National Biotechnology Innovation System in the United States

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Abstract

Biotechnology has strategic importance related to the development of start–up companies, industries and nations in the near future. Therefore, many countries have promoted and developed biotechnology. The United States has led the world in promoting biotechnology. American biotechnology policies are diverse, and thus no comprehensive systematic studies have been done on it.

In our paper, we will discuss American biotechnology policy in detail. For effective analysis, we will rely on the concept of a national innovation system, which emphasizes the institutional settings of innovation actors and their interaction. This paper deals with the American national innovation system for biotechnology. We will analyze the role of major actors, academia, public research institutes, and venture companies and their interactions. The American biotechnological innovation system is composed of diverse actors and numerous start-up companies in the biotechnology industry. In addition, there are many diverse policy programs for promoting biotechnology.

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Because of country-specific frame conditions, every country has different institutional settings and policies for promoting biotechnology.

Our paper will render meaningful implications for various countries. We also think that this paper will be of interest for international readers.

Keywords: *Biotechnology, National Innovation System(NIS), National System of Innovation(NSI), U.S. National Innovation System for Biotechnology, Biotechnology Policy, Country specific frame conditions*

I. Introduction

Nowadays, most countries seek to enhance their competitiveness and sustain economic growth. Driven by technology and innovation, global economic competition is strong. And there is heightened interest in technological advantage for nations(Kogut, 1991; Porter, 1990). Newly rising technologies such as 6T (Biotechnology, Culture Technology, Environment Technology, Information Technology, Nanotechnology, and Space Technology) are the center of the competition. In particular, biotechnology (BT) is regarded as a major driving force for economic development in this century. Because development in biotechnology provides new opportunities for economic development, many countries have been investing huge amounts of resources in this field. For example, the USA has been leading biotechnological innovations by investing large of amounts of money, according to the report 'Biotechnology for the 21st Century' (FCCSET[1], 1992). As a result, U.S. R&D activities in biotechnology are active and the government's budget in biotechnology is high.

Similarly, for most countries in the world, biotechnology will be one of the most important technologies of the next century. They understand that scientific and technological progress in biotechnology contributes to new innovations essential to quality of life and international competitiveness. Therefore, they have promoted and developed biotechnology. Among them, the U.S. is the most advanced country

1) FCCSET: Federal Coordinating Council for Science, Engineering and Technology.

in biotechnology. As such, American biotechnology policies and systems can serve as a model for other nations. However, American biotechnology policies are diverse. This has deterred comprehensive and systematic studies on American systems.

In our paper, we will discuss U.S. biotechnology policies in detail. For an effective analysis, we will rely on the concept of a national innovation system, which emphasizes the institutional settings of innovation actors and their interaction. Therefore, this paper aims to investigate the American national innovation system for biotechnology. We call for a national innovation system as most countries biotechnology has developed in a very systematic way with active participation by all innovation actors in biotechnology. This is because biotechnology is a generic technology and has a significant impact on diverse industrial sectors and society as a whole. In our analysis of the American national innovation system for biotechnology, we will also look into cooperation between biotechnology innovation actors as well as synergy and cross-fertilization effects. This analysis will also be very helpful for other countries.

Every country has made great efforts to set up an efficient national system of innovation for biotechnology. Biotechnology has always been regarded as one of the major strategic technology areas for their S&T policies. They have also sought a systematic approach to the development of biotechnology. For example, South Korea has tried to implement effective national biotechnology innovation systems(Chung, 2002). Such efforts have produced good results, but Korea needs to learn from advanced national innovation systems. At the same time, many countries have distinctive experiences in developing national innovation systems. These experiences will also be helpful for the U.S. efforts to develop its biotechnology innovation system. Therefore, the purpose of this study is to provide reference materials and implications for the USA and developing countries.

The paper is organized as follows. In Section 2 we will discuss the concept of a 'national innovation system (NIS)' and its relationship with the biotechnology sector. Here, we also review some important discussions on a national innovation system for biotechnology. In section 3, we will discuss the American national innovation system (NIS) in biotechnology in detail, based on the concept of a national innovation system. Finally, in Section 4, we will conclude our discussion and identify some strategic implications.

II. Literature Review on National Innovation System for Biotechnology

In a global and knowledge-based society, S&T (science and technology) development for accomplishing national competitive advantage has changed rapidly. Within innovation systems, interactions between these players are guided by both formal and informal rules(Freeman, 2001). And, development of the nation' s S&T is the result of an interactive process(Kline, 1986).

2.1. Theoretical approach to the national system of innovation

National innovation systems have been discussed by many experts and policy makers(Freeman, 1987; Nelson, 1993b). For example, Freeman(1988, 1992), Lundvall(1992), Nelson(1993a), and Chung(2002a) have developed the concept of national systems of innovation. Scholars in this area emphasize the appearance of interactive learning between knowledge producers and users, and these innovation actors lead innovation. Within innovation systems, the interactions among players are guided by both formal and informal rules(Freeman, 2001).

The main focus of an innovation system is the interrelationships between innovation actors and the institutions. There are several concept related to a national innovation system. A broad concept refers to interrelated institutional and non-institutional factors that are linked by generating, diffusing, and exploiting technology innovation. But a more narrow concept focuses on directly R&D-related organizations such as public research institutes, universities and companies(Lundvall, 2002). Lundvall emphasizes that because national economic conditions differ, there are striking differences in production systems and institutional set-ups between countries (Lundvall, 1992).

