission of the owner of the patent; (2) Citing patent number in advertisement or other publicity materials without permission of the owner of the patent so as to make people think that the involved technology is the patented technology of another person; (3) Citing patent number in contract without permission of the owner of the patent so as to make people think that the

[580] UNCTAD-ITCSD (2004), 'Resource book on TRIPS and Development'. P 620.
[581] Ibid.
[582] See note 151, in UNCTAD-ITCSD (2004), 'Resource book on TRIPS and Development', p620.
[583] The term 'patent counterfeiting' herein refers to the offence of misrepresenting counterfeit good as patented products even though the TRIPS Agreement doesn't use this terminology.
[584] SPC &SPP (2004) 'Interpretation by the Supreme People's Court and the Supreme People's Procuratorate on Several Issues of Concrete Application of Laws in Handling Criminal Cases of Infringing Intellectual Property', available at http://www.chinaipr.gov.cn/laws/laws/others/232859.shtml.

> involved technology in the contract is the patented technology of another person; (4) Counterfeiting or altering the patent certificates, patent documents or patent application documents of another person.

Article 4 of the '2004 Interpretations on Violating IPRs' establishes specific quantitative or monetary thresholds for punishing acts of patent counterfeit with criminal prosecution stipulated by Article 216 of the Chinese criminal Code.[585] The provision reads:

> Whoever counterfeits the patent of another person in any of the following circumstances and thus falls under the definition of "the circumstances are serious" stipulated in Article 216 of the Criminal Law shall be sentenced to fixed-term imprisonment of not more than three years or criminal detention and shall also, or shall only, be fined for committing the crime of counterfeiting the patent of another person: (1) the amount of illegal business volume being more than RMB 200,000 or that of illegal gains being more than RMB 100,000; (2) causing direct economic loss of more than RMB 500,000 to the owner of patent; (3) counterfeiting more than two patents, the amount of illegal business volume being more than RMB 100,000 or that of illegal gains being more than RMB 50,000; (4) other circumstances of a serious nature.

In addition, '2007 Interpretations on Infringement of IPRs' further provides:[586]

> People's Courts should decide monetary penalties on the basis of the illegal gains, the illegal business volume, the losses suffered by the right holder, and relevant harm to society etc. The amount of fine shall be established/ set between the range of one time and five times of the illegal gains, or between one half and one time of the illegal business volume.

Table 6.3 summarises the Chinese criminal procedures in relation to the TRIPS standards. It focuses on the criminal liabilities applied to patent infringement.

---

[585] 'The Interpretation by the Supreme People's Court and the Supreme People's Procuratorate of Several Issues Concerning the Specific Application of Law in Handling Criminal Cases of Infringement of Intellectual Property Rights (II)', in SPC & SPP (ed.), (2004:19), in Chinese available at http://www.court.gov.cn/sfjs/show.php?file_id=98384&key=%B7%A8%CA%CD, last access on December 15, 2009.

[586] Article 4, 'the Interpretation by the Supreme People's Court and the Supreme People's Procuratorate of Several Issues Concerning the Specific Application of Law in Handling Criminal Cases of Infringement of Intellectual Property Rights (II)', in SPC & SPP (ed.), (2007:6), in Chinese, available at http://www.chinacourt.org/flwk/show1.php?file_id=117517, accessed on September 25, 2010.

Table 6.3 Criminal Procedures under the TRIPS and Chinese law

(With a focus on criminal liabilities for infringing patent)

	Scope	Content	Standard
TRIPS	1.Trademark counterfeiting 2.Copyright piracy	1.Imprisonment and /or 2.Penalties 3.The seizure and forfeiture of infringing products 4. Destruction of infringing products	The remedies should 1. be 'sufficient to provide a deterrent' 2. be consistent 'with the level of penalties applied for crimes of a corresponding gravity'
Chinese laws	1. Passing off another's registered trademark 2.Selling products bearing the counterfeit trademark 3.Illegally producing/selling produced representations of a registered trademark 4.**Counterfeiting patent** 5.Copyright infringement 6.Selling infringing reproductions 7.Infringing on **business secret**	1. Imprisonment 2. Penalties 3. The seizure and forfeiture of infringing products	In case of **counterfeiting patent**, serious crimes shall be subject to 'fixed-term imprisonment of not more than three years or criminal detention and shall also, or shall only, be fined'. The seriousness of the crime is defined as in following circumstance: 1. the amount of illegal business volume being more than RMB 200,000 or that of illegal gains being more than RMB 100,000; 2. causing direct economic loss of more than RMB 500,000 to the owner of patent; 3. counterfeiting more than two patents, the amount of illegal business volume being more than RMB 100,000 or that of illegal gains being more than RMB 50,000; 4. other circumstances of a serious nature **The amount of penalties shall be set as**

			1.more 100% time and less than 500 % of the illegal gains, or, 2. more than 50% and less than 100% of the illegal business volume.

Sources: the legal sources referred are listed below:
(1) Criminal Law of the People's Republic of China.
(2) SPC& SPP (2004): the Interpretation by the Supreme People's Court and the Supreme People's Procuratorate of Several Issues Concerning the Specific Application of Law in Handling Criminal Cases Involving Infringement of Intellectual Property Rights
(3) SPC&SPP (2007): the Interpretation by the Supreme People's Court and the Supreme People's Procuratorate of Several Issues Concerning the Specific Application of Law in Handling Criminal Cases of Infringement of Intellectual Property Rights (II)

The above analysis of China's enforcement remedies in light of the PhRMA criticism has found some of PhRMA allegations to be warranted but not others. It has confirmed the allegation that China's administrative remedies appear to have insufficient deterrent effect for repeat offences. On the other hand, PhRMA's demand for a greater use of criminal liability in the patent area is viewed here as a TRIPS-plus standard. The discrepancy between the level of Chinese enforcement measures and PhRMA's expectations is foreseeable given their different interests in the interpretation of TRIPS rules. Nonetheless, the Chinese IPRs enforcement measures are deemed to be effective and adequate as long the provisions meet the minimum standards of the TRIPS Agreement, regardless whether foreign rights holders such as PhRMA argue that TRIPS minimum standards just provide a 'floor' rather than 'ceiling' for this implementation. Even so, the high level of counterfeit and piracy problems justifies the demand for the adoption of higher levels of enforcement than TRIPS minimum standards in China, but there may be other ways to accomplish this than by burdening the criminal legal system with endless criminal claims against individuals for violations of intangible property rights.

6.3 'Over-enforcement' of pharmaceutical patents in China: a pro-competition perspective

The interests of powerful Western pharmaceutical companies have ensured an intense scrutiny of the weaknesses in China's developing IPRs enforcement system. Meanwhile, other weaknesses that benefit those same interests have been largely ignored, such as the system's weakness in preventing abuses of the system. One of these abusive practices is an increasing misuse of the provisional enforcement procedure by originator

companies that aim to delay or impede generic competition in China. The typical result of such strategic litigation is that the originator company loses the case but wins 'the war' for strategic gains at the expense of the public and generic competitors. This thesis defines such a scenario as 'over-enforcement'. The following section illustrates this problem through an analysis of the preliminary injunction process in the Chinese enforcement system and a case study.

6.3.1 Pre-litigation injunction in China

Article 44 of the TRIPS Agreement requires state members to adopt procedures for the granting of a preliminary injunction as one of the mandatory enforcement measures. This measure enables the rights holders to seek judicial relief to stop any act infringing upon their IP rights at the earliest stage. This provision was first codified into the revised Chinese patent law under Article 61 in its 2000 amendment. The Chinese law uses the term, 'pre-litigation injunction'. Article 61 reads as follows:

> Where any patentee or interested party has evidence to prove that another person is infringing or will soon infringe its or his patent right and that if such infringing act is not checked or prevented from occurring in time, it is likely to cause irreparable harm to it or him, it or he may, before any legal proceedings are instituted, request the people's court to adopt measures for ordering the suspension of relevant acts and the preservation of property.

This provision has a lacuna when compared with Article 52.2 of the TRIPS Agreement; the measure of evidence preservation is omitted. To close this loophole, the Supreme People's Court (SPC) issued the SPC Stipulations on Preliminary Injunctions against the Acts of Infringement of Patent in June 2001. Article 16 provides that the People's Court may simultaneously preserve the evidence or preserve the property in accordance with the provisions of Articles 74, 92 and 93 of the Chinese Civil Procedure Law upon

application to the interested parties.[587] Consequently, provisional measures required by the TRIPS Agreement have been implemented into Chinese law.

The 2008 amendment has updated the existing provision under Article 66, which further clarifies the application procedures, such as the requirement for a security deposit from the petitioner, the 48-hour time limit for the court to make a ruling if it finds that all procedural requirements have been properly met, and the responsibility of the petitioner for any loss suffered by the respondent in the case of their mistake in requesting a motion for injunction.[588]

Both the 2000 and 2008 amendments strengthen the protection of rights without balancing it with safeguarding mechanisms against the misuse of this system. The imbalanced legal provisions, coupled with the inexperience of the Chinese courts in executing this novel measure, have often resulted in uneven playing fields between originator companies and generic manufacturers under the system. The following analysis will illustrate the legal loopholes of Chinese pre-litigation injunction through a case study.

6.3.2 A case study: Eli Lilly vs. Hansoh & SIPI

A. Case brief

In *Eli Lilly vs. Hansoh & SIPI*,[589] the plaintiff, Eli Lilly, is a multinational pharmaceutical company which has been operating in the PRC since 1993.[590] The

[587] SPC Stipulations on Preliminary Injunctions against the Acts of Infringement of Patent (2001) http://www.court.gov.cn/sfjs/show.php?file_id=37510&key=%B7%A8%CA%CD, in Chinese.
[588] Article 66, Chinese Patent Law (2008).
[589] Source: Judgment of the case *Eli Lilly and Company* vs *Hansoh Pharmaceutical Group & Shanghai Institute of Pharmaceutical Industry*, Chinacourt.org (Shanghai Supreme People's Court), available at http://ipr.chinacourt.org/public/detail_sfws.php?id=5657, in Chinese.

defendants were Hansoh Pharmaceutical Group (Hansoh) and Shanghai Institute of Pharmaceutical Industry (SIPI), two domestic suppliers of generic products.[591] The case continued through two trials, and lasted over four years, beginning on 15 May 2002, when Eli Lilly requested a pre-litigation injunction order against Hansoh & SIPI, to 13 October 2006 when the final judgment was announced.

Facts

- Eli Lilly and Company (Eli Lilly) obtained two patents, coded as ZL91103346.7 and ZL96192775.5 respectively, in China (hereafter referred to as 91 patent and 96 patent).[592]
- Hansoh Pharmaceutical Group and the Shanghai Institute of Pharmaceutical Industry (Hansoh & SIPI) were granted a New Drug Certificate and Production Authorisation for their Olanzapine raw material and tablets on 17 December 2001.

Procedure

- *Eli Lilly* believed that the preparation method of Olazapine and its use in clinical trials by *Hansoh & SIPI* had constituted an infringement against its 91 and 96 patents. Thus *Eli Lily* brought *Hansoh & SIPI* to the Shanghai Second Intermediate Court and requested the court to issue a pre-litigation injunction against *Hansoh & SIPI* on 15 May 2002. Eli Lilly filed a patent infringement lawsuit against *Hansoh & SIPI* with Shanghai Second Intermediate Court (the first instance court) in 26 June 2002.

---

[590] See 'Company history in China', at http://www.lillychina.com/china/1999year.html.
[591] See Hansoh's product profile at http://www.hansoh.cn/.
[592] The patent names were omitted here due to translation problems.

- On 24 November 2004, *Hansoh & SIPI* requested the Patent Re-examination Board (PRB) to invalidate *Eli Lilly's* 96 patent on the ground that its claims 1 to 8 and 10 lacked novelty and inventiveness.

- On 28 April 2005, *Eli Lilly* requested PRB to re-examine its 96 patent on the revised specifications which cancelled the original claims 1 to 8 and 10. PRB issued its decision to maintain *Eli Lilly*'s 96 patent based on its updated claim on 20 May 2005.

- On 25 November 2005, Shanghai Second Intermediate Court ruled in favour of *Hansoh & SIPI*, adjudicating that the technical features of the preparation methods for both Olanzapine raw materials and tablets are not covered by the scope of *Eli Lilly*'s patents claims. The decision cancelled the order of injunction against *Hansoh & SIPI*.

- *Eli Lilly* disagreed with the ruling and appealed to Shanghai Supreme People's Court (the appellate court). (It is noted that *Eli Lilly* withdrew the allegation in which it claimed the defendants infringed its 96 patent. This request was accepted by the court during the trial on 28 April 2005).

- The appellate court made the final judgment rejecting the appeal from *Eli Lilly* and maintaining the original ruling on 31October 2006.

Issues[593]

Did the court of first instance observe the procedure required for the issuance of a pre-litigation injunction strictly?

Has the court balanced the right holders' interests with those of the accused parties and the patients in its consideration?

Why did it take so long to cancel the injunction order?

Holding

Initially, Shanghai Second Intermediate Court approved the request for a preliminary injunction from *Eli Lilly* and granted a motion of suspension of production and marketing of Olanzapine raw material and tablets against *Hansoh & SIPI.*

Shanghai Second Intermediate Court adjudicated, on 25 November 2005 that the technical features of the preparation methods for both Olanzapine raw materials and tablets were not covered by the scope of *Eli Lilly'*s patents claims.

Reasoning

Concerning pre-litigation injunction, Shanghai Second Intermediate Court approved the request for a preliminary injunction from *Eli Lilly* on the ground that its application was in accordance with the law. *Eli Lilly*'s request for a motion was based on the claims that the defendants had completed the preparation needed to infringe *Eli Lilly'*s patents. They had applied for and obtained the production and market authorisation for the alleged infringing drugs from SFDA on 15 May 2002. *Eli Lilly* provided US$20,000 as guarantee for their request.

[593] This part of writing was drafted from the perspective of this research, rather than following the conventional writing formality of a case brief.

Regarding the verdict of the court of first instance, the technical examination was conducted by the IPR Division of the Science and Technology Department from 29 August 2003 to 21 October 2004. These results demonstrated that the technical features of the preparation method for both Olanzapine raw material and tablets are not covered by the scope of *Eli Lilly*'s patents claims.

The final decision by the appellate court was that the Shanghai Supreme People's Court adjudicated that the ruling from the first instance was in accordance with facts and legal procedure and thus upheld its decision, while rejecting the appeal from the appellant for lacking factual support.

B. Implications

1. Undue injury to the defendants and other social costs

As the below sales statistics show, *Eli Lilly* has greatly profited from its 1996 patent in the Chinese market before *Eli Lilly* itself cancelled the majority of the original claims of the patent (9 out of 10) upon the invalidation challenge in 2005. .On the side of *Hansoh & SIPI*, both the courts of first instance court and appeal ruled that the company's new products did not infringe the remaining one claim of *Eli Lilly*'s 1996 patent, the company eventually won the case but paid enormous costs. Their losses may include at least the following aspects:.

- The preliminary injunction delayed the market entry of its product by at least three years. In contrast, it is reported that Eli Lilly's related branded product (Zyprexa) enjoyed good sales in China during the period of litigation. *Eli Lilly* obtained sales

income of RMB Yuan (CY) 8,850,000, CY $ 80,430,000 and CY 150,220,000 in 2001, 2002 and 2003 respectively, and global sales amounted to over US $40 billion in both 2004 and 2005.[594]

- The first-mover business advantages previously possessed by *Hansoh & SIPI* might have already been lost when it returned to the market after the cancellation of the preliminary injunction. They might have bleak prospects of recouping their investment in given products.
- The total loss for *Hansoh & SIPI* is far beyond the compensation that could be provided by the guarantee of $ 20,000 *Eli Lilly* deposited when it requested the injunction order, compared with the profited obtained by *Eli Lilly* during the period of litigation.

What lies behind the economic loss of *Hansoh & SIPI* is the otherwise unnecessary cost that patients or governments have paid for Olanzapine (Zyprexa), *Eli Lilly's* patented medicine priced at an advantage of exclusivity. In this case, *Eli Lilly* effectively delayed the market entry of its generic competitors by resorting to two means: its weak patents, consisting mostly of invalid claims, and patent litigation including the injunction order.

It is important to note this case is just one of increasingly instances of litigation that *Eli Lilly* has recently launched against local generic competitors in China. *Eli Lilly* filed a series of injunction motions and legal proceedings against other local generic

[594] Xu, W (5 August 2008), 'Win the Case but not the Market', http://www.qxyc.net/html/23428.html,, in Chinese, accessed on November 20, 2009.

competitors, such as, Gan &Lee Pharmaceutical Ltd,[595] and Changzhou &Watson Pharmaceuticals Incorporated. [596] *Eli Lilly* lost its litigations against Gan &Lee Pharmaceutical Ltd at the first instance court the Beijing Second Intermediate People's Court and the second instance court the Beijing High court. The legal status of Eli Lilly's lawsuit against the Changzhou &Watson Pharmaceuticals is unclear so far due to the unavailability of the official documents. *Eli Lilly* is now known and cited for advice on how local firms can avoid becoming embroiled as victims of the abusive use of pre-litigation injunctions in China.

2. Loopholes of the Chinese injunction measures

To understand the legal origin of the over-enforcement problem in the above case, the following section reviews the terms of the Chinese injunction provision and their possible application to the case.

Relevant provisions under the TRIPS

Injunctive relief is one of the mandatory enforcement measures against any act of IPR infringements required under the TRIPS Agreement. Article 41.1 states the basic obligations and the conditions for establishing this measure. Article 50 provides procedural rules to guide legal actions against infringements that take place or are imminent (Article 50.3). A combined reading of these two provisions indicates that member states should adopt provisional measures under the following principles:

(1) Injunctive relief is one of the provisional measures established in national laws against any act of infringement on IPRs (Article 41.1). The judiciary

[595] See the ruling decisions at http://case.ipr.gov.cn/ipr/case/info/Article.jsp?a_no=236734&col_no=1390&dir=200809, accessed on September 25, 2010.
[596] The Supreme People's Court's Notification on the Jurisdiction appointed to the Patent Dispute between Eli Lilly and Company and Changzhou &Watson Pharmaceuticals, Incorporated. http://www.lawyee.net/Act/Act_Print.asp?RID=316644,There is a lack of access to the official documents about the progress of the case so far.

authorities should be empowered to use preliminary injunctions to prevent the occurrence of infringements against any IPR (Articles 50.1, 2 and 3).

(2) The application of injunctive measures also requires: 'These procedures shall be applied in such a manner as to avoid the creation of barriers to legitimate trade and to provide for safeguards against their abuse' (Article 41.1).

Injunctive relief under Chinese laws and judicial practice

Article 61 of the Chinese patent law governs preliminary injunctive relief in the Chinese system, but the provision is drafted in general and imprecise terms.[597] The detailed procedure for execution of such measure is specified through a Judicial Interpretation, 'Regulations of the Supreme People's Court on Certain Issues Concerning Pre-litigation Injunction against Patent Infringement' (2001: No. 20), issued by the Supreme People's Court (SPC) on 7 June 2001.[598]

Under the Chinese Regulations, it is rather easy for patent owners to obtain injunctive relief, and no requests for injunction orders by patent owners have been denied, at least in the early stage of the implementation of this system.[599] To obtain a pre-litigation injunction, the plaintiff is only required to satisfy certain formal procedures by presenting:

---

[597] Chinese laws are usually drafted in general and imprecise terms, and their implementation requires the further interpretations from various authorities. Three types of authoritative interpretations are provided under the Chinese legal system: legislative, administrative and judicial. Judicial Interpretations are provided by the Supreme People's Court and the Supreme People's Procuratorate, See Chen, JF (1999), *Chinese Law: Towards an understanding of Chinese law, its nature and development* (The Hague: Kluwer Law International), p106.

[598] 'Regulations of the Supreme People's Court on Certain Issues Concerning Pre-litigation Injunction against Patent Infringement', (2001) (China: SPC), available at http://www.court.gov.cn/sfjs/show.php?file_id=37510&key=%B7%A8%CA%CD, in Chinese, accessed on November 23, 2009.

[599] Zhang, GL(2001), 'Remedies for Patent Infringement: Comparative Studies of US and Chinese law', *John Marshall Review of Intellectual Property Law,* 1 (35), p58.

(1) Documentation of ownership and validity of the patent or patent licence agreements (Rule 4.1&2);

(2) Documents of evidence that demonstrate that that patent is being infringed or that infringement is imminent (Rule 4.3); and

(3) Payment of a sum of valid security (Rule 6).

Rule 9 requires the court to issue a written decision ordering the cessation of the alleged infringing act within 48 hours, if the application for such decision meets the requirements under Rule 4.1–4.3. The decision must be effected immediately. In addition, Rule 6 requires the applicants to deposit a reasonable and valid security. In general, the requirements for using this system may be no more than a mere formality.

The terms for obtaining a Chinese pre-litigation injunction make it rather easy for right holders to gain rapid injunctive relief. In comparison, the rules for obtaining a preliminary injunction in the US are deemed to be far more demanding and complex.[600] The key requirements are: (1) a reasonable likelihood of success in the lawsuit; (2) proof of irreparable harm if no injunction were issued; (3) the balance of interests of both parties; (4) a tolerable effect on the public interests.[601] It is apparent that the US preliminary injunction system has adopted a more difficult and balanced approach for patentee claims than the Chinese system does.

Returning to the case of *Eli Lilly vs. Hansoh & SIPI*, the plaintiff requested an order for a pre-litigation injunction in the Shanghai Second Intermediate Court on the following evidence:

[600] Zhang, GL (2001 & WJ (2012), ' Si, WJ (2012), 'The Pre-litigation Injunction to Cease Patent Infringement Law in China ', (DeBund Law Offices) '

[601] 7 Donald..S. Chisum, Chisum on Patents § 20.04, at 659 (2000) cited in Zhang, GL (2001);.

(1) Documentation alleging that the preparation method of one of the defendants' new products might have violated its Chinese patents.
(2) A claim of imminent and irreparable injury on the ground that the defendants had obtained the licences for manufacturing and marketing the alleged products
(3) The plaintiff had paid security of US$20,000 as a guarantee.

The report of the *Eliy Lilly* decision does not describe the legal procedure used nor contain the reasoning behind the court's decision to approve Eli Lilly's application for the injunction. However, the case history reveals that the majority of the patent claims Ely Lilly included in its application were later found to be invalid. Moreover, the amount of its security was manifestly insufficient in relation to the direct damages suffered by the defendant as a result of this action. As a policy matter, it is cause for concern when a decision by one of China's most highly regarded, competent and experienced courts can cause so much damage to a party because it is inhibited from exercising sound judgment by procedural rules effectively prohibiting discretion and demanding a rapid decision.

This case highlights several legal and policy deficiencies of Chinese injunction system. Firstly, the requirements for granting an injunction order are too vague and loosely defined and too readily met by applicants. The applicant is only required to state reasons rather than to prove the alleged irreparable harm. Secondly, the procedures for application or grant injunction are biased in favour of the convenience of rights holders and provide no proper consideration of the interests of the accused party. For example, there is no compulsory hearing before the decision is made, and the respondents are not

equal in the procedures and have no opportunity to submit evidence and refute the applicant's claims.[602] Lastly, there is a lack of measures to safeguard against patent abuses, such as limits on the length of an injunction, a required deadline for initiating the case in the court, and checks on filings of consecutive litigation against the same act. If the law and the court had adopted a more balanced approach, the injunctive order in this case may not have been issued or may have been granted on stricter terms that could have reduced defendants' damages.

Demand for technological development in the Chinese market has intensified frictions between right holders and their aspiring competitors It is likely that this will increase rights holders interest in using injunctions. In fact, Chinese courts now routinely grant pre-litigation injunctions. This enforcement measure is a drastic and extraordinary remedy. It restricts courts in their exercise of discretion in granting the injunction order in situations where judicial prudence is needed. The *Eli Lilly* case illustrates the serious need for additional safeguards in the Chinese system and for improvements to the courts' capabilities and discretion in making their decisions on issuing injunctions in a more balanced manner.

6.4 Concluding remarks

This chapter has found that the adequacy of Chinese enforcement measures differs from the conventional perception. In addition to its administrative remedies, Chinese law includes criminal liabilities for IP infringements covering not only trademark and copyright but also patents and trade secrets. This is a higher enforcement standard than required by the TRIPS Agreement. Chinese legal reforms to strengthen enforcement

[602] Si, WJ (2012), 'The Pre-litigation Injunction to Cease Patent Infringement Law in China ', (DeBund Law Offices).

have focused on toughening administrative sanctions. This approach is in line with the TRIPS rules and Chinese WTO accession commitment, and is therefore TRIPS-compliant.

On the other hand, the legal evaluation also found the system to be at risk of over-enforcement, particularly in the abusive use of the enforcement procedure known as the pre-litigation injunction measure. The legal 'loopholes' and the inexperience of the courts create room for manipulating the system. As the case of *Eli Lilly* demonstrates, this measure is now routinely used by and granted to originator companies to impede generic competition in China. This trend raises a great concern about China's capabilities in designing and implementing a pro-competition and pro-health patent system.

Chapter 7: Economic effects of TRIPS implementation on Chinese pharmaceutical innovation

This chapter moves from the foregoing legal evaluations to the second research question of this thesis: what effect has China's patent policy and law had on the development of domestic pharmaceutical innovation within China? To this end, it first assesses innovation performance of the domestic pharmaceutical industry during the past two decades. Then, it analyses the roles of patents and other government policies and economic factors on improving or impairing innovation in the Chinese pharmaceutical industry.

The chapter is organised into five sections. Section 7.1 analyses the strengths and limitations of R&D indicators used in innovation measurement. Section 7.2 assesses the newly emerged innovation capability in terms of its scale, level and research orientations in the Chinese pharmaceutical industry. Section 7.3 investigates the evolving patterns of FDI from the pharmaceutical MNCs following two major Chinese patent reforms. Section 7.4 discusses the roles of patents and other complementary factors in fostering local innovation. The last section of the chapter consists of some concluding remarks.

7.1 Measurement of innovation

Traditionally, innovation has been measured using two indicators: R&D expenditures and patent count. The R&D expenditure, together with numbers of R&D personnel, is used as a proxy for R&D input while patent count represents the direct output of

R&D .[603] The major advantages of using R&D expenditures and patents as indicators are that they are readily available, easily understandable, and have been, in general, consistently collected over time.[604] Also, these measurements provide a statistical answer to important questions relevant to policy choices, such as the allocation of resources in R&D, the priority or the balance between R&D choices, and the efficiency of research.[605] Thus, these indicators can be very useful for governments to assess the anticipated economic effects of their innovation policy and to help them define their policies for the future.

Yet, these traditional innovation indicators have the disadvantage of constraining policymakers' decision-making by reinforcing a linear model of innovation.[606] Under a linear model, innovation is understood as a straight line production process which 'starts with basic research, followed by applied research and development, and ends with production and diffusion'.[607] A new understanding of innovation has developed that recognises that innovation is not such a simple and straightforward process in which 'funding and research are invested here and innovation pops out there' [608] This current insight acknowledges that innovation involves complex and interactive processes

[603] CIPIH Studies (2005), '"Case Studies: developing innovative capacity in developing countries to meet their health needs"', (MIHR report to CIPIH, WHO Ref. CIPIH Study 10d (DGR)
[604] Comanor, W. S. and Scherer, F. M. (1969), 'Patent Statistics as a Measure of Technical Change', The Journal of Political Economy, 77 (3), 392-98; Anonymous (1997), 'Measuring Performance: Strengths and Limitations of Research Indicators', (United States General Accounting Office Report to Congressional Requesters).
[605] Godin, B (2008), 'The Making of Statistical Standards: The OECD and the Frascati Manual, 1962-2002', (Series on the History and Sociology of Science, Technology and Innovation Statistics, Working Paper No. 39), p5.
[606] Anonymous (2008), 'Policy Brief: Measuring Innovation ', (London: National Endowment for Science, Technology and the Arts).
[607] Godin, B (2006), 'The Linear Model of Innovation: The Historical Construction of an Analytical Framework', (INRS: Working Paper No. 30).
[608] Mahdjoubi, D (1997), 'The Linear Model of Technological Innovation: Background and Taxonomy ', (UTexas working paper).

involving multiple actors of involved in a productive system.[609] The productive system is commonly referred as the 'National Innovation System' (NIS), and it incorporates the entire body of policies, laws, infrastructure, and activities concerned with the creation, dissemination and utilisation of science and technology.[610] In addition, recent empirical studies have revealed other shortcomings of R&D indicators. For example, R&D expenditure data do not provide insights concerning the ability to convert R&D efforts into successful innovative products. [611] Moreover, patent data are inadequate for capturing innovation relevant to the modern economy for inventions that are not patented or protected under intellectual property rights law.[612] This has prompted policymakers to search for and develop new ways to measure innovation around the world.[613]

With the above caveats, R&D expenditures and patent counts should be used with caution in studies of innovation and developing innovation capacities. Nevertheless, the nature and pattern of innovation are often industry-specific; different industries innovate differently. Although patents and R&D spending may fail to measure innovation in many sectors, they are still widely deemed to be valuable innovation indicators for the pharmaceutical industry.[614] For pharmaceuticals, novel product design is the key to competitiveness so companies are highly motivated to engage in R&D in the industry.

