

Emerging Markets Studies

Edited by Joachim Ahrens, Alexander Ebner, Herman W. Hoen, Bernhard Seliger and Ralph Michael Wrobel

Dirk Johann

The Reconfiguration of a Latecomer Innovation System

Governing Pharmaceutical Biotechnology Innovation in South Korea





The book examines the evolving governance of pharmaceutical biotechnology in South Korea in order to derive conclusions about the dynamics of a latecomer system transition. Based on an analysis of innovation activities in the biomedical sector, which is complemented by expert interviews, the research contends that the Korean post-developmental state should be geared towards coordinating the interplay of technologies, modes of organization and institutions. An integrative framework is developed to describe system change as a co-evolutionary process in which the national and sectoral dimensions intersect. The case shows that the shaping of an environment in which innovation systems can develop sectoral transformative capacity is a central aspect of latecomer innovation governance.

Dirk Johann, MSc from the London School of Economics and Political Science and Dr. phil. from the University of Freiburg. He has been Marie Curie research fellow at the University of Sussex (SPRU) and worked as expert for innovation policy development for international and national organizations, most recently as a researcher at the Austrian Institute of Technology. The Reconfiguration of a Latecomer Innovation System

Emerging Markets Studies

Edited by Joachim Ahrens, Alexander Ebner, Herman W. Hoen, Bernhard Seliger and Ralph Michael Wrobel

Vol. 4



Dirk Johann

The Reconfiguration of a Latecomer Innovation System

Governing Pharmaceutical Biotechnology Innovation in South Korea



Bibliographic Information published by the Deutsche Nationalbibliothek

The Deutsche Nationalbibliothek lists this publication in the Deutsche Nationalbibliografie; detailed bibliographic data is available in the internet at http://dnb.d-nb.de.

Zugl.: Freiburg (Breisgau), Univ., Diss., 2012

© Cover Design: Olaf Gloeckler, Atelier Platen, Friedberg

Library of Congress Cataloging-in-Publication Data

Johann, Dirk, 1972-

The reconfiguration of a latecomer innovation system : governing pharmaceutical biotechnology innovation in South Korea / Dirk Johann. pages cm

ISBN 978-3-631-64334-1 — ISBN 978-3-653-03326-7 (ebook) 1. Pharmaceutical biotechnology industry—Technological innovations—Korea (South) 2. Pharmaceutical biotechnology—Technological innovations—Korea (South) 3. Pharmaceutical industry—Technological innovations—Korea (South) 4. Biotechnology industries—Technological innovations—Korea (South) 5. Industrial policy—Korea (South) I. Title. HD9672.K652J64 2013 338.4'76151095195—dc23

2013021603

D 25

ISSN 2190-099X ISBN 978-3-631-64334-1 (Print) E-ISBN 978-3-653-03326-7 (E-Book) DOI 10.3726/978-3-653-03326-7

© Peter Lang GmbH Internationaler Verlag der Wissenschaften Frankfurt am Main 2013 All rights reserved. PL Academic Research is an Imprint of Peter Lang GmbH.

Peter Lang – Frankfurt am Main · Bern · Bruxelles · New York · Oxford · Warszawa · Wien

All parts of this publication are protected by copyright. Any utilisation outside the strict limits of the copyright law, without the permission of the publisher, is forbidden and liable to prosecution. This applies in particular to reproductions, translations, microfilming, and storage and processing in electronic retrieval systems.

www.peterlang.de

Acknowledgements

As with any research undertaken over several years, this is also the result of a reflection process that draws on the involvement of many different people that helped me to express the ideas in it. The first ideas for this book, which is based on my doctoral dissertation in Sociology at the Albert Ludwig University of Freiburg, were developed during a Marie Curie fellowship at the University of Sussex (SPRU). The initial formulation of the theme received encouragement from Keith Pavitt whose ideas have become important guideposts for my own development to conduct the research that led to the dissertation. My interest in industrial policy for catch-up development was initially raised by Robert Wade's research on Korea and Taiwan that decisively shaped the academic view on the coordinative capacity of the East Asian developmental state.

During the field research for this book, the interactions with dozens of researchers, policymakers and R&D managers provided a rich source of information and advice. In Korea, I would like to thank researchers at the Science and Technology Policy Institute (STEPI), the Korea Institute for Industrial Economics and Trade (KIET), the Korea Development Institute (KDI), and the Korea Research Institute of Bioscience and Biotechnology (KRIBB) for the generous support I received. Without their orientation, the access to interview partners would often have been more difficult. I would also like to thank my interview partners at various Korean bioventure firms for sharing valuable information and providing access to materials often very difficult to locate.

The financial support from the *Landesgraduiertenförderung* (LGFG) and the German Academic Exchange Service (DAAD) during the initial stage of the doctoral project are most gratefully acknowledged. I would to like to thank my supervisor Hermann Schwengel (University of Freiburg), Matthias Weber at the Austrian Institute of Technology (AIT), and Joachim Ahrens (Private University of Applied Sciences Göttingen) for their support during the publication. I would like to thank Beatrice Rath for her support with the final graphic image editing.

I also want to acknowledge the continued encouragement I received from many colleagues and friends. I have greatly benefited from discussions with Mónica Casalet Ravenna, Daniel Villavicencio, Rigas Arvanitis, and Gabriel Yoguel. I am particularly indebted to Beatriz Nava-Domínguez.

This book is dedicated to my parents for years of unconditional support.