Nelson(1993a) argues that a process of innovation requires linkage among companies, public research institutions, and universities. Thus, a simple aggregation of innovation actors is not enough for a national innovation system. Therefore, various actors like universities, companies, and public research institutes should actively cooperate within the national innovation system. Nelson also insisted that the nature and intensity of the interactions decisively influence the innovation performance of enterprises in a given innovation system.

Chung(2002a) emphasizes that research on innovation systems should focus on analyzing organizations directly able to generate, search and explore technological innovation. He emphasizes the interaction among innovation actors, i.e. industrial enterprises, public research institutes, universities, and government. According to his arguments, any single actor cannot cover all technological development and such interaction is essential for implementing a competent national innovation system. He emphasizes that a national innovation system can be effectively formulated by combining sectoral and regional innovation systems.

As illustrated above, experts have different opinions on the concept of a national innovation system. However, they all agree that the interaction and relationship among innovation actors are essential for a national innovation system. We can classify innovation actors into three categories: academia, industry, and public research institutes. However, we must also add government as an important constituent of the national innovation system. Business firms, academia, and public research institutes accomplish diverse innovation activities. Government is a supporter of these interactions. As a result, we will examine the roles of academia, the public research sector, industry, and government in our discussion of the U.S. national innovation system for biotechnology.

2.2. National innovation system for biotechnology

We can extend the concept of a national innovation system into the sectoral level. National innovation systems can be formulated and implemented for important industrial sectors. In general, the major technology of such industry has generic characteristics and a strong impact on other sectors. Biotechnology is a good example of this. This has a widespread impact on diverse industrial sectors, such as biomedical device, biofood, bioagriculture, bioprocess, biosecurity, biofuel, biotechnology, biodrug, biopharmaceutic and so on. Therefore, it is not surprising that many countries in the world have been trying to develop biotechnology to grow their economies.

There have been several studies on national innovation systems for biotechnology. As a relevant analytical framework for innovation, they have concentrated on the analysis at a national level. The systematic formation of technological capabilities will make it possible for a nation to gain and secure competitiveness and leadership in biotechnology. In biotechnology, the innovation system is both highly regionalized(European Commission, 2002). Senker(1996) discusses the effects of national systems on organizational learning by companies, by comparing U.K. and U.S. biotechnology systems. She focuses on the industrial response to opportunities offered in biotechnology. According to her study, national differences between two countries, for example, its science base, venture capital, S&T policies, and national culture, play important roles in commercializing biotechnology. Because of differences, most new American biotechnology firms came from universities, while most new biotechnology firms in the U.K. came about from industry.

Bartholomew(1997) explores the relationship between national institutional contexts and the development of biotechnology in the United States, United Kingdom, Japan, and Germany. She argues that national patterns in biotechnology R&D are linked to the configuration of country-specific institutional features of innovation systems that support the accumulation and diffusion of biotechnological knowledge. She emphasizes the institutional features of a national innovation system, which affect the stock of biotechnological knowledge and the flow of knowledge between research institutions and industry. In addition, she suggests that when technology challenges our notions of social identity, the nation-state becomes even more important both for its institutional mechanisms to integrate technological progress and public interest, as well as for its symbolic significance as a community that helps strengthen our sense of identity itself.

Chung(2002b) analyzes Korean biotechnology from the viewpoint of national innovation systems. He insists that the concept of national systems of innovation should be applied not only at the national level, but also at the sector level, or an important technological level. According to his analysis, Korea has formulated a satiable national innovation system for biotechnology that is composed of universities, public research institutes, and industrial companies. He also argues that public research institutes have played an important role in the development of Korean biotechnological capabilities.

The OECD(2006) produced a comparative study on the national biopharmaceutical innovation system in eight major OECD countries. The purpose of this study is to develop policy recommendations that enhance the effectiveness of policies and to foster the economic competitiveness of national pharmaceutical innovation systems. Based on intensive case studies, this report emphasizes an integrative innovation policy approaches: In order to enhance national pharmaceutical innovation systems, countries should maintain coherent innovation policies, activate cooperation and networking among innovation actors, support industrial innovation activities, have transparent and stable regulations, activate technology transfer and promote research.

Chaturrvedi(2005) analyzes the Singapore national innovation system for biotechnology. He emphasizes that the Singaporean government selects the biomedical sector as one of its future strategic industrial sectors and this sectoral approach, together with active governmental support, is very successful for economic development in Singapore. He also emphasizes that the concept of national biotechnological innovation system is instrumental for activating industrial cooperation with universities and public research facilities.

Cooke(2002) adopts the concept of a regional innovation system, which is a sub-concept of a national innovation system, to biotechnological innovation. He argues that a cluster or regional innovation system approach is helpful for the development of biotechnology. He carries out a comparative analysis of German, U.K., and American regional innovation systems in biotechnology and identifies different characteristics among these three regional biotechnology clusters. However, he stresses, based on his analysis of these biotechnology clusters, that active support for industrial companies, labor division between public and private sectors, and collaboration between national and regional governments are essential for the effective development of biotechnology.

Our review above on national innovation systems for the development of biotechnology indicates that there are different approaches for analyzing a national biotechnological system around the world. Our review indicates the following three implications. First, there has been a lack of discussions on the national biotechnological innovation system, especially in consideration of the importance of biotechnology. Second, there have been only a few comprehensive discussions on the national biotechnological system as a whole. As a result, we could not understand the innovation effort of major players, their interactions, and governmental promotion. Finally, there has been no systematic study on the American national innovation system for biotechnology, even though the USA is the leading country in biotechnology. The reason for this might be that it would be very difficult to understand the American system because there are so many players and complicated interactions.