---

[609] Johnson, B , Edquist, C , and Lundvall, B (2003), 'Economic Development and the National System of Innovation Approach ', (First Globelics Conference); Nelson, R (1993), 'National Innovation Systems: A Comparative Analysis', (New York:Oxford University Press)
610UN (2003), 'New Indicators for Science, Technology, and Innovation in the Knowledge-Based Society', (Economic and Social Commission for Western Asia, United Nations); Nelson, R (1993).
[611] USGAO (1997), 'Measuring Performance: Strengths and Limitations of Research Indicators ',(United States General Accounting Office).
[612] Ibid.
[613] Anonymous (2008), 'Policy Brief: Measuring Innovation ', (London: National Endowment for Science, Technology and the Arts). OECD (2005), 'Oslo Manual: Guideline for Collecting and Interpreting Innovation Data (3rd Edition)', (Paris: OECD).
[614] Anonymous (2008), 'Policy Brief: Measuring Innovation '

[615] On the other hand, there are potentially great risks and high costs involved in develop and testing new pharmaceutical chemical entities to satisfy national regulatory standards on safety and efficiency before they can reach the markets. To recoup R&D costs and generate a substantial profit, the industry therefore relies on patent law much more than most other industries.[616] Furthermore, the industry ia also inclined to take advantage of patent laws as tools to improve their competitive advantages against imitations and alternative products.[617] Thus, the pharmaceutical industry invests more money in R&D and is more interested in filing patents for their products than many other industries. Patent and R&D expenditure as indicators may capture the innovation of the pharmaceutical industry better than other sectors.[618] These reasons may explain why these two indicators are the main ones applied in the existing innovation studies on the industry.[619]

The research examined in this chapter focuses on the Chinese pharmaceutical industry. Contemporary China is one of the largest and fastest growing markets for pharmaceutical products in the world, and thus, it has become one of the principal FDI destinations for pharmaceutical MNCs.[620] As a result, competition for market share is intense for both foreign and domestic producers. The enhancement of patent protection and enforcement

---

[615] Odagiri, H, et al. (2010), Intellectual Property Rights, Development, and Catch-up (Oxford University Press), p421.
[616] Levin, R. C., et al. (1987), 'Appropriating the Returns from Industrial Research and Development ', Brookings Papers on Economic Activity, (Special Issue 3); Scherer, F.M. (2001) "The Patent System and Innovation in Pharmaceuticals", Revue Internationale de Droit Economique, (Special Edition, "Pharmaceutical Patents, Innovations and Public Health"), pp.109-112;
[617] Scherer, M and Weisburst, S (1995), 'Economic Effects of Strengthing Pharmaceutical patent Protection in Italy ', International Review of Intellectual Property and Competition Law 1995, (26).
[618] Anonymous (2008), 'Policy Brief: Measuring Innovation ', (London: National Endowment for Science, Technology and the Arts).
[619] For example, Scherer, M and Weisburst, S (1995), 'Economic Effects of Strengthening Pharmaceutical patent Protection in Italy ', International Review of Intellectual Property and Competition Law 1995, (26).; Lanjouw, J (2001), 'New Pills for Poor People? Empirical Evidence after GATT', World Development 29 (2); WHO/CIPIH (2005), 'Innovation in Developing Countries to Meet Health Needs: experiences of Brazil, China, India, and South Africa', (MIHR report, CIPIH Studies, 10d).
[620] Lippoldt, D (2006), 'Intellectual Property Rights, Pharmaceuticals and Foreign Direct Investment ', (Groupe d'Economie Mondiale de Sciences Po.); BMI (2008), 'China Pharmaceuticals & Healthcare Report ', (Q1; London: Business Monitor International Ltd).

rules in China has encouraged foreign companies to seek and enforce more and more patents there. The increased legal and technical challenges make it far more difficult for domestic players to compete, given their imitative nature in production and far weaker financial strength. To reduce these risks and sustain their vitality, many domestic companies have started to increase their R&D efforts to develop their own novel products.[621] Despite such effort, thus far they have mainly only managed to develop minor innovations, or 'me-two' or 'me-better' drugs. Nevertheless, their ability and inclination to use patents as competitive tools have become extraordinarily well developed. This provides another reason that the indicators of patent numbers and R&D expenditures remain very relevant measures to assist our understanding of innovation changes in the Chinese pharmaceutical industry.

7.2 The emergence of new innovative capability: scale and nature

The Chinese pharmaceutical industry has achieved remarkable growth in many aspects of its operations since 1990. Production and revenue have grown at an average rate of 25 % per year from 1995 to 2003.[622] The industry has become one of the world's largest producers of active pharmaceutical ingredients (APIs),[623] with its largest exporting markets in the EU, the US, India and Japan.[624] Moreover, its manufacturing sophistication has advanced so significantly that local firms have been manufacturing and exporting finished drugs to the US market since 2007.[625]

[621] Li, YH (2010), Imitation To Innovation In China: the Role of Patents in Biotechnology and Pharmaceutical Industries (Cheltenham: Edward Elgar).
[622] CIPIH Studies (2005), 'Case Studies: developing innovative capacity in developing countries to meet their health needs', (MIHR report to CIPIH, WHO Ref. CIPIH Study 10d (DGR)), p 62.
[623] Grace, C. (2005), 'A briefing paper for DFID: Update on China and India and access to medicines', in FDID (ed.), (London: DFID), p10.
[624] BMI (2008), 'China Pharmaceuticals & Healthcare Report ', (Q2; London: Business Monitor International Ltd), p42.
[625] Ibid. p28.

The harbingers of advanced local innovation have also emerged, particularly in the area of developing gene therapies in recent years. Chinese expertise in genomics, proteomics, stem cells, and other biomedical technologies has become particularly prominent at the international level.[626] For example, there are more than 30 clinical trials for gene therapies currently ongoing in China.[627] Also, in 2003, a Chinese company, SiBiono, successfully developed and commercialised the first gene therapy in the world for treating head and neck cancer. Furthermore, more gene therapy drugs, such as Oncine, Endostar and vaccines have also been developed and approved for marketing in China.[628]

Nevertheless, a few successes in developing gene therapies do not represent the *general* innovation performance of the Chinese pharmaceutical industry. There is insufficient knowledge available relating to the general state and nature of innovation change for the whole industry for the past two decades of apparently increasing innovation. The following investigations are therefore devoted to gathering relevant data as empirical evidence to fill this knowledge gap.

Survey 1: R&D inputs

Chinese pharmaceutical companies traditionally have engaged in the production of generic drugs and devoted few resources to R&D activities. Nevertheless, in recent years, this has started to change as a number of factors have aroused their interest in engaging in innovation. Such influences include increased market competition, patent

[626] Grace, C (2004), 'The Effect of Changing Intellectual Property on Pharmaceutical Industry Prospects in India and China: Considerations for Access to Medicines', (London: UK Department of International Development); Li, YH (2010), Imitation To Innovation In China: the Role of Patents in Biotechnology and Pharmaceutical Industries (Cheltenham: Edward Elgar),p30.
[627] Peng, ZH, Yu, Q, and Bao, L (2008), 'The Application of Gene Therapy in China', IDrugs,11 (5), 346-50.
[628] Li,YH(2010), pp34-35.

incentives, government initiatives, increased profits and a greater availability of talented researchers at their disposal. Table 7.1 below documents the R&D expenditures invested and research personnel employed by large and medium-sized domestic pharmaceutical companies and research institutions in China between 2001 and 2007.[629] Both sets of data were obtained from the China Statistic Year Books for the years 2000 to 2008. The relevant data were not available in the China Statistic Year Books prior to 2000.

The total amount of R&D expenditure invested by Chinese companies from 2001 to 2007 was 57466330,000 RMB, which is equivalent to 7.1 billion US dollars,[630] and the total number of research personal employed was 216,888. A general trend of rapid growth in financial inflow and in employment of technical engineers can be observed in terms of the aggregate numbers, despite the fact that the growth of R&D personnel in the years 2003 and 2004 was less. Most years saw a growth rate in double digits. The average growth in numbers of research personnel was at 14%, whereas the average increase in research funding was 42%. These growth rates clearly demonstrate the expansion of R&D investment in the local pharmaceutical industry during the period studied.

[629] Chinese National Statistic Year Books only cover information from large and medium-sized companies in the reports about the scale of economic activities of domestic enterprises. There are no explanations provided about the selected standards in the year books.
[630] The equivalent US amount was calculated at the exchange rate 8.07 by the date of January 1,2006.

Table 7.1: Domestic pharmaceutical R&D input from large and medium enterprises (2001-2007)

Years	R&D personnel (Unit: per person)	Annual growth rate of R&D personnel	R&D expenditure (Unit: 10,000 yuan)	Annual growth rate of R&D expenditure
2001	23542		243905	
2002	26139	11%	277383	14%
2003	25646	-2%	359326	30%
2004	22713	-11%	782073	118%
2005	30716	35%	1054835	35%
2006	39206	28%	1314779	25%
2007	48926	25%	1714332	30%
Average	216888	14%	5746633	42%

Sources:

1 Data were collected from the subsections 'Basic Statistics on Scientific and Technological Activities Funds of Large and Medium-sized Industrial Enterprises in High-tech Industry' and 'Basic Statistics on Scientific and Technological Activities Outputs of Large and Medium-sized Industrial Enterprises in High-tech Industry', National Statistic Year books from 2002 to 2008 , available at http://www.stats.gov.cn/english/statisticaldata/yearlydata/

Survey 2: R&D outputs

In this second survey, the numbers of patent applications are used as proxies representing the R&D output of local pharmaceutical innovators in China. Patent filing data provides not only good indications of the scale of innovative activities and the types of innovation,[631] but also conveys information about who is patenting what types of innovations in a country. Such information can be very useful to determine the scale and level of Chinese pharmaceutical innovation as well as its competitiveness in comparison with foreign innovative activities in China.

[631] Li, X (2008), 'Patent Accounts as Indicators of the Geography of Innovation Activities: problems and perspectives ', p2-3.

The objective of Survey 2 is to assess the scale of local innovative activities; however, the pattern of foreign patenting is also examined in order to compare foreign responses to Chinese patent law reforms with those of domestic players. The patent filing data were obtained from the Annual Statistic Year Books of the Chinese State Intellectual Property Office (SIPO) for the twenty-year period from 1987 to 2006. Although it would have been ideal to include in this evaluation the data for 1984, the year in which the first patent law was introduced into the country, the systems used to classify the statistics in the year books for 1985 and1986 were not compatible with the later system employed in the official gazettes and thus could not be used as comparables.

Table 7.2 below presents the data available on the numbers of domestic and foreign A61[632] pharmaceutical patent filings in China and their percentage growth rates from 1987 to 2006. The data has shown that during the period 1984 to 1992, although not surprising, there was an impressively large number of initial pharmaceutical patents filed by domestic applicants in response to the newly established Chinese patent system, but there were very few foreign applications. After 1992, the strong growth trend in the filing of domestic patents continued, and the absolute number of domestic patents filed increased very rapidly. The total number of domestic applicants was 46,780 from 1993 to 2000, nearly 3.7 times more than the total number of 12,692 in the earlier period of 1987 to 1992. By 2006, the total number of filed patents from domestic applicants was 155,566.

In contrast, during the period from 1987 to 1992, the foreign patent filings generally decreased, except for a small growth in 1992. After 1993, however, the general rate of

[632] A61 is a standard code for patents in the pharmaceutical technology field under the International Patent Classification Code (IPC), established by the WIPO.

growth in foreign filings rocketed, although the annual growth rate was highly uneven between 1993 and 2000, with four years of highly positive growth and four of negative growth. The growth rates of the four years of positive growth were 99%, 28%, 659%, and 709% respectively. With regard to filings, the total number of foreign patent applications filed in the four years of negative growth was 2.4 times greater than the total filings during the entire six-year period from 1987 to 1992, (2981 versus 1239, respectively). The total number of foreign patent applicants was 8860 from 1993 to 2000, 7.2 times more than the total amount of 1239 in the period from 1987 to 1992. After 2000, foreign patent filings exhibited a steady and significant pattern of growth, and by 2006, the total number of foreign patents filed reached a total of 32,135.

Table 7.2: A61 patent filings with the Chinese patent office from 1987 to2006

Years	Domestic filings	Domestic growth rates	Foreign filings	Foreign growth rates
1987	937		152	
1988	1519	62%	280	84%
1989	1640	8%	221	-21%
1990	2060	26%	208	-6%
1991	2648	29%	185	-11%
1992	3888	47%	193	4%
1993	5404	39%	385	99%
1994	5735	6%	492	28%
1995	5720	0%	457	-7%
1996	5892	3%	311	-32%
1997	5228	-11%	2361	659%
1998	5379	3%	341	-86%
1999	5998	12%	2759	709%
2000	7424	24%	1872	-32%
2001	10229	38%	2280	22%
2002	10383	2%	2813	23%
2003	14138	36%	2445	-13%
2004	13939	-1%	3509	44%
2005	19910	43%	4965	41%
2006	27495	38%	5906	19%
	155566(Total)	21% (Average)	32135 (Total)	80% (Average)

Taken together, the survey data shows a rapid growth trend in domestic patent filing, even before 1992 when Chinese patent law provided little protection to pharmaceuticals.[633] In contrast, the filing of foreign patents presented a varying growth pattern with a negative increase in the early years, a rocketing period of growth between 1992 and 2000, followed by a steady growth rate afterwards.

The Chinese growth pattern confirms the relevance and importance of a patent system to innovation in China There was no meaningful legal protection provided for inventions or creations before 1984 in China. Regulations governing intellectual activities granted the right of inventions to the state and allowed all other organisations

[633] The 1984 Chinese patent law provided non-product patents for pharmaceuticals, a patent term was fifteen years, and legal remedies were very limited and weak. For further details, see Chapter 4.

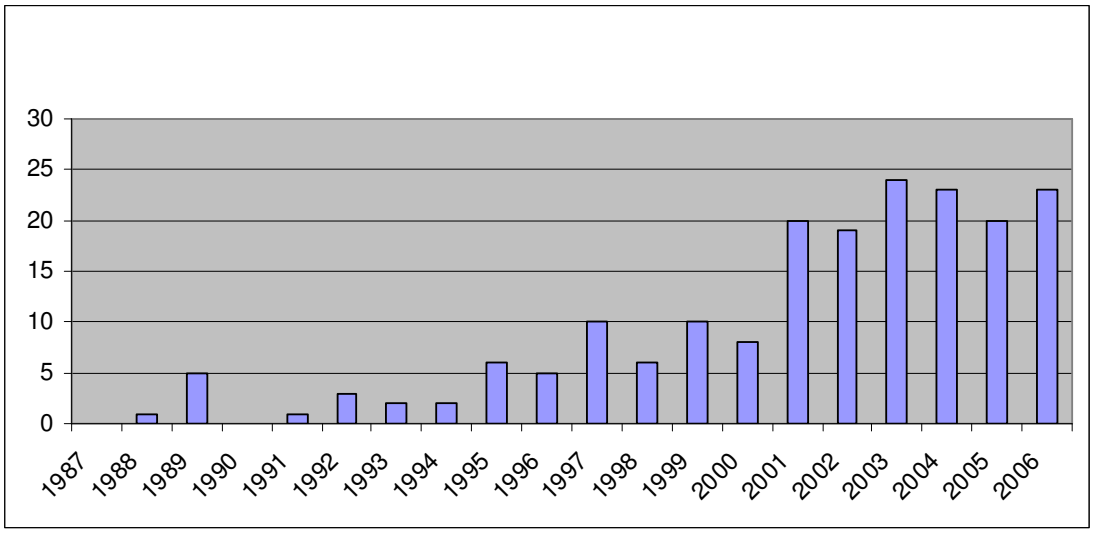
to freely exploit them. The inventors were only entitled to nominal monetary rewards and honourable certificates. The introduction of the 1984 patent law not only recognised the private ownership of inventions, but also provided comprehensive rights of exclusivity at right holders' disposal. These new rights, coupled with the prospect of rapid market expansion and other instructional stimuli, undoubtedly provided individuals and enterprises unprecedented motivation for the engagement or investment in innovative activities.

The low foreign interest in seeking patents under the 1984 Chinese patent law reflects the foreign drug originators' preferences and demands for stronger patent protections discussed earlier. In response, China's 1992, and 2000 patent reforms implemented a very strong TRIPS-plus patent legal regime for pharmaceuticals and took significant steps to strengthen it rules on patent enforcement. Furthermore, China continued to increase protections for patent holders in its 2008 law revision. With such legal changes in the Chinese context, it is reasonable to expect a surge in foreign interest in using the Chinese patent system and filing applications for patents for their pharmaceutical products with its patent office.

In addition to a booming patenting activity domestically, Chinese companies have also started seeking patents and commercialising their pharmaceutical inventions in the advanced foreign markets. For example, before 1985 there was only one US pharmaceutical patent granted to a Chinese national, but by 2007, this number had increased to 215 (see Chart 7.1 below). Moreover, several Chinese biotech and pharmaceutical companies, such as Zesun Sci & Tech Co. and Hutchisom MediPharma, are now conducting clinical trials in Europe and the US while researching within China.

This strategy is taken as a fast-track way to move their products into the international market. These developments reveal the rising improvements in domestic Chinese pharmaceutical R&D capabilities.

Chart 7.1 Chinese pharmaceutical patents granted by the USPTO



Source: USPTO, 'Patenting in Technology Classes, Breakout by Geographic Origin (State and Country), Count of 1963 - 2008 Utility Patent Grants, available at http://www.uspto.gov/web/offices/ac/ido/oeip/taf/tecstca/clstc_gd.htm

It needs to be stressed, however, that although the recent patenting boom may indicate the rapid expansion of R&D activities or the growing interest in using patents in competition, this does not necessarily mean the same thing as innovation attainment. Firstly, patents do not directly correlate to innovation in strict terms. Inventions can be transformed into innovation only after inventions are applied and commercialised successfully into marketable goods or services. The scope of innovation attainment thus depends not just on patents but also on firms' other complementary business capabilities. Secondly, it is a well-known practice for originator companies to pursue 'patent thickets' in order to deter potential rivals from entering into the market.[634] Patents secured for this purpose are often not truly innovative but have overlapping or dubious

[634] A 'patent thicket' is "a dense web of overlapping intellectual property rights that a company must hack its way through in order to actually commercialize new technology.', see Shapiro, C (2001), 'Navigating the Patent Thicket: Cross Licenses, Patent Pools, and Standard Setting', in A Jaffe, J Lerner, and S Stern (eds.), Innovation Policy and the Economy (1: National Bureau of Economic Research).

features.[635] These caveats warrant consideration and suggest using care in interpreting the above patent survey results.

Survey 3: R&D orientations

The second survey above has demonstrated a steady and rapid growth of pharmaceutical patenting from both domestic and foreign players in China since adoption of patent protection laws. This trend may soon transform the Chinese drug development system into a patent-based one not too long. This raises the question of how such a trajectory might affect public health and well-being? The lesson of the United States is that a powerful patent-based drug development system tends to reduce the public's access to medicine.[636] The accessibility problems are not only due to the high prices of patented medicines but also the unavailability of essential medicines. Pharmaceutical R&D orientations are driven by market profitability and the large firms are not interested in investing in drug markets with low profitability. This often results in the under-provision of R&D targeted at health problems of the poor.[637] This leads to the question whether China is now also experiencing such an under-provision in its domestic pharmaceutical R&D efforts? The following survey is intended to find empirical answers to this question.

Method

The following survey firstly studies three types of patenting data, i.e. relating to patent applications associated with the major infectious diseases, the major chronic diseases, and the sampled lifestyle therapies. Then, it compares the scale of each type data to the

[635] Correa, C (2004), 'The Role of Patents in Pharmaceutical Innovation', Bulletin of the World Health Organisation, 82 (10).
[636] Barton, B and J, Emanuel (2005), 'The Patent-based Pharmaceutical Development Process, Rationale, Problems , and Pottential Reforms', The Journal of the American Medical Association, 294 (16).
[637] CIPIH (2006), 'Public Health, Innovation and Intellectual Property Right', (Geneva: World Health Organisation).

aggregate number of domestic pharmaceutical patent applications filed over a span of twenty years. These comparisons aim to demonstrate the extent to which the domestic pharmaceutical R&D efforts have been oriented toward finding cures for the principal disease affecting Chinese patients.

There are three relevant variables, defined as follows: (1) 'DBx' represents the group of patent statistics associated with therapies concerning the major disease burdens in China. 'x' stands for the variation of disease types. Specifically, 'DBi' stands for patents associated with infectious diseases and 'DBc' for patents related to chronic diseases; (2) 'LSx' represents the group of patent statistics related to lifestyle therapies. Again, 'x' stands for the variation of the sample lifestyle conditions. (3) The total number of pharmaceutical patent filings is represented by '∑A61'.[638]

After collecting the data for the above three groups of variables, the quotients were computed for DBx/∑A61 and LSx /∑A61. The result of the former represents the level of Chinese pharmaceutical R&D dedicated to medications relevant to the major health problems facing Chinese patients, while the latter corresponds to the amount of R&D effort allocated to the lifestyle luxury market.

Sources of data:

1. China Health Statistic Digest 2004

This digest was published by China's Ministry of Health. It reported on the data on the Morbidity Rate of 10 Main Chronic Diseases and the Incidence and Death Rate of 27 infectious diseases in China from 2003. The thesis sourced this information from a

[638] As mentioned previously, A61 is the international patent classification code for pharmaceuticals.

report assigned by the WHO Commission on IPRs, Innovation, and Public Health on China.[639]

2. Chinese patent database

This database is provided by the China Patent Information Centre, an affiliate of the State of Intellectual Property Office in China. The database is available in both English and Chinese versions. The Chinese version contains more abstracts than the English version. Therefore, this study used the Chinese version as the source of information. The Chinese patent database publishes the abstracts of patent applications which have passed preliminary examinations.[640]

Patent search

The patent search was conducted using keywords regarding the targeted diseases and classifications concerning the patent types and the country of origin. The search period for infectious and chronic diseases covered the period from January 1, 1985 to May 24, 2009.[641] The search period for patent filings associated with lifestyle therapies covered the period from January 1, 1985 to December 23, 2010.[642] It should be noted that patent search by keyword is not generally considered to be an exhaustive method given that therapeutic solutions may be described by chemical substances. However, the patent abstracts published in the China patent database have a special section where the key diseases targeted by the invention are described. By means of this section, it is believed

[639] Li, ZZ, Ke, W, and Guang, C (2005), 'Developing Innovation Capabilities in China to Meet Health Needs'.
[640] Liu, M, Xiu, W, and Fu, A (2009), 'Current technical state and trend of the development of patenting for Cancer Therapies in China'. The authors are examiners of the medical and biological unit under the SIPO.
[641] January 1, 1985 is the date the Chinese patent database began recording data. May 24, 2009 is the date when patent search was conducted relating to relevant infectious diseases and chronic diseases.
[642] A comparative study herein was introduced in the later stage of the research. This is why the patent search concerning respective groups of diseases was carried out in the different dates.

that the patent search method employed by this research can result in a reasonable approximation of the total patent statistics useful for the analysis.

Assessment:

1. The targeted diseases and lifestyle conditions

The improvement of living standards in China has changed the disease burden structure of its population over the past two decades. Although infectious diseases remain a major health concern, the incidence of chronic diseases has grown very rapidly and has become another prominent threat to health. [643] According to the 2003 national health survey (see tables 7.5 & 7.6), the top 10 infectious diseases by incidence rate in China are: Pulmonary Tuberculosis, Gonorrhea, Measles, Syphilis, Malaria, Hemorrhage Fever, Scarlet Fever, Encephalitis B, Brucellosis, and Pertussis.[644] In addition, HIV/AIDS, listed as number 17 by its significance in the national survey,[645] was added to the analysis given its growth potential and the intensive attention from the global debate. The top 10 chronic diseases by morbidity rate are: Hypertension, Gastroenteritis, Rheumatoid Arthritis, Chronic obstructive pulmonary disease (COPD), Cerebrovascular Disease, Cholelith & Cholecystitis, Diabetes Mellitus, Intervertebral Disc Disorders, Ischaemic Heart Disease, and Peptic Ulcer.[646]

In the global debate on patents and public health, critics have argued that the incentive effect of patents tends to direct global research into lavish markets where customers are able and willing to pay high prices. The market for lifestyle medicines is a good

[643] Li, ZZ, Ke, W, and Guang, C (2005), 'Developing Innovation Capabilities in China to Meet Health Needs', ("Case Studies: developing innovative capacity in developing countries to meet their health needs" WHO. CIPIH report). pp.39-40.
[644] Source: China Health Statistic Digest 2004, Ministry of Health (MOH), 2004, cited in Li, ZZ, Ke, W, and Guang, C (2005),.
[645] Ibid, p39.
[646] Ibid, p41.

example of this market. In light of this argument, this thesis also chose to study the correlation between the lifestyle medicine market and the orientation of Chinese pharmaceutical patenting. The targeted lifestyle conditions include complexion beauty therapy, anti wrinkle therapies, slimming solutions, anti baldness therapy, and breast enlargement therapy.

Table 7.4: Reported Incidence and Death Rates of 27 Infectious Diseases (2003)

Diseases	Incidence Rate (1/100 000)	Death Rate (1/100 000)	Deaths per 100 patients
Pulmonary Tuberculosis	52.36	0.08	0.16
Gonorrhea	14.09	0	0
Measles	5.55	0.01	0.11
Syphilis	4.5	0	0.05
Malaria	3	0	0.14
Hemorrhage Fever	1.68	0.01	0.76
Scarlet Fever	0.75	0	0.01
Encephalitis B	0.58	0.03	4.66
Brucellosis	0.48	0	0
Pertussis	0.41	0	0.05
SARS	0.4	0.03	6.55
Typhus Fever	0.3	0	0.05
Encephalitis	0.19	0.01	5.48
Newborn Tetanus	0.18	0.03	14.51
Hydrophobia	0.15	0.15	97.2
Leptospirosis	0.13	0	3.33
HIV/AIDS	0.08	0.03	33.1
Anthrax	0.04	0	1.66
Kala Azar	0.01	0	0
Dengue Fever	0.01	0	0
Poliomyelitis	0	0	0
Diphtheria	0	0	33.33

Source: China Health Statistic Digest 2004, Ministry of Health (MOH), 2004, cited in MIHR (2005), 'Innovation in Developing Countries to Meet Health Needs: experiences of Brazil, China, India, and South Africa', (MIHR report to CIPIH, WHO Ref. CIPIH Study 10d).

Table 7.5: 2003 Morbidity Rates of 10 Main Chronic Diseases (%)

Diseases	Urban	Rural	Total
Hypertension	54.7	16.4	26.2
Gastroenteritis	9.8	10.5	10.3
Rheumatoid Arthritis	8.4	8.7	8.6
COPD	8.2	7.3	7.5
Cerebrovascular Disease	13	4.4	6.6
Cholelith & Cholecystitis	8.5	4.7	5.7
Diabetes Mellitus	16.3	1.9	5.6
Intervertebral Disc Disorders	8.1	4	5
Ischaemic Heart Disease	12.4	2	4.6
Peptic Ulcer	3.4	3.8	3.7
Total (computed by patients)	177.3	104.3	123.3

Source: China Health Statistic Digest 2004, Ministry of Health, 2004, cited in cited in MIHR (2005), 'Innovation in Developing Countries to Meet Health Needs: experiences of Brazil, China, India, and South Africa'

2. Results and data analysis

Table 7.7 illustrates the computed quotients between patent applications associated with the top 10 infectious diseases and the total number of pharmaceutical patent applications to the Chinese patent office from January 1, 1985 to May 24, 2009.[647] The total record of pharmaceutical patent applications in the given period was 265, 296. The results of the computed quotients were recorded under the category of DBix/∑A61. The quotients ranged from 0.0033 for HIV/AIDS down to only 0.000004 for scarlet fever. The average quotient was 0.0006, i.e. there were only 6 inventions targeting infectious diseases per 10,000 pharmaceutical patent applications. The data also showed that most of these patents were filed by domestic R&D applicants. The average percentage filed by domestic applicants was 88%.

[647] Note that there is a delay of the publication of patent application in the Chinese patent database due to the fact that the Chinese patent office publishes applications 18 months after the first date of filing by law (Article 34 of Chinese patent law 2008).