Contents

Acknowledgements	5
List of figures	10
List of tables	11
Abbreviations and acronyms	13

PART 1

1	Inti	roducti	on	15
	1.1	Object	ive of the research	19
	1.2	Metho	dology	22
	1.3	Struct	ure	24
	1.4	Backg	round concepts, context and definitional issues	25
		1.4.1	The intellectual framing of latecomer innovation research	25
		1.4.2	Towards a post catch-up mode of industrial governance in	
			Korea	37
		1.4.3	Putting pharmaceutical biotechnology into perspective	61
_	_	_		
2	Төу	vards a	n integrative conceptual framework	71
	2.1	Unders	tanding the sectoral dynamics and socio-technical constituency	
		of nati	onal systems of innovation	72
		2.1.1	National systems of technological learning and innovation	72
		2.1.2	The sectoral dynamics of technological learning	81
		2.1.3	Technological systems	89
		2.1.4	Socio-technical networks and systems	96
	2.2	Conce	ptualising the reconfiguration of a latecomer innovation system	105
		2.2.1	Defining the role of the state in a changing triple helix	105
		2.2.2	The coordinative capacity of the post-developmental state in	
			East Asia	111
		2.2.3	Socio-technical regime shift and system innovation	119
	2.3	Summ	ary and conclusions	124

Gov in b	ernanc iotechn	e dimensions of technological learning and innovation bology	127
3.1	The po	litical economy of biotechnology	128
	3.1.1	Technological and institutional-organisational co-evolution of	
		the biotechnology sector	128
	3.1.2	Governance structures and evolving state policies in	
		biotechnology	134
	3.1.3	The political economy of biotechnology in Asia	139
3.2	Config	uring national innovation systems for the biotechnology regime	146
	3.2.1	The interaction between scientific and organisational change	
		in biotechnology and pharmaceuticals in national innovation	
		systems	146
	3.2.2	Implications for latecomer innovation systems	151
3.3	Summ	ary and conclusions	156
	Gov in b 3.1 3.2 3.3	Governance in biotechm 3.1 The pc 3.1.1 3.1.2 3.1.3 3.2 Config 3.2.1 3.2.2 3.3 Summ	 Governance dimensions of technological learning and innovation in biotechnology 3.1 The political economy of biotechnology 3.1.1 Technological and institutional-organisational co-evolution of the biotechnology sector 3.1.2 Governance structures and evolving state policies in biotechnology 3.1.3 The political economy of biotechnology in Asia 3.2 Configuring national innovation systems for the biotechnology regime 3.2.1 The interaction between scientific and organisational change in biotechnology and pharmaceuticals in national innovation systems 3.2.2 Implications for latecomer innovation systems 3.3 Summary and conclusions

PART 2

4	Ενα	lution	and reform of Korea's national system of innovation	159
	4.1	A histe	orical perspective on the Korean system of innovation	160
		4.1.1	Origins and development of the Korean system of industrial	
			innovation	160
		4.1.2	Catch-up, crisis and adaptive policies	165
		4.1.3	The reform of government-business relations	170
	4.2	Towar	ds a coherent mode of science, technology and innovation	
		policy	coordination	175
		4.2.1	Restructuring STI policy governance	175
		4.2.2	Remaining challenges for innovation policy coordination	180
	4.3	Summ	ary and conclusions	184

5	Evo for	lving structures and dynamics of Korea's innovation system biotechnology	187
	5.1	Evolution and status of the national system of biotechnology	
		promotion in Korea	188
		5.1.1 Brief historical review of Korean biotechnology policies5.1.2 Actors and structures in policymaking and programme	188
		management	198
	5.2	Framework conditions affecting the rate and direction of innovation in	
		biotechnology	208
		5.2.1 Current status of biotechnology-related regulatory	
		frameworks	208
		5.2.2 Rates of innovation in health-related biotechnology	215
	5.3	Evolving structure and dynamics of the biomedical and	
		biopharmaceutical system	227
		5.3.1 Organising the structure and dynamics of the biomedical	
		system	227
		5.3.2 The role and evolution of new biotechnology firms	233
	5.4	Summary and conclusions	238

6	Conclusions and final considerations	241
---	--------------------------------------	-----

References	247
Annex	300

Figures

Figure 1.1	The evolution of science and technology capability in Korea by stages of industrialisation	49
Figure 1.2	Biotechnology and the multi-disciplinary process of drug discovery	66
Figure 2.1	Framework to understand the inter-relationship between the formation of industrial networks and the emergence and transformation of technological systems	94
Figure 2.2	Actors and dynamics in techno-economic networks	99
Figure 2.3	Multi-level framework for the analysis of socio-technical transitions	103
Figure 2.4	Transition contexts and the coordination of socio-technical regime shift	121
Figure 3.1	Components of a national system of biotechnology innovation	150
Figure 5.1	Evolution of government investment in biotechnology, 1994 - 2008	198
Figure 5.2	Governmental biotechnology investment ratio by ministry, 2005	198
Figure 5.3	Operating structure of the Korean national system of biotechnology promotion, 2004 - 2008	203
Figure 5.4	Domestic and foreign patent applications for inventions in micro- organisms, enzymes and genetic engineering (IPC C12N), 1998 - 2004	225
Figure 5.5	Number of clinical trials in Korea as approved by the KFDA, 1998 – 2010	228

Tables

Table 1.1	Comparative growth rate of technological capability for Korea and Japan, 1985 - 2009	48
Table 1.2	Selected indicators of R&D and innovation in Korea and Japan, 1995 – 2000	50
Table 1.3	The evolution of R&D investment in Korea, 1965 - 1995	53
Table 1.4	Flows of R&D funds by sector of performance in Korea, 2001	55
Table 1.5	Concentration rates of R&D in Korean top companies	56
Table 1.6	Number of corporate R&D centres in Korea, 1995 - 2000	57
Table 1.7	Number of spin-offs from major Korean <i>chaebol</i> , 1997 - 2001	57
Table 1.8	List-based definition of biotechnology techniques as proposed by the OECD	69
Table 1.9	Indicators to measure the sectoral innovation performance of pharmaceutical biotechnology	69
Table 4.1	Sectoral versus multi-sectoral innovation policy approach	183
Table 5.1	Total production amount of Korean biotechnological products, 1993 - 1994	191
Table 5.2	Status of biopharmaceutical market in Korea, 1993	192
Table 5.3	Participating companies in HAN projects related to the develop- ment of new functional materials of biological sources, 1992	193
Table 5.4	Development of funds invested by the MOHW for new drug development using biotechnology, 1991 - 1998	194
Table 5.5	R&D subsidies for the development of new drugs allocated by the KDRA, 1992 - 2000	195
Table 5.6	Strategies and tasks of the Second Framework Plan <i>Bio-Vision</i> 2016	197
Table 5.7	Budgetary status of promising new technologies, 2002 - 2004	200