Therefore, despite many difficulties, this paper aims to investigate the American national innovation system for biotechnology. In particular, we will focus on analyzing the roles of major actors for national biotechnological innovation system: government, industrial companies, public research institutes, and universities. Based on this investigation, we will identify some strategic implications.

Ⅲ. American National Innovation System for Biotechnology

3.1 Importance of U.S. innovation system for biotechnology

This study investigates major innovation actor groups: federal and state governments, public research institutes, academia, and industry.

The study of the U.S. national innovation system in biotechnology is very important from an academic point of view because there have been no comprehensive and systematic studies on it. It is very difficult to analyze the U.S. national innovation system in the field of biotechnology because large, difficult to define, and there are numerous actors in the system.

In particular, there is a variety of U.S. biotechnology industries. For example, agriculture and pharmaceutical sectors are profiting from this trend. They generated about 7 billion dollars of sales volume in new biotechnology areas and the sales are expected to reach approximately 50 billion dollars this decade (BIO[2]). The United States leads the world in technological innovation and new company formation in biotechnology. The biotechnology industry is responsible for approximately 885,000 jobs in 17,000 establishments in the 50 states as of 2002 (BIO, 2004). The fourteenth greeting at the BIO 2006 in Chicago offered

2) BIO: Biotechnology Industry Organization; World Wide Web, http://www.bio.org.

access to American biotechnology companies seeking to do business with companies from other countries. Attendance records showed 19,479 executives from 62 countries attended BIO 2006. This is an increase of over 8.2% from last year.

Table 1 indicates the global biotechnology industry status in 2004, which was presented by Ernst & Young in 2005, an expert organization in the biotechnology field. This shows that the United States occupies the biggest portion of the world biotechnology industry by a large amount.

<Table 1> Global Biotechnology Industry Status (2004)

(Units: $ million, persons)

	World total	USA	Europe	Canada	Asia/Pacific
Listed enterprise					
Total revenue	54,613	42,740	7,729	2,091	2,052
R&D cost	20,888	15,701	4,151	782	253
Net loss	5,304	4,317	484	408	94
Employment	183,820	137,400	25,640	7,370	13,410
Number of enterprise	4,416	1,444	1,815	472	685
List	641	330	98	82	131
Unlisted	3,775	1,114	1,717	390	554

Source: Ernst & Young(2005).

American biotechnology has grown rapidly. This shows that the U.S. national innovation system for biotechnology has worked because of the performance of the national biotechnological innovation system and competitiveness of biotechnological firms. All innovation actors seem to have dealt effectively with the rapid change of the technological environment and achieved several technological breakthroughs. This country has been operating the most successful national innovation system for biotechnology. That is why we study from U.S. national innovation system for biotechnology.

In fact, the United States has dominated performance in the field of biotechnology. Therefore, most countries should creatively learn from the U.S. national innovation system for biotechnology and try to improve their national biotechnological innovation system. According to the theoretical analysis on national innovation system, we should analyze major innovation actors of the U.S. national innovation system of biotechnology and their interactions to obtain significant implications from it.

3.2 Role of federal l government

Biotechnology is a generic technology and needs governmental support. This means that the governmental sector should be an important constituent of a national innovation system for biotechnology. The American federal government is an important component of the U.S. national innovation system for biotechnology. The federal government has engaged in many areas of development in biotechnology, especially funding R&D activities. Its investment in biotechnology has focused on health and human services sectors that have significant biotechnological R&D activities. According to Table 2, there are several federal departments and agencies that engaged in biotechnological R&D activities. However, the Department of Health and Human Services accounts for 83.8% of the total biotechnological R&D budget of the U.S. federal government. This implies that the United States has had long-range perspectives on biotechnology and concentrated on enhancing the welfare of the human being by utilizing biotechnological R&D results.

<Table 2> R&D budget for biotechnology of major federal departments (2003)

Departments	Total	HHS	DoD	NASA	DOE	NSF	USDA	Others
Absolute amounts ($ million)	28,673	24,037	862	380	346	513	1,469	1,066
%	100	83.8	3.0	1.3	1.2	1.8	5.1	3.7

Source: NSF[3].
Note. DoD=Department of Defense
HHS=Department of Health and Human Services
NASA=National Aeronautics and Space Administration
DOE=Department of Energy / NSF=National Science Foundation
USDA=Department of Agriculture

Table 3 shows the R&D expenditures of the United States federal government

3) NSF: National Science Foundation; World Wide Web, http://www.nsf.gov.

in major functional areas. The area of health and human services has been the most important investment area in nondefense R&D activities. About 52% of total federal R&D expenditures are invested in health and human services. Compared to other important functional areas, energy, environment, transportation and so on, this area maintains top priority with regard to federal R&D investment. This confirms that the American federal government has made efforts to implement a competent national biotechnological innovation system. In this sense, the federal government is an important component of a national biotechnological innovation system.