Table 7.6: Patent filings associated with top 10 infectious diseases (1985.1-2009. 5)

Diseases targeted by inventions	Total filings	BDi / ∑A61(265296)	Domestic filings
Pulmonary Tuberculosis	284	0.0010	93%
Gonorrhoea	169	0.0006	91%
Measles	96	0.0004	75%
Syphilis	113	0.0004	97%
Malaria	196	0.0008	37%
Haemorrhage Fever	27	0.0001	89%
Scarlet Fever	1	0.000004	100%
Encephalitis B	26	0.00010	100%
Brucellosis	6	0.00002	100%
Pertussis	83	0.0003	99%
HIV/AID	879	0.0033	82%
Average		**0.0006**	**88%**

Notes:
EDi = the number patent filings associated with each infectious diseases
∑A61= the aggregate amount of pharmaceutical patents = 265296

Table 7.8 shows the computed quotients between patent filings related to the top 10 chronic diseases and the total number of pharmaceutical patents applied for in the Chinese patent office from January 1, 1985 to May 24, 2009. The quotients of this study group were generally improved when compared to those concerning infectious diseases. The improvement of living standards following rapid economic growth has impacted on the disease burden in China. Chronic diseases have increasingly threatened public health, especially populations in urban areas.[648] Given the growing demand for treatments, as well as the relatively higher profitability in treatments for chronic diseases than for infectious diseases, it is reasonable to assume that there is greater attention being paid to pharmaceutical R&D investment in the former rather than the latter. Yet, serious shortages of treatments and cures for some treatable chronic diseases remain. For example, patent filings devoted to therapeutic solutions for gastroenteritis, COPD, and

[648] Li, ZZ, Ke, W, and Guang, C (2005), 'Developing Innovation Capabilities in China to Meet Health Needs', p.40.

ischaemic heart disease were as low as 0.0006, 0.0002, and 0.0003, respectively. There was no research found on either medications or medical equipment dedicated to choleliths & cholecystitis. Considering the mortality rates of 10.3%, 7.5%, and 4.6 %, associated with these diseases, respectively (See Table 5.6), the under-provision of R&D on these health problems remains a great concern.

Table 7.7: Patent filing associated with top 10 chronic diseases (1985.1-2009. 5)

Diseases targeted by inventions	**Total filings**	**BDc /∑A61(265296)**	**Domestic filings**
Hypertension	3248	0.0122	67%
Gastroenteritis	154	0.0006	87%
Rheumatoid Arthritis	260	0.0010	96%
COPD	62	0.0002	26%
Cerebrovascular Disease	2399	0.0090	93%
Cholelith & Cholecystitis	0	0	
Diabetes Mellitus	5559	0.0210	62%
Intervertebral Disc Disorders	257	0.0010	100%
Ischaemic Heart Disease	77	0.0003	57%
Peptic Ulcer	456	0.0017	46%
Average		**0.0045**	**71%**

Notes:
EDCx = the number of patent filings associated with each each chronic diseases
∑A61= the aggregate amount of pharmaceutical patents = 265296

This survey of R&D orientations also included a search of patents filed on inventions targeting five popular lifestyle treatments as examples used to illustrate the level of R&D attention devoted to the lavish market. Table 7.9 summarises the proportion of patent filings associated with each category of lifestyle therapy compared with the total amount of pharmaceutical patents filed (∑A61) between January 1, 1985 and August 10,

2010. The number of ∑A61 stood at 211,065.[649] The resulting quotients were 0.0137, 0.0051, 0.0041, 0.0016, and 0.0005, respectively, for complexion beauty therapy, anti wrinkle therapies, slimming solutions, anti baldness therapy, and breast enlargement therapy. The average of the quotients was 0.005.

Table 7.8 Patents filing associated with popular lifestyle therapies (1985.1-2010. 08)

Inventions	Total filings	LSx/ ∑A61 (211065)	Domestic filings
Complexion beauty therapy	2883	0.0137	80%
Anti wrinkle therapies	1079	0.0051	67%
Slimming solutions	874	0.0041	97%
Anti baldness therapy	335	0.0016	83%
Breast enlargement therapy	103	0.0005	89%
Average		**0.0050**	**83%**

Notes:
LSx = the number of patent filings associated with each lifestyle therapy
∑A61= the aggregate amount of pharmaceutical patents = 211065

Comparing the above three statistical results, several observations can be made.

First, domestic companies show a greater interest in investing in R&D targeted at local health needs. This is evident from the fact that 88% of patent applications associated with infectious diseases were filed by domestic applicants. Infectious diseases tend to be

649 The patent search on the sampled lifestyle therapies was conducted on August 10, 2010 while the earlier patent search on infectious and chronic diseases was done on May 24, 2010. In consequence, the two aggregated numbers of patent application (∑A61) resulted from the two different search dates differ from each other. The ∑A61 record of 211, 065 on August 10, 2010 is smaller than that of 265,296 on May 24, 2010. There are two possible explanations for this difference: first, patent applications in China are published promptly after the expiration of eighteen months from the date of filling. Some applicants may decide not to request substantive examination and thus withdraw their applications after the publication. Secondly, the 2008 patent law amendment heightened the threshold of patentability from a 'relative novelty' to an 'absolute novelty'. This change may have also lead to either withdrawals or more failures in passing the substantive examination. These two possibilities may have reduced the numbers of patents in database.

more prevalent in rural populations than urban populations.[650] Given the generally low income of the Chinese rural population, it is expected that foreign companies have little incentive to devote R&D effort to this market.

Nevertheless, domestic R&D efforts are far from sufficient in their patent filings to adequately address the needs of the domestic major disease burdens. Patent filings associated with therapeutic treatments for the top 10 infectious diseases were the lowest, with a average quotient of 0.0006, while the relevant quotients related to chronic diseases and the sampled lifestyle therapies were 0.0045 and 0.0050, respectively. R&D efforts dedicated to lifestyle therapies were more than eight times higher than the level given to infectious diseases. This discrepancy demonstrates that the majority of domestic pharmaceutical R&D efforts are oriented by interests in private profit rather than public and humanitarian needs in China.

Survey 4: R&D Level

The previous analysis in Survey 1, 2, 3 centred on the *quantitative* growth of innovation in the Chinese pharmaceutical industry under its patent legal regime. This section turns to an examination of the *qualitative* change of innovation in the industry under this law. Qualitative change of innovation implies an evolution of the degree of sophistication in the technical characteristics of innovation. To this end, the research involved consulting and analysing the patenting data filed to and granted by the SIPO from local companies. Chinese patents have three definite forms: inventions, utility models (UMs) and design. Under the 2008 patent law,[651] an invention patent and a UM share the same standard on Novelty and Utility, but the former requires a substantially higher threshold in

[650] Z.Z. Li,et al. (2005), 'Developing Innovative Capacity in China to Meet Health Needs' pp.39-40.
[651] Article 22.1, 22.3 of Chinese patent law 2008, available at http://english.sipo.gov.cn/laws/lawsregulations/201101/t20110119_566244.html.

Inventiveness than the latter. Article 22.2 of the Chinese patent law provides that to be entitled to a Chinese Invention Patent, a new technical solution must 'possess prominent substantive features and represent a remarkable advancement', whereas, for a UM protection, inventions are only required to show 'substantive features and an indication of advancement'. Given the different thresholds in Inventiveness, this research used data on the pharmaceutical invention patents as a proxy for substantial and breakthrough inventions, and pharmaceutical UM data signifying incremental inventions.[652]

It is cautioned that this methodology may provide only an approximate distinction between various levels of innovations. As Shadlen has noted, 'patents are imperfect indicators of innovations'; consequently, the assessment of the relations between invention patents and substantive or breakthrough innovations is rather general and inexact [653] To minimise any weaknesses in the methodology, this research also draws on information obtained from personal interviews and other relevant surveys to supplement the patent analysis.

1. The consistent dominance of utility model patents

The graphs in Charts 7.2, and 7.3 below illustrate the change over time in numbers of pharmaceutical patent applications (A61) filed by domestic and foreign applicants, respectively, from 1987 to 2007. It can clearly be seen that domestic filings for 'UM' far exceeded those for 'invention' in most years, except for 2005 and 2006. As summarized above in Table 7.7, Chinese applicants filed 93,173 UM, and 75,912 'invention' patents, whereas only 15,590 patents were granted for 'invention', but

[652] The data concerning design patents are dismissed herein due to the two reasons: i) they are not provided under the class of IPC in the Chinese patent gazettes; 2) the form of design patent is not very relevant to pharmaceutical inventions.
[653] Shadlen, K. (2011), 'The political contradictions of incremental innovation: lessons from pharmaceutical patent examination in Brazil', Politics and society, 39 (2).

66,962 were granted for 'UM' by the SIPO. In contrast, the majority of foreign A61 applications fell into the category of patents for 'invention', with only 588 'UM' filings versus 33,444 'invention' filings, whereas the numbers of patents granted for foreign A61 applications were 376 'UM' versus 11,223 patents for 'invention'.

In summary, there have been far more patents filed and granted for UM protection than for invention patents under the Chinese patenting law. Given the limited nature of UM patents, this suggests that qualitatively, the majority of Chinese pharmaceutical innovations have been of a minor, rather incremental character.

Chart 7.2: Type of patents filed by Chinese inventors

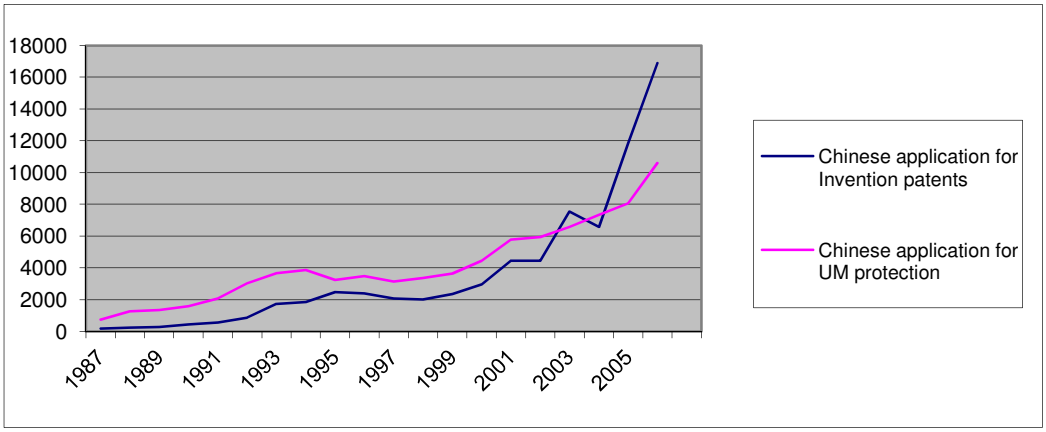


Chart 7.3: Types of patents filed by foreign inventors

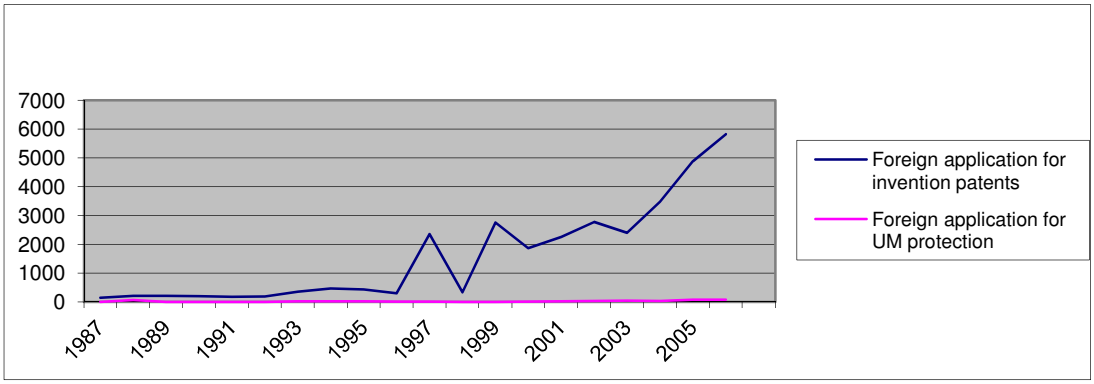


Table 7.9: Comparison of types of A61 patents filed and granted by domestic and foreign innovators (the aggregate from 1987-2007)

	Inventions		**Utility models**	
	Application	Grants	Application	Grant
Domestic invention	75,912	15,590	93,173	66,962
Foreign invention	33,444	11,223	588	376

Source: Compiled by the author based on data from SIPO gazettes from 1987 to 2007

2. The scarcity of NCEs

In recent years, Chinese pharmaceutical firms appear to have adopted 'incremental innovation' as an industrial strategy. Moreover, more researchers are finding that engaging in higher level innovation is 'tough but unrewarding' given the low level of technical and scientific capability available and the shortage of research funding. As a result, domestic R&D produces few inventions and instead, principally focuses on developing and producing 'me too' or 'me-better' results.[654] A general consensus in the literature is that so far Chinese pharmaceutical companies have only very rarely developed new chemical entities (NCEs).[655] Local researchers, drug administrators and lawmakers interviewed for this research also agreed with this observation.[656]

There is only one Chinese drug, Qing Hao Su (QHU) (see Box 7.1 below), that both the literature[657] and my interviewees have acknowledged as qualifying as a NCE. Chinese

[654] Li, YH (2010), pp53-54.
655 Chen, Xh and Watanabe, M (2007), 'Pharmaceutical Industry in China-Intellectual Property Protection, Pricing and Innovation-', (Institute of Development Economics, Japan External Trade Organisation); Li, YH (2010), Imitation To Innovation In China: the Role of Patents in Biotechnology and Pharmaceutical Industries;
[656] Interview with Xong Hui, SCIIA, Wu Rui, Deputy Director of Sichuan Food and Drug Administration (SCFDA), Wen Xi Kai, China Intellectual Property Training Centre (CIPRC).
[657] Li, YH (2010), p57.

scientists developed and produced QHU, also called Artemisinin, during the 1970s and the early 1980s before intellectual activities in the PRC were oriented to or governed by a patent law system.[658] Information about QHU and its derivatives was disseminated to the international community through publications from 1979 to the early 1980s. This promoted wider interest in researching and developing Artemisinin-based therapies around the world.[659] After a decade of worldwide application, the World Health Organisation (WHO) recognised Artemisinin-based combination therapies, or ACTs, as 'the most effective treatment for falciparum malaria - the most lethal form of the disease' and listed it as one of the essential anti-malarial drugs in the 2000 WHO Essential Drug List.[660] It can be argued that open access to the knowledge about QHU and its derivatives in 1970s greatly facilitated worldwide access to Artemisinin-based therapies and thus, benefited malaria patients much earlier and at far less cost than would have been the case had patents been granted and in force.

Despite its one major success, as several recent surveys conducted by industry analysts and Chinese patent examiners have found, in comparison with other countries , Chinese innovation still exhibits shortcomings in technological categories and sophistication. Firstly, the International Federation of Pharmaceutical Manufacturers Associations (IFPMA) reports that 80% of domestic applications filed for plant medicines and healthcare products, only 3.7% were related to synthetic drug substances.

---

[658] Mount, D, Todd, G, and Navaratnam., V (1995), ''Packed-column supercritical fluid chromatography of artemisinin (qinghaosu) with electron-capture detection' ', *Journal of Chromatography B: Biomedical Sciences and Applications,* 666 (1).

[659] Klayman, DL (1985), 'Qinghaosu (artemisinin): an Antimalarial Drug from China', Science 228 (4703), 1049-55.

[660] See http://www.who.int/features/qa/26/en/index.html, WHO listed Artesunate, a derivative of Artemisinin which was developed and produced by a Chinese pharmaceutical company Guilin Pharmaceutical Ltd, in the model list of Essential Medicines (12th Edition) in 2002, p 25 in English Version, p26 in Chinese version, at http://www.who.int/medicines/publications/essentialmedicines/en/, accessed on March 12, 2009.

In contrast, 54% of foreign applications were for synthetic drug substances. [661] Secondly, some SIPO examiners conducted a survey of patent applications for cancer therapies filed with the office from 1996 to 2006. They found that, in general, foreign applications were greater than domestic applications. In terms of the patents granted during 1996 to 2006, only 30% of Chinese patents were for synthetic drug substances, compared to 68.6% of US patents and 74.4% of Japanese patents. [662] Another survey on patenting therapies for AIDS prevention and treatment reported that although Chinese filings accounted for 45% of all applications, the majority of Chinese patents and applications were for traditional medicines. The rest mainly consisted of utility model patents and design patents, but few invention patents were related to novel chemical compounds.[663] In contrast, foreign filing accounted for the majority of the remaining applications, with the US (28%) and Japan (5%) leading.

[661] FPMA (2004), 'Accelerating Innovative Pharmaceutical Research and Development in China: a case study', (Geneva: International Federation of Pharmaceutical Manufacturers Associations (IFPMA), p16.
[662] Liu, M, Xiu, W, and Fu, A (2009), 'Current Technical State and Trend of the Development of Patenting for Cancer Therapies in China'. *Report on the State and Prospect of Chinese Patents of Key Industry (2008-2009)* (Beijing: Intellectual Property Right Press) pp.188-189.
[663] Ibid, p.217.

Box 7.2: The discovery of Qing Hao Su

From the PRC's early years, malaria was one of the principal epidemic diseases its national health policy makers targeted for a cure. The search for anti-malarial compounds accelerated after the (North) Vietnamese government asked China for medical aid and medications to combat the malaria that was threatening their soldiers' lives during the Vietnam War.[664] The National Science and Technology Committee(NSTC) together with the General Logistics Department of the People's Liberation Army (GLDPLA) convened a meeting on May 23, 1967, titled 'The coordination meeting on Malaria medicine research', bringing together political leaders and pharmaceutical professionals.[665] This meeting endorsed a collaborative research project called the '1967-1970 Collaborative Planning on Malaria Medicine Research', which was coded as the '523 Project' due to the confidentiality requirements at that time.[666] The project involved over five hundred researchers from prestigious research institutes throughout China.[667] Scientists systematically examined indigenous plants used traditionally as the remedies for malaria in traditional, classical Chinese medicine. They isolated the substance responsible for anti-malaria action from a plant called Qin Hao in 1972, and scientists named it 'Qinghaosu', meaning 'active principle of qing hao'.[668]

[664] Liu, DW 'China '523'Project' at www.yyqhw.2008red.com/yyqhw/article_351_3838_1.shtml, accessed on March 14, 2009. To be noted, the Chinese source originally referred to the government as 'the Vietnamese government'.
[665] Zhang Jf. *A Detailed Chronological Record of Project 523 and the Discovery and Development of Qinghaosu (Artemisinin)*,Yangcheng Evening News Publisher, 2006.
[666] Liu, DW 'China '523'Project' at www.yyqhw.2008red.com/yyqhw/article_351_3838_1.shtml, accessed on March 14, 2009.
[667] Ibid.
[668] Klayman, DL (1985), 'Qinghaosu (artemisinin): an Antimalarial Drug from China', *Science,* 228(4703), p1049.

In summary, this survey has shown that Chinese pharmaceutical inventions are overwhelming associated with imitative and low-level technologies, whereas patents held by foreign nationals are largely associated with the leading or 'upstream' technologies, and the presence of such foreign patents in China is rapidly growing. As a consequence, the prospect of foreign dominance in the leading or upstream biopharmaceutical technology could effectively raise roadblock for Chinese industry's efforts at 'incremental innovation' and make its technological catch-up far more difficult for its pharmaceutical industry

7.3 Patent strength and R&D-oriented FDI inflow in China

An important objective of Chinese pro-patent policy is to attract greater inflow of foreign advanced technologies. This policy expectation assumes that patent strength correlates positively with the inflow of international technology transfer (ITT), which includes foreign direct investment (FDI) and technological licensing. The direct channels for the acquisition of foreign advanced technologies comprise international trade, FDI and licensing. Import of new products and service can transfer and diffuse technology to a country, but FDI and technological licensing are perceived to bring in greater technological advantages through local R&D spillover and direct transfer of advanced technology.[669] Economic theory predicts that patent strength can affect MNCs' incentives to choose between trade, FDI or licensing and that stronger patent protections induce higher levels of ITT.[670] Nevertheless, the relationship between patent and ITT may be deeper and more complex than that and requires more evidence and

[669] Maskus, K (2000), *Intellectual Property Rights in the Global Economy* (Washington DC: Institute of International Economics).
[670] Ibid.

research.[671] Survey 4 herein examines the Chinese experience with the relationship between the strengthening of its patent regime and levels of ITT.

China has become one of the world's top destinations for pharmaceutical FDI projects.[672] According to FDI Intelligence, in 2005, China ranked second with 44 pharmaceutical FDI projects, after the US, which ranked first with 52 projects, and India ranked third with 30 projects.[673] This section looks at the forms of investment pharmaceutical FDI projects have taken in the Chinese market and how they have evolved to test the thesis posed above.

Method

This research collates data concerning the composition of FDI in China from the 12 leading pharmaceutical MNCs from 1980 to 2009. This research collates data concerning the composition of FDI in China from the 12 leading pharmaceutical MNCs from 1980 to 2009. According to the *Fortune Global 500*, in July 2009 these MNCs were ranked as the world's top 12 pharmaceutical companies by revenue.[674] They included Johnson & Johnson, Pfizer, GlaxoSmithKline, Roche Group, Sanofi-Aventis, Novartis, AstraZeneca, Abbott Laboratories, Merck, Wyeth, Bristol-Myers Squibb and Eli Lilly, in order of their rank. In addition to being the global leaders in pharmaceutical R&D, they are also the major foreign pharmaceutical MNCs operating in China. Most of them commenced their Chinese operations in the 1980s. This research adopts the reasonable inference that the FDI considerations of these companies may represent the general concerns of pharmaceutical MNCs seeking R&D activities in China.

[671] Maskus, K (2000), p130, p150.
[672] Lippoldt, D (2006), 'Intellectual Property Rights, Pharmaceuticals and Foreign Direct Investment ', (Groupe d'Economie Mondiale de Sciences Po.), p4, p8.
[673] FDI Intelligence (2006), 'Pharma pulls in $15bn", cited in note 12 of Lippoldt, D (2006),
[674] The ranking list can be viewed at http://money.cnn.com/magazines/fortune/global500/2009/industries/21/index.html..

Accordingly, the research involved gathering data on the forms of FDI these companies have undertaken. The data was collected from: (1) business reports, (2) targeted company information published on their official websites, and (3) company press news.

Survey

The forms of FDI can be categorised into distribution, production and R&D facilities. Table 7.4 below summarises the composition of FDI associated with the world's leading pharmaceutical MNCs in China over the past two decades. Many of these companies started their operations as major exporters to China in the 1970s.[675] Since China embarked on its policies of economic reforms and openness, it has attracted increasing numbers of pharmaceutical MNCs to operate in China, and by the 1990s, it had become one of the world's top destinations for FDI for the world's leading pharmaceutical MNCs.[676]

This survey shows that in the 1980s and 1990s all 12 MNCs chose to limit their Chinese operations to the FDI forms of manufacturing plants or distribution. During this period, China was widely perceived as a risky place for investment-involved R&D and technology due its weak law on patent protection and enforcement.[677] It was rational for the 12 MNCs to decide to explore the Chinese market only through trading or manufacturing. Nevertheless, the 12 MNCs did not respond consistently in their FDI decisions following China's compliance with the TRIPS patent rules in 2000. The companies have either been slow to engage in R&D-oriented investment or have continued their traditional operational modes in China since the 2000 patent law reform.

[675] International, Business (1974), 'China Industry Surveys, Pharmaceutical Sector', (Hong Kong Business International Asia Pacific).
[676] Lippoldt, D. (2006), 'Intellectual Property Rights, Pharmaceuticals and Foreign Direct Investment ', (Groupe d'Economie Mondiale de Sciences Po.), p 4.
[677] West, A (1997), 'The pharmaceutical and healthcare industries of China ', (London: FT Pharmaceuticals & Healthcare Publishing), p56.

Six of the companies opened R&D centres within five to six years and another four opened them within seven to nine years. Two of the companies continue to operate only as either manufacturers or distributors.

The Chinese experience demonstrates that the association between stronger patents and ITT is not as straightforward as claimed by the mainstream economic theory. FDI decisions are far more complex and involve a variety of strategic factors. Sometimes, other factors can prevail over IPRs concerns even when essential legal protection exists.[678] For example, this was evident in Roche's recent R&D relocation decision. When Roche was planning to establish a R&D research headquarters in Asia (excluding Japan), several advanced cities in India and China were the first destinations which interested the company. After a number of fieldwork trips, Shanghai stood out and was selected as the site due to its excellent infrastructure, talent pool and preferential local policy toward IP-intensive sectors, even though the mixed IPR performance in China was still of concern to the company.[679] In addition, the Chinese market also offered other advantages, such as the size of patient population, a broad diseases profile and the potential for rapid patient recruitment.[680] Such strengths may have helped China to become one of the most attractive global locations to conduct clinical trials outside the US.[681] In short, this Chinese experience indicates that strengthening patent protection can be a factor in attracting greater ITT to developing countries, but it is certainly not the only consideration. To increase ITT inflow also depends upon other national initiatives and economic factors.

---

[678] Lippoldt, D (2006), 'Intellectual Property Rights, Pharmaceuticals and Foreign Direct Investment '.
[679] Communication with Andreas Tschirky, the general manager of Roche R&D Centre, China.
[680] BMI (2006), 'China Pharmaceuticals & Healthcare Report ', (Q1; London: Business Monitor International Ltd), p32.
[681] Barnes, K (2007-01-04), 'China 'most attractive' offshore clinical trial location ', Pharma Technologist. <http://www.in-pharmatechnologist. com/news/ng.asp?n=72702-a-t-kearney-china-offshoring-clinical-trials.>.

. **Table 7.3: The evolution of FDI composition from the leading pharmaceutical MNCs in China**

Companies	Years	Operation /Investment	Location
1. Johnson & Johnson		**Manufacturing Joint Ventures (JV)**	
	1985	Xian Janssen	Xian
	1990	Johnson Shanghai	Shanghai
	1991	Johnson & Johnson China Ltd	Shanghai
		R&D projects	Shanghai
	2009	J & J Pharmaceutical R&D Centre , Shanghai,	
2. Pfizer		**Manufacturing JV**	
	1989	Pfizer & Dalian pharmaceutical Joint Venture	Dalian
	1997	Pfizer Investment Cooperation	Shanghai
		R&D projects	Shanghai
	2005	Pfizer R & D Centre	
3. GSK (SmithKline)	1970	Exporting antibiotics to China First Joint venture TianJin	TianJin
	1987	SmithKline French Laboratories Ltd, a manufacturing site	TianJin
		R&D projects	
	2003	OTC R&D organization Global	Tianjing
	2007	GSK R&D centre	Shanghai
4.Roche		**Manufacturing plants**	
	1994	Shanghai Roche	-
		Roche Taishan Vitamin	Shanghai
		Products	Shanghai
		Roche Sunve Vitamins Ltd	Shanghai
		R&D projects	
	2004	Roche China R&D Centre	Shanghai
	2007	Roche's Pharmaceutical Development Centre China	Shanghai
5. Sanofi Aventis	1982	**Distribution Office**	Beijing
		R&D projects	
	2005	China Clinical Research Unit, R&D centre	Shanghai

	2008	Sanofi Aventis Biometrics Centre	Beijing
6.Novartis	 2008 2009	**R&D projects** Novartis Pharmaceutical Research ChangSu Novartis Institutes for Biomedical research shanghai	 Shanghai Shanghai
7.AstraZenneca	1985 2006	**Manufacturing** Sino-Swed Phrmaceutical Companies **R&D projects** AstraZenneca R&D Centre	Wuxi Shanghai
8.Abbott laboratories	2000 2009	Joint Venture : Abbot Pharmaceutical Manufacturing Shanghai Plant **R&D project** Shanghai R&D Centre	Shanghai Shanghai
9.Merck		Merck Chemicals (Shanghai) Co., Ltd, Distribution	Shanghai
10Wyeth	 1994 1995 2006	**Manufacturing** Wyeth Pharmaceutical Co.Ltd(China) Suzhou plant Shanghai Wyeth Nutritional Co. Ltd **R&D project** Clinical trial centre	 Shanghai Suzhou Beijing
11Bristol-myers squibb	1982	**Manufacturing plants** Sino American Shanghai Squibb, Mead Johnson Co Ltd, Squibb-ConvaTech Medical Products Ltd, **Distribution**: Zimmer Division	Shanghai Guangzhou Shanghai Shenzhen
12 Eli Lilly	1970s 1995 2008	Exporting to China A Joint Venture **R&D projects** R&D Centre	Suzhou Shanghai

Sources of Information:

Industry reports:

International, Business (1974), 'China Industry Surveys, Pharmaceutical Sector', (Hong Kong Business International Asia Pacific).
West, A (1997), 'The pharmaceutical and healthcare industries of China ', (London: FT Pharmaceuticals & Healthcare Publishing).
BMI (2006), 'China Pharmaceuticals & Healthcare Report ', (Q1; London: Business Monitor International Ltd).
BMI (2008), 'China Pharmaceuticals & Healthcare Report ', (Q2; London: Business Monitor International Ltd).

Johnson & Johnson:

1) West, A (1997),'The pharmaceutical and healthcare industries of China ', pp109-110. accessed on August 5, 2010.
2) Company profile, at www.xian-janssen.com.cn/default.aspx?menu_uid=110202. August 5, 2010.
3) Drug Discovery & Development,(2009-6-12), 'J&J Opens R&D Centre in Shanghai '.
4) BMI (2008), 'China Pharmaceuticals & Healthcare Report ‘, pp35-36.