List	of	tables

Table 5.8	Biotechnology sector budget distribution of the government for R&D and infrastructure, 2004	200
Table 5.9	Role of current ministries in support of bioindustry development (since 2008)	204
Table 5.10	List of critical and candidate biotechnologies as identified by the <i>577 Initiative</i>	207
Table 5.11	Number of scientific publications in genomics by Korea and other leading and emerging economies, 1991 – 2002	217
Table 5.12	Number of scientific publications in health biotechnology by Korea and other leading and emerging economies, 1991 - 2002	217
Table 5.13	Number of scientific publications and specialisation index in genomics and health biotechnology by subfields for Korea and other emerging economies, 1991 - 2002	219
Table 5.14	Number of scientific publications and distribution of scientific output in genomics and health biotechnology in Korea and other emerging economies by sector of activity, 1991 - 2002	219
Table 5.15	Scientifically most productive Korean institutions in genomics and health biotechnology, 1991 - 2002	221
Table 5.16	Annual status of biotechnology related patent applications in Korea as filed by year, 1985 - 2004	223
Table 5.17	Trends in biopharmaceutical patent applications in Korea, 1990 - 1999	224
Table 5.18	Evolution of sectoral pattern of biotechnology patent applications from Korean companies by principal sector of activity, 1986 – 2001	226
Table 5.19	Number of technology transfers from KRIBB to industry, 2001 – 2010	231
Table 5.20	Status of strategic alliances between Korea Green Cross and Korean bioventure firms (as of 2002)	232
Table 5.21	Bioventure firms as spin-offs from KRIBB (as of 2004)	235
Table 5.22	R&D expenditures of KOSDAQ-listed Korean bioventure firms, 2002 - 2003	235

Abbreviations and acronyms

API	Active Pharmaceutical Ingredient	
BOK	Bank of Korea	
BVC	Bio Venture Centre	
CEO	Chief Executive Officer	
DBF	Dedicated Biotechnology Firm	
DNA	Deoxyribonucleic Acid	
EPB	Economic Planning Board	
EPO	European Patent Office	
FDA	Food and Drug Administration	
FDI	Foreign Direct Investment	
GERI	Genetic Engineering Research Institute	
GRI	Government-funded Research Institute	
HAN	Highly Advanced National Project	
HCI	Heavy Chemical Industry	
HTS	High-throughput Screening	
ICT	Information and Communication Technology	
IPC	International Patent Classification	
IRB	Institutional Review Board	
KAIRB	Korean Association of Institutional Review Boards	
KBRA	Korea Biotechnology Research Association	
KDRA	Korean Drug Research Association	
KFDA	Korea Food and Drug Administration	
KFRI	Korea Food Research Institute	
KGCP	Korean Good Clinical Practice	
KIOM	Korea Institute of Oriental Medicine	
KIPO	Korean Intellectual Property Office	
KOGERA	Korean Genetic Engineering Research Association	
KORDI	Korea Ocean Research and Development Institute	
KOSDAQ	Korea Securities Dealers Automated Quotations	
KRFC	Korean Research Council for Fundamental Science and Technology	
KRIBB	Korean Research Institute of Bioscience and Biotechnology	
KRICT	Korea Research Institute of Chemical Technologies	
MEST	Ministry of Education, Science and Technology	
MIC	Ministry of Information and Communications	
MKE	Ministry of Knowledge Economy	

MOAF	Ministry of Agriculture and Forestry
MOCIE	Ministry of Commerce, Industry and Energy
MOER	Ministry of Energy and Resources
MOE & HRD	Ministry of Education and Human Resource Development
MOFE	Ministry of Finance and Economy
MOHW	Ministry of Health and Welfare
MOMAF	Ministry of Maritime Affairs and Fisheries
MOST	Ministry of Science and Technology
MOTI	Ministry of Trade and Industry
NCE	New Chemical Entity
NIE	Newly Industrialised Economy
NIS	National Innovation System
NRDP	National Research and Development Programme
NRL	National Research Laboratory Programme
NSTC	National Science and Technology Council
OBM	Own Brand Manufacturing
OECD	Organisation for Economic Cooperation and Development
OEM	Original Equipment Manufacturing
OSTI	Office of Science and Technology Innovation
OTA	Office of Technology Assessment
PACST	Presidential Advisory Council on Science and Technology
POSCO	Pohang Iron and Steel Company
PRO	Public Research Organisation
R&D	Research and Development
RNA	Ribonucleic Acid
SME	Small and Medium-sized Enterprise
S&T	Science and Technology
STI	Science, Technology and Innovation
USPTO	United States Patent and Trademark Office

South Korea (hereinafter Korea) has experienced a profound economic and industrial transformation, which remains an important subject of academic inquiry. After riding successfully the wave of East Asia's economic dynamism for more than three decades, Korea plunged into a recession in the wake of the 1997 Asian crisis. The crisis, which caused a systemic meltdown in the financial and corporate sectors across the economies of the region, revealed that the extended post-War era of interventionist developmental state leadership in directing industrial development through vertical industrial policies ('picking winners') has finally drawn to a close. It also raised a fundamental question mark over the coordinative capacity of the East Asian newly industrialised economies (NIEs) to cope with the new economic order shaping in the context of technological globalisation. A central aspect of this order that developed in the aftermath of the Cold War has been the emergence of technology-based innovation as the primary source of industrial development and economic prosperity.