<Table 3> Importance of biotechnology related R&D in US federal R&D budgets

(Units: $ million)

	2004 Actual	2005 Estimate	2006 budget	2005-2006 Change		% of total (2006)
				Amount	Rate (%)	
1. Defense	69,859	74,887	75,208	321	0.40	56.80
2. Nondefense	55,479	56,684	57,096	412	0.70	43.20
Aeronautics and space	9,517	10,084	10,675	591	5.90	8.10
Health and human service (Portion of nondefence R&D)	28,869 (52.0%)	29,495 (52.0%)	29,558 (51.8%)	63	0.20	22.30
Energy	1,427	1,252	1,363	111	8.90	1.00
General Science	7,396	7,404	7,390	-14	-0.20	5.60
Environment	2,262	2,158	2,045	-113	-5.20	1.50
Agriculture	1,910	2,101	1,721	-380	-18.10	1.30
Transportation	1,733	1,672	1,660	-12	-0.70	1.30
Commerce	491	498	448	-50	-10.00	0.30

Source: OMB[4].
Note. Round to the nearest million
1. Includes Department of Defense, defense R&D in Department of Energy, defense-related R&D in Department of Homeland Security
2. Includes all R&D not defense / 3. Includes natural resource R&D.

As a result of such efforts, the United States government received 8,836 patents in biotechnology from 1985 to 2004. The Department of Health & Human Service occupies the highest rate, 6,511 patents, which is 73.7% of total U.S.

4) OMB: Office of Management and Budget; World Wide Web, http://www.whitechouse.gov/omb.

government patents (KIPI[5], 2006). And, based on strong biotechnological capabilities, the United States has the most dominant GMO (Genetically Modified Organism) cultivation areas and crops (ISAAA[6], 2002, 2003), world biochip market (GIA[7], 2006), and other major biotechnological areas. This strength has come from the active support of the United States federal government. These biotechnological industry sectors will continue to grow, as long as the U.S. federal government continues its support of biotechnological R&D activities.

3.3 Role of state governments

State governments play an important role in research and development in biotechnology. In any country, state or regional governments are more active in promoting technology-intensive firms in their regions. This is especially true for countries, like the USA, that have a federal governmental system. In addition, states in the USA have their own state universities, which are research oriented. State governments encourage universities to sustain education and training in disciplinary sciences and to collaborate with industrial companies, recognizing the need for communication and collaboration among disciplines. Therefore, state governments, universities, and industries collaborate very closely in order to enhance their regional technological and economic competitiveness. For this purpose, state governments prepare for various programs and funds in order to foster industry-academic interrelationships. As they recognize the importance of biotechnology for their regional economic development, their promotion efforts have focused on biotechnology. Table 4 shows some representative examples of state governments in promoting biotechnological capabilities.

5) KIPI: Korea Institute of Patent Information.
6) ISAAA: International Service for the Acquisition of Agri-biotech Applications.
7) GIA: Global Industry Analysts, Inc.

<Table 4> Examples of state governmental R&D programs for biotechnology

State	Bioscience R&D Programs	Annual Funding
Arizona	Arizona Biomedical Research Commission	$12 million
Arkansas	Arkansas Biotechnology Institute Arkansas Science and Technology Authority Research Matching Fund	$12million to $13million $1million
California	California Institute of Regenerative Medicine	-
Connecticut	Stem Cell Research Funding	$20million through 2007
Georgia	Georgia Cancer Research Fund	$1.4million contributed since 2000
Florida	James and Esther King Biomedical Research Program	$8 million
Kansas	Higuchi Bioscience Center Kansas Technology Enterprise Corporation's Strategic Technology and Research Fund and Experimental Program to Stimulate Competitive Research support	$6.5million supports 5 CsEs $2.4million
Kentucky	Research Challenge Trust Fund Regional University Excellence Trust Fund Kentucky Science and Engineering Foundation R&D Excellence Program	$6million a years for transferred to the base budgets of the university to create a perpetual source of funding $120million bond issue in 2002-2004
Louisiana	Louisiana Cancer Research Consortium (LCRC) Louisiana Board of Regents Support Fund	$10.5million $20million to $25million
Maryland	University Maryland Biotechnology Institute	$15million
Massachusetts	Research Center Matching Fund of the Adams Innovation Institute University of Massachusetts (UMass) Science and Technology(S&T) Initiatives Fund	$20million $1million
Michigan	21st Century Jobs Fund	$100million
Minnesota	Minnesota Partnership for Biotechnology and Medical Genomics U of M Initiative for Renewable Energy and the Environment	$15million from state to be matched by Mayo and U of M $2million
Mississippi	Mississippi State University's (MSU's) Life Sciences and Biotechnology Institute	-
Nebraska	Nebraska Research Initiative	-
New Jersey	Stem Cell Research	TBD
New York	Centers for Advanced Technology	Varies

North Carolina	Multidisciplinary Research Grants	-
Ohio	Wright Centers of Innovation Biomedical Research and Commercialization Program	$50million to $60million over 5 years
Oklahoma	Oklahoma Health Research Program	$3.6million
Pennsylvania	Commonwealth Universal Research Enhancement Fund	$72million
Puerto Rico	Science Technology and Research Trust	$14million
South Dakota	Research Centers Program Research Seed Grants	Initial awards of $2.8 million $445,000
Tennessee	Tennessee Mouse Genome Consortium	-
Texas	Advanced Research Program Research Grant Matching Program	$3million for the biosciences Part of Emerging Technologies Fund
Washington	Life Science Discovery Fund	$3.5million starting in 2008
Wisconsin	Consortium on Bio-based Industry	$5million

Source: Battelle Technology Partnership Practice and SSTI (2006).

Table 4 indicates that most states have engaged in promoting biotechnological capabilities. We can identify some characteristics. First, state governments have relied on state universities in promoting biotechnological R&D activities. Second, they also rely heavily on state research centers. For example, Mississippi utilizes the Life Sciences and Biotechnology Institute and Kansas operates the Higuchi Bioscience Center. Third, many state governments establish funds in order to activate biotechnological R&D activities. Connecticut, Kentucky, Louisiana, Michigan, Pennsylvania, and Texas are good examples of this. Fourth, some states promote research consortiums in order to activate collaborative research in biotechnology. Louisiana, Tennessee, and Wisconsin are good examples of this. Finally, most state governments operate their own programs and initiatives in biotechnology.