Pfizer:

1) Company profile: http://www.pfizer.com.cn/htmls/edex/edex2.htm, accessed on August 5, 2010.
2) West, A (1997), 'The pharmaceutical and healthcare industries of China ', (London: FT Pharmaceuticals & Healthcare Publishing), pp100-101.
3) BMI (2006), 'China Pharmaceuticals & Healthcare Report ', (Q1; London: Business Monitor International Ltd), p35.

GSK:

1) International Business (1974), 'China Industry Surveys, Pharmaceutical Sector', (Hong Kong Business International Asia Pacific), p14-15, accessed on August 5, 2010.
2) Company profile, at http://www.tskf.com.cn/26.htm, accessed on August 5, 2010.
3) Company profile, at http://www.gsk-china.com/english/html/research-development/collaborations-in-china.html, accessed on August 5, 2010.
4) BMI (2008), 'China Pharmaceuticals & Healthcare Report ‘, pp35-36.

Roche:

1) West, A (1997), 'The pharmaceutical and healthcare industries of China ', (London: FT Pharmaceuticals & Healthcare Publishing), p110-111, accessed on August 6, 2010.
2) Roche media release at http://www.roche.com/med-cor-2004-01-16, accessed on August 6, 2010.
3) Industry projects: at http://www.pharmaceutical-technology.com/projects/novartis-pharma/ , accessed on August 6, 2010.
4) Industry projects, http://www.pharmaceutical-technology.com/projects/novartis-institute/, accessed on August 6, 2010.
5) Company profile: Media release, at http://www.roche.com/med-cor-2004-01-16, accessed on August 6, 2010.
6) BMI (2008), 'China Pharmaceuticals & Healthcare Report ', pp35-36.
7) McCurry (March 2008), 'R&D on Mainland China? ‘Site Selection, 53.

Sanofi-aventis:

Sanofi, aventis (October 21, 2008), 'Press Release Sanofi-aventis:Sanofi-aventis expands its R&D presence in China', (Beijing), accessed on August 8, 2010.

Novartis:
1) Pharmaceutical development: http://www.novartis.com/research/pharmaceutical.shtml, accessed on August 8, 2010.
2) Industry projects: at http://www.pharmaceutical-technology.com/projects/novartis-pharma/, accessed on August 8, 2010.
3) BMI (2008), 'China Pharmaceuticals & Healthcare Report ‘, pp35-36.

AstraZenneca
1) Company profile: AstraZeneca in China, at http://en.astrazeneca.com.cn/502867/502748?itemId=8875980&nav=yes, accessed on August 8, 2010.
2) West, A (1997), 'The pharmaceutical and healthcare industries of China ', p103.
3) BMI (2008), 'China Pharmaceuticals & Healthcare Report ‘, pp35-36.

Abbott laboratories

1) Global citizenship China profile http://www.abbott.com/global/url/content/en_US/40.75:75/general_content/General_Content_00483.htm, accessed on August 8, 2010.
2) Global citizenship: R& D Activities and Capability: http://www.abbott.com/global/url/content/en_US/40.15.5:5/general_content/General_Content_00522.htm, accessed on August 8, 2010.
3) BMI (2008), 'China Pharmaceuticals & Healthcare Report ‘, pp35-36.
4) Abbot press release, http://www.abbott.com/global/url/pressRelease/en_US/Press_Release_0851.htm, accessed January 28, 2011, accessed on August 8, 2010.

Merck:
1) Company profile: at http://www.merck-china.com/en/company/merck_in_china/merck_in_china.html, last accessed on August 8, 2010.
Wyeth:
1) Company profile: at http://www.wyeth.com.cn/english/About/default.asp, accessed on August 6, 2010.
2) Company profile: at http://www.wyeth.com.cn/english/About/wyeth-whitehall.asp, August 8, 2010.
3) PWC (2009), 'Investing in China’s Pharmaceutical Industry ', (Second Edition: PricewaterhouseCoopers).

Bristol-myers squibb:
1) BMS worldwide facilities at http://www.bms.com/sustainability/worldwide_facilities/asia/Pages/shanghai_china.aspx, August 8, 2010.

2) West, A (1997), 'The pharmaceutical and healthcare industries of China ', p107.

Eli Lilly

1) Company profile: http://www.lillychina.com/china/default.cfm, accessed on August 8, 2010.
2) West, A (1997), 'The pharmaceutical and healthcare industries of China ', p107.
3) BMI (2008), 'China Pharmaceuticals & Healthcare Report ', pp35-36.

7.4 The roles of patents and other complementary factors in innovation change

7.4.1 Positive impacts

Previous studies have found a correlation between the remarkable growth in Chinese domestic pharmaceutical innovation and ITT inflow along with the evolving system of stronger patent protections in China. Pharmaceutical players have become increasingly interested in seeking and enforcing their patents in China. The growth rate of patent application filings in the Chinese patent office is the highest in the world.[682] Meanwhile, China is also becoming the world 'leader' in patent litigation.[683] These trends indicate a growing importance of patents in innovation and business operation in the Chinese market. Indeed, one can argue that the stronger Chinese patent regime has led to national gains in pharmaceutical innovation and additional FDI and foreign R&D relocation in the Chinese pharmaceutical market.

A major advantage of a patent law system lies in its information-disclosure function. In China, reverse-engineering is a common means for indigenous innovation. Patent documents may be the most important open source for local firms to absorb advanced technologies. More importantly, the introduction of a patent system and its incremental improvement has incorporated a formal rule of law governing intellectual activities in China. Innovative activities are now generally directed by business decisions rather than by political agendas. These include the recognition of the private rights of ownership of

[682] WIPO (2009), 'World Intellectual Property Indicators 2009 ', p15, at http://www.wipo.int/ipstats/en/statistics/patents/, last accessed on 28/08/10.
[683] Burns, Robert L. (2007 December), ' Will China Become the World Leader in Patent Litigation?' Lexis Nexis China Legal Review. <http://www.finnegan.com/resources/articles/articlesdetail.aspx?news=5baf9931-12cd-4d65-8f27-4644b9010b98>.

inventions, the creation of requirements and obligations of protection, and the provision and terms concerning sanctions for violation of rights. Thus, with law in place and despite some imperfections, it is increasingly secure, predictable and rewarding for both domestic and foreign users to do business and engage in R&D in the Chinese market.

Nonetheless, the roles of patents need to be considered together with other necessary policy and related factors relevant to improving Chinese innovation efforts. Firstly, it is essential for the state to have the educational policies required to develop the necessary skills and expertise essential to enable local business to benefit from the information function of a patent system. To learn from patent information, it is crucial to have expert scientific researchers capable of absorbing and improving new technologies. Another basic necessity for the attainment of the intended productivity is to have a workforce trained in fundamental technical skills, including the ability to operate various types of advanced equipments. To fulfil these needs requires the development of appropriate training and education policies.[684] To foster local innovation, many Chinese cities and large domestic research institutes or companies have initiated a variety of policies to attract overseas Chinese talents. Many of these offer competitive salaries, funding support, executive positions, free housing, favourable conditions to encourage participants to set up and run start-up companies, and other benefits. For example, it is estimated that in recent years, Shanghai alone has attracted over 50,000 PhD level returnees from such programmes in the pharmaceutical and biotechnology fields.[685] In addition, educational programmes in pharmacology and biotechnology are rapid expanding in Chinese universities. In 2006, Chinese universities produced 39,000 and

[684]Odagiri, H, et al. (2010), Intellecutal Property Rights, Development, and Catch-up (Oxford University Press), p415, p421.
[685] Luo, Y (2008), 'China: Current trends in pharmaceutical drug discovery', IDrugs, 11 (4).p280.

22,000 graduates in chemistry & pharmacology and biotechnology studies, respectively.[686]

National fiscal initiatives have also contributed to the growth of indigenous innovation. In China, innovative biopharmaceutical research depends largely on the governmental financial support. Despite the remarkable growth achieved in the past two decades, the total scale of China's domestic pharmaceutical industry remains small, and financial capacity to fund R&D activities is rather limited. The national government continues to plays a major role in supporting innovation and fostering development of research-based industries. The main national fiscal initiatives are direct state funding and tax incentives.

1. Direct State funding. One account has reported that the Chinese government has invested some US$180 million between 1996 and 2000 and US$600 million between 2000 and 2005.[687] The scale of funding support has been further enhanced recently. Under the Key New Drug Funding Scheme, the government has committed US$2.7 billion for the period from 2008 to 2010 and has planned to invest a further US$6 billion during 2011 to 2016.[688] In addition, the government has also directly invested in many strategic laboratories to improve domestic R&D infrastructure. By 2003, China had established 6 new drug selection centres, 3 Good Laboratory Practice (GLP) centres and 3 GLP key laboratories.[689] Local governments have played their part in founding

[686] PWC(2009), p13.
[687] Grace, C (2004), 'The Effect of Changing Intellectual Property on Pharmaceutical Industry Prospects' in *India and China: Considerations for Access to Medicine'*, (London: UK Department of International Development).p43
[688] The Implementation Instruction and Application Guide of 'Key New Drug Funding Scheme' , available at download.most.gov.cn/20110401091230781.doc. Qi, JZ, et al. (2011), 'Innovative drug R&D in China', *Nature Reviews Drug Discovery* 10 (333-334).
[689] Wang, MX, et al. (2004), *Strategic Research of Medicine Intellectual Property* (Beijing: Military Medical Science Press), cited in Li, YH (2010), p43.

many hi-tech incubators to provide low-cost office space and strategic advice on issues such as management and financing.[690] Such business services are important to help industry to turn new inventions into manufacturable and marketable products.

2. Tax incentives. China's High-New Technology Enterprise (HNTE) Tax Scheme provides for a general tax relief for R&D-based enterprises. It offers a reduced Corporate Income Tax (CIT) rate of 15 % as compared with the standard CIT rate of 25%, a tax exemption for the portion of income derived from technology transfer during a tax year not exceeding RMB 5 million, and a 50% reduction in CIT for the portion exceeding RMB 5 million. In addition, newly established HNTEs in the five special economic zones (Shenzhen, Hainan, Zhuhai, Xiamen and Shantou) and the high technical zone of Shanghai (Pudong New Area) may enjoy a 'two plus three' tax holiday. This means 2 years of full tax exemption followed by 3 years of a 50 % reduction in CIT.[691]

Therefore, it can be seen that strengthening patent protection has promoted innovation to the extent that it has helped to foster a new national innovative spirit and encouraged greater R&D investment in the Chinese pharmaceutical industry. Still, the scope of innovation achieved has depended to a large degree on the other governmental policies and complementary factors just discussed.

[690] IFPMA (2004), 'Accelerating Innovative Pharmaceutical Research and Development in China: a case study', (Geneva: International Federation of Pharmaceutical Manufacturers Associations (IFPMA)).
[691] PWC (2009), 'Investing in China's Pharmaceutical Industry ', (Second Edition: PricewaterhouseCoopers), p14.

7.4.2 Concerns and uncertainties:

The previous surveys have also raised some fundamental concerns about the implications of the new Chinese patent regime for the ability of local firms to supply low cost medicines and to advance their levels of innovation. Firstly, the growth in the numbers of pharmaceutical patents granted has been phenomenally fast. It can be expected that the Chinese drug development system will be transformed into a completely patent-based one before long. It is also observed that both foreign and domestic 'big pharmas' have increasingly been inclined to use their patents strategically to deter the entry of generic competition. Moreover, our patent surveys have also demonstrated that the newly emerged R&D efforts show little interests in doing research relevant to the national major health burden. All these trajectories could lead to rising costs of healthcare, declines in suppliers of low-cost medicines or even the under-provision of essential medicines in China.

Secondly, it is also a concern how the new Chinese patent regime could affect the ability of local firms in national technological catch-up. The previous studies have indicated that China has adopted a TRIPS-plus patent regime for pharmaceuticals, and that the scope of patent law is now extremely extensive and covers almost everything relating to drugs. Stronger patent protections and intensified competition have increasingly prompted the pharmaceutical MNCs to seek and enforce their patents in China.

On the other hand, Chinese innovation remains tied to its long-standing imitative and incremental tradition. Most Chinese firms can only manage to develop and produce 'me-too' drugs with technical characters closely resembling those of foreign NECs.

Consequently, many local companies are facing tremendous legal and technological challenges, with the related financial burdens involved in defence, and with some being forced to terminate their existence. To avoid infringement and compete effectively with foreign competitors, Chinese firms will need to advance their innovation levels.

Limited by low innovative capacity and insufficient funding, Chinese firms now widely regard innovation targeted on developing 'me-better' drugs as a realistic step forward.[692] 'Me-better' drugs are still imitated drugs, but they have a substantial difference in structure in comparison with the original drug.[693] However, the problem with this strategy is that NCEs are now increasingly protected by the MNCs' 'patent thicket' tactic. To innovate around patents, it is essential for Chinese firms to find the loophole in the original patent and develop drugs with distinctive characters. This requires experts with knowledge in both patents and pharmacology to design the drug which is based on the original drug but distinctive enough to be outside of the scope of original drugs' patents. However, such expertise is rare in Chinese firms.[694] Therefore, Chinese local firms are facing great legal and technical challenges in developing either me-too or me-better drugs. So until China can develop sufficient capacity to develop its own NCEs, the prospects for indigenous innovation appear bleak, and this would significantly affect the speed and ability of the Chinese pharmaceutical industry in its aspirations for technological catch-up.

7.5 Concluding remarks

[692] Li, YH (2010), *Imitation To Innovation In China: the Role of Patents in Biotechnology and Pharmaceutical Industries* (Cheltenham: Edward Elgar), pp54-58.
[693] Ibid., pp54-55.
[694] Li, YH (2010), p56.

Based on the review of R&D indicators relating to the scale, level and research orientations, the statistical assessment of this chapter found a paradox in the innovation change for the Chinese pharmaceutical industry. While it empirically identified a remarkable growth in numbers of patent applications and grants, R&D expenditures, and ITT inflow, it also found that Chinese pharmaceutical innovation has retained its long-standing imitation-oriented nature. NCEs are rarely developed locally, and little R&D is devoted to research into the cure for major disease burdens.

The studies in this chapter also have found a relationship between such consequences and the roles of patents and of other complementary factors. Firstly, strengthening patent protection has contributed greatly to promoting innovation growth and fostered greater ITT inflow; however, the scope of the attainment of such benefits has also depended on other complementary factors, such as education policy, fiscal policy, available talent pool and market advantages. Secondly patent can also impede or be detrimental to innovation. As reverse-engineering is the common means for local innovation in the Chinese pharmaceutical industry, a stronger patent regime that limits technology access can raise fundamental roadblocks that impede Chinese firms from advancing their level of innovation.

Chapter 8: The effects of China's pro-patent policy

This chapter argues that a 'pro-patent policy' has been the driving force behind China's TRIPS-plus implementation approach and examines the effects of this policy on patents produced in China. It explores the questions of whether and how China's pro-patent policy, its administration and enforcement have contributed to the proliferation of low quality patents and helped undermine domestic incentives to innovate. The chapter is organised into four sections. The first section looks at the how a pro-patent policy has affected the Chinese pharmaceutical patent legal framework. Section two then considers the impacts of pro-patent policy on the quality of patents. The third section turns to an exploration of how the pro-patent features of Chinese patent administration have affected the quality of patents. Section four studies the recent trend of excessive IP litigation in China. Finally, the last section sets out some conclusions.

8.1 Pro-patent policy in Chinese law

The traditional public policy purpose for the creation and existence of a legal system governing patents is to promote innovation and technical progress by creating private rights in the products resulting from intellectual efforts and protecting those rights by conferring temporary monopoly privileges on the originators.[695] This public-benefit foundation of the patent law system vies with a rival conception that views its purpose as being to serve the commercial interests of those who seek and hold the rights. Under this rights-centred theory, the public interests are considered to be served by the

[695] Drahos, P (2005), 'Death of a Patent System - Introduction', in P Drahos (ed.), *Death of Patents* (Lawtext), 1-9; Cowan, R, et al. (2005), 'Policy Options for the Improvement of the European Patent System'. (IP/A/STOA/FWC/2005-28/SC16: Europe Parliament Scientific Technology Options Assessment); CIPR (2002), 'Integrating Intellectual Property Rights and Development Policy'.

availability of a right that facilitates the spread of products in the marketplace.[696] A system of patent strategies shaped by this theory is termed a 'pro-patent policy'. Under a pro-patent policy, the driving force in patent design, implementation and enforcement is to promote the increase in kinds of and greater availability of patent rights.

The rights-centred conception of the patent system has gained momentum in recent years, particularly in the process of TRIPS implementation. China has rather readily embraced this conception of a pro-patent policy. This tendency can be seen clearly in the objectives articulated in the four versions of Chinese patent law as listed in Table 8.1 below.

Table 8.1: The evolution of the objective of the Chinese patent law:

	Legal text
1984 & 1992	This law is formulated in order to protect patent rights for inventions, encourage inventions and facilitate their popularization and application, promote the development of science and technology and meet the ends of socialist modernization.
2000	This Law is enacted to protect patent rights for inventions-creations, to encourage invention-creation, to foster the spreading and application of inventions-creations, and to promote the development and innovation of science and technology, for meeting the needs of the construction of socialist modernization.
2008	This law is enacted in order to protect the legitimate rights of patentees, encourage invention-creations, promote the application of invention-creation, enhance innovative capacity, and promote scientific progress and economic social development.

With slight variations of the wording, these provisions all express the same functions that the Chinese patent system is intended to serve: (1) protecting inventors' rights, and (2) promoting innovation, scientific and technological progress, and economic and

[696] Llewellyn, D (2005), 'Schrodinger's Cat: An Observation on Modern Patent Law', in P Drahos (ed.), *Death of Patents* (Lawtext Publishing Limited & Queen Mary Intellectual Property Research Institute, University of London).

social development. These objectives indicate two policy messages. Firstly, commercial rights are regarded as the primary driving force of the system. Secondly, in each the private rights purposes are superior to the public rights purposes, protect patent rights, encourage invention-creation, etc. versus meeting needs of socialist modernization/economic social development. This Chinese conception not only departs from the original intended objective for the introduction of the patent system, as commonly understood, of promoting a public good through the granting of private privileges to inventors,[697] but it is also inconsistent with the objectives and principles expressly agreed under the TRIPS Agreement.

As stated in the literature review above in Chapter 3, section 3.1.2, the objectives of implementation of the TRIPS Agreement are contained in Articles 7 and 8. These articles provide that TRIPS implementation should fulfil multiple objectives, including 'protection and enforcement of IPRs… in a manner conducive to social and economic welfare, and to a balance of rights and obligations' (Article 7), protecting public health and other social interests (Article 8.1), and preventing abusive use of patents and anti-competitive acts (Article 8.2). The express language in Article 7 and the existence of a mix of public and private interest objectives requires policymakers to balance private IP interests against a variety of interests that concern wider socio-economic issues in TRIPS interpretation and implementation.

In comparison with the TRIPS objectives, the scope of the objectives of Chinese patent law is narrower and its weight is heavily placed on private patent interests and economic expectations of the system. There is no express or implied objective of balancing the

[697] For the discussion of the justification of patents, see Drahos, P (1996), *A Philosophy of Intellectual Property* (Dartmouth Publishing); Sherman, B and Bently, L (1999), *The Making of Modern Intellectual Property Law* (Cambridge University Press).

interests of rights producers against those of rights users and society in general. Such a reading may be explained by appreciating how the prevailing global political ideology of economic-centric development has dominated and influenced policy-making since the 1980s. Also, the use of such restrictive language may be attributable to the policy-makers' inadequate understanding of the implications of patents and TRIPS on China's development. A third consideration is of the unforeseen effects that transplants of alien legal concepts into different legal cultures can have. As currently designed, the Chinese policy objectives could lead to an imbalance between rights and obligations and between commercial interests and the public, social interests in law formulation and application.

Yet, China's policy options between TRIPS flexibilities and TRIPS-plus provisions may provide opportunities for achieving a better form of pro-patent system. As reviewed in chapter 5, the interpretation of TRIPS under Chinese law has emphasised increasing the control of rights; while safeguarding measures for public interests has been largely ignored. Under the 1992 and 2000 patent reforms, the rights provided for pharmaceutical patentees were broadened and strengthened. In addition, Chinese legislation has incorporated other TRIP-plus measures negotiated under the bilateral IPRs agreement, such as data exclusivity, restrictions on the use of compulsory licences, and patent registration linkage. These measures provide a much higher level of protection than those mandated by the TRIPS Agreement.[698] On the other hand, the earlier Chinese law failed to introduce TRIPS flexibilities, including the international exhaustion regime, the early working exception, provisions on anti-competitive practises, and the working requirement for the issuance of compulsory licences.

[698] Correa, C (2006), 'Implication of Bilateral Free Trade Agreement to Access to Medicines', p399.

The 2008 patent reform is widely acknowledged with an improved balance between the interests of right producers and users. All the key TRIPS flexibilities are also incorporated into law. Nevertheless, it remains to be determined whether the 2008 patent reform can ameliorate the entrenched bias in the Chinese pharmaceutical patent system. The new rules are widely acknowledged to have improved the balance between the interests of rights producers and users. Also, all the key TRIPS flexibilities are now incorporated into Chinese law. Yet, there are still some challenges under the reformed law. The first problem is that TRIPS-plus standards remain unchanged under Chinese patent law and drug regulations. Their presence could affect the effectiveness or reduce the scope of the newly introduced safeguarding measures. Secondly, various procedural or compensatory hindrances are built into the TRIPS framework, making the application of the TRIPS flexibilities difficult. Moreover, the effectiveness of the new rules also depends upon the availability of expert legal practitioners capable of applying them in their advice to clients and in actual cases. China is not yet well-equipped in this vitally required area.

8.2 The quality of patents

The currently prominent form of pro-patent policy as presented above is commonly perceived to have originated in the US during the late 1980s.[699] This policy has created serious problems in the US that undermine the true invention incentive.[700] The main problems have related to a proliferation of patents of poor quality and excessive

[699] Asano, T (2006), 'Trends in the U.S. Pro-Patent Policy in the Pharmaceutical and Biotechnology Fields: Focusing on the Hatch-Waxman Act', *Institute of Intellectual Property Bulletin* <www.iip.or.jp/e/e_summary/pdf/detail2005/e17_20.pdf>.
[700] Arai, Koki (2010), 'Patent Quality and Pro-patent Policy', *Journal of Technology Management & Innovation* 5(4).

litigation. Since the late 1980s, many poor quality patents have emerged under the US pro-patent regime. A 'poor quality patent' is one likely to have invalid patentability or overly broad claims[701]. Patents with such qualities can deter or raise the cost of innovation. If a competitor has chosen to pursue R&D in the area improperly protected by the poor quality patent, this party is compelled to seek a licensing agreement, challenge the patent in court, or expend resources to avoid infringement by inventing around the patent. Whichever of these options is taken, it is likely to be very costly and in fact, wasteful.[702]

In addition, poor quality patents have also been manipulated as tools to deter competitive products from reaching the market, or to prevent others from sharing ideas in order to maintain their own leading competitive position. It is also observed that many firms neither commercialise these patents nor licence their use to others, but merely put them on hold and wait. As others make the relevant commercial move, the patent holder will then file a suit against them for infringement. The litigation is expensive and time-consuming for all parties involved. Such litigation costs are wasteful and unjustifiably raise costs to business and ultimately to customers.[703] In 2011, the US has passed 'The Leahy-Smith America Invents Act' to address these issues But, it remains an unclear whether this can fix the problem of excessive litigation under the US patent system.

As mentioned above, China has embraced a pro-patent policy since the early 1990s. The effects of this policy can be seen in the wide domestic use of utility models and design

[701] FTC (2003), 'To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy', (Washington, DC Federal Trade Commission (FTC)).
[702] FTC (2003), Sag, M and Rohde, K (2006), 'Patent Reform and Differential Impact', Minnesota Journal of Law, *Science & Technology*, 8 (1).
[703] FTC (2003).

patents to protect trivial inventions, the traditionally lenient standards for substantive patent examination, and the significant rise in recent years following the law reforms of damage claims and court decisions granting such claims. A more direct effect of a pro-patent policy can be seen in the benefits states' grant to inventors or patent holders. For example, all local governments subsidise the entire patent application process of qualifies enterprises or individuals. Mere ownership of a certain number of Chinese patents increases a researcher's chances to advance and acquire tenure in universities or research institutes, and qualifies companies as high-technology enterprises enabling them to take advantage of preferential corporation tax rates and tax holidays.[704]

With all these pro-patent strategies in place, it can be expected to see an even greater increase in patents filed with or granted by the CPO, regardless of their quality. Already in 2010, China received 1,221,000 (391,177 invention patents) patent application filings, and it became the world's second largest recipient patent office.[705] Also in 2010, the Chinese patent office granted 815,000 patents, but most (680,000) were non-examined utility and design patents.[706] The quality of such a vast amount of patents is highly questionable. Despite the large number of commentators sceptical of, the quality of many Chinese patents, no one has offered a precise measurement due to the constraints of methodology and limited data available.[707] It is submitted that the observations of the professional users of the system may provide a useful gauge. The Intellectual Asset

[704] Wild, J (2011), 'Quality is China's Biggest Patent Challenge ', *IAM Magazine*. http://www.iam-magazine.com/blog/Detail.aspx?g=e81c5421-bccc-4eb5-9895-f347443cf73e; Liang, M (2012), 'Chinese Patent Quality: Running the Numbers and Possible Remedies', *The John Marshall Review of Intellectual Property Law,* (478).
[705] SIPO (2010), 'Annual Report of the State Intellectual Property Office of China '. http://english.sipo.gov.cn/laws/annualreports/2010/; WIPO (2011) 'IP Filings Worldwide Rebound in 2010 despite Economic Turmoil', (PR/2011/701) http://www.wipo.int/pressroom/en/articles/2011/article_0028.html;.
[706] SIPO (2010), 'Annual Report of the State Intellectual Property Office of China '.
[707] LIANG, M (2012), 'Chinese Patent Quality: Running the Numbers and Possible Remedies', *The John Marshall Review of Intellectual Property Law*, (478).

Management/Thompson Reuters benchmark surveys conducted in 2009 and 2010 on the quality of patents granted by the world's largest five largest patent offices, China stood at the bottom of the class with 22% and 23 % of in-house counsels considering the quality of patents granted by SIPO to excellent or very good in 2009 and 2010, respectively (compared to 71% and 74% for the EPO topping the list in 2009 and 2010, respectively) [708] With a more than 70 % dissatisfaction rate, it is reasonable to assume that the CPO is not commonly recognized as a quality patent issuing authority and that the quality of many Chinese patents is questionable.

The proliferation of poor quality patents can be very detrimental to innovation in China.[709] The persistence of Chinese indigenous innovation in being imitative and incremental means Chinese firms need to monitor new developments in patent technology closely to develop their own 'me-too' or 'me-better' drugs. Transaction costs are extensive and substantial for follow-on innovations when the existing patents are overlapping.[710] This is particularly relevant to pharmaceutical patents, as the industry is keen to pursue 'patent thickets' by seeking a wide portfolio of patents around a single invention.[711] Given the scale of questionable patents in China, it is reasonable to assume that poor quality patents have contributed significantly to the patent thicket and other anti-competitive practices. The *Eli Lilly* case discussed in Chapter 6 gives further

[708] EPO (2011), 'EPO Again Tops Patent Quality List '. http://www.epo.org/news-issues/news/2011/20110628.html; Wild, J (2011), 'Quality is China's Biggest Patent Challenge ', *IAM Magazine*. <http://www.iam-magazine.com/blog/Detail.aspx?g=e81c5421-bccc-4eb5-9895-f347443cf73e>.
[709] 'For the definition of 'patent thicket' see n. __ above. A patent thicket is 'a "dense web of overlapping intellectual property rights that a company must hack its way through in order to actually commercialize new technology.' Shapiro, Carl (2001), 'Carl Shapiro, Navigating the Patent Thicket: Cross Licenses, Patent Pools, and Standard-Setting, in', in A Jaffe, J Lerner, and S Stern (eds.), *Innovation Policy and the Economy* (MIT Press).
[710] Rangnekar, D (2006), 'No Pills for Poor People? Understanding the Disembowelment of India's Patent Regime', *Economic and Political Weekly*, p412.
[711] Ibid. For the definition of 'patent thicket' see note 633 above.

support to the argument that poor quality patents have helped suppress innovation and generic competition in China.

8.3 Patent administration

In this section, this thesis examines how external influences and resource constraints affect the performance of the Chinese patent office (CPO) in patent administration.