From whichever angle we look at Korea's successful entry to the global industrial scene, the most arresting feature has been a developmental state¹ that proved highly effective in coordinating the process of industrial catch-up in sectors where the rate of technological change was low and factor accumulation was more important than scientific knowledge production. While the worldwide spread of science-driven industrial technologies made endogenous knowledge generation imperative for industrial development strategies², the building of catch-up competitiveness in Korea was largely based on *behind the frontier* innovation achieved by absorbing, assimilating and improving borrowed

¹ In the literature, Korea is commonly described as a typical paragon of the post-War developmental state (Amsden, 1989; Chang, 1994; Wade, 1990; Evans, 1995, Rodrik *et al.*, 1995; Kohli, 1999).

² The lack of a knowledge-based technological dynamism has been identified as a major weakness of the East Asian model of economic development already long before the Asian crisis became full-blown in 1997. Krugman (1994), for example, attacked the idea of an East Asian economic miracle in his widely discussed Foreign Affairs article. He argued that East Asia's growth had historically been the result of high capital investment and increasing participation in the labour market, thus leading to productivity growth. However, total factor productivity had increased only marginally or not at all. Krugman argued that only increases in factor accumulation without growth in total factor productivity would not be conducive to long-term economic prosperity in East Asia. In other words, he maintained that economic growth in East Asia was based on *perspiration* (i.e. the use of more factor inputs) rather than on *inspiration* (i.e. technological change driven by innovation).

technology. When a country is far from the technological frontier it is easier to catch up through imitating and licensing technology. The critical task here is to manage the flow of resources to carry out the investments required for nurturing the process of imitation. However, as latecomers move towards the technology frontier, they can only grow by innovating, which requires the management of the flow of ideas that drive innovation processes. It has been argued that the need to adapt the Korean developmental state to the challenges of the innovation-fuelled knowledge economy³ long predated the crisis moment of the late 1990s. Korea's prospects to catch up with the more advanced industrial economies in science-based industries increasingly depend now on the adoption of system-oriented policies and governance arrangements that facilitate new modes of technological learning.

The arrival of a new techno-economic paradigm has been widely associated with the emergence and spread of new science-driven technologies as the key source of national industrial competitiveness in the global technology race. Biotechnology is a generic technology reflecting a new science-based innovation regime (Coriat *et al.*, 2003), which is characterised by its pervasive effects on the technological dynamics of many branches. The emergence of modern biotechnology⁴ proved highly disruptive for patterns of industrial production and technological innovation in chemicals, the agro-food sector and particularly the pharmaceutical sector. While the accelerated scientific progress of modern biotechnology has been clearly linked to the globalisation of research and development (R&D), there has also been a rising need to bring national institutions in line with the techno-scientific advances of the emerging technology.

³ In 2008, President Lee Myung Bak took office and merged the former Ministry of Commerce, Industry, and Energy (MOCIE) with elements of the Ministry of Information and Communications (MIC), the Ministry of Finance and Economy (MOFE) and the Ministry of Science and Technology (MOST) into the Ministry of Knowledge Economy (MKE). The establishment of this key body in the Korean governance system with the principal mission to provide the policy directions in trade, energy and industry reflects the government's mandate to invigorate the economy as Korea transforms into a knowledge-based economy.

⁴ The new technologies that are associated with the birth of modern biotechnology received their principal scientific impetus from the discovery of recombinant DNA technology in the early 1970s. The OECD defines modern biotechnology as "the application of science and technology to living organisms, as well as parts, products and models thereof, to alter living or non- living materials for the production of knowledge, goods and services." (OECD, 2005: 9)

As biotechnology evolved and achieved practical application in pharmaceuticals on an unprecedented scale in the $1990s^5$ – with many genetically based drugs in clinical trials - the new technology turned into a feasible alternative to conventional approaches for chemical synthesis, such as organic chemistry. In the 1990s, firms in pharmaceuticals and other biotechnology related industries therefore had to realise that their existing knowledge base has been increasingly supplemented - if not supplanted - by a new technological paradigm, which radically transformed the cognitive and organisational nature of industrial learning. While incumbent firms in the United States, in some European countries and in Japan fell under the spell of the new paradigm and therefore already developed early capabilities to harness biotechnology for a range of commercial applications, industrial laggards embarked on the biotechnology revolution at different paces and rates. Latecomers often face difficulties to accommodate biotechnology in their industrial systems because it requires the fusion of several science-based disciplines as well as large outlays on basic and applied research. Since this aspect has become more salient in recent years latecomer firms involved in biotechnology related product development need to engage in R&D activities, either by building in-house capabilities or through extramural research arrangements. As the collaboration between science and industry becomes more important for the evolution of a market environment for biotechnology, there is also a greater need to create institutions that facilitate and enhance the cooperation of firms with a variety of actors of the science system.

Biotechnology, which is not an industry itself but a generic technology with potential applications across many different industries, has been described as a non-linear technological system built on a network structure (Achilladelis and Antonakis, 2001; Carlsson, 2002; Galambos and Sturchio, 1995; Galambos and Sewell, 1998; McKelvey *et al.*, 2004; Orsenigo *et al.*, 1998, 2001; Pyka and Saviotti, 2005; Staropoli, 1998) that presents a great deal of uncertainty for processes of industrial learning. Its emergence in a context of late-industrialisation requires the departure from past modes of industrial organisation and governance that were based on low-risk strategies of industrial catch-up and associated with a strong central government directing technological capability building. Unlike earlier strategies of technological followership, which relied on the anticipation of standard product life-cycles and

⁵ The surfacing of novel techniques derived from the field of molecular biology (including genomics, gene sequencing and proteomics) in conjunction with the introduction of combinatorial technologies revitalised the process of random screening as a paradigm for drug discovery and thus enabled researchers to break through many former constraints on rational drug design.

the predictability of learning curves, the design and implementation of policies within this new industrial learning paradigm need to acknowledge the fundamental uncertainties surrounding the process of innovation.