In addition, some states have prepared for and refined the legal framework for biotechnology. Arizona passed legislation in 2003 authorizing $440 million for the construction of university research facilities, primarily in the biosciences. South Carolina passed the Research University Infrastructure Act loosening a cap on state borrowing to accommodate $220 million in general obligation bonds for university facilities. The Minnesota Legislature approved $240 million in bond funding for bioscience-related science laboratories. In Utah, legislation authorized $111 million in bonding authority to fund construction. Other state governments also make great efforts to develop bioscience. Many states have programs to support university-industry collaborative research. Through these programs industrial companies have an access to research facilities and equipment in universities and universities can easily commercialize biotechnological R&D results. The Pittsburgh Life Sciences Greenhouse offers a Collaborative Research Fund, in which participating firms invest matching funds. The North Carolina Biotechnology Center and the Kenan Institute for Engineering, Technology and Science at North Carolina State University jointly offer Collaborative Funding Grants up to $50,000 a year for three years. California State University' s Program for Education and Research in Biotechnology offers grants of up to $30,000 for faculty conducting collaboration projects with a Californian companies.

State governments have implemented several incubation programs for activating biotechnological start-ups. Table 5 shows some examples of biotechnology incubation programs. There are some differences in the major focuses of state governments and in their promotion of biotechnological start-ups. As a whole, we can identify diverse policy instruments for promoting biotechnological ventures: assistance of start-up process, management help, consulting and education, connection with universities and venture capitals. State governments are in a better position to activate biotechnological ventures than the federal government because they understand problems associated with start-up companies better and thus provide effective measures to solve challenges.

<Table 5> State supported bioscience entrepreneurial support programs

State	Program	Description
Georgia	Life Science Innovation Center	Offers entrepreneurial assistance on a statewide basis, with an emphasis on entrepreneurs and companies in rural areas. Awards matching grants for translational research
Maryland	MdBio	Provides up to 2 days of consulting services for any aspect of business development with assistance provided by consultants on contracts with MdBio

Michigan	BioTech Connect Bioseiences Research And Commercialization Center Frontline Accelerator Spark Accelerator	Helps entrepreneurs build bioscience businesses Provides contract development services, gap funding, and start-up assistance Assistance to emerging bioscience companies Assistance to emerging bioscience companies
Missouri	Biogenerator	Designed to bridge gap between research universities and venture capital investors, thereby assuring the transfer of new technologies to the marketplace
New York	Bioconnex/Bufflink/CNY Med Tech/Long Island Life/Sciences Initiative	Commercialization support programs located in four regions of the state
Ohio	Omeris	A nonprofit organization designed to build and accelerate bioscience industry, research, and education in Ohio.
Pennsylvania	Life Science Greenhouses	Three comprehensive centers for commercialization of bioscience research
South Carolina	SCBio	A collaborative of the state's 3 research universities and the Greenwood Genetics Center. It operates as a full-service commercialization center in the bioscience sector

Source: Battelle Technology Partnership Practice and SSTI (2006).

Based on state governments' investment in biotechnological research, the accumulation of knowledge in the biosciences has been substantial and universities have emerged as major centers of biotechnological research, particularly biomedicine (Mowery, 1993). For this reason, academia-government-industry-public research institution collaboration has increased.

R&D actors, which obtain excellent results, are diversified. This is because of the investments of U.S. states governments in biotechnology. Between 1985 and 2004, research and development actors for American biotechnology patents occurred mostly at the university level. But, we see a variety of actors as time goes by. We can also find that situation has R&D actors which are harmonious, at the major owners of patents in U.S. biotechnology patent field (Table 6).

<Table 6> The number of patent and share of federal government department and R&D actors

Department	Research Actor	'85-'89		'90-'94		'95-'99		'00-'04	
		Number	Share	Number	Share	Number	Share	Number	Share
HHS	Person	6	2.3	19	3.4	72	2.8	85	2.7
	Firm	86	33.6	201	35.9	934	36.3	941	30.2
	Public institution	4	1.6	0	0.0	11	0.4	33	1.1
	University	160	62.5	340	60.7	1,558	60.5	2,061	66.1
DOE	Person	0	0.0	2	3.7	12	6.1	5	2.3
	Firm	0	0.0	14	25.9	72	36.7	74	33.5
	Public institution	10	52.6	16	29.6	4	2.0	2	0.9
	University	9	47.4	22	40.7	108	55.1	140	63.3
NSF	Person	0	0.0	6	13.0	8	5.6	6	3.0
	Firm	2	16.7	9	19.6	24	16.9	17	8.6
	Public institution	0	0.0	0	0.0	0	0.0	2	1.0
	University	10	83.3	31	67.4	110	77.5	173	87.4
USDA	Person	0	0.0	1	4.8	0	0.0	6	3.8
	Firm	0	0.0	1	4.8	18	17.0	20	12.7
	Public institution	0	0.0	0	0.0	2	1.9	5	3.2
	University	5	100.0	19	90.5	86	81.1	126	80.3
Others	Person	3	5.6	7	4.6	19	4.2	22	4.5
	Firm	22	40.7	72	47.7	206	45.2	218	44.8
	Public institution	8	14.8	24	15.9	40	8.8	38	7.8
	University	21	38.9	48	31.8	191	41.9	209	42.9
Total		346		832		3,475		4,183	

Source: KIPI (2006).