8.2.1 Political interests in patent expansion

Unlike the most popular 'statutory person' model of other patent offices,[712] the State Intellectual Property Office of the PRC (SIPO) is a governmental agency directly affiliated under the State Council of the PRC. Its predecessor was the Patent Office of the PRC.[713] The SIPO was established as part of a governmental policy attempt to coordinate China's IPR protection and enforcement bodies under one national authority, although this objective has yet to occur. Today, SIPO's legal affairs cover the administration of patents and layout designs of integrated circuits, international applications, patent re-examination and invalidation, and administrative review. The Patent Affairs Administration Department (PAAD), a SIPO major affiliate and commonly referred to as the Chinese Patent Office (CPO), oversees the legal work relating to patents.[714] Also, SIPO plays an explicit role in policy formulation.[715] It has a special policy unit, the 'Legal Affairs Department,' with a major role in policy development. More unusually, it runs a business unit for technology commercialisation

[712] Thambisetty, S (2007), 'The Institutional Nature of the Patent System: Implications for Bioethical Decision-Making', in C Lenk, N Hoppe, and R Andorno (eds.), *Ethics and Law of Intellectual Property: Current Problems in Politics, Science and Technology* (Surrey: Ashgate).
[713] 'Introduction of SIPO', available at http://www.sipo.gov.cn/sipo_English/about/basicfacts/200904/t20090415_451001.html, accessed on August 18, 2010.
[714] About the SIPO, http://www.sipo.gov.cn/sipo_English/about/.
[715] Para 1.3, 7 etc, 'Introduction of SIPO'.

services, the China Patented Technology Development Corporation, which began its operations in 1986.[716] There are several problems with such an organisational structure.

First, SIPO's political affiliation may interrupt its integrity in patent administration. As a governmental agency, SIPO depends heavily on the central government for finance, welfare, personnel, and other operations. This dependence makes SIPO susceptible to political influence in its patent administration. In fact, the fundamental function of the SIPO is to serve the objectives of the national technological development agenda. Under the Outline of National Intellectual Property Strategy issued by the State Council recently, SIPO is assigned the mission to improve 'China's capacity to create, utilize, protect and administer intellectual property, making China an innovative country and attaining the goal of building a moderately prosperous society in all respects.' [717] Specifically, the patent office is required to '[m]ake advanced development plans according to the nation's strategic needs in some sectors such as biology, medicine, information,..., and to obtain a group of patents in these core areas of technology to support the development of China's new and high technology industries.'.[718] Clearly, this strategy manifests not only the country's aspiration to update China's reputation from 'made in China' to 'innovated in China', but also the political interest in patent expansion. Under such influence, the work of the SIPO can be greatly affected by the notion that patents are good for economic and technological development, the more the better. This is likely to boost its enthusiasm for granting patents

[716] See SIPO structure in SIPO (2008), 'A Brief Introduction and Review of the State Intellectual Property Office of P.R. China', in SIPO (ed.), (Beijing SIPO Press), p6, in Chinese; also See the introduction about the business unit affiliated with the SIPO, available at http://www.sipo.gov.cn/sipo2008/gk/zzjg/jgjs/qtzsdwjs/200804/t20080401_364051.html, in Chinese.
[717] See the preamble in The State Council (2008), 'Outline of the National Intellectual Property Strategy'.
[718] Para 16, Ibid.

The second concern is SIPO's ownership of a profit-driven business unit that directly engages in patent commercialisation. It is understandable that as a State agency with a considerably smaller budget and lower salaries for its personnel in comparison with those of privately-owned enterprises, there is pressure on SIPO's management to generate extra revenue to improve the organisation's finances. Nonetheless, the profit motive of business involvement in patent affairs makes the SIPO a direct beneficiary of the expansion of patenting. Thus, the SIPO' motivation of revenue generation may have added another driving force encouraging the proliferation of patents in China.

8.2.2 Resource limitation

The disparity between the growing numbers of patent applications and constant examination resources can contribute to the poor quality of patent examination.[719] The CPO is one of the fastest growing patent offices in the world. Between 1995 and 2007, filings in China grew on average by 23.9% a year, which is far above the growth rate of filings at the EPO and the USPTO. The CPO became the world's second largest patent receiving office in 2010.[720] The surge of patenting filing has led to a large and growing backlog of unprocessed patent applications at the office, since there are insufficient numbers of examiners to deal with the incoming load of patent applications.[721] According to SIPO, the CPO was staffed with 2844 personnel by 2008, with 1913 examiners for invention patents, 312 for UM and Design patents, 249 for preliminary examination and flow management, and the rest for other supporting tasks.[722] Also, IAM (Intellectual Asset Management) has reported that the SIPO now has 5000

[719] Sag, M and Rohde, K (2006), 'Patent Reform and Differential Impact', *Minnesota Journal of Law, Science & Technology*, 8 (1).p18.
[720] WIPO 'World Intellectual Property Indicators - 2011 Edition', <http://www.wipo.int/ipstats/en/wipi/>.
[721] Yin, XT (1998/1999), 'A Brief Introduction to the Patent Practice in China ', *Duke Journal of Comparative & International Law* 9.
[722] SIPO (2008), 'A Brief Introduction and Review of the State Intellectual Property Office of P.R. China',(Beijing SIPO Press).

examiners and the rate of new recruits is growing at around 250 per year.[723] Thus, growth is underway but like other major world patent offices, the CPO continues to experience patent backlog problems.[724] Against this environment, the CPO confronts constant demands to improve its productivity. The pressure to accelerate the processing of patent examinations may induce examiners to be less rigorous in their application of the patent examination standards. In turn, this could have affected the quality of patents.

8.2.3 Convergence with the Trilateral Offices' practices

The CPO has so increased its cooperation with the Trilateral Offices, the USPTO, EPO and JPO combined (TO) that its administrative patent practices have effectively converged with those of the TO. Most significantly, by incorporating TO patent examination techniques, the CPO has enhanced its ability to grant greater numbers of patents. Since the 1980s, the TO members have established powerful joint cooperative arrangements among themselves. Over time, this trilateral cooperation has brought greater compatibility and alignment among their technical systems for exchanging data and for the search and examination of applications. [725] At the same time, the TO members have also actively sought to integrate developing country patent offices into a global system of patent administration through 'technical assistance' programmes.[726] China has been absorbed within such global patent administration system through bilateral and multilateral co-operation, such as the EU-China IPR 2 and the Five Offices Cooperation, which includes the USPTO, EPO, JPO, SIPO and KIPO. [727] These international technical assistance programmes have spread widely and deeply in the area of patent

[723] Wild, J (2011), 'Quality is China's Biggest Patent Challenge ', IAM Magazine, at <http://www.iam-magazine.com/blog/Detail.aspx?g=e81c5421-bccc-4eb5-9895-f347443cf73e>
[724] UK IPO 'Patent backlog' http://www.ipo.gov.uk/pro-types/pro-patent/p-policy/p-policy-backlog.htm.
[725] Drahos, Peter (2007), '"Trust me": Patent offices in developing countries', (ANU working paper), p6.
[726] Ibid.,p33.
[727] Trilateral 'Four Office Statistics Report 2008', available at http://www.trilateral.net/statistics/tsr.html.

administration. The EU-China IPR co-operation is useful illustration. Phase 1 of the co-operation programme operated between 1999 and 2004. The main tasks of this phase aimed to support administrative, legislative and judicial reforms.[728] The second phase of the project (EU-China IPR 2), launched in 2007, focuses on patent enforcement. Through this second co-operation phase, the EU aims to improve the effectiveness of the IPR enforcement system in China through technical assistance with Chinese legislative, judicial, administrative and enforcement institutions.[729]

The Trilateral Offices, through their technical assistance programmes, not only help the CPO improve its efficiency but also influence its decision-making processes. Thus, the CPO is becoming increasingly integrated into the emerging global system of patent administration. The system is currently structured and operated under the principle of productive efficiency.[730] It can be expected that the CPO will become more 'efficient' and grant many more pharmaceutical patents. This emphasis on efficiency may well be to the detriment of quality of patents unless the there is a shift to a more balanced administrative policy.

8.4 Excessive patent litigation

The proliferation of poor quality patents has generated a large, even excessive amount of patent litigation in China. Presumably mirroring the trend in patenting, China has become the country having the most IP litigation in the world.[731] In the US, the

[728] EPO 'EU-China Project on the Protection of Intellectual Property Rights in China (IPR2)', available at http://www.epo.org/about-us/office/international-relations/projects/ipr2.html, accessed on August 28, 2010.
[729] See EU-China IPR 2 introduction, available at http://www.ipr2.org/index.php?option=com_content&view=article&id=44&Itemid=1, accessed on August 28, 2010.
[730] Drahos, P (2007), '"Trust me": Patent Offices in Developing Countries', p33.
[731] Wild, J (2010), 'There is More IP litigation in China than Anywhere Else on Earth', Intellectual Asset Management. <www.iam-magazine.com/ctredir.ashx?g=3a9c9c06-dd4f-4adc...>. urns, R (2007), 'Will

historical record number of civil patent cases in one year was 3075 in 2004. [732] In China, the number of civil patent cases in 2007, the earliest year that data was available, already exceeded the US record and stood at 4041 (Table 8.2). In 2010, the number of Chinese patent cases has grown further by 43% when compared to 2007 to a total of 5785 cases. It is well established that excessive patent litigation can deter innovation, considering the involved high legal costs, long term in court, the expensive damages or settlement sums, and the patent troll problems.[733]

Table 8.2 Patent litigation statistics (China vs US)

	2007	**2008**	**2009**	**2010**
China	4041	4074	4422	5785
US	2896	2892	2744	2892

Sources:

1. Intellectual Property Protection in China (2007) http://www.sipo.gov.cn/zwgs/zscqbps/200805/t20080505_395442.html
2. Intellectual Property Protection in China (2008) http://www.sipo.gov.cn/zwgs/zscqbps/200904/t20090427_457166.html
3. Intellectual Property Protection by Chinese Courts (2009) http://www.court.gov.cn/zscq/znss/201004/t20100426_4544.html
4. PWC Patent Litigation Studies 2007, 2008, 2009 and 2010.

In addition to the poor quality of patents, the courts' pro-patent stance could also have contributed to the growth of patent litigation.[734] This is particularly the case with the Chinese courts because of their strong political and economic dependency on the government. In China, the judiciary is not designed as a constitutionally independent

---

China Become the World Leader in Patent Litigation?' *Lexis Nexis China Legal Review*. <http://www.finnegan.com/resources/articles/articlesdetail.aspx?news=5baf9931-12cd-4d65-8f27-4644b9010b98>.

[732] PWC (2011), 'Patent Litigation Study: Patent litigation trends as the "America Invents Act" becomes law', (PricewaterhourseCoopers), p8.

[733] FTC (2003), 'To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy', (Washington, DC Federal Trade Commission (FTC)). Lemley, A and Shapiro, C (2006), 'Patent Holdup and Royalty Stacking ', (324: Stanford Law School Working Paper); Arai, Koki (2010), 'Patent Quality and Pro-patent Policy', *Journal of Technology Management & Innovation* 5(4).

[734] Landes, W and Posner, R (2004), 'The Political Economy of Intellectual Property Law', (AEI-Brookings Joint Center for Regulatory Studies) , at ww.aei.org/docLib/20040608_Landes.pdf>.

branch of the government. The courts' decisions are influenced by three sources of external influence: (1) constitutionally, courts are subject to the supervision of the NPC (legislature); the NPC exercises supervisory power over all administrative, judicial and procuratorial organs of the state,[735] (2) politically, courts are subject to the leadership of the Party, and (3) economically, courts also depend on local governments for their budget. [736] With such affiliations, Chinese courts are expected to support the government's innovation agenda and thus are more likely to embrace the state's pro-patent bias.

As explored in Chapter 6, China's compliance with and implementation of its obligations in multilateral treaties relating to patents has required it to increase judicial powers of enforcing both civil and criminal claims of patent-holders. This creates a judicial predisposition in their favour and strong procedures for the protection of their interests. The case study on *Eli Lilly* in section 6.3.2, for example, illustrated how the Chinese Pre-Litigation Injunction procedure required the court to issue and execute its injunction rapidly to benefit the patent-holder, despite eventual invalidation of most of its claims and great damages to the defendant and its ability to market its product. In addition, as the analysis of Chinese litigation summarized in Table 8.2 below shows, patent-holder plaintiffs have won in an average of 86% of the cases filed between 2006 and 2009. This high average plaintiff win rate is another indication that there may be an inherent judicial preference in the system. More interestingly, China IP Litigation Analysis, created by Rouse, a leading foreign IP firm in China,[737] has reported that the

[735] Article 3, Constitution of the People's Republic of China (2004).
[736] Ambler, T, Xi, C, and Witzel, M (2009), Doing Business in China (3 edn.; New York: Routledge). p120, also in Gechlik, M (2007), 'Protecting Intellectual Property Rights in Chinese Courts: an analysis of recent patent judgments', p7.
[737] China IP Litigation Analysis (CIELA) 'is a unique, highly innovative service providing statistical analysis of civil IP litigation cases in China. CIELA analyses and compiles key data from more than 10,000 published IP judgments and settlements across all major IP courts in China since 2006 to provide

average duration of proceedings for IPRs cases in China is only about 7 months (Table 8.3). Compared with the average of 2 to 3 years' duration in many other countries, this may suggest another cause for concern.

The increase in litigation may indicate that there is a growing confidence in the Chinese litigation system and an enhanced ability of right-holders to protect and enforce their rights there. This development could promote higher level of R&D investment and thus innovation growth; however, paradoxically, it is just as likely that poor quality patents would also be increasingly protected and enforced.

Table 8.3 IP litigation analysis in China (2006-2009)

Years	IPR cases filed	IPR cases decided	Average duration of proceedings	Average plaintiff win
2006			7 months	84%
2007	17877	17395	7 months	86%
2008	24406	23518	7 months	84%
2009	30626	30509	6 months	91%
Average			**6.75 months**	**86%**

Sources:

1. China IP litigation analysis: available at http://www.ciela.cn/Content2.aspx?pageId=14&ppId=3&language=en
2. Intellectual Property Protection in China (2007) http://www.sipo.gov.cn/zwgs/zscqbps/200805/t20080505_395442.html
3. Intellectual Property Protection in China (2008) http://www.sipo.gov.cn/zwgs/zscqbps/200904/t20090427_457166.html
4. Intellectual Property Protection by Chinese Courts (2009) http://www.court.gov.cn/zscq/znss/201004/t20100426_4544.html

8.5 Concluding remarks:

By building upon the previous empirical studies, this chapter identified a pressing concern with the Chinese patent system: patents of poor quality have become too easy

---

the information rights owners need to develop an informed approach to enforcement in China' 'Rouse, the creator of CIELA, is a leading IP consultancy specialist consistently ranked amongst the top foreign IP firms in China', see'.http://www.ciela.cn/Content2.aspx?pageId=4&ppId=4&language=en.

to obtain and enforce in China. The studies have indicated that this problem appears to be a product of the interplay of China's adoption of the dominant global pro-patent policy, resource constraints, and lack of experience in patent administration and litigation. As a consequence, every year the system produces an astonishing number of low quality patents which have no relation with innovation. Furthermore, these poor patents generate excessive, deleterious patent litigation in China. Both these trends can impair innovation and undermine the intended objective of the patent system.

Chapter 9 Conclusions

This thesis has drawn on empirical evidence and expert insights to determine the actual policy and economic effects of China's implementation of TRIPS' stronger patent rules on innovative capabilities of its pharmaceutical industry. Its findings can be summarised as: (1) China has not succeeded in establishing a pro-development patent regime under the TRIPS legal framework, but instead, has embraced an economic-oriented pro-patent approach to its patent law. (2)The effects of China's pro-patent policy on innovation have been multifaceted and mixed. Whereas, positive effects of patent strengthening were indentified empirically through innovation indicators, including patent applications and grants, R&D expenditure and ITT inflow, Local innovation remains imitation-oriented, little R&D is devoted to researching cures for major diseases, more MNC patents control leading and upstream technologies, and patent litigation has greatly increased. (3) China' experience may imply that the pro-patent approach in TRIPS implementation is not as constructive for economic development as the promoters have claimed and as many Chinese policymakers have assumed. China's experience also demonstrates the challenges and experimental nature of the process involved for developing countries to design an optimal patent regime under the TRIPS legal framework. The three sections below discuss them in turn.

9.1 The evolution of Chinese patent policy for pharmaceuticals

Chinese law concerning protection for pharmaceutical patents has harmonized rapidly since 1984 to achieve numerous TRIPS-plus standards. Under its modern patent system introduced in 1984, pharmaceuticals were excluded from patentability, the patent term

was fifteen years, and the working requirement was provided under the compulsory licensing provision; however, these provisions were soon eliminated by the 1992 amendment. Subsequently, patent protection standards were further broadened and strengthened under the 2000 amendment to fully conform with its obligations under TRIPS and other measures negotiated under bilateral IPR agreements. Immediately following its accession to the WTO in September 2001, China incorporated *additional* TRIPS-plus provisions in its drug registration and administrative laws. These included a 6-year data exclusivity, a 7.5-year administrative patent protection rule specifically designed for foreign pharmaceutical products, and a US-style patent linkage system. Paradoxically, the built-in TRIPS flexibilities, such as the international exhaustion regime, the regulatory exception/early working exception and provisions on anti-competitive practises were omitted from China's TRIPS implementation until recently. As a result, Chinese law governing pharmaceutical patents has conferred more weight to protecting interests of rights producers and greater importance to the economic dimensions of the patent system, while considerably neglecting to balance concerns for right users' interests and wider socio-economic issues.

This 'pro-patent' approach is also evident in the execution of enforcement measures. Firstly, following this policy approach Chinese judicial bodies have been inclined to interpret TRIPS enforcement measures in a simplistic and imbalanced manner. The Chinese patent law has introduced provisions enhancing private control rights but has largely left out complementary rules of obligation safeguarding interests of rights users and the public. Secondly, Chinese criminal enforcement rules cover not only trademark and copyright but also patents and trade secrets. This is a higher standard than TRIPS requires. Thirdly, the pre-litigation injunction enforcement measure was structured for

the benefit and convenience of rights-holders. The fact that the requirements for granting an injunction order are so loosely defined and readily met by the applicants creates a risk of imposing damages unfairly on competing patent seekers and delaying the entry of valuable innovative medicines to the market. Thus, although China has more than met its international patent protection and enforcement obligations, it has neglected important domestic ones in the process of achieving this,

This thesis has found a number of rationales behind China's embrace of its particular pro-patent pharmaceutical regime. On the international sphere, China's dependence on the US market and technology and US political influence on China's accession to the WTO made it vulnerable to US demands to increased TRIPS implementation. Domestically, China's adoption of an economic-centric development policy also channelled it towards favouring a TRIPS-plus approach to IPRs. Under the economic-centric development policy, development was measured by economic indicators, such as the amount of gross domestic output (GDP), trade, and FDI flow, whereas humanitarian considerations, such as access to education and health care, employment opportunities, economic security, and political freedom, were of little concern. Law and legal reforms were viewed as institutional tools for the attainment of the economic agendas. This development policy has encouraged China to adhere to the private rights-centred conception of a patent system and a pro-patent policy.

Finally, given the findings that China has adopted a pro-patent rather than a pro-development policy towards pharmaceuticals, it follows to consider whether this study provides any guidance regarding the feasibility of developing countries' building a pro-development policy in compliance with their TRIPS obligations. China's experience

demonstrates the challenges and experimental nature of the process involved for developing countries to design an optimal patent regime under the TRIPS legal framework. This is particularly potent for countries with conflicting legal cultures regarding property law. As seen with China, increasing IPR protections beyond the TRIPS requirements makes this process even more difficult even for countries like China with relatively stronger economic and institutional capacities. This thesis also found that the pro-patent approach in TRIPS implementation are not as constructive for economic development as the promoters have claimed and as many Chinese policymakers have assumed. Nonetheless, there are some policy spaces within the TRIPS regime that may be useful in furthering a pro-development policy that China has not utilised effectively in its TRIPS interpretation and implementation.

9.2 Effects of Chinese pro-patent policy on innovation change

This research has found that the effects of China's pro-patent policy on innovation in the Chinese pharmaceutical industry are multifaceted and diverse. The establishment of a patent system and its continual improvement have introduced the rule of law and private property concepts to intellectual activities in China. Despite being at an early stage, these developments are making the Chinese market an increasingly secure, predictable and rewarding place to undertake R&D and trade high-technology goods. In this sense, the patent law has played a positive role in increasing both domestic and foreign interest in innovation and investment in China. Still, not all the effects are positive.

This thesis has examined the State of local pharmaceutical innovation under both quantitative and qualitative standards. The empirical analyses found strong evidence to

support the above propositions. The number of pharmaceutical patents filed to the Chinese patent office has grown at an average rate of 22 % between 1987 and 2007 (Appendix .1), and the number of pharmaceutical patents granted have grown by as much as 24 % (Appendix 2). The increasing growth of domestic patenting began in 1984 with the introduction of the patent system, whereas foreign patenting started to grow later in 1992 after China introduced a product patent regime for pharmaceuticals. This indicates at least a quantitative increase in innovation.

The research has also found that patent incentives have contributed to a measurable growth in pharmaceutical R&D activities and investment in China. In terms of the inflow of FDI and ITT, the thesis examined the evolution of the composition of FDI inflow from the world's top 12 pharmaceutical MNCs to China before and after the 2000 patent reform. It found that in the 1980-90s when China had a weak patent system, all 12 MNCs had limited their operations to forms of distribution or manufacturing, but following the 2000 patent reform in line with TRIPS requirements, R&D-oriented FDI emerged from most of the sampled MNCs. Moreover, in recent years local players also successfully developed, patented and commercialized a number of innovative gene therapy drugs.

On the other hand, these innovation and investment statistics cannot be interpreted narrowly and simplistically, and the roles of patents in China need to be understood qualitatively along with the following five complementary aspects. Firstly, the economic effects of patent policy have to be understood together with other indispensable economic and policy factors. As the survey in chapter 7 has shown, there are other important factors also attributable to the growth of innovation, FDI and ITT in

the Chinese pharmaceutical industry. These specifically include national fiscal and industrial policies, national funding initiatives, market advantages and human resources.

Secondly, a significant portion of Chinese pharmaceutical patents may actually represent impediments to innovation. This is because China's pro-patent policy has rendered numerous patents of low quality that are too easy to obtain and enforce. This has caused a proliferation of poor quality patents and excessive patent litigation. These trends not only hurt innovation but also distort the incentive rationales of the patent system. The case study in Chapter 6 illustrated how Eli Lilly's poor quality patent had disrupted generic competition and local innovation.

Thirdly, Chinese domestic innovation has not made as much progress in the pharmaceutical industry as its policymakers had expected. Chapter 7 has revealed that the Chinese pharmaceutical industry has retained its long-standing imitation-oriented nature. No NCEs have been produced locally since the patent incentive mechanism was introduced two decades ago. Chinese patents are overwhelming characterised by imitative and follow-on technology, while the patents held by foreign rights owners are largely associated with leading or upstream technologies. The presence of such foreign patents in China is rising and foreign rights holders are increasingly inclined to use their rights strategically in competition against local rivals. These trends impose high economic, technological and legal costs on Chinese follow-on innovation, thus make the catch-up more difficult.

Fourthly, the geographical distribution of FDI and IT benefits are uneven. The survey has shown that the emerging R&D-oriented FDI projects are overwhelmingly

concentrated in Beijing and Shanghai or cities in close proximity to them (Table 7.4). Such geographical distribution of R&D-oriented FDI implies that the majority of domestic pharmaceutical companies are excluded from the benefits induced by the strengthening of patent protection, while they also have to bear higher operating costs resulting from such legal change. These disadvantages impose serious burdens on the business prospects of these companies. This could have implications on access to medicine and local employment, given that these companies are important providers of low cost medicines and local jobs.

Lastly, the increasing R&D activities have not responded properly to the primary local health needs. The patent analysis in Survey 3 in section 7.2 above has revealed that the quotient/ratio of patent application filings associated with therapeutic treatments for the infectious diseases was the lowest with an average of 0.0006, while the relevant ratios related to the chronic disease and the sampled lifestyle therapies were 0.0045 and 0.0050, respectively, approximately eight times greater than the former. These results support the view that the patent incentive may not be effective in improving the inadequate R&D efforts devoted to research into cures for the diseases essentially important to Chinese patients, particularly the poor.

Put together, the examination of China's experience has provided several important lessons for developing countries about the roles of stronger patents required by the TRIPS Agreement in inducing indigenous innovation First of all, as far as the economic effects are concerned, it is submitted that China's experience cannot be applied generally to other developing countries, given China's unique political and business conditions. Nonetheless, the Chinese experience may testify to the proposition that

TRIPS obligations make technological catch-up more difficult, at least in the context of the pharmaceutical industry, and a pro-patent approach to pharmaceuticals may be not well-suited to the growth of indigenous innovation, which largely relies on reverse-engineering.

9.3 Implications and directions for further research

The primary goal of China's national IPR strategic plan is to promote China as one of the world's most important centres for technological innovation through the policy of stronger and increased numbers of patent filings by 2020.[738] The pharmaceutical industry is one of 16 strategic sectors in which China desires to achieve this goal.[739] But this research finds that so far, strengthening patent protection by TRIPS or TRIPS-plus standards has promoted the growth of patenting, but not advancements in the innovation level of the industry. Given the findings of this thesis, particularly the persistence of domestic imitative and follow-on innovation and increasing foreign litigation tactics and superiority in pharmaceutical patents in the Chinese and world markets, China's expectation that a stronger patent regime can engender faster catch-up is likely to be frustrated.

Despite its dissatisfaction with the role of patents in fostering local pharmaceutical innovation in China, the Chinese patent office and other nation's patent offices can be reasonably expected to continue to grant increasing numbers of pharmaceutical patents to Chinese nationals, with little regard for the technical value they present. Given the diverse interests in the expansion of patent rights, this prospect may fulfil the intended

[738] Para II.2 (6) The state council (2008), 'Outline of the National Intellectual Property Strategy'.
[739] Para IV,1(16), Ibid.

policy goals of the law drafters, but it casts shadows on the campaign for better access to medicines both domestically and internationally.

The empirical studies herein have also indicated that Chinese ignorance of the development implications of IPRs may be the greatest concern with the TRIPS Agreement in China. Early in its introduction to these new rights, China had abandoned the TRIPS flexibilities and agreed to TRIPS-plus standards on medicines, and it was not until the 2008 patent law amendment that the TRIPS flexibilities were accommodated into national law, while all TRIPS-plus provisions remain in force. As reviewed in Chapters 4 and 8, that decision was not well-informed. Generally, it is assumed that legislators should not make decisions without full knowledge of the appropriateness and various implications it will have on domestic law and the national interest. There should be particular care paid to the introduction of a legal concept fundamentally new to its legal culture, such as is the idea and issues of intellectual property. Chinese decision-makers, despite their crash course on the subject compelled by China's WTO membership, remain novices in their understanding and experience in this area and particularly regarding the roles of patents in economic and social development. This limits China's ability to make informed policy decisions.

Just as problematic is the fact that personnel involved in IP law-making and management in China have been deeply influenced by the international legal framework. As discussed above, the global IPRs regime is systemically biased in favour of patent-holder rights. The work of the patent office, drug administration, courts, and other administrative bodies has tended to adhere to the political dogma that 'patents are good for innovation and economy' and 'the more and stronger the patents, the greater the

economic efficiency'. Meanwhile, considerations of public health and the wider socio-economic issues have been neglected. With such scant IP experience and the influence of unbalanced information, China has great challenges in establishing an optimal patent system that is truly compatible with its internal economic and social interests while fulfilling its international obligations.

Therefore, there is an urgent need to address the asymmetry of the existing IP-related foreign assistance, and to help China to develop its national patent system on the basis of balanced information. It is submitted that Chinese policymakers should consult international non-governmental organisations for IP and health (IP/health INGOs) in its patent policy formulation and implementation processes. These NGOs have accumulated experience and knowledge in assisting other developing countries in forming their pro-health IP policies and supporting their negotiations in multilateral agreements.[740]

Yet, IP/health INGO engagement with China seems to be rather limited in these areas. In comparison with other large developing countries like Brazil, India, and South Africa, although China may have relatively stronger IPRs institutions, its experience and substantive knowledge on IPRs and development may be weaker. Given the influence of Chinese patent policy on access to medicine nationally and internationally, IP/health INGOs' research on Chinese health-related patent issues could contribute supplementary policy suggestions from pro-health and pro-development perspectives useful to China and other countries. After thirty years of Chinese experience in international economic legal relations, the law-making process has become more

[740] Matthews, D. (2006 b) 'NGOs, Intellectual Property Rights and Multilateral Institutions' (ESRC).

transparent and accessible domestically or internationally, but the state and the CPC continue to exercise absolute authority in the development of China's legislation. The low political tolerance for public participation and foreign intervention may impose great challenges for international NGOs' engagement efforts in China.

In addition to the initiatives aiming to balance information asymmetry in Chinese patent policy-making processes, there are other interesting topics waiting for more empirical studies. The most compelling question is whether or how China can make effective use of TRIPS flexibilities while it is bound by TRIPS-plus provisions. What are the possible legal barriers to this objective? What policy options can be made available to soften the restrictions imposed by TRIPS-plus provisions? Finally, if it could be shown, comparatively and empirically, that other TRIPS implementation approaches, adopted by countries in a similar position to China, achieved greater benefits in terms of innovation and health welfare, this would increase political awareness and the will to reform the current patent regime.