With the post-crisis rebound, Korea embarked on a comprehensive agenda of policy and institutional reforms aimed at boosting the scale of knowledgeintensive activities in science-driven sectors, such as biotechnology, nanotechnology and advanced information and communication technologies (ICT) (MOST, 2000). However, the industrial governance challenges associated with the rise of modern biotechnology have put the Korean developmental state under significant strain. It is clear that the reconfiguration of the institutional linkages and modes of coordination on which the state-directed model of industrialisation was based has become unavoidable, although this does not imply the complete redundancy of the state's capacity for steering certain aspects of industrial transformation processes. On the contrary, as Korea has evolved over different stages of economic and industrial development and continuously approaches the innovation frontier with emerging science-based industrial technologies, the role of the state needs to be revisited and based on a different type of intervention. Instead of directly controlling market parameters and orchestrating industrial development from the top down, the post-industrial developmental state (Wong, 2004b) is supposed to assist technological learning through the support for organisational adaptiveness and institutional innovation.

The discussions throughout the analysis are premised on the idea that most of the inherited industrial policy instruments used to manage industrial transformation in the past have outlived their usefulness. Since the dynamics of evolving innovation system are increasingly driven by complex reciprocal relationships between large and small firms as well as diffuse networks of innovation actors, the approach of government intervention associated with the catch-up period appears as ever less practical or is even considered as intrusive. The bulk of studies on the coordinative capacity of the state in the field of biotechnology have as yet examined the variety of experiences of the industrial leaders at the technological frontier (for example Dodgson, 1991; Giesecke, 2000; Casper, 2000; McKelvey, 1996, 2000; Prevezer, 2001; Peter, 2002; Kaiser and Prange, 2004), while in-depth analyses of the systemic aspects of the coordination of science-industry linkages in the biomedical field and the role of distinctive national R&D environments for the emergence and diffusion of modern biotechnology in a latecomer context remain scarce.⁶ This book intends

⁶ Notable exceptions are the studies of biotechnological capability building in developing countries by Gonsen (1998) and Acharya (1999a). More recent contributions include, among others, Chaturvedi (2005) and Krishna (2007).

to make a contribution to filling this void. It contends that the emergence of biotechnology has significant implications for the configuration of the relationship between government, science and industry, and thus for the transition from a developmental state to an *innovation state* in Korea.

The analysis makes extensive use of concepts rooted in different strands of literature on institutional governance, firm strategy, development economics and innovation theory to explore the multifaceted transformative process Korea's innovation system is undergoing. Furthermore, the analysis takes an evolutionary perspective by placing particular emphasis on the co-evolution of technological, institutional and organisational change in this transformation.

1.1 Objective of the research

The innovation literature almost unanimously rejects the market failure approach as a basis for policy intervention (for example Malerba, 1992a; Metcalfe, 1997; Carlsson and Jacobsson, 1997) and considers the system approach to innovation as the more appropriate alternative. During the past 20 years⁷, the *innovation system* as an analytical construct has increasingly gained acceptance among the growing number of scholars dealing with the dynamics of innovation. However, the innovation system literature, because of its conceptual heterogeneity, describes and interprets innovation systems, their structure, modes of operation, dynamics and performance in a variety of different ways. In general terms, the picture emerging is that innovation systems, although predominantly defined as national in scope⁸, are influenced significantly by technology-specific sectoral factors. A number of different conceptual frameworks have been proposed to analyse the structure and dynamics of systems of innovation at different levels, including national systems of innovation (Lundvall, 1992; Nelson, 1993; Freeman, 1995), regional systems of innovation (Cooke et al., 1997), sectoral innovation systems (Breschi and Malerba, 1997; Breschi et al., 2000; Malerba, 2002), and technological systems (Carlsson, 1994; Carlsson and Stankiewicz, 1991; Carlsson et al., 2002). All

⁷ Lundvall (1992), Nelson (1993) and Edquist (1997) are landmark publications that deserve particular mention for having consolidated the character of innovation systems research as an 'epistemic community'.

⁸ It is clear that in an era of transnational enterprises and multinational research collaborations science-derived technological systems, such as biotechnology, transcend national borders. Nevertheless, the nation-state has still an important role to play in shaping the sectoral dynamics of innovation systems.

these approaches define the boundaries, structural components and functional dynamics of innovation systems in various ways. In addition, there are also concepts of socio-technical systems (Hughes, 1987; Pinch and Bijker, 1987; Geels, 2004a, 2004b; Geels and Kemp, 2007) with a focus on the co-evolution of technical, economic, institutional, cognitive and behavioural transformations of innovation systems driven by the diffusion of new technologies.

The innovation system concept is not a coherent theory. Primarily it is an analytical tool to explore the functional dynamics and describe the performance of systems. Particularly when we consider the sectoral factors driving the transformation of innovation systems, this implies that the system under study does not have to exist as a fully fledged system in reality (Bergek *et al.*, 2008). Instead, the concept with its various analytical elements enables describing systemic interaction between evolving structural components (i.e. actors, institutions, networks) of developing innovation systems or systems undergoing a transformation.

The subject of this research is the role of the sectoral dynamics of biotechnology in reconfiguring the Korean national system of innovation. The national and sectoral perspectives are brought together for the analysis of the fundamental relationships underpinning the transition of Korea's latecomer innovation system from state-directed industrial development to a new mode of innovation-led growth. Particular attention will be paid to the networks between science and industry, which are evolving in a less orchestrated fashion than during Korea's late industrial development and have now begun to determine the functional dynamics of the Korean innovation system. These networks will be studied under the aspect of the sectoral transformative capacity (Dolata, 2009) of emerging biotechnology in a latecomer context.