3.4 Industry for biotechnology

The success of a national innovation system for biotechnology can be measured by the competitiveness of the biotechnology industry. The world biotechnology industry has grown rapidly in recent years. Therefore, much attention should be given to the innovation potential of the biotechnology industry. A biotechnology industry is viewed as a combination of industrial companies that are engaged in producing, distributing and selling biotechnological products. As biotechnology is foundation area , it can be applied to many industrial sectors, so that there are diverse biotechnology sectors, especially pharmaceutical, chemical, agricultural, and environmental sectors. The success of these sectors comes from the competent national biotechnological innovation system. Table 6 summarizes the statistics of the American biotechnology industry over the past decade. We can easily see the rapid growth of the American biotechnology industry. In last ten years, the number of biotechnology firms in the United States increased significantly and their revenues grew by 250 percent. American biotechnology firms have contributed to employment. The number of employees at biotechnology firms increased from 103,000 persons in 1994 to 198,000 persons in 2003. This represents about a 100% increase in 10 years. The rapid growth of American biotechnology firms could be because of their strong R&D effort. The R&D expenditures of American biotechnology firms increased from 7 billion US $ to 17.9 billion US $ in 2003. This represents an over 150% increase.

<Table 7> Growth of the American biotechnology industry (1994-2003)

(Units: $ billions, thousands)

	'94	'95	'96	'97	'98	'99	'00	'01	'02	'03
Revenue	11.2	12.7	14.6	17.4	20.2	22.3	26.7	28.5	29.6	39.2
R&D expenditure	7.0	7.7	7.9	9.0	10.6	10.7	14.2	15.7	20.5	17.9
No. of private companies	1,311	1,308	1,287	1,274	1,311	1,273	1,379	1,457	1,466	1,473
No. of public companies	265	260	294	317	316	300	339	342	318	314
Market capitalization	45	41	52	83	93	137.9	353.5	330.8	225	206
No. of employees	103	108	118	141	155	162	174	191	195	198

Source: BIO (1995-2004).

Current statistics on American biotechnology firms confirm the rapid development of this industry (see Table 8). In 2004, the American biotechnology industry shows a strong increase in sales volume, revenues, employment, and R&D investment.

<Table 8> Statue of U.S. biotechnology industry (2003-2004)

(Units: $ billion, person, %)

Classification	Listed companies			Whole biotechnology industry		
Year	2003	2004	Increase (%)	2003	2004	Increase (%)
Sales	25.9	31.0	19.4	28.4	33.3	17.4
Revenue	35.9	42.7	19.2	39.2	46.0	17.2
R&D expenditure	13.6	15.7	15.7	17.9	19.8	11.0
Special company	314	330	5.1	1,473	1,444	-2.0
Employment	124,800	137,400	10.1	177,000	187,500	6.0

Source: Ernst & Young (2005).

In the biotechnology industry, biotechnology research firms tend to be small, new, and mostly engaged in research and development. Nowadays there have been many start-ups in biotechnology. They are also major components of the national biotechnological innovation system. However, pharmaceutical firms are much larger, older, and well-developed in R&D, manufacturing, and marketing operations. That' s why biotechnology business is risky. Biotechnology firms are exposed to high risks. Most biotechnology firms should engage in R&D activities, which are risky by nature. Not only that but there is also a considerable amount of work that must be completed before a drug is developed. In addition, any promising products must endure lengthy testing and clinical trials to prove their safety and efficacy. Development of a new drug typically takes between five and twelve years. Most biotechnology firms operate at a loss. They spend large amounts of money on research and development for several years in advance of earning any sales revenue. For this reason, there are many collaboration researches in U.S. biotechnology industry.

There are many venture capital investments in biotechnology firms. Table 8 shows the increase of venture capital financial support. The number of biotechnology investment deals increased from 133 deals in 1992 to 146 deals in 2002. The total amount raised from the biotechnology deals increased dramatically from $668 million in 1992 to $2,163 million in 2002. This indicates that the average investment per deal has increased on a very large scale. The share of venture capital investment during the early rounds of start-ups has increased significantly, especially since the end of the 1990s. This implies that venture capital plays an important role in the American innovation system in biotechnology. These statistics on venture capital are a good indicator of the American biotechnology industry' s prosperity.

<Table 9> U.S. venture capital financing

(Units: $ million)

	'92	'93	'94	'95	'96	'97	'98	'99	'00	'01	'02
Early rounds (%)	38	46	28	17	22	34	54	51	37	28	44
Later Rounds (%)	62	54	72	83	78	66	46	49	63	72	56
Total no. biotechnology deals	133	126	155	94	124	137	146	129	155	149	146
Total raised in all biotech deals	668	719	679	568	818	1,080	1,275	1,458	2,778	2,392	2,164
Average raised	15	16	18	11	9	8	7	6	6	6	5

Source: Ernst & Young (2004).
Note. Numbers may appear inconsistent because of rounding.

Table 10 shows American biotechnology and pharmaceutical firms. In particular, biotechnology firms were spun off from universities and public research institutes and have had strong relationships with their mother organizations. These biotechnology firms employ highly-skilled workers and some companies like Amgen and Genentech generate a great deal of revenue. They invest resources in R&D activities. R&D expenditures per employee are much bigger than those of pharmaceutical companies. We can also note that pharmaceutical companies have grown based on their R&D activities. They invest huge amounts of resources in R&D activities and generate lots of revenue based on their strong R&D activities. These biotechnology and pharmaceutical companies have a strong relationship with universities and public research institutes because they need to incorporate new biotechnological development in R&D and production processes. In addition, a large number of established firms form relationships with start-up biotechnology firms in order to gain access to new scientific advances (Bartholomew, 1997).