Appendix 1: The annual growth rate of A61 patents filed to the Chinese patent office (1987-2006)

Years	Aggregate Number	Annual growth rate	Inventions	Utility models
1987	1089		340	749
1988	1799	65%	457	1342
1989	1861	3%	495	1366
1990	2268	22%	664	1604
1991	2833	25%	750	2083
1992	4081	44%	1049	3032
1993	5789	42%	2090	3699
1994	6227	8%	2326	3901
1995	6177	-1%	2911	3266
1996	6203	0%	2700	3503
1997	7589	22%	4431	3158
1998	5720	-25%	2353	3367
1999	8757	53%	5115	3642
2000	9296	6%	4827	4469
2001	12509	35%	6705	5804
2002	13196	5%	7216	5980
2003	16583	26%	9953	6630
2004	17448	5%	10059	7389
2005	24875	43%	16730	8145
2006	33401	34%	22713	10688
Average		**22%**		

Notes:
1. The sources of data are the Chinese patent statistic books from 1987 to 2006.
2. The calculations are executed by the author with the assistance of Excel Sheet.

Appendix 2: The annual growth rate of A61 patents granted by the Chinese patent office (1987-2006)

Years	Aggregate number	Annual growth rate	Invention	Utility models
1987	377		13	364
1988	639	69%	32	607
1989	1002	57%	54	948
1990	1146	14%	79	1067
1991	1350	18%	118	1232
1992	1719	27%	128	1591
1993	3526	105%	246	3280
1994	2891	-18%	218	2673
1995	2517	-13%	173	2344
1996	2084	-17%	138	1946
1997	2250	8%	187	2063
1998	2555	14%	256	2299
1999	4865	90%	661	4204
2000	5285	9%	1204	4081
2001	4781	-10%	1387	3394
2002	5367	12%	1454	3913
2003	6838	27%	2605	4233
2004	9094	33%	4426	4668
2005	10179	12%	4967	5212
2006	12279	21%	4995	7284
Average		**24%**		

Notes
1. The sources of data are the Chinese patent statistic books from 1987 to 2006.
The calculations are executed by the author with the assistance of Excel Sheet.

Bibliography

Anonymous 'Korean foreign economic relation'. <http://www.country-studies.com/south-korea/foreign-economic-relations.html>, accessed April 17, 2008.

Anonymous 'Brazil Trade Patterns and Regional Economic Integration'. <http://www.country-studies.com/brazil/trade-patterns-and-regional-economic-integration.html>.

Anonymous 'Patent Law of People's Republic of China', (China: SIPO).

Anonymous 'Hatch Waxman: A Work in Progress, Responding to the Conundrum: How to Encourage Innovative New Drugs While Reducing the Cost of Access', (Ferskos LLC or Fish & Richardson, P.C.).

Anonymous 'Nanjing Intermediate People's Court IP Division White Paper (2001-2005)', (Nan Jing Nanjing Intellectual Property Administration).

Anonymous 'Four Office Statistics Report 2008', (http://www.trilateral.net/statistics/tsr.html: Trilateral).

Anonymous 'Do Stronger Intellectual Property Rights Increase International Technology Transfer? Empirical Evidence from U.S. Firm-Level Data '.

Anonymous 'Patent Lawsuit Duration |Length of Patent Litigation'. <http://www.inventionstatistics.com/Duration_of_Patent_Lawsuits_Litigation_Length.html>.

Anonymous (200), 'There is More IP litigation in China than Anywhere Else on Earth', *Intellectual Asset Management*

Anonymous (1984), 'Patent Law of the People's Republic of China'.

Anonymous (1992), 'Memorandum of understanding between the Government of the United States of America and the Government of the People's Republic of China on the Protection of Intellectual Property '.

Anonymous (1993), 'Anti Unfair Competition Law of the People's Republic of China'.

Anonymous (1994), 'Agreement on Trade-related Aspects of Intellectual Property Rights ', (Blackstone's Statutes on Intellectual Property).

Anonymous (1995), 'Judges Law of the People's Republic of China', (The Congressional-Executive Commission PRC).

Anonymous (1997), 'Regulations of the People's Republic of China on Protection of New Varieties of Plants', in the State Council of the People's Republic of China (ed.), (Decree No. 213).

Anonymous (2001), 'Copyright Law of the People's Republic of China '.

Anonymous (2001), 'Regulations of the Supreme People's Court on Certain Issues Concerning Pre-litigation Injunction against Patent Infringement', (China: SPC).

Anonymous (2001), 'Implementing Regulations of the Patent Law of the People's Republic of China ', (PRC: SIPO).

Anonymous (2002), 'Integrating Intellectual Property Rights and Development Plicy', in Commission on Intellectual Property Rights (ed.).

Anonymous (2002), 'Regulations for Implementation of the Drug Administration Law of the People's Republic of China', (45; China: SFDA).

Anonymous (2003), 'The Patent Protection for Biological Inventions in China ', in Biodiv-IP (ed.), (Beijing SIPO).

Anonymous (2004), 'Intellectual Property Rights: Tools or Obstacles to Development', (Ottawa: The Canadian-Council for International Co-operation & the North-South Institute).

Anonymous (2004), 'the Interpretation by the Supreme People's Court and the Supreme People's Procuratorate of Several Issues Concerning the Specific Application of Law in Handling Criminal Cases of Infringement of Intellectual Property Rights (II)', in SPC & SPP (ed.), (2004:19).
Anonymous (2005), 'China Intellectual Property Law Guide', *Asia Business Law Guide* (The Netherlands: Kluwer Law International).
Anonymous (2005), 'China's WTO Implementation and Other Issues of Importance to American Business in the U.S.-China Commercial Relationship', in U.S. Chamber of Commerce (ed.).
Anonymous (2006), 'Governance for Equitable Development (GED) – Strengthening Rule of Law and Civil Society Participation in China', in Government of the People's Republic of China and United Nations Development Programme (eds.), (UNDP).
Anonymous (2006), 'Eli Lilly and Company vs Hansoh Pharmaceutical Group & Shanghai Institute of Pharmaceutical Industry', *Chinacourt.org* (Shanghai Supreme People's Court).
Anonymous (2006), 'Overview on Patent Linkage', (Finston Consulting LLC).
Anonymous (2006 -09-01), 'Chinese Biogenetics and Protection of IP', *Genetic Engineering & Biotechnology News,* Vol. 26 (15). <http://www.genengnews.com/articles/chitem_print.aspx?aid=1875&chid=0>.
Anonymous (2007), 'the Interpretation by the Supreme People's Court and the Supreme People's Procuratorate of Several Issues Concerning the Specific Application of Law in Handling Criminal Cases of Infringement of Intellectual Property Rights (II)', in SPC & SPP (ed.), (2007:6).
Anonymous (2007), 'Eli Lilly & Company Vs Gan Li Pharmaceutical Ltd.' *Beijing Second Intermediate People's Court*.
Anonymous (2008), 'Pharmaceutical Sector Inquiry Preliminary Report', in EU DG Competition (ed.).
Anonymous (2008), 'Policy Brief: Measuring Innovation ', (London: National Endowment for Science, Technology and the Arts).
Anonymous 'Bill and Melinda Gates Urge Global Leaders to Maintain Foreign Aid', (updated January 30, 2009) <http://www.gatesfoundation.org/press-releases/Pages/2009-world-economic-forum-090130.aspx>.
Anonymous (2009), 'Recommendations on the Further Reform of Pharmaceutical and Healthcare System from Chinese Central Government, State Council, ' in State Council (ed.), (Beijing).
Anonymous (2009), 'Central Commission for Discipline Inspection of the Communist Party of China is investigating the corruption case with previous Vice -President of the SPC', *Xinhuanet*.
Anonymous (2009), 'Bayer vs Cipla & Union of India ', (18.08.2009: The High Court of Delhi).
Anonymous (2009), 'The third amendment to the Chinese Patent Law and its impacts', (Sutherland).
Anonymous (2009), 'World Intellectual Property Indicators ', in WIPO (ed.), (Geneva).
Anonymous (2009), 'Patents, Enforcement, and Seizures.' *China Business Review,* 36 (2), 34-35.
Anonymous (2009), 'Third revision of China's Patent Law: Legal texts and documents on the drafting process 2006-2008, ' (EU_China IPR 2).
Anonymous (2009-3-10), 'China strives to weed out judicial corruption', *China Daily*.
Anonymous (April 15, 2009), 'Chint v. Schneider', (Zhejiang High People's Court).

Anonymous (December 02, 2008), 'Eli Lilly and Company vs Gan &Lee Pharmaceutical Ltd', (The Second Intermediate People's Court of Beijing).
Anonymous (December 03, 2003), 'Eli Lilly and Company v Changzhou &Watson Pharmaceuticals Incorporated', (The Supreme People's Court of the PRC).
Anonymous (January 26, 2009), 'China v United States of America ', (WTO (DSB)).
Anonymous (March 17, 2000), 'Canada v Patent Protection of Pharmaceutical Products', *WTO* (DSB).
Anonymous (May 30, 2000), 'Argentina v United States of America ', (WTO (DSB)).
Abbot, F, Cottier, T, and Gurry, F (1999), *The International Intellectual Property System: Commentary and Materials* (1; The Hague: Kluwer Law International).
Abbot, F (2001), 'The TRIPS Agreement, Access to Medicines and the WTO Doha Ministerial Conference', (Quaker UN Office Occasional Paper No. 7).
Abbott, F (2004), 'The Doha Declaration on the TRIPS Agreement and Public Health and the Contradictory Trend in Bilateral and Regional Free Trade Agreements', (Geneva: Quaker United Nations Office).
Abbott, F. (2005), 'The WTO Medicines Decision: World Pharmaceutical Trade and the Protection of Public Health', *American Journal of International Law,* 99, 137-58.
Abbott, F. (2007), 'China in the WTO 2006: 'Law and its Limitation' in the Context of TRIPS ', in G Bermann and P Mavroidis (eds.), *WTO Law and Developing Countries* (Cambridge University Press).
Agarwal, Anil (1978), *Drugs and the Third World* (London: Earthscan).
Akkermans, D, Castaldi, C, and Los, B (2007), 'Do 'Liberal Market Economies' Really Innovate More Radically than 'Coordinated Market Economies'? Hall & Soskice Reconsidered', (Groningen Growth and Development Centre).
Alford, W (1995), *Steel a Book is a Elegant Offence* (Stanford: Stanford University Press).
Allen, T and Thomas, A (2000), *Poverty and Development into the 21 Century* (Oxford University Press).
Ambler, T, Xi, C, and Witzel, M (2009), *Doing Business in China* (3 edn.; New York: Routledge).
An, L and Xu, Y (2009), 'The Turbulent History of the State Intellectual Property Office in the Past Three Decades', *SIPO online publications,* In Chinese. <http://www.sipo.gov.cn/ztzl/qtzt/qzjj30/dtbd/201001/t20100111_487451.html>.
Anderfelt, U (1971), *International Patent-Legislation and Developing Countries* (Hague: Martinus Nijhoff).
Arai, Koki (2010), 'Patent Quality and Pro-patent Policy', *Journal of Technology Management & Innovation* 5(4).
Arnold, K (1993), 'Qinghaosu and Derivatives in the Treatment of Malaria — A personal review*', *Journal of Hong Kong Medical Association* 45 (3).
Arora, A (1996), 'Contracting for tacit knowledge: the provision of technical services in technology licensing contracts', *Journal of Development Economics,* 50 (2), 233-56.
Arora, A, Fosfuri, A, and Gambardella, A (2005), 'Markets for Technology, Intellectual Property Rights, and Development', in K Maskus and J Reichman (eds.).
Arrow (1962), 'Economic Welfare and the Allocation of Resources for Invention', *The Rate and Direction of Inventive Activity: Economic and Social Factors* (National Bureau of Economic Research).
Asano, T (2006), 'Trends in the U.S. Pro - Patent Policy in the Pharmaceutical and Biotechnology Fields: Focusing on the Hatch-Waxman Act', *Institute of*

Intellectual Property Bulletin <www.iip.or.jp/e/e_summary/pdf/detail2005/e17_20.pdf>.
Athanasakou, K (2007), 'China IPR Enforcement: Hard as Steel or Soft as Tofu? Bring the Question to the WTO under TRIPS', *Georgetown Journal of International Law,* 39 (1).
Bachner, Bryan (2008), *Intellectual Property Rights and China: the Modernization of Traditional Knowledge* (AJ Utrecht: Eleven International Publishing).
Balasubramaniam, K (1987), 'Pharmaceutical Patents in Developing Countries: Policy Options', *Economic and Political Weekly* 22.
Barner, S and Wegner, H (2007), 'Second Generation Chinese Patent Sophistication: lessons from Chint V.Schnerider ', *Changes Are Afoot in China and the US: Proactive IP and Business Risk Management* (Tokyo).
Barnes, K (2007-01-04), 'China 'most attractive' offshore clinical trial location ', *In-pharmatechnologist*. <http://www.in-pharmatechnologist. com/news/ng.asp?n=72702-a-t-kearney-china-offshoring-clinical-trials.>.
Barraclough, Emma (2007), 'Pfizer Victorious over Viagra in China', *Managing Intellectual Property,* September (7).
Barry, T (2001), 'WTO in Focus – new series on policy briefs and policy on trade'. <http://www.fpif.org/wto/contents.html>.
Barton, B and Emanuel, J (2005), 'The Patent-based Pharmaceutical Development Process, Rationale, Problems , and Potential Reforms', *The Journal of the American Medical Association* 294 (16).
Bell, M. (1990), *Brave New Third World: Strategies for Survival in the Global Economy* (London: Earthscan).
Bellmann, Christophe, Dutfield, Graham, and Melendez-Ortiz, Ricardo (eds.) (2003), *Trading in Knowledge: development perspective on TRIPS, trade and sustainability* (London: Earthscan).
Bello, J (1989/1990), 'Section 301: The United States' Response to Latin American Trade Barriers Involving Intellectual Property', *The University of Miami Inter-American Law Review,* 21 (2), 495-505.
Bently, L and Sherman, B (2004), *Intellectual Property Law, Second Edition* (Oxford: Oxford University Press).
Bergsten, C., et al. (2006), *China: The Balance Sheet: What the World Needs to Know Now About the Emerging Superpower* (cited in Yu (2009)).
Bertin, G and Wyatt, S (1988), *Multinationals & Industry Property* (New Jersey: Harvester.Wheatsheaf).
Blakeney, M (1995), 'Intellectual Property in World Trade', *International Trade Law and Regulation,* 1 (3).
BMI (2006), 'China Pharmaceuticals & Healthcare Report ', (Q1; London: Business Monitor International Ltd).
BMI (2008), 'China Pharmaceuticals & Healthcare Report ', (Q2; London: Business Monitor International Ltd).
Boldrin, M and Levine, D (2008), *Against Intellectual Monopoly* (New York: Cambridge Univ. Press).
Borecki, T (2001), 'The Hatch-Waxman Act and Abbreviated New Drug Applications '. <www.law.washington.edu/casrip/symposium/.../1-Borecki.pdf >.
Braga, C and Fink, C (1999), 'The Economic Justification for the Grant of Intellectual Property Rights: Patterns of Convengence and Conflicts', in F Abbot, T Cottier, and F Gurry (eds.), *The International Intellectual Property System: COmmentary and Materials* (1; The Hague: Kluwer Law International).

Branstetter, L and Sakakibara, M (2001), 'Do Stronger Patents Induce More Innovation? Evidence from the 1988 Japanese Patent Law Reforms', (45: Carnegie Mellon University Research Showcase).
Branstetter, L and Nakamura, Y (2003), 'Is Japan's Innovative Capability in Decline? ' (NBER Working Paper 9438).
Branstetter, L, Fisman, R, and Foley, C (2005), 'Do Stronger Intellectual Property Rights Induce More Technology Transfer? Empirical Evidence from U.S. Firm-Level Panel Data', (Harvard Business School Working Paper).
Browning, T and Wang, C (2004), 'Ten years of enforcement in China ', *Managing Intellectual Property -,* China IP Focus 2004.
Buhler, D and Glas, H (2006), 'Utility Models for New Medical Indications ', *Managing Intellectual Property,* May. <http://www.managingip.com/Article/1254650/Utility-models-for-new-medical-indications.html>.
Burns, R (2007), 'Will China Become the World Leader in Patent Litigation?' *Lexis Nexis China Legal Review*. <http://www.finnegan.com/resources/articles/articlesdetail.aspx?news=5baf9931-12cd-4d65-8f27-4644b9010b98>.
Business, International (1974), 'China Industry Surveys, Pharmaceutical Sector', (Hong Kong Business International Asia Pacific).
Cao, JM (2007), 'Forward: the Recent Development and Current Status of Judicial Protection of Intellectual Property in China', in P Torremans, J Erauw, and HL Shan (eds.), *Intellectual Property And TRIPS Compliance In China: Chinese and European perspectives* (Cheltenham: Edward Elgar Publishing Limited).
CBO (2006), 'Research and Development in the Pharmaceutical Industry', (The Congressional Budget Office (CBO), the US).
Chadha, A (2009), 'TRIPs and Patenting Activity: Evidence from the Indian Pharmaceutical Industry', *Economic Modelling,* 26,PP 499–505.
Chamber, European (2004), 'European Business in China Position Paper 2004: Pharmaceutical Working Group ', (European Chamber).
Chan, G (2009), 'The Third Amendment to China's Patent Law Introduces 'Absolute novelty' - Some Practical Implications'. <http://www.lexology.com/library/detail.aspx?g=ae99e313-ef6c-4715-8a6e-6d837250e9f6>.
Chang, H-J (2001), 'Intellectual Property Rights and Economic Development: Historical Lessons and Emerging Issues', *Journal of Human Development* 2(2).
Chang, HJ (2002), *Kicking Away the Ladder: Development Strategy in Historical Perspective* (London: Anthem Press).
Chaudhuri (2009), 'Is Product Patent Protection Necessary to Spur Innovation in Developing Countries?' in Netanel (ed.), *The Development Agenda: Global Intellectual Property and Developing Countries* (Oxford Scholarship Online).
Chen, JF (1999), *Chinese Law: towards an Understanding of Chinese Law, its Nature and Development* (The Hague: Kluwer Law International).
Chen, Tony (2007), 'Beijing High Court Upholds'.
Chen, Xh and Watanabe, M (2007), 'Pharmaceutical Industry in China-Intellectual Property Protection, Pricing and Innovation-', (Institute of Development Economics, Japan External Trade Organisation).
Chen, T and Chen, A 'What Does The Third Amendment To China´s Patent Law Mean To Pharmaceutical Companies?'

<http://www.mondaq.com/article.asp?articleid=65218>, accessed Last access on 09/07/10.
Chert, J (2001), 'The Amended PRC Patent Law', *China Business Review,* 28 (4).
Chi-yeung, Eric (2008), 'Judicial Corruption and its Threats to National Governance in China', *Journal of Administration and Governance* 3(1).
Chow, KB, et al. (2007), 'China and Taiwan', in S Uma, G Dutfield, and KB Chow (eds.), *Innovation without patents: harnessing the creative spirit in a diverse world* (Cheltenham: Edward Elgar Publishing Ltd).
CIPIH (2006), 'Public Health, Innovation and Intellectual Property Right', (Geneva: World Health Organisation).
CIPIH Studies (2005), '"Case Studies: developing innovative capacity in developing countries to meet their health needs"', (MIHR report to CIPIH, WHO Ref. CIPIH Study 10d (DGR)).
CIPR (2002), 'Integrating Intellectual Property Rights and Development Policy', in UK International Development (ed.), (London).
Cohen, M, et al. (2009-12-07), 'New patent law amendment codifies some IP protections', *China Daily*.
Comanor, W. S. and Scherer, F. M. (1969), 'Patent Statistics as a Measure of Technical Change', *The Journal of Political Economy,* 77 (3), 392-98.
Cornish, W and Llewellyn, D (2007), *Intellectual Property: Patents, Copyrights, Trademarks and Allied Rights, 6th Edition* (London: Sweet & Maxwell).
Correa, C (1994), 'The GATT Agreement on Trade-Related Aspects of Intellectual Property Rights: new standards for patent protection', *European Intellectual Property Review,* 16 (8), 327-35.
Correa, C (2000 e), *Intellectual Property Rights, the WTO and Developing Countries* (London: Zed Books Ltd).
Correa, C (2000 f), 'Integrating Public Health Concerns into Patent Legislation in Developing Countries', (Geneva: South Centre).
Correa, Carlos M. (2001), 'Some Assumptions on Patent Law and Pharmaceutical R&D', (Quaker UN Office).
Correa, C (2002), 'Protection of Data Submitted for the Registration of Pharmaceuticals: Implementing the Standards of the TRIPS Agreement ', (South Centre & WHO).
Correa, C (2002 a), 'Internationalization of the Patent System and New technologies', *Wisconsin International Law Journal,* 20 (3).
Correa, C (2002 b), 'Formulating Effective Pro-development National Intellectual Property Policies', (ICTSD-UNCTAD Dialogue, Bellagio).
Correa, C (2002 c), 'Protection of Data Submitted for the Registration of Pharmaceuticals: Implementing the Standards of the TRIPS Agreement', (Geneva: South Centre).
Correa, C (2002 d), 'Protection and Promotion of Traditional Medicine - Implications for Public Health in Developing Countries ', (Geneva: South Centre).
Correa, C M (2004), 'Protecting Test Data for Pharmaceutical and Agrochemical Products under Free Trade Agreements', (UNCTAD-ICTSD UNCTAD Dialogue (Bellagio)).
Correa, C (2004 a), 'Ownership of knowledge- the Role of Patents in Pharmaceutical R&D ', *Bulletin of the World Health Organisation,* 82 (10).
Correa, C (2004 b), 'The Role of Patents in Pharmaceutical Innovation', *Bulletin of the World Health Organisation,* 82 (10).
Correa, C (2005 a), 'Implementing the TRIPSA Agreement in the Patents Field: Options for Developing Countries', *The Journal of World Intellectual Property,* 1 (1).

Correa, C (2005 b), 'Can the TRIPS Agreement Foster Technology Transfer to Developing Countries?' in K Maskus and J Reichman (eds.), *International Public Goods and Transfer of Technology under a Globalized Intellectual Property Regime* (Cambridge University Press).
Correa, C (2006), 'Implication of Bilateral Free Trade Agreement to Access to Medicines', *Bulletin of the World Health Organisation* 84 (5).
Correa, C (2007a), 'Guidelines for the Examination of Pharmaceutical Patents: Developing a Public Health Perspective', (Geneva: ICTSD, WHO, and UNCTAD).
Correa, C (2007b), *Trade Related Aspects of Intellectual Property Rights: A Commentary on the TRIPS Agreement* (New York: Oxford University Press Inc.).
Cottier, T and Schefer, K (1999), 'The Relationship between World Trade Organisation Law, National and Regional Law', in F Abbot, T Cottier, and F Gurry (eds.), *The International Intellectual Property System: Commentary and Materials* (1; The Hague: Kluwer Law International).
Cowan, R, et al. (2005), 'Policy Options for the Improvement of the European Patent System', ((IP/A/STOA/FWC/2005-28/SC16): Europe Parliament Scientific Technology Options Assessment).
CPtech (2005), 'WTO members should reject bad deal on medicines: Joint statement by NGOs on TRIPS and Public Health
'. <http://www.cptech.org/ip/wto/p6/ngos12032005.html>.
Dai, QW and Feng, WZ and He, XP (2009), 'The State and Prospect of Chinese Patents for Therapies of AIDS Prevention and Treatment ', in Intellectual Property Right Institute of China (ed.), *Report on the State and Prospect of Chinese Patents of Key Industry (2008-2009)* (Beijing: Intellectual Property Right Press), Pp212-34.
Dalal, P (2006), 'Data Exclusivity: An Indian Perspective', *IPfrontline*. <http://www.ipfrontline.com/depts/article.asp?id=12300&deptid=6>.
Daniel, Yergin and Joseph, Stanishlaw (1998), *The Commanding Heights: the Battle between Government and the Marketplace That is Remaking the Morden World* (New York: Simon and Schuster).
David, H and Judith, E (1993/1994), 'Chinese patent law: Recent changes align China more closely ', *The George Washington Journal of International Law and Economics,* 27 (2.3).
Davidson, J and Carnabuci, C (2004), 'Preliminary Patent Injunctions in China: Fact or Fiction? ' *China Law & Practice,* (October 2004). <http://www.chinalawandpractice.com/Article/1692698/Channel/9930/Preliminary-Patent-Injunctions-in-China-Fact-or-Fiction.html>.
Deere, C (2009), *The Implementation Game: The TRIPS Agreement and the Global Politics of Intellectual Property Reform in Developing Countries* (Oxford Scholarship Online).
Deng, RL and Kaitin, K (2004), 'The Regulation and Approval of New drugs in China', *Drug Information Journal,* 37.
Development, Drug Discovery &, (2009), 'J&J Opens R&D Centre in Shanghai '.
Diwan, I and Dani, R (1991), 'Patents, Appropriate Technology, and North-South Trade', *Policy Research Working Paper* (Washington D.C.: The World Bank).
Drahos, P (1996), *A Philosophy of Intellectual Property* (Dartmouth Publishing).
Drahos, P (1997), 'Thinking Strategically about Intellectual Property Rights ', *Telecommunications Policy,* 21 (3).

Drahos, P (2001), 'Bits and Bips : Bilateralism in Intellectual Property ', *The Journal of World Intellectual Property,* 4 (6).
Drahos, P (2002), 'Negotiating Intellectual Property Rights: Between Coercion and Dialogue', in P Drahos and R Mayne (eds.), *Global Intellectual Property Right: Knowledge, Access and Development* (Hamphshire: Palgrave Macmillan), 161-82.
Drahos, Peter (2002), 'Developing Countries and International Intellectual Property Standard-setting', *Journal of World Intellectual Property,* 5.
Drahos, P and Braithwaite, J (2002), *Information Feudalism* (London: Earthscan Publications).
Drahos, P (2003), 'When the Weak Bargain with the Strong: Negotiations in the World Trade Organisation', *International Negotiation,* 8, 79-109.
Drahos, P (2005), 'Death of a Patent System - Introduction', in P Drahos (ed.), *Death of Patent* (Lawtext), 1-9.
Drahos, P (2007), 'Four Lessons for Developing Countries from the Trade Negotiations over Access to Medicines ', *Liverpool Law Review,* 28, 11-39.
Drahos, P (2007), '"Trust me": Patent Offices in Developing Countries', (ANU working paper).
Dreier, T (1999), 'TRIPS and the Enforcement of Intellectual property Rights', in F Abbott, T Cottier, and F Gurry (eds.), *The International Intellectual Property System: Commentary and Materials* (The Hague: Kluwer Law International).
Dufield, G (2003), *Intellectual Property Rights & the Life Science Industries: A Twentieth Century History* (Aldershot: Ashgate.).
Dutfield, G and Suthersanen, U (2004), 'Harmonisation or Differentiation in Intellectual Property Protection? The Lessons of History', (; Geneva: Quaker United Nations Office).
Dutfield, Graham (2005), 'Is the World Ready for Substantive Patent Law Harmonisation? A Lesson from History', in Peter Drahos (ed.), *Death of Patents* (Witney: Lawtext).
Dutfield, G (2006), 'Patent Systems as Regulatory Institutions ', *Indian Economic Journal* 54 (1), 62-90.
Dutfield, G (2008), 'Delivering Drugs To The Poor: Will The TRIPS Amendment Help?' *American Journal of Law & Medicine 2008 Symposium*, 61.
Easterly, W (2001), 'The lost Decades : Developing Countries' Stagnation in Spite of Policy Reform 1980-1998', in G Meier and J Rauch (eds.), *Leading Issues in Economic Development* (Oxford: Oxford University Press).
EC (2001), 'Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use', in the European Parliament and of the Council (ed.).
EC (2004), 'Directive 2004/27/EC of the European Parliament and the Council of 31 March 2004 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use (Directive 2004/27/EC) ', in the European Parliament and the Council (ed.).
Economist (2009), 'Health care in China: will patients be rewarded?' *The Economist* April 16th 2009
Edwards, C (1992), 'Industrialisation in South Korea ', in T Hewitt, H Johnson, and D Wield (eds.), *Industrialisation and Development* (London: Oxford University Press in association with the Open University Press).
EGA (2008), 'Patent-related Barriers to Market Entry for Generic Medicines in the European Union', (Brussels: European Generic medicines Association).