The primary focus of this research is on the institutional-organisational coevolution of that part of biotechnology that supports the development of the pharmaceutical industry and contributes to the evolution of a specific pattern of innovation in the biomedical field. We examine institutional arrangements and policy processes shaping the governance framework for biotechnology innovation, as well as effective ways of commercialising it in a latecomer context. Furthermore, we attempt to understand the interaction of technological, institutional and organisational determinants in reconfiguring innovation systems, as well as the need to build on the interaction of these determinants for the design of appropriate system-oriented policies. In detail, the research addresses the following questions:

- i. Is the institutional composition of Korea's latecomer innovation system geared towards effectively governing the interaction of all relevant players, in terms of research actors and networks that are engaged in pharmaceutical biotechnology innovation?
- ii. To what extent does the Korean biopharmaceutical sector require research and innovation policies that should be customised according to the specific evolutionary dynamics of the sectoral innovation system in pharmaceutical biotechnology?
- iii. To what extent does the sectoral technological imperative in the field of biomedical drug development matter as a driver of a new institutional and organisational pattern of science-driven post catch-up innovation in Korea?

For some years, most of the literature on technological learning and innovation in a latecomer context has emerged from a focus on the development of dynamic capabilities at the firm level (for example Figueiredo, 2001; Hobday, 1995a, 1995b; Kim, 1997; Teece, 2000), defining technological learning as (latecomer) firms' ability to learn and innovate through absorbing, assimilating and improving available technological knowledge. This literature has largely focused on the analysis of learning processes involved in the gradual accumulation of a minimum technological knowledge base needed for carrying out innovative activities. However, this strand has paid only limited attention to the dynamics of science-driven sectors and their role in the transition process from technological capability development to technological leadership in a latecomer context. From a sectoral perspective, only little academic effort has gone yet into unravelling the role of the co-evolving scientific and institutional environment for inducing technological innovations.

This research draws from a variety of theoretical frameworks and empirical contributions that have emerged in the field of innovation research over the past decade. It makes systematic use of institutional and organisational concepts underpinning the evolving understanding of the sectoral dynamics of innovation systems. It is aimed at developing a coherent framework for redefining the coordinative capacity of the state as a facilitator of technological learning in a changing socio-technical environment for post catch-up.

1.2 Methodology

A diversity of factors accounts for the development of sectoral systems of innovation along different pathways. This research presents a systematic study of the structure, dynamics and performance of a latecomer innovation system at the sectoral level. The general aim is to explore the specific characteristics of the Korean biotechnology and biomedical innovation system, in particular the structure and dynamics of innovation networks as well as the influence of the socio-technical context on the Korean path of biotechnology development.

Given that there is a considerable blurring of the boundaries between the disciplines that provide a workable perspective on the structure and functional dynamics of innovation systems, the research combines elements from sociology, innovation theory, development economics and organisational theory. This multifarious theoretical approach is necessary to answer the key research questions and to provide an appropriate assessment of the coordinative capacity of the Korean policies and institutions to make the innovation system more responsive to the socio-technical dynamics and requirements of advanced science-driven industrial development.

The research rests on the use of a mix of the following quantitative and qualitative methods:

- i. A *descriptive analysis of the Korean innovation system*, including the structural components (actors, organisations, networks, and institutions) and framework conditions that affect the dynamics of innovation in biotechnology and the biomedical system. For this purpose, the research relies on the analysis of secondary data and materials that primarily have been collected from the websites of research institutes, governmental and non-governmental organisations, industrial associations, and companies.
- ii. A *patent-based analysis of innovative activities in biotechnology*. Because the biotechnology / biomedical innovation system in Korea is still in the formative phase, statistical resources are very scarce and existing research on Korean biotechnology tends to be very descriptive. Since there are only few secondary data sources available on the economic performance and innovative activity of new Korean biotechnology firms, a large database on domestic biotechnology patent applications has been created from the online database of patent abstracts of the Korean Intellectual Property Office (KIPO).

- iii. An analysis of R&D activities in the biopharmaceutical and biomedical sector. Due to the lack of a uniform quantitative data source on the biomedical sector in Korea, the research draws on a number of different sources, including data from *Pharma Koreana*, which is a monthly journal published in English in Korea that provides a range of information on the Korean pharmaceutical industry as well as specific information on the profile of actors in the Korean health sector in general.⁹
- iv. *Interviews* and a *field survey* have been carried out to complement the secondary data analysis. During a three-month pilot research stay in Korea in 2004 information on programmes, institutions and actors in Korean biotechnology was collected. During two short-term field trips in 2006 and a short-term stay in October 2009 semi-structured in-depth expert interviews were conducted with policymakers, R&D managers and individual scientists at public research institutions, bioventure firms, industry associations, technology transfer institutions and venture capitalists. The interviewed research institutions were primarily identified through the patent-based analysis. Furthermore, a number of interviewees were identified during the field research through interview partners that pointed to additional relevant interviewees.

While the analysis of secondary sources of information allowed for a description of the principal components of the operating structure of the system of public funding and biotechnology promotion in Korea, the patent-based analysis enabled a view on the evolving sectoral pattern of biotechnology use in manufacturing and applied R&D by private companies. For the purpose of this analysis, biotechnology patent applications as defined by the OECD definition of IPC codes (see Annex 1) have been filtered from the patent online database of the Korean Intellectual Property Office (KIPO) for the years between 1986 and 2001. The identified Korean companies that filed biotechnology patent applications during this period have been grouped into five categories by their principal sectoral activity (see Table 5.18) with the help of several online databases, such as the website of the Korean Chamber of Commerce and Industry (KCCI).

⁹ For the purpose of this research journal issues between 1992 and 2004 have been used. Hardcopies of the journal issues were accessed through the medical library of the Yonsei University, Seoul.

1.3 Structure

The book is structured in six chapters. The first chapter provides background concepts, context and definitional issues. A large part of the first chapter introduces general aspects related to the intellectual framing of Korea's transition from the catch-up model to a post catch-up mode of industrial governance.

The second chapter puts forward the elements of the theoretical framework of analysis. It is divided in two parts. The first part presents the building blocks of a framework to analyse the dynamics of sectoral systems as constitutive for the transformative dynamics of national systems of innovation. The second part focuses on the major aspects of the limitations of the coordinative capacity of the developmental state that have emerged from discussions on modes of knowledge production and changing authority relationships in the field of economic sociology.