<Table 10> U.S. biotechnology & pharmaceutical companies (2004)

(Units: $ million, person)

	Revenue	Revenue per person	R&D expenditures	R&D expenditures per person	Net revenue	Employment
Biotechnlogy companies						
Amgen	10,550	733	2,028	141	2,363	14,400
Genentech	4,621	604	948	124	785	7,646
Biogen IDEC	2,212	518	688	161	25	4,266
Genzyme	2,201	310	392	55	87	7,100
Chiron	1,723	319	431	80	79	5,400
Gilead Sciences	1,325	801	224	135	449	1,654
Medimmune	1,141	577	327	166	-4	1,976
Biovail	887	387	70	31	161	2,291
Weighted average		551		114		
Pharmaceutical companies						
Pfizer	52,516	457	7,684	67	11,361	115,000
Johnson&Johnson	47,348	431	5,203	47	8,509	109,900
Merck & Co.	22,939	364	4,010	64	5,813	63,000
Bistol Myers Squibb	19,380	451	2,500	58	2,388	43,000
Eli Lilly Co.	13,858	311	2,691	60	1,810	44,500
Weighted average		416		59		

Source: Ernst & Young (2005).

3.5 Public research institutes in biotechnology

There are many public research institutions in the U.S.A. involved in biotechnology. Among them, the National Institute of Health (NIH) is one of the largest and most important public research institutes. NIH is under the Department of Health and Human Services (HHS) and is the primary federal agency for conducting and supporting biotechnological research. This institute consumes most of the HHS R&D budget. Table 11 shows the R&D budgets of major federal agencies in the United States. It shows that most of HHS' s R&D budget is invested in NIH. For example, in 2006, NIH used about 96% of HHS' s R&D.

<Table 11> R&D in the FY 2008 Budget by Agency

(Unit: $ million)

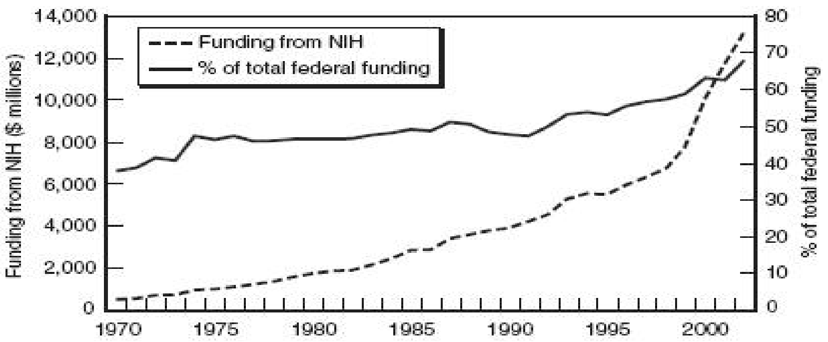
	FY 2006 Actual	FY 2007 Estimate *	FY 2008 Budget	Change FY 07-08 Amount	Change FY 07-08 %
Total R&D (Conduct and Facilities)					
Defense (military) **	74,289	78,231	78,996	765	1.0%
Health and Human Services	28,990	29,650	29,364	-286	-1.0%
Nat'l Institutes of Health	27,760	28,405	28,080	-325	-1.1%
All Other HHS R&D	1,230	1,245	1,284	39	3.1%
NASA	11,295	11,698	12,593	896	7.7%
Energy	8,556	8,744	9,224	480	5.5%
Nat'l Science Foundation	4,183	4,482	4,856	374	8.3%
Agriculture	2,438	2,255	2,010	-245	-10.8%
Commerce	1,086	1,091	1,088	-3	-0.3%
Interior	639	636	621	-15	-2.4%
Transportation	820	796	812	16	2.0%
Environ. Protection Agency	622	567	547	-20	-3.5%
Veterans Affairs	824	818	822	4	0.5%
Education	323	318	317	-1	-0.3%
Homeland Security	1,406	948	933	-15	-1.5%
All Other	765	760	782	22	2.9%
Total R&D	136,236	140,993	142,966	1,973	1.4%

Source: AAAS[8] (2008), Justifications, and information from agency budget offices.
Note: The projected inflation rate between FY 2007 and FY 2008 is 2.4 percent.
* FY 2007 figures reflect AAAS estimates of pending FY 2007 appropriations (H.J. Res. 20).
** FY 2007 and 2008 figures include requested supplementals, Preliminary February 7, 2007 - will be revised.

Table 11 shows that NIH has the biggest R&D budget, accounting for 27,760 million dollars. Its R&D budget is much bigger than that of all other budgets. Therefore, regarding biotechnology, NIH is the biggest agency in performing and

8) AAAS: American Association for the Advancement of Science.

supporting biotechnological R&D activities. In 2006, NIH invested 5,604 million dollars in basic research related to biotechnology. The budget of NIH was estimated at15,868 million dollars for basic research in 2007.



Source: NSF.

<Figure 1> NIH funding for universities (1970-2002)

For many decades, the federal government has spent a large amount of money on R&D in biotechnology. Here NIH has been playing a leading role. NIH has conducted not only its own intensive biotechnological research but also provided R&D grants for universities. Fig. 1 shows the trend in university research funding by NIH over the past three decades. For many years, NIH has been an important source of federal funding for universities. NIH funds for universities increased 20 times between 1970 and 2000. In particular, there was a rapid increase in NIH' s support for universities' biotechnological research. This indicates that NIH has played an essential role in promoting interaction among innovation actors in the national innovation system for biotechnology in the United States. Through this, NIH provides leadership and direction to programs designed to improve biotechnological capabilities.

NIH has many institutes and centers that help interaction of national innovation systems in biotechnology. One of them is the National Library of Medicine (NLM), which plays a significant role in the design and development of data systems to handle and integrate human and other genome data. Recently, NLM has begun to provide linkages to sequence data systems where information is cited in the literature they index. This is a major achievement. The National Center for Biotechnology Information was established within the NLM. It primarily works to assure adequate integration of molecular, microbial data and information resource. There are plenty of programs from various institutes and centers in NIH that help biotechnology firms and universities to enhance their R&D capacity.

3.6 Academia for biotechnology

In today' s highly competitive global economy, talented people, particularly those who possess ability and capacity for scientific and technological innovation and management of such creative activities are more in demand than ever before. The biotechnology industry is extremely knowledge intensive: About 47 percent of venture-backed biotechnology firm founders were university professors, scientists at research institutes, or new Ph.D.s. More than 40 percent of the CEOs in the American biotech industry hold doctoral degrees. More than 80 percent of biotechnology R&D officers hold doctoral degrees. The percentage is even higher for chief scientists in biotech firms (Zang, 2005). Thus, academia and university play an important role in the biotechnology field. The biotechnology industry relies on research universities as a source of technological innovation. American university researchers have carried out a great deal of research in biotechnology. As a result, universities hold a large share of biotechnology patents and properties (Table 12).

<Table 12> Major actors in U.S. patent R&D in biotechnology field

Ranking	Main owners	Classification	'85-'89	'90-'94	'95-'99	'00-'04	'85-'04
1	University of California	University	32	45	328	475	880
2	University of Texas	University	6	49	115	115	285
3	Johns Hopkins University	University	7	22	110	117	256
4	The Scripps Research Institute	Enterprise	0	25	102	88	215
5	Harvard College, President and Fellows	University	6	23	75	79	183
6	General Hospital	Enterprise	6	8	98	65	177
7	Stanford University	University	15	14	60	82	171
8	Wisconsin Alumni Research Foundation	University	11	20	57	81	169
9	Washington University	University	0	11	63	94	168

10	Columbia University	University	13	11	51	88	163
11	MIT/Mass Inst of Technology	University	27	29	59	46	161
12	Salk Institute for Biological St	Enterprise	17	29	63	47	156
13	University of Pennsylvania	University	0	9	66	69	144
14	Rockefeller University	University	2	8	45	73	128
15	Cornell Research Foundation	University	8	14	41	63	126

Source: KIPI (2006).

Table 12 indicates that American universities occupy a great portion of U.S. R&D activities in the biotechnology field. As a whole, the number of patents in biotechnology has increased remarkably since the middle of the 1990s. The major producers of biotechnology patents are universities. This confirms the importance of universities in the American biotechnological innovation system.

However, the role of universities in biotechnology was not meant solely to carry out R&D activities. They educate and produce many well-qualified research personnel who work all over the world. Comprehensive education is needed to provide continuous supplies of well-trained researchers. The challenges of biotechnology require problem-solving capabilities that cross traditional disciplinary boundaries. American universities make great efforts to train and advance career development programs in biotechnology. This includes the areas of cell and molecular biology, plant biology, biophysics, structural biology, genetics, biotechnology-related engineering, math, physical sciences, and materials sciences, as well as specialized training programs for technical level personnel. As a consequence of American universities' efforts, the United States has occupied second place on average impact factor in biotechnology field during last five years (2000-2004) with an average impact factor of 6.17. However, by having 1,304,533 papers and 8,050,224 impact factors, American universities ranked at the top (KRIBB[9], 2005).

We mentioned that the U.S. has many biotechnology clusters that can be explained as a regional biotechnological innovation system. U.S. universities are building stones in these clusters. Each cluster has research-intensive universities. These universities play a pivotal role in R&D collaboration in biotechnology. As discussed above, states seek to build their bioscience R&D

9) KRIBB: Korea Research Institute of Bioscience and Biotechnology.

capacity by investing in bioscience R&D, facilities and equipment needed to support biotechnology researchers and providing fund for universities to attract high quality researchers. States invest in facilities and equipment in order to build biotechnology clusters capacity at their universities under the assumption that research facilities affect institutions' ability to recruit and retain outstanding researchers. For example, Arizona passed legislation in 2003 authorizing $440 million for the construction of university research facilities, primarily in the biosciences. South Carolina passed the Research University Infrastructure Act loosening a cap on state borrowing to accommodate $220 million in general obligation bonds for university facilities. In order to attract talent to their universities, some states also provide funding to recruit prominent faculties from all over the world. They have programs that specifically target biotechnology faculties. These supports have produced various synergies in the biotechnology field.

IV. Conclusions and Implications

This paper has discussed the American national innovation system for biotechnology and its innovation actors, such as the federal government, states governments, industry, public research institutes, and academia. The major reason for the U.S. success in biotechnology up to the present can be explained by the effective operation of the national innovation system in biotechnology. Specific implications are follows. The first implication is that, the federal government has strongly engaged in many areas of development in biotechnology, especially by funding R