EPO 'Patent Information: China', <http://www.epo.org/patents/patent-information/east-asian/helpdesk/china/faq.html#new5>, accessed 10/09/09.
--- (2011), 'EPO Again Tops Patent Quality List '. <http://www.epo.org/news-issues/news/2011/20110628.html>.
Evans, G (1994), 'Intellectual Property as a Trade Issue: The Making of the Agreement on Trade-Related Aspect of Intellectual Property Rights', *World Competition,* 18 (2), 137-80.
Falvey, R, Foster, N, and Greenaway, D (2006), 'Intellectual Property Rights and Economic Growth', *10 Rev Dev Econ 700,* 10.
Feng, A (01/06/08), 'Take Local Practice into Account - Managing Intellectual Property ', *Managing Intellectual Property*
Frankel, S (2005), 'The WTO's Application of 'The Customary Rules of Interpretation of Public International Law' to Intellectual Property', *Virginia Journal of International Law,* 46.
Freshfields (2007), 'Patent litigation in Asia: People's Republic of China'. <www.freshfields.com/publications/pdfs/2007/dec19/20496.pdf>.
FTC (2003), 'To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy', (Washington, DC Federal Trade Commission (FTC)).
Gad, M (2006), *Representational Fairness in WTO Rule-Making* (London: British Institute of International and Comparative Law).
Gallini, N (2002), 'The Economics of Patents: Lessons from Recent U.S. Patent Reform', *Journal of Economic Perspectives,* 16 (2).
Gao, LL (2008), ' China's Patent System and Globalization ', *Research Technology Management,,* 56 (6).
Garrison, C (2006), 'Exceptions to Patent Rights in Developing Countries' (UNCTAD - ICTSD Project on IPRs and Sustainable Development).
Gechlik, M (2007), 'Protecting Intellectual Property Rights in Chinese Courts: an analysis of recent patent judgments', (Washington, DC: Carnegie Endowment for International Peace).
Genuineways, Inc (06/08/2010), 'Chint V. Schneider, a milestone of patent enforcement in China', *Case studies* <http://www.genuineways.com/nr/cont.aspx?itemid=3&id=4>.
Gereffi, G (1983), *The Pharmaceutical Industry and Dependency in the Third World* (Princeton N J: Princeton University Press).
Gerhardsen, Tove Iren S. (2007), 'Chances Diminish for Solution on TRIPS And Public Health before Hong Kong', <http://www.ip-watch.org/weblog/index.php?p=147&res=1024&print=0>, accessed 22/04/07.
Gervais, D (2003), *The TRIPS Agreement, Drafting History and Analysis (Second Edition).* (London: Sweet and Maxwell).
Gervais, Daniel J. (2009), 'TRIPS 3.0: Policy Calibration and Innovation Displacement', in Neil W.Netanel (ed.), *The Development Agenda: Global Intellectual Property and Developing Countries* (Oxford: Oxford University Press).
Gibson, Johanna (2008), *Intellectual Property, Medicines and Health: current debates* (Surrey Ashgate Publishing Limited).
Gilpin, R (1987), *The Political Economy of International Relation* (Princeton: Princeton University Press).
--- (2000), 'The Nation - state in the Global Economy', in D Held and A McGrew (eds.), *The Global Transformations Reader* (Cambridge: Polity Press).
Glasgow, L (2001), 'Stretching the Limits of IPRs: Has the Pharmaceutical Industry gone two far? 'The *Journal of Law and Technology,* 41 (2).

Godin, B (2006), 'The Linear Model of Innovation: The Historical Construction of an Analytical Framework', (INRS: Working Paper No. 30).
--- (2008), 'The Making of Statistical Standards: The OECD and the Frascati Manual, 1962-2002', (INRS: Working Paper No. 39).
Gong, JH (April 2007), 'Bewilderment in Judging Inventiveness', *China Intellectual Property* (17).
Gontijo, C (2005), 'Changing the Patent System from Paris Convention to the TRIPS Agreement: the Position of Brazil', (2005; Berlin: Heinrich Böll Foundation).
Goren, David (2006), 'Pharmaceutical Innovation and Intellectual Property Right: a Global Public Good? ' in M. Pugatch (ed.), *The Intellectual Property Debate: Perspectives from Law, Economics Political Economy* (Cheltenham: Edward Elgar), 159-69.
Gorlin, J (2000), 'Encouragement of New Clinical Drug Development: The Role of Data Exclusivity,
' (Geneva: IFPMA,).
Grace, C (2004), 'The Effect of Changing Intellectual Property on Pharmaceutical Industry Prospects in India and China: Considerations for Access to Medicines', (London: UK Department of International Development).
Gray, H (1990), 'The Role of Services in Global Structural Change', in A Webster and J Dunning (eds.), *Structural Change in the World Economy* (London: Routledge), 70.
Grier, Jean Heilman, (2005), 'SECTION 301 OF THE 1974 TRADE ACT'.
Grubb, P (2004), *Patents for Chemicals, Pharmaceuticals and Biotechnology* (Oxford Oxford University Press) 37.
Guo, SK and Zuo, XG (2007), 'Are Chinese Intellectual Property Laws Consistent with the TRIPS Agreements? ' in P Torremans, HL Shan, and J Erauw (eds.), *Intellectual Property and TRIPS Compliance In China: Chinese and European Perspectives* (Cheltenham: Edward Elgar Publishing Limited).
Haggard, S (1995), *Developing Nations and the Politics of Global Integration* (Washington, D.C Brookings Institution).
Hallstein, H (1975), 'Patent Protection, Transfer of Technology and Developing Countries - a Survey of the Present Situation', (ICC Heft 04).
Harris, D (2004/2005), 'TRIPS' Rebound: A Historical Analysis of How the TRIPS Agreement Can Ricochet Back Against the United States', *Northwestern Journal of International Law & Business,* 25 (99).
Hase, A.M.V (1998), 'The Application and Interpretation of the Agreement on Trade-Related Aspects of Intellectual Property Rights', in Carlos Correa and Abdulqawi Yusuf (eds.), *intellectual Property and International Trade: the TRIPs Agreement* (London: Kluwer Law).
HCHC (2004/05), 'The Influence of the Pharmaceutical Industry', in UK House of Commons Health Committee (HCHC) (ed.), (London: The Stationery Office Limited).
Heinze, W (15/04/ 2009), 'Utility Model Protection In China ', *I/P Updates*. <http://ip-updates.blogspot.com/2009/04/utility-model-protection-in-china.html>.
Heller, M and Eisenberg, R (May 1998), 'Can Patents Deter Innovation? The Anticommons in Biomedical Research ', *Science,* 280 (5364), 698 - 701.
Hettne, B (1990), *Development Theory and the Three Worlds* (Hong Kong: British Library Cataloguing in Publication Data).

Hewitt, Tom, Johnson, Hazel, and Wield, Dave (eds.) (1992), *Industrialisation and Development* (Oxford: Oxford University Press in association with the Open University).
Hill, S and Johnson, K (2004), 'Emerging Challenges and Opportunities in Drug Registration and Regulation in Developing Countries', (DFID Health Systems Resource Centre).
Hoekman, B and Javorcik, B (2006), *Global Integration and Technology Transfer (World Bank Trade and Development Series)* (World Bank Publications).
Hoen, E (2002), 'TRIPS, Pharmaceutical Patents, and Access to Essential Medicines: A Long Way From Seattle to Doha.' *Chicago Journal of International Law* 3(1).
Hoen, E (2009), *The Global Politics of Pharmaceutical Monopoly Power* (Diemen: AMB Publishers).
Houlton, S (24/08/2009), 'Indian Court Dismisses Bayer's Patent Linkage Case '. <http://www.rsc.org/chemistryworld/News/2009/August/24080902.asp>, accessed 04/11/09.
Hu, SL (2008), 'Universal coverage and health financing from China's perspective', *Bulletin of the World Health Organization,* 86 (11).
Hughes, K (1990), 'Competition, innovation, and industrial performance', in A Webster and J Dunning (eds.), *Structural Change in the World Economy* (London: Routledge), pp52-53.
ICC (2006), 'Comments on the Draft Third Amendment of the Patent Law in China', (Paris: International Chamber of Commerce (ICC)).
ICTSD (28January 2009), 'Ruling in US-China Piracy Dispute Raises Controversy', *Bridges Weekly,* 13 (3). <http://ictsd.net/i/news/bridgesweekly/38830/>.
ICTSD (2007), 'US Files WTO Complaints Against China Over Counterfeiting, Trade Barriers', *Bridges Weekly* 11 (13). <http://ictsd.net/i/news/bridgesweekly/7741/>.
ICTSD (2009), 'China, US Accept Mixed Verdict in Piracy Dispute', *Bridges Weekly,* 13 (11).
IFPMA (2000), 'Encouragement of new clinical drug development: the role of data exclusivity', (International Federation of Pharmaceutical Manufacturers (IFPMA)).
IFPMA (2004), 'Accelerating Innovative Pharmaceutical Research and Development in China: a case study', (Geneva: International Federation of Pharmaceutical Manufacturers Associations (IFPMA)).
IP, Ming &Sure (2008-6-18), 'Chinese Pharmaceutical Enterprises Confront Predicament in IP Law Suit'.
IP, Dragon (July 30, 2008), 'Patent Quality in China: "You could patent a wheel"'. <http://ipdragon.blogspot.com/2008_07_01_archive.html>.
Jackson, John H. (ed.), (1997), *The World Trading System* (Cambridge: The MIT Press).
Jaffe, A, Trajtenberg, M, and Henderson.R (1993), 'Geographic Localization of Knowledge Spillovers as Evidenced by Patent Citations', *Quarterly Journal of Economics,* 108 (3), 577-98.
Jaffe, A and Lerner, J (2004), *Innovation and Its Discontents: How Our Broken Patent System is Endangering Innovation and Progress, and What to Do About It* (Princeton University Press).
JCCT (2005), 'US-China Joint Commission on Commerce and Trade Medical Device and Pharmaceutical Subgroup Pharmaceutical Task Force', (August 30, 2005, Beijing, China).

Jenkins, R (1992), 'Industrialisation and the Global Economy ', in T Hewitt, H Johnson, and D Wield (eds.), *Industrialisation and Development* (Oxford: Oxford University Press), 22-23.
--- (1992), 'Theoretical perspectives', in T Hewitt, H Johnson, and D Wield (eds.), *Industrialisation and Development* (Oxford: Oxford University Press in association with the Open University), 132.
Jia, H and Kling, J (2006), 'China Offers Alternative Gateway for Experimental drugs', 24 (117-118). <http://www.nature.com/nbt/journal/v24/n2/full/nbt0206-117.html>.
Jiang, QY (2006), *Court Delay and Law Enforcement in China: Civil process and economic perspective* (Gabler).
Jiang, Qing-Yun (2006), *Court Delay and Law Enforcement in China: Civil Process and Economic Perspective* (DUV).
Johnson, B , Edquist, C , and Lundvall, B (2003), 'Economic Development and the National System of Innovation Approach ', (First Globelics Conference).
Jones, P (2008), 'Changes to Patent Law tightens requirements ', *China Law and Practise*. <http://www.chinalawandpractice.com/Article/2004389/Channel/12591/Changes-to-Patent-Law-tightens-requirements.html>.
Jones, K (2009), 'The Political Economy of WTO Accession: the Unfinished Business of Universal membership', *World Trade Review,* 8 (2).
JPO 'Comparison of Utility Model Systems by Nation', (Japan Patent Office).
Jucker, E (1980), *Patent and Pharmaceuticals* (Basle: E Jucker).
Kahn, B (2008), 'An Economic History of Patent Institutions', *EH.Net Encyclopaedia*
Kameri-Mbote, Patricia (2007), 'Patents and Development', <http://www.ielrc.org/content/a9401.pdf>, accessed 16/04/07.
Kau, M and Marsh, S. (1997), *China in the Era of Deng Xiaoping: A Decade of Reform (Studies on Contemporary China)* (New York: M.E. Sharpe).
Kay, D (1985/86), 'The Patent Law of the People's Republic China in Perspective ', *University of California Los Angeles Law Review,* 33.
KEI (12 February 2007), 'KEI "Special 301" Submission to USTR on Pharmaceutical Test Data Protection'. <http://www.keionline.org/content/view/1/1>.
Klayman, DL (1985), 'Qinghaosu (artemisinin): an Antimalarials Drug from China', *Science* 228 (4703), 1049-55.
Kong, QJ (2005), *WTO, Internationalisation and the Intellectual Property Rights Regime in China* (Singapore: Mashall Cavendish Academic).
Königer, K (2009), 'Registration without Examination: the Utility Model - a Useful Model? ' in W Pyrmont, et al. (eds.), *Patents and Technological Progress in a Globalized World: Liber Amicorum Joseph Straus* (Berlin: Springer).
Kortum, S (2005), 'Comment, TRIPS and Technology Transfer -Evidence from Patent Data', in K Maskus and J Reichman (eds.), *International Public Goods and Transfer of Technology Under a Globalised Intellectual Property Regime* (Cambridge University Press).
KPMG (2011), 'China's Pharmaceutical Industry: Poised for the Giant Step', (KPMG.China).
Krasner, Stephen D (1985), *Structural Conflict: The Third World against Global Liberalism* (Berkeley: University of California Press).
Kremer, M (2002), 'Pharmaceuticals and the Developing World ', in G Meier and J Rauch (eds.), *Leading Issues in Economic Development* (Oxford: Oxford University Press), 218-24.

--- (2002), 'Pharmaceuticals and the Developing World', *Journal of Economic Perspective,* 16 (4).
Lachat, S and Lachat, D (2006), 'The nature of the Chinese IPR administrative enforcement system', *halshs-00118654, version 1*
Ladas, S (1975), *Patents, Trademarks, and Related rights : National and International Protection* (2; Cambridge: Harvard University Press).
Lall, S. (1975), 'Major issues in the Transfer of Technology to Developing Countries: a Case Study of the Pharmaceutical Industry', in UNCTAD (ed.), (UNCTAD).
Landes, W and Posner, R (2004), 'The Political Economy of Intellectual Property Law', (AEI-Brookings Joint Centre for Regulatory Studies).
Langer, Eric (2007), 'Biogenetics in China: An Evolving Industry', *BioPharm International*.
Lanjouw, J (1997), 'The Introduction of Pharmaceutical product patents in India: 'Heartless exploitation of the poor and suffering ? ' *Discussion Paper* (Economic Growth Centre @Yale, working paer No.775).
--- (2001), 'New Pills for Poor People? Empirical Evidence after GATT', *World Development* 29 (2).
Lardner, Foley & (4/15/2009), 'The Chint V. Schneider Settlement: 157 Million Reasons to Believe Chinese Patent Holder's Rights Have Muscle', *Legal News Alert: China*. <http://www.foley.com/publications/pub_detail.aspx?pubid=5949>.
Law360 (June 10, 2009), 'Real And Present Danger: Patent Litigation In China'. <www.law360.com>.
Lee, J.-Y and Mansfield, E. (1996), 'Intellectual Property Protection and U.S. Foreign Direct Investment', *Review of Economics and Statistics,* 78.
Lee, Rachel (2006), 'China Pharmaceutical R&D - A Strategic Choice', *The Global Pharmaceutical Industry in the 21st Century: China's emerging role and the scope for R&D* (London: Chatham House).
Leesti, M and Pengelly, T 'Institutional Issues for Developing Countries in Intellectual Property Policymaking, Administration & Enforcement', (CIPR, Study Paper 9).
Lehman 'What is the patent linkage in pharmaceuticals?' <<http://www.lehmanlaw.com/resource-centre/faqs/health-sciences/what-is-the-patent-linkage-in-pharmaceuticals.html>,>.
Lei , JQ (2006), *The Enforcement of Intellectual Property Rights in China* (London: Cameron May).
Lemley, A and Shapiro, C (2006), 'Patent Holdup and Royalty Stacking ', (324: Stanford Law School Working Paper).
Lerner, Josh (2002), 'Patent Protection and Innovation Over 150 Years ', *NBER Working Papers 8977* (National Bureau of Economic Research).
Letterman, G (2001), *Basic of International Intellectual Property Law* (New York: Transnational Publishers Inc).
Lettington, R and Munyi, P (2004), 'Willingness and Ability to Use TRIPs Flexibilities: Kenya case study ', (DFID Health Systems Resource Centre).
Levin, R. C., et al. (1987), 'Appropriating the Returns from Industrial Research and Development ', *Brookings Papers on Economic Activity,* (Special Issue 3).
Li, LT and Tai, TH (01/04/2009), 'Features of Swiss-type Claims', *Managing Intellectual Property*
Li, ZZ, Ke, W, and Guang, C (2005), 'Developing Innovation Capabilities in China to Meet Health Needs', ("Case Studies: developing innovative capacity in developing countries to meet their health needs" WHO. CIPIH report).

Li, R (2006), *The Global Pharmaceutical Industry in the 21st Century: China's Emerging Role and the Scope for R&D Collaboration* (London: Chathamhouse).
Li, X (2008), 'The Impact of Higher Standards in Patent Protection for Pharmaceutical Industries under the TRIPS Agreement – A Comparative Study of China and India', *The World Economy,* 31 (10), 1367-82.
Li, YH (2010), *Imitation To Innovation In China: the Role of Patents in Biotechnology and Pharmaceutical Industries* (Cheltenham: Edward Elgar).
Liang, M (2012), 'Chinese Patent Quality: Running the Numbers and Possible Remedies', *The John Marshall Review of Intellectual Property Law,* (478).
Lin, M C H (2004), 'The Judicial System of China', *Recent Developments and Enforcement of Asian IP Law*
Lippoldt, D (2006), 'Intellectual Property Rights, Pharmaceuticals and Foreign Direct Investment ', (Groupe d'Economie Mondiale de Sciences Po.).
Liu, DM (2006), 'The Transplant Effect of the Chinese Patent Law', *Chinese Journal of International Law* 5(3).
Liu, Charles C. (2008), 'Waves of Changes in Chinese Patent Law and Regulations', *ChinaBioToday*. <http://www.chinabiotoday.com/articles/20080110_2>.
Liu, XH (2008), 'A Study on Patent Compulsory License System in China – With Particular Reference to the Drafted 3rd Amendment to the Patent Law of the P.R. of China ', in W Pyrmont, et al. (eds.), *Patents and Technological Progress in a Globalized World* (Springer Berlin Heidelberg).
Liu, M, Xiu, W, and Fu, A (2009), 'Current Technical State and Trend of the Development of Patenting for Cancer Therapies in China'.
Llewellyn, D (2005), 'Schrodinger's Cat: An Observation on Modern Patent Law', in P Drahos (ed.), *Death of Patents* (Lawtext Publishing Limited & Queen Mary Intellectual Property Research Institute, University of London).
LLP, Foley & Lardner (2/26/2009), 'Third Amendment to PRC Patent Law'. <http://www.foley.com/publications/pub_detail.aspx?pubid=5766>.
Lo, C (1992), 'Deng Xiaoping's Ideas on Law: China on the Threshold of a Legal Order', *Asian Survey,* 32 (7), 649-65.
Long, Charisa (ed.), (2000), *Intellectual Property Rights in Emerging Markets* (Washington, D,C: The AEI Press).
Long, Yongtu (2002), 'Implications of China's Entry into the WTO in the Field of Intellecutl Property Rights ', in Carlos A Magainos, Long Yongtu, and Francisco Sercovich (eds.), *China in the WTO : the birth of a new catching-up strategy* (New York: Palgrave Macmillan).
Long, YT (2002), 'Implications of China's Entry into the WTO in the Field of Intellectual Property Rights ', in C Magainos, Long YT, and S Francisco (eds.), *China in the WTO : the Birth of a New Catching-up Strategy* (New York: Palgrave Macmillan).
Luo, Y (2008), 'China: Current trends in pharmaceutical drug discovery', *IDrugs,* 11 (4).
M Kau and Marsh, S. (1997), *China in the Era of Deng Xiaoping* (New York: M.E. Sharpe).
Machlup, F (1958), 'An Economic Review of the Patent System', (Study of No 15 of the Subcommittee on Patents, Trademarks, and Copyrights of the Committee on the Judiciary, US Senate,).
Maggiolino, Mariateresa (2011), *Intellectual Property and Antitrust: a Comparative Economic Analysis of US and EU Law* (Edward Elgar).
Mahdjoubi, D (1997), 'The Linear Model of Technological Innovation: Background and Taxonomy ', (UTexas working paper).

Mak, T (2011), 'Utility model and invalidation in China', *The Journal of the Chartered Institute of Patent Attorneys* April.
Mansfield., E (1994), *Intellectual Property Protection, Foreign Direct Investment, and Technology Transfer* (Washington, D.C: World Bank).
Mara, Kaitlin (24 March 2009), 'Parties Accept WTO Dispute Settlement Report On China IP Protection ', *IP Watch*. <http://www.ip-watch.org/weblog/2009/03/24/parties-accept-wto-dispute-settlement-report-on-china-ip-protection/>.
Margiano, R (2009), 'Cost and Duration of Patent Litigation', *Managing Intellectual Property*. <http://www.managingip.com/Article/2089405/Cost-and-duration-of-patent-litigation.html>.
Maskus, K (2000), *Intellectual Property Rights in the Global Economy* (Washington DC: Institute of International Economics).
--- (2001), 'Parallel Imports in Pharmaceuticals: Implications for Competition and Prices in Developing Countries', (WIPO).
Maskus , K (2001), 'PARALLEL IMPORTS IN PHARMACEUTICALS: IMPLICATIONS FOR COMPETITION AND PRICES IN DEVELOPING COUNTRIES', (WIPO).
Maskus , K and Reichman, J (2005 a), 'The Globalisation of Private Knowledge Goods and the Privatization of Global Public Goods', in K Maskus and J Reichman (eds.), *International Public Goods and Transfer of Technology* (Cambridge: Cambridge University).
Maskus, K , Dougherty, S, and Merth, A (2005 b), 'Intellectual Property Rights and Economic Development in China', in K Maskus C Fink (ed.), *Intellectual property and development: lessons from recent economic research* (Washington, DC World Bank).
Maskus, K and Reichman, J (2005 c), *International Public Goods and Transfer of Technology Under a Globalized Intellectual Property Regime* (Cambridge University Press).
Mason, D (1984), 'China four modernizations: Blueprint for Development or Preclude to Turmoil ', *Asian Affairs* 11 (3), 47-70.
Matthews, D (2002), *Globalising the Intellectual Property Rights* (London: Routledge).
--- (2004), 'WTO Decision on Implementation of Paragraph 6 of the Doha Declaration on the TRIPs Agreement and Public Health: a Solution to the Access to Essential Medicines Problem? ' *Journal of International Economic Law,* 7 (1), 73-107.
--- (2006 a), 'From the August 30, 2003 WTO Decision to the December 6, 2005 Agreement on an Amendment to TRIPS: Improving Access to Medicine in Developing Countries', *Intellectual Property Quarterly,* 2, 91-130.
Matthews, Duncan (2006 b), 'NGOs, Intellectual Property Rights and Multilateral Institutions', (ESRC).
--- (2006a), 'From the August 30, 2003 WTO Decision to the December 6. 2005 Agreement on an Amendment to TRIPS: Improving Access to Medicines in Developing Countries', *Intellectual Property Quarterly,* 2, 91-130.
--- (2007), 'Lessons from Negotiating an Amendment to the TRIPS Agreement: Compulsory Licensing and Access to Medicines', in Guido Westkamp (ed.), *Emerging Issues In Intellectual Property: Trade, Technology and Market Freedom Essays in Honour of Herchel Smith* (Cheltenham: Edward Elgar), 222-49.

--- (2008), 'The Fight Against Counterfeiting and Piracy in the Bilateral Trade Agreements of the EU', (Brussels European Parliament).
Maureen, R (2002), 'Beyond Hatch Waxman: Legislative Action Seeks to Close Loopholes in U.S. Law that Delay Entry of Generics into the Market', *Cenear,* 80 (38).
May, Christopher and K.Sell, Susan (2006), *Intellectual Property Right: a Critical History* (London: Lynne Rienner).
May, Christopher and Sell, Susan (2006), *Intellectual property rights: a critical history* (Boulder: Lynne Rienner Publishers).
McCalman, P (2001), 'Reaping What You Saw: An Empirical Analysis of International Patent Harmonisations', *Journal of International Economics,* 55 (1), 161-86.
McCurry (March 2008), 'R&D on Mainland China? ' *Site Selection,* 53.
Meier, G and Rauch, J (eds.) (2005), *Leading issues in economic development* (Oxford Oxford University Press).
Meng, QY, et al. (2005), 'The Impact of China's Retail Drug Price Control Policy on Hospital Expenditures: a Case Study in Two Shandong Hospitals ', *Health Policy and Planning* 20 (3), 185-96.
Menghaney, Leena (2006), 'Data exclusivity: a new threat to affordable generic medicines', *HIV Treatment Bulletin* 7(7/8). <http://www.i-base.info/htb/v7/htb7-7-8/Data.html>, accessed 19/06/08.
Mercurio, B (2006), 'TRIPS-Plus Provisions in FTAs: Recent Trends'. <Available at SSRN: http://ssrn.com/abstract=947767>.
Michalopoulos (2001), *Developing countries in the WTO* (New York: Palgrave).
Miller, E and Miller, H (2007), 'A Review of TRIPS and TRIMs Enforcement Issues In the People's Republic of China: Background and Analysis of the Intellectual Property Protection and Enforcement Crisis Facing U.S. Industry', (the U.S. Small Business Administration).
Moga, T (Nov/Dec 2002), 'The TRIPS Agreement and China', *The China Business Review*.
MOH (2004-12-03), 'Press Release Brief of the Third National HealthCare Survey from the Ministry of Health (MOH)'. <http://www.china.com.cn/zhuanti2005/txt/2004-12/03/content_5719473.htm>.
Mokyr, J (1990), *The Lever of Riches* (Oxford University Press).
Morris, J and Stevens, P (2006), 'Counterfeit Medicines in Less Developed Countries: Problem and Solutions', (London: International Policy Network).
Mossinghoff, Gerald J (1999), 'Overview of the Hatch-Waxman Act and Its Impact on the Drug Development Process', *Food and Drug Law Journal* 54.
Mount, D, Todd, G, and Navaratnam., V (1995), ''Packed-column supercritical fluid chromatography of artemisinin (qinghaosu) with electron-capture detection' ', *Journal of Chromatography B: Biomedical Sciences and Applications,* 666 (1), 183-87.
Mowery, D (1983), 'Economic Theory and Government Technology Policy', *Policy Sciences,* 16, 27- 43.
MSF (2001), 'South Africa: Big Pharma Backs Down'. <http://www.doctorswithoutborders.org/publications/ar/report.cfm?id=1204>.
Musungu, S and Dutfield, G (2003), 'Multilateral Agreements and a TRIPS-plus World: The World Intellectual Property Organisation (WIPO)', (Quaker UN Office Paper).

Musungu, S, Villanueva, S, and Blasetti, R (2004), 'Utilizing TRIPS Flexibilities for Public Health Protection through South-South Regional Frameworks', (South Centre).
Musungu, S and Oh, C (2005), 'The Use of Flexibilities in TRIPS by Developing Countries: Can They Promote Access to Medicines?' (Commission on Intellectual Property Rights, Innovation and Public Health) .
National, People Congress 'The Draft for the Third Amendment of Chinese patent Law and its specification', <http://www.npc.gov.cn/huiyi/lfzt/zlfxzaca/2008-08/29/content_1447395.htm>.
Nelson, R (1993), *National Innovation Systems: A Comparative Analysis* (Oxford University Press).
Netanel, N (2009), 'The Development Agenda', in N Netanel (ed.), *The Development Agenda: Global Intellectual Property and Developing Countries* (Oxford Scholarship Online).
Neumayer, E (2011), 'Strategic Delaying and Concessions Extraction in Accession: Negotiations to the World Trade Organization', (London: LSE Working Paper).
New, W (2009), 'Broad Plan On IP, Innovation In Developing Countries Approved At WHO', *IP watch* <http://www.ip-watch.org/weblog/2009/05/22/who-committee-approves-broad-plan-on-ip-innovation-in-developing-countries/>, accessed 26/05/09.
New, W (2009), 'WHO Or Who Should Guarantee The Right To Health?' *IP Watch* <http://www.ip-watch.org/weblog/2009/06/24/who-or-who-should-guarantee-the-right-to-health/print/>, accessed 25/06/09.
Nie, JQ (2006), *The Enforcement of Intellectual Property Rights in China* (London: Cameron May Ltd).
Noehrenberg, Eric (2006), 'The Realities of TRIPS, Patents and Access to Medicines in Developing Countries', 170-86.
Nogues, J (1993), 'Social Costs and Benefits of Introducing Patent Protection for Pharmaceutical Drugs in Developing Countries', *The Developing Economics,* 31 (1).
Nolt, J. (1999), 'China in the WTO: The Debate', *Interhemispheric Resource Centre and Institute for Policy Studies* 4(38).
Nordstrom, HK (2007), 'Participation of Developing Countries in the WTO - New Evidence Based on the 2003 Official Records', in George A Bermann and Petros C Mavroidis (eds.), *WTO Law and Developing Countries* (Cambridge: Cambridge University Press), 146-94.
Odagiri, H, et al. (2010), *Intellectual Property Rights, Development, and Catch-up* (Oxford University Press).
Odagiri, H, Goto, A, and Sunami, A (2010), 'IPR and the Catch-UP Process in Japan'.
OECD (1997), 'Oslo Manual:Proposed Guidelines for Collecting and Interpreting Technological Innovation Data (1st edition) ', (Paris: OECD).
--- (2004), 'Patents and Innovation: Trends and Policy Challenges'
--- (2005), 'Oslo Manual: Guideline for Collecting and Interpreting Innovation Data (3rd Edition)', (Paris: OECD).
Orsi, F, Camara, M, and Coriat (2006), 'AIDS, TRIPS and 'TRIPS Plus': the Case for Developing and Less Developing Countries', in B Andersen (ed.), *Intellectual Property Rights: Innovation, Governance and the Institutional Environment* (Cheltenham Edward Elgar).