The third chapter discusses the co-evolving institutional and organisational dynamics of biotechnology as a complex challenge for governance. The different governance dimensions concerning knowledge production and commercialisation of emerging biotechnology are discussed in the context of the continuously reshaping triadic relationships between government, science and industry. The chapter presents a generic perspective on the potential systemic failures and coordination gaps in the governance of biotechnology between science and society.

The fourth chapter provides an overview on the evolution of Korea's innovation system. It summarises the key aspects of three generations of innovation policy and the practices that shaped the governmental organisation of the public S&T system, as well as the framing of policies to enhance the generic S&T capabilities of the evolving system of industrial innovation.

The fifth chapter presents the in-depth analysis of the institutional conditions and dynamics that shape the evolution of Korea's sectoral pathway of biotechnology development from a systems perspective. While the building of a sectoral system is dependent on the configuration of the national institutional framework to structure the effective management of stocks and flows of knowledge, the analysis centres upon the coordinative role of the state in promoting sectoral innovation capabilities in biotechnology as well as on the evolving differentiation of functions of public and private actors engaged in the inherently uncertain environment of biotechnology innovation and technology commercialisation.

The sixth chapter provides conclusions and discusses the implications from the Korean experience.

1.4 Background concepts, context and definitional issues

1.4.1 The intellectual framing of latecomer innovation research

The dynamics of latecomer firms' capability building behind the technology frontier

For many years during the second half of the twentieth century, development economists and economic historians have studied how developing countries catch up with the developed countries by proceeding through clearly delineated stages of industrial and economic development (Chenery, 1968; Kuznets, 1966). They argued that once a process of industrialisation has set in, the development of latecomer economies follows a linear pattern of predictable phases (Rostow, 1959).¹⁰ Alexander Gerschenkron (1962), who accepted the notion that development progresses in certain stages, rejected the assumption that industrial followers have to invariably continue along the same development trajectory as their precursors. He systematically explored the constraining conditions for latecomers in pursuit of a peculiar path of industrialisation driven by the endeavour to emulate the experiences of their forerunners. His research laid particular emphasis on the importance of capital mobilisation for successful lateindustrialisation. Gerschenkron convincingly argued that the divergence in the rate and direction of latecomers' industrial development is in large part owed to the different strategies by which they make institutional arrangements to compensate for their backwardness and to overcome the barriers for the evolution of modern capital-intensive industries.¹¹

The technological trajectories of developing countries are greatly determined by their position as followers behind the world technological frontier. At the onset of industrial development, they are technologically weak

¹⁰ Recently, there has been a noticeable breaking away from the notion of a recurrent pattern of well-defined stages of late industrialisation. This is also owed to the fact that the formerly backward East Asian NIEs have shown significant deviation from their precursors' earlier course of late industrial development.

¹¹ Gerschenkron's work basically prepared the ground for subsequent research that has furthered our understanding of the process of technological learning in late industrialisation, such as Amsden's (1989) influential study on Korean latecomer firms.

and typically do not know how to master complex technologies. Far from the world technology frontier latecomers are reliant on borrowed technology to gain growth momentum and usually have to learn the process of technological learning itself before being effectively able to leverage technology that has been imported from the industrially advanced nations (Stiglitz, 1987; Amsden, 1991). Technological capability¹² can therefore not be obtained simply 'off the shelf' but must rather be acquired through a process of sequential learning (Bell, 1984; Bell and Pavitt, 1993).

Kim (1997) and Dahlman et al. (1987) provide important insights into the different stages of capability building during the early period of technological catch-up. Kim (1997) argues on the basis of a three-staged model, which extends ideas from the industry life-cycle model originally put forth by Utterback and Abernathy (1975), that technological learning in a latecomer context follows a pattern that is different from that of the industrially advanced countries. In his model, the acquisition of packaged foreign technology is followed by stages of assembly-based assimilation and improvement of the technology, until eventually an advanced stage is reached where at some point of industrial development the latecomer shifts towards making products of higher sophistication. Since the initial products tend to be based on technologies several generations behind the frontier, Kim argues that entry strategies of latecomer firms seeking to close the technological gap between themselves and the technological leaders follow the reversed sequence of technological capability building as it occurs in the industrially mature nations. At an early stage, capability building is driven by imitative learning and the endeavour to maximise shop floor productivity. He further asserts that capability building in a late-industrialising environment also requires investment in imitative R&D for incremental product innovations.¹³ Kim suggests that industrial latecomers, if

13 The defining characteristic of industrialising *late* is the absence of new technology. Innovation in a late-industrialising context is synonymous with learning from borrowed technology (Amsden, 1991). During the early years of Korean industrialisation, turnkey-based plants and assembly technologies were imported for the purpose of

¹² Technological capability, which is defined as "the ability to make effective use of technological knowledge" (Westphal *et al.*, 1985) must be built by firms through learning processes. In this sense, technological capability building refers to the dynamic process of firms' technological learning. Bell (1984) distinguishes 'doing-based' learning such as learning by operating and learning by changing from other mechanism where firms' technological learning depends on the allocation of resources such as learning by training or learning by searching. But this definition of technological capability building is not only applicable at the firm level but also at the national level where legislation, administrative processes and operations by national organisations and institutions promote technological learning to attain economic and social goals.

they have successfully acquired, assimilated and improved mature foreign technologies in a significant number of industrial sectors, "may eventually be able to accumulate indigenous technological capability to generate emerging technologies" (Kim, 1997: 90). Similarly, Wong (1999) argues that latecomer firms undertaking a transition from technology users to technology generators need to overcome inherent latecomer disadvantages *vis-à-vis* the firms in the technological leader countries. He puts it the following way:

"Latecomer firms from late-industrialising countries [...] suffer[ing] several additional disadvantages than other late-entrant firms in the more advanced countries: (1) their distance from lead-user markets, which are typically located in the advanced countries; (2) their distance from the leading sources of technology, which typically belong either to advanced firms or universities/public research institutes located in the advanced countries; (3) their relative shortage of specialised input resources and inadequate public infrastructures, which are often induced locally in support of the leading firms' activities located in the advanced countries. Thus, not only do latecomer firms have to overcome the general disadvantages of being late-movers, they have to do so under more adverse conditions than those faced by other potential late-mover firms in the advanced countries." (Wong, 1999: 5)