Ostergard, R (2002), *Development Dilemma: The Political Economy of Intellectual Property Rights in the International System* (New York: LFB Scholarly Publishing LLC).
Palit, P and Bhattacharya, B (2008), 'Does Intellectual Property Law in India and China Encourage Innovation?' *Journal of Japan Intellectual Property Association* 4(3).
Palmedo, M 'How reporters covered the 6 December 2005 WTO deal that amended the TRIPS Agreement on the topic of exports of generic medicines manufactured under a compulsory license'.
Pattloch, Thomas (2005), 'Enforcement', in Thomas Pattloch Peter Ganea, Christopher Heath (ed.), *Intellectual property law in China* (The Hague Kluwer Law International).
Pearson, Ruth (1992), 'Technology and Industrialisation', in Tom Hewitt, Hazel Johnson, and Dave Wield (eds.), *Industrialisation and Development* (Oxford University Press), 202.
Pécoul B, et al. (1999), 'Access to Essential Drugs in Poor Countries: a Lost Battle? ' *Journal of the American Medical Association* 281(4) (4), 361-7.
Peng, ZH, Yu, Q, and Bao, L (2008), 'The Application of Gene Therapy in China', *IDrugs,* 11 (5), 346-50.
Penrose, E., Machlup, F 'The Patent Controversy in the Nineteenth Century'.
Penrose, E (1951), *The Economics of the International Patent System* (Johns Hopkins).
Petrin, J 'Regulatory Implication of Global Clinical Trial '. <prs-clinical.com/.../Global%20Clinical%20Trial%20-...>.
PhRMA (2004), 'Pharmaceutical Research and Manufacture of American (PhRMA) Special 301 Submission 2004 ', (PhRMA).
--- (2007), 'Pharmaceutical Research and Manufacture of American (PhRMA) Special 301 Submission 2007', (PhRMA).
--- (2009), 'Pharmaceutical Research and Manufacture of American (PhRMA) Special 301 Submission '.
--- (2012), 'PhRMA Special 301 Submission 2012'.
Potter, P (2001), *The Chinese Legal System: Globalization and Local Legal Culture* (London: Routledge).
PRB 'The Patent Re-examination Board of the State Intellectual Property Office ', <http://www.sipo-reexam.gov.cn/bmgk/>, accessed 09/09/09.
Preston, Samuel H (1975), 'The Changing Relation between Mortality and Level of Economic Development ', *Population Studies,* 29 (2), 231-48.
Pugatch, M. (2004), 'Intellectual Property and Pharmaceutical Data Exclusivity in the Context of Innovation and Market access', *ICTSD-UNCTAD Dialogue on Ensuring Policy Options for Affordable Access to Essential Medicines* (Bellagio).
PWC (2009), 'Investing in China's Pharmaceutical Industry ', (Second Edition: PricewaterhouseCoopers).
PWC (2009), 'Patent Litigation Trends and the Increasing Impact of Nonpracticing Entities', (PricewaterCooper).
PWC (2011), 'Patent Litigation Study: Patent litigation trends as the "America Invents Act" becomes law', (PricewaterhourseCoopers).
Qi, JZ, et al. (2011), 'Innovative drug R&D in China', *Nature Reviews Drug Discovery* 10 (333-334).
Qian, Y (2007), 'Do National Patent Laws Stimulate Domestic Innovation in a Global Patenting Environment? a Cross-Country Analysis of Pharmaceutical Patent Protection, 1978–2002', *The Review of Economics and Statistics,* 89 (3), 436–53.

Qu, J and Ollier, P (Feb. 2009), 'The Tasks of Tian', *Managing Intellectual Property,* (186).
Ramanna, A (2005), 'Shifts in India's Policy on Intellectual Property: The Role of Ideas, Coercion and Changing Interests', in P Drahos (ed.), *Death of Patent* (Witney, OXON
London: Lawtext Publishing Ltd and Queen Mary Intellectual Property Research Institute.).
Rangnekar, D (2006), 'No Pills for Poor People? Understanding the Disembowelment of India's Patent Regime', *Economic and Political Weekly*
Reichman, J and Hasenzahl, C (2003), 'Non-voluntary Licensing of Patented Inventions: Historical Perspective, Legal Framework under TRIPS, and an Overview of the Practice in Canada and the USA', (UNCTAD-ICTSD).
Reichman, J.H. (2004), 'Undisclosed Clinical Trial Data under the TRIPS Agreement and its Progeny: a Broader Perspective', *CTSD-UNCTAD Dialogue on Ensuring Policy Options for Affordable Access to Essential Medicines* (Bellagio).
Reichman, J. and Dreyfuss, R (2007), 'Harmonization without Consensus: Critical Reflections on Drafting a Substantive Patent Law Treaty', *Duke Law Journal,* 57 (1).
Reichman, J (2009), 'Intellectual Property in the Twenty-First Century: Will
the Developing Countries Lead or Follow?' *Houston Law Review,* 46 (4).
Reynolds, j (1990), 'UK Manufacturing Industry: structural change and competitiveness - a lesson for other countries? ' in A Webster and J Dunning (eds.), *Structural Change in the World Economy* (London: Routledge), 12.
Richards, Ronald G (2004), *Intellectual Property Rights and Global Capitalism* (Armonk: M.E.Sharpe).
Richards, Donald G. (2004), *Intellectual Property Rights and Global Capitalism* (Armonk: M.E.Sharpe).
Rivette, Kevin G. and Kline, David (2000), *Rembrandts in the Attic: Unlocking the Hidden Value of Patents* (Boston: Harvard Business School Press).
Rodrik, D (1995), 'Getting Interventions Right: How South Korea and Taiwan Grew Rich', *Economy Policy* 20.
Roffe, P (2004), 'Bilateral Agreements and a TRIPS-plus World: the Chile-USA Free Trade Agreement', (Quaker International Affairs Programme).
--- (2005), 'Comment: Technology Transfer on the International Agenda', in K Maskus and J Reichman (eds.), *International Public Goods and Transfer of Technology under a Globalized Intellectual Property Regime* (Cambridge University Press).
Roffe, P and Vea, G (2009), 'The WIPO Development Agenda in a Historical and Political Context', in N Netanel (ed.), *The Development Agenda: Global Intellectual Property and Developing Countries* (Oxford Scholarship Online).
Rosch, J. Thomas (2008), 'Patent Trolls: Broad Brush Definitions and Law Enforcement Ideas', (Federal Trade Commission (FTC)).
Ross, Lester, Woll, Robert, and Zhou, Kenneth (2007), 'China Reforms Drug Registration', (WilmerHale).
Ryan, M (1998), *Knowledge Diplomacy: global competition and the politics of intellectual property* (Washington, D.C.: The Brookings Institution).
Sag, M and Rohde, K (2006), 'Patent Reform and Differential Impact', *Minnesota Journal of Law, Science & Technology,* 8 (1).
Sanjuan, Judit Rius (2006), 'U.S and E.U Protection of Pharmaceutical Test Data1', *CPTech Discussion Paper*. <www.cptech.org>.

Sanjuan, J, Love, J, and Weissman, R (2006), 'Protection of Pharmaceutical Test Data: A Policy Proposal', (Knowledge Ecology International).
Sanofi- aventis (October 21, 2008), 'Press Release Sanofi-aventis:Sanofi-aventis expands its R&D presence in China', (Beijing).
Scherer, M and Weisburst, S (1995), 'Economic Effects of Strengthen Pharmaceutical patent Protection in Italy ', *International Review of Intellectual Property and Competition Law 1995,* (26).
Scherer, F.M (1999), *New Perspectives on Economic Growth and Technological Innovations* (Maryland: The Brooklings Institution).
Scherer, F.M (2001), 'The Patent System and Innovation in Pharmaceuticals ', *Revue Internationale de Droit Economique,* Special Edition: Pharmaceutical Patents, Innovations and Public Health, 109-12.
Secretary-General, Office (2009), 'New York, 15 June 2009 - Secretary-General's concluding remarks at Forum on Global Health'.
Sell, S (1998), *Power and Ideas: North - South Politics of Intellectual property and Antitrust* (New York: State university of New York press).
Sell, S (2003), *Private Power, Public Law: The Globalization of Intellectual Property Rights* (Cambridge: Cambridge university press).
Sen, A (1999), 'Health in Development', (WHO).
Sen, A --- (2006), 'Human Development and Health', *The Human Development Forum 2006* (Beijing: Centre for Human and Development Studies, Beijing University).
SFDA 'Provisions for Drug Registration', *SFDA Order No. 28* (PRC: SFDA).
Shadlen, K (2004), 'Patents and Pills, Power and Procedure: The North-South Politics of Public Health in the WTO', *Studies in Comparative International Development,* 39, 76-108.
--- (2005), 'Policy Space for Development in the WTO and Beyond: the Case of Intellectual Property Rights', (Global Development and Environment Institute).
--- (2009), 'The Politics of Patents and Drugs in Brazil and Mexico: the Industrial Bases of Health Policies', *Comparative Politics,* 42 (1), 41-58. <http://eprints.lse.ac.uk/27051/>.
--- (2011), 'The Political Contradictions of Incremental Innovation: Lessons from Pharmaceutical Patent Examination in Brazil', *Politics and society,* 39 (2).
Shaffer, G (2003), 'How to Make the WTO Dispute Settlement System Work for Developing Countries', (ICTSD Resource Paper No. 5).
Shaffer, G (2004), 'Recognizing Public Goods in WTO Disputes Settlement: Who Participates? Who Decides? The Case of TRIPS and Pharmaceutical Patent Protection', *Journal of International Economic Law,* 7 (2), pp. 459-82.
Shaffer, G (2005), 'Power, Governance and the WTO: A Comparative Institutional Approach ', in M Barnett and B Duvall (eds.), *Power in Global Governance* (Cambridge University Press).
Shapiro, C (2001), 'Navigating the Patent Thicket: Cross Licenses, Patent Pools, and Standard Setting', in A Jaffe, J Lerner, and S Stern (eds.), *Innovation Policy and the Economy* (1: National Bureau of Economic Research).
Shen, Jl (1993), 'Some Important Amendments to the Chinese Patent Law', *World Patent Information,* 15 (4).
Shen, YZ (Dec 2002/Jan 2003), 'China Sweeps Away Outdated IP''', *Managing Intellectual Property*.
Sherman, B and Bently, L (1999), *The Making of Modern Intellectual Property Law* (Cambridge University Press).

Sherwood, R (1990), *Intellectual Property and Economic Development* (Boulder: Westview Press).
Sherwood, R (1999), 'A Larger Context for Considering Pharmaceutical Patent in Developing Countries'.
Sherwood, R (2000), 'The TRIPS Agreement: Benefits and Costs for Developing Countries', *International Journal of Technology Management* 19 (1/2).
Shiels, M (02/06/2004), 'Technology Industry Hits out at 'Patent Trolls''. <http://news.bbc.co.uk/2/hi/business/3722509.stm>.
Si, WJ (2012), 'The Pre-litigation Injunction to Cease Patent Infringement Law in China ', (DeBund Law Offices).
Singh, J (2000), 'Weak Powers and Globalism: the Impact of Plurality on Weak-Strong Negotiations in the International Economy ', *International Negotiation* 5, 449-84.
Sinha, S (11/10/ 2009), 'Storm over Drug-Patent Linkage after Court Rejects Bayer Petition', *Livemint.com & the Wall Street Journal*. <http://www.livemint.com/2009/10/11205401/Storm-over-drugpatent-linkage.html>.
SIPO (2008), 'A Breif Introduction and Review of the State Intellectual Property Office of P.R. China', in SIPO (ed.), (Beijing SIPO Press).
SIPO (2009), 'Users satisfy with patent examination quality'. <http://www.chinaipr.gov.cn/news/government/281784.shtml>.
SIPO (2009), 'China's Intellectual Property Protection in 2008', (State Intellectual Property Office).
SIPO 'Users satisfy with patent examination quality', <http://www.chinaipr.gov.cn/news/government/281784.shtml>, accessed 10/09/09.
SIPO (2010), 'Annual Report of the State Intellectual Property Office of China '. <http://english.sipo.gov.cn/laws/annualreports/2010/>.
SIPO (2010), 'Annual Report of the State Intellectual Property Office of China '. <http://english.sipo.gov.cn/laws/annualreports/2010/>.
SIPO (2011), 'White Paper on China's Intellectual Property Protection in 2010'. <http://english.sipo.gov.cn/laws/whitepapers/201104/t20110429_602312.html>.
Smith, P (2001), 'How do Foreign Patent Rights Affect U.S. Exports, Affiliate sales, and Licences', *Journal of International Economics* 55 (2), 411-39.
Smith, S (2006), ''TRIPS Plus' Bilateral Agreements - a Threat to Public Health', *Third World Resurgence* (196), 16-18.
SPC (2007), 'Judicial Protection for Intellectual Property in China ‘, (Beijing: The Supreme People’s Court of the PRC).
Steger, M (2003), *Globalisation: a Very Short Introduction* (Oxford: Oxford University Press).
Stewart, F (1978), *Technology and Underdevelopment* (London: Macmillan).
Stewart, T. (2002), 'Accession of the People's Republic China to the World Trade Organisation: Baseline of Commitments, Initial Implementation and Implication for US- PRC Trade Relation and US Security Interests', (USCC Research Paper).
Sun, Q, et al. (2008), 'Pharmaceutical Policy In China ', *Health Affairs* 27 (4), 1042-50.
Sun, Lei (2008), 'The standards to identify counterfeit drugs', (Beijing: SIPO).
Sutherland (2009), 'The Third Amendment to the Chinese Patent Law', *IP Legal Alert*
Suthersanen, U. (2006), 'Utility Models and Innovation in Developing Countries', *UNCTAD-ICTSD Project on IPRs and Sustainable Development*.

Suthersanen, U, Dutfield, G, and Chow, K (2007), *Innovation without Patents: Harnessing the Creative Spirit in a Diverse World* (Cheltenham: Edward Elgar Publishing Ltd.).
Takalo, T and Kanniainen, V (2000), 'Do Patents Slow down Technological Progress?- Real Options in Research, Patenting, and Market Introduction ', *International Journal of Industrial Organization,* 18 (7), 1105-27.
Taylor, M (1994), 'Trips, Trade, and Growth', *International Economic Review,* 35 (2), 361-81.
Tellez, Viviana M (2006), 'The WIPO Development Agenda: the campaign to reform international intellectual property policy-making '.
Thambisetty, S (2007), 'The Institutional Nature of the Patent System: Implications for Bioethical Decision-Making', in C Lenk, N Hoppe, and R Andorno (eds.), *Ethics and Law of Intellectual Property: Current Problems in Politics, Science and Technology* (Surrey: Ashgate).
The State Council (2008), 'Outline of the National Intellectual Property Strategy '. <http://www.sipo.gov.cn/sipo_English/laws/developing/200906/t20090616_465239.html>.
Thomas, K (2007), 'The Fight against Piracy: working with the administrative enforcement system in China', in P Torremans, J Erauw, and HL Shan (eds.), *Intellectual Property And Trips Compliance In China: Chinese and European perspectives* (Cheltenham: Edward Elgar Publishing Limited).
Thomas, M and Raiti, J (Nov/Dec2002), 'The TRIPS Agreement and China', *China Business Review,* 29 (6).
Timmermans, K and Hutadjulu, Ti (2004), 'The TRIPS Agreement and Pharmaceuticals: Report of an ASEAN Workshop on the TRIPs Agreement and its Impact on Pharmaceuticals', (Jakarta: WHO).
Todaro, M (1989), *Economic Development in The Third World* (London: Longman).
Uekkull, A and Holder, N (June 2006), 'A Clever Move: Utility Models for Second Medical Use Inventions in Germany', (183: Patent World).
UKIPO 'New UK-China Intellectual Property deals to help business exploit new ideas', <http://www.ipo.gov.uk/about/press/press-release/press-release-2009/press-release-20090202.htm>, accessed 08/09/09.
UN (2003), 'New Indicators for Science, Technology, and Innovation in the Knowledge-Based Society', (Economic and Social Commission for Western Asia, United Nations).
UNCTAD-ICTSD (2003), 'Intellectual Property Rights: Implications for Development', (Geneva: UNCTAD-ICTSD).
UNCTAD-ITCSD (2005), 'Resource Book on TRIPS and Development'. <http://www.iprsonline.org/unctadictsd/ResourceBookIndex.htm>.
Unit, Lawyers Collective HIV/AIDS (18 August 2009), 'Delhi High Court Rejects Bayer's Plea for Patent Linkage ', *Lawyers Collective.com*. <http://www.lawyerscollective.org/amtc/current-issues/patentlinkagecase>.
USDC (2003), 'Protect Your IPR in China: a Practical Guide for the US Companies ', in International Trade Administration U.S. Department of Commerce (USDC) (ed.).
USGAO (1997), 'Measuring Performance: Strengths and Limitations of Research Indicators', (United States General Accounting Office Report to Congressional Requesters).
USTR (2004), '2004 Report to Congress on China's Compliance', in USTR (ed.).
USTR (2006), 'U.S.-China Trade Relations: Entering a New Phase of Greater Accountability and Enforcement', in United States Trade Representative (ed.).

Wacks, Raymond (2008), *Law* (Oxford: Oxford University Press).
Wadhwa, V, et al. (2008), 'The Globalization of Innovation: Pharmaceuticals Can India and China Curethe Global Pharmaceutical Market?' (Global Engineering and Entrepreneurship @ Duke).
Waldmeir, P (July 2 2008), 'The value of branding becomes patent', *FT.com*. <http://www.ft.com/cms/s/0/3389c83a-4850-11dd-a851-000077b07658,s01=1.html>.
Wang, MX, et al. (2004), *Strategic Research of Medicine Intellectual Property* (Beijing: Military Medical Science Press).
Wang, SG (2005), 'State Extractive Capacity, Policy Orientation, and Inequity in the Financing and Delivery of Health Care in Urban China', in Asian Research Center (ed.), (London School of Economic and Political Science:).
Wang, J and Yang, Y (2011), 'Perfecting Drug Data Protection System in China', *Asian Journal of Social Pharmacy,* 6 (4).
Watal, J (1998), 'The TRIPS Agreement and Developing Countries Strong, Weak or Balanced Protection?' *The Journal of World Intellectual Property* 1 (2), 179 - 441.
Watal, J (2001), *Intellectual Property Rights in the WTO and Developing Countries* (London: Kluwer Law International).
Waxman, Henry A. (2003), 'Statement of the Honourable Henry A. Waxman, a Representative in Congress from the State of California '.
Wei, T (2009), 'Health Minister Gao Qang: Six Causes for the High Expenditure for 'Using Hospital Service'', *People*. <http://politics.people.com.cn/GB/1027/4119230.html>.
Weissman, R (2006), 'Public Health-friendly Options for Protecting Pharmaceutical Registration Data', *International Journal of Intellectual Property Management,* 1 (1/2).
West, A (1997), 'The pharmaceutical and healthcare industries of China ', (London: FT Pharmaceuticals & Healthcare Publishing,).
--- (1997), 'The pharmaceutical and healthcare industries of China ', (London: FT Pharmaceuticals & Healthcare Publishing).
WHO (1996), 'Ad Hoc Committee on Health Research Relating to Future Intervention Options: Investing in health research and development ', (WHO, TDR/Gen/96.1).
--- (2008), 'Country Experiences in Using TRIPS Safeguards', (WHO Regional Office for South-East Asian).
WHO/CIPIH (2005), 'Innovation in Developing Countries to Meet Health Needs: experiences of Brazil, China, India, and South Africa', (MIHR report, CIPIH Studies, 10d).
Wild, J (2010), 'There is More IP litigation in China than Anywhere Else on Earth', *Intellectual Asset Management*. <www.iam-magazine.com/ctredir.ashx?g=3a9c9c06-dd4f-4adc...>.
--- (2011), 'Quality is China's Biggest Patent Challenge ', *IAM Magazine*. <http://www.iam-magazine.com/blog/Detail.aspx?g=e81c5421-bccc-4eb5-9895-f347443cf73e>.
Wilmerhale (July 2007), 'China Reforms Drug Registration', *Briefing series China* (Wilmerhale).
Winston, K (2005), 'The Internal Morality of Chinese Legalism', (Harvard Kennedy School Working Paper No. RWP05-041).
WIPO 'Where can Utility Models be Acquired?' <http://www.wipo.int/sme/en/ip_business/utility_models/where.htm>.

WIPO 'Protecting Innovations by Utility Models', <http://www.wipo.int/sme/en/ip_business/utility_models/utility_models.htm>, accessed 02/09/09.
WIPO (1988), 'Existence, Scope and Form of Generally Internationally Accepted and Applied Standards/Norms for the Protection of Intellectual Property', in Negotiating Group on TRIPS (ed.).
WIPO (2008), 'World Patent Report: A Statistical Review (2008)', (Geneva: WIPO).
WIPO (2009), 'World Intellectual Property Indicators '. (Geneva: WIPO).
WIPO (2009), 'World Intellectual Property Indicators 2009 '. (Geneva: WIPO).
WIPO (2011) 'World Intellectual Property Indicators2011 Edition', <http://www.wipo.int/ipstats/en/wipi/>.
Wise, Michael and Wang, Zoe (2006), 'Protecting Biotech Inventions in China ', *IP Frontline*.
World,Bank (1997), *Financing health care: problems and options for China* (Washington D.C.: World Bank).
World Bank (2001), 'Global economic prospects and the developing countries : making trade work for the world's poor 2002', (Washington DC: the World Bank), 17.
World Bank (2002), 'World Development Indicators', (Washington DC::World Bank).
World Bank (2008), 'Technology Diffusion in the Developing World', *The Global Prospects* (Washington D. C: World Bank).
World Bank (2009), 'China from Poor Areas to Poor People', in Poverty Reduction and Economic Management Department (ed.), (Washington DC: World Bank).
WTO 'Under the WTO: The Agreements', <http://www.wto.org/english/thewto_e/whatis_e/tif_e/agrm7_e.htm>, accessed 04/05/10.
WTO 'Intellectual property: protection and enforcement', <http://www.wto.org/english/thewto_e/whatis_e/tif_e/agrm7_e.htm>, accessed 20/05/10.
WTO --- 'How to join the WTO: the Accession Process '. <http://www.wto.org/english/thewto_e/whatis_e/tif_e/org3_e.htm>.
WTO (1 October 2001), 'Report of the Working Party on the Accession of China', (WT/ACC/CHN/49: WTO).
WTO (20 November 2001), 'Minsterial Conference Fourth Session Doha, Ministerial Declaration ', (WT/MIN(01)/DEC/1).
.WTO (2001), 'Declaration on the TRIPS Agreement and Public Health ', (WT/MIN(01)/DEC/2, 20 November 2001).
WTO (2001), 'Accession of the People's Republic of China', (WT/L/432, 23 November 2001).
WTO (2001), 'Report of the Working Party on the Accession of China ', (WT/ACC/CHN/49,1 October 2001).
WTO (2005), 'Transitional Review Under Section 18 of the Protocol on the Accession of the People's Republic of China: Report to the General Council by the Chair', (Geneva: Council for Trade-Related Aspects of Intellectual Property Rights).
WTO (2005), 'Members OK Amendment to Make Health Flexibility Permanent', (WTO press release).
WTO (2005 &2008), 'Council for Trade-Related Aspects of Intellectual Property Rights, Report to the General Council by the Chair: Transitional Review Under Section 18 of the Protocol on the Accession of the People's Republic of China, ' (IP/C/39 (Nov. 21, 2005) & IP/C/50 18 November 2008).

WTO (2007), 'China — Measures Affecting the Protection and Enforcement of Intellectual Property Rights: Request for Consultations by the United States', (Dispute Settlement).
WTO - (2007), 'China — Measures Affecting Trading Rights and Distribution Services for Certain Publications and Audiovisual Entertainment Products', in (Dispute Settlement)
WTO (2009), 'China – Measures Affecting the Protection and Enforcement of Intellectual Property Rights: Report of the Panel ', (Dispute Settlement Body).
Xie, CJ (2007), 'Chief judge pledges to fight judicial corruption', *China Daily,* 2007-03-24
XinHua (20/03/09), 'The Panel Report on China US IP disputes rejected the majority of the US claims ', in Ministry of Commerce of People's Republic of China (ed.), (XinHua).
Xu, W (5 August 2008), 'Win the Case but not the Market '. < http://www.qxyc.net/html/23428.html,>.
Xuan, Li (2008), 'Patent Accounts as Indicators of the Geography of Innovation Activities: problems and perspectives '.
Yang, S (01/04/ 2009), ' An Overlooked But Powerful Tool', *Managing IP, China Focus 2009*. <http://www.aplf.org/utility-model-an-overlooked-tool/>.
Yang, HJ (2008), 'Examination and Approval Of Patent Applications', in JC Wang, et al. (eds.), *Guide to the Newly Amended Patent Law* (Beijing: State Intellectual Property Office Press).
Yee, L (2011), 'China tops U.S, Japan to Become Top Patent filer', *Reuters*. <http://www.reuters.com/article/2011/12/21/us-china-patents-idUSTRE7BK0LQ20111221>.
Yin, XT (1998/1999), 'A Brief Introduction to the Patent Practice in China ', *Duke Journal of Comparative & International Law,* 9.
Yip, W and Mahal, A(2008), 'The Health Care Systems Of China And India: Performance And Future Challenges ', *Health Affairs* 27 (4), pp 921-32
Yu, P (2000), 'From Pirates to Partners: Protecting Intellectual Property in China in the Twenty-first Century', *American University Law Review,* 50 (34).
Yu, X (2001), 'The Second Amendment of the Chinese Patent Law and the Comparison between the New Patent Law and Trips', *The Journal of World Intellectual Property,* 4 (1), 137-55.
Yu, P (2002), 'The Second Coming of Intellectual Property Rights in China', *Benjamin N. Cardozo School of Law Occasional Paper No 11*.
--- (2008), 'Access to Medicines, BRICS Alliances, and Collective Action', *American Journal of Law & Medicine 2008 Symposium,* 34.
Yu, Peter (2009), ' The US-China WTO Cases Explained', *Managing Intellectual Property*
Yu, P (2009), 'Sino Trade Agreements and China's Global Intellectual Property Strategy', in C Antons and R Hilty (eds.), *IP Aspects of Free Trade Agreements in the Asia Pacific Region* (Kluwer Law International, accessed at SSRN: http://ssrn.com/abstract=1333431).
--- (2009), 'The Objectives and Principles of the TRIPs Agreement ', *Houston Law Review, Vol. 46* 46. <Available at SSRN: http://ssrn.com/abstract=1398746>.
Yusuf, A (1998), 'TRIPS: Background, Principles and General Provisions', in C Correa (ed.), *Intellectual Property and International Trade* (London: Kluwer Law International Ltd).

Yusuf, Abdulqawi A (1998), 'TRIPs: background, principles and general provisions', in Carlos Correa and Abdulqawi Yusuf (eds.), *Intellectual Property and International Trade: the TRIPs Agreement* (London: Kluwer Law), 4.
Zhang, GL (2001), 'Remedies for Patent Infringement: a Comparative Studies of US and Chinese Law', *John Marshall Review of Intellectual Property Law,* 1 (35).
Zhang, SN, Liu, ZB, and GU, ZW (2002), 'Disease Control and Prevention in China in the 20th Century and Prospects for the New Millennium', *Environmental Health and Preventive Medicine,* 7.
Zhang, QQ (2008), *Intellectual Property Strategy and Practice in the Pharmaceutical and Biotechnological Fields* (Beijing Intellectual Property Rights Press).
Zhang, SN, Liu, ZB, and Gu, ZW (2009), 'The Remarkable Achievement of Judicial protection on IPR in Past Thirty Years in China'. <http://www.court.gov.cn/news/bulletin/release/200909110014.htm>.
Zhai, JX 'Judicial Information of the People's Republic of China: A Survey', *Law and Technology Resources for Legal Professionals* <http://www.llrx.com/features/chinajudicial.htm>, accessed 18/09/09.
Zhao, YG (2003), *The History of the Formulation of the First Patent Law in the PRC* (Beijing Intellectual Property Rights Press).
Zhao, YG (2005), 'A major founder of the Chinese Patent System: Wu Heng', *SIPO online publications*. <http://www.sipo.gov.cn/sipo/bgs/lzp/200605/t20060517_100006.htm>.
Zheng, CS (1998), 'The TRIPS Agreement and Intellectual Property Protection ', *Duke Journal of Comparative & International Law,* 9 (219).