The above mentioned stage models study firm-level patterns of technological capability enhancement during the shift from imitation to innovation. They do not address the dynamics of technological innovation after late-industrialisers are making the transition into a post catch-up phase of development. In this sense, Hobday *et al.* (2004) highlight that Korea's transition from a catch-up model to the technological frontier needs to be reflected in the

knock-down production and original equipment manufacturing (OEM). After this period, technological self-reliance was pursued, although the pattern of transition of Korean latecomer firms from technology users to technology generators significantly differs across industries (Choung *et al.*, 2000). A number of studies (Hobday, 1995a, 1995b, 2000; Kim, 1997) have detailed how Korea managed from the basis of its early assembly-based market entry to become a world leader in the D-RAM segment of semiconductor industries. Hobday (1995a) provides a detailed analysis of specific forms of subcontracting between foreign buyers and suppliers (OEM and later the so-called own brand manufacturing OBM) that represented the institutional mechanism for technology leverage and subsequent technological learning, particularly in the semiconductor industry. Several other studies on East Asian high-technology development also point out that what makes the Korean path stand out among other catch-up countries – even among the East Asian NIEs – is that the stages of economic development in Korea are mirrored by the stages of technological progress (Kim, 1980, Westphal *et al.*, 1985).

analyses of capability building processes at the firm level since this shift also involves new patterns of learning beyond latecomer firms' focus on the imitation of standardised products that are associated with low technological uncertainty and a strong reliance on mass production systems. Lee and Lim (2001) provide empirical evidence of three different types of catching-up development, which they label *path-following*, *path-skipping* and *path-creating*. In particular, the evolution of *path-creating* capabilities in sectors where latecomers approach the global technological frontier reflect this shift into a phase of post catch-up innovation beyond a path-following pattern of imitation. In this vein, Choi's (2010) analysis of the Korean model of latecomer innovation provides a summary of stylised cases of successful technological innovation where Korean latecomer enterprises have created path-breaking new products or technologies. Choi uses the term *collective creation* to describe the dynamics of learning that shapes the post catch-up pattern of technological progress of Korean firms and thus replaces the learning-by-using type of earlier stages. He also claims that to reach a more comprehensive understanding of the key characteristics of capability building and innovation beyond the latecomer paradigm more indepth research on the transformation of learning processes at the firm level from an insider perspective is needed.

The competitive advantage of being a latecomer

The technology gap between technological leaders and their followers typically turns into a source of rapid industrial growth if the latter acquire technologies that have been engendered by the former. A great deal of thinking about strategies to overcome technological backwardness refers to the special advantages that may be derived from the recognition of this latecomer effect, which enables industrial laggards to embark on a trajectory of *fast followership*. This concept is built on insights from Gerschenkron's (1962) seminal comparative study of the nineteenth century processes of late-industrialisation in Great Britain, Germany and Russia. What explains the late entrants' ability to outperform early entrants is their *relative backwardness* in conjunction with the decision "to concentrate at a relatively early point of their industrialisation on the promotion of those branches of industrial activity in which recent technological progress had been particularly rapid" (Gerschenkron, 1962: 9), as Gerschenkron argues.¹⁴ If we follow his argument that "it was largely by

¹⁴ The work of Abramovitz (1986), which is built on Gerschenkron's original argument about the virtues of latecomers' backwardness, explores the dynamics of the advantages

application of the most modern and efficient techniques that backward countries could hope to achieve success, particularly if their industrialisation proceeded in the face of competition from the advanced country" (ibid: 9), we see that key to the East Asian NIEs' successful entry in international markets was their ability to exploit the potential for catch-up by turning their latecomer disadvantage into a source of competitive advantage. This was achieved through the accumulation of initial technological capabilities in factor intensive manufacturing industries as a strategic base for targeting later the more technologically progressive sectors.

According to a Gerschenkronian pattern of late-industrialisation, Korea achieved to build up static competitive advantages - i.e. with importance being placed on static scale economies - on the basis of large-scale, capital-intensive production in sectors of the heavy and chemical industries (HCIs) and to become the world's largest shipbuilder in the 1980s.¹⁵ Regardless of this success though, the process of catching up did not stop with the attainment of a leadership position in shipbuilding and other HCIs, but Korea moved gradually into more complex sectors such as semiconductors and automobiles, which made endogenous technology development and consistent R&D-based learning efforts a necessary requirement (Pack, 2000).

Recent research on technology leverage strategies in the East Asian NIEs dedicated special attention to the phenomenon of $leapfrogging^{16}$ and the

- 15 For details on the evolution of technological capabilities in Korean shipbuilding see the case of POSCO (Amsden, 1989).
- 16 The idea of technological leapfrogging is that latecomers may be able to skip earlier vintages of technology, thus embarking on already defined technological paths. Leapfrogging may also imply a reversal of technological leadership positions among early-entrants and latecomers.

and disadvantages of latecomers at the national level. Abramovitz developed the hypothesis that a latecomer's potential for rapid catch up is determined by its societal characteristics which he calls *social capability*. He contends that the simple catch-up hypothesis, i.e. that followers tend to catch up faster the more backward they initially are, is not sufficient to explain the causes underlying the relative success of late-industrialising economies. He writes: "Countries that are technologically backward have a potentiality for generating growth more rapid than that of more advanced countries, provided their social capabilities are sufficiently developed to permit successful exploitation of technologies already employed by the technological leaders. The pace at which potential for catch-up is actually realised in a particular period depends on factors limiting the diffusion of knowledge, the rate of structural change, the accumulation of capital, and the expansion of demand. The process of catching up tends to be self-limiting, but the strength of the tendency may be weakened or overcome [...] by an endogenous enlargement of social capabilities." (Abramovitz, 1986: 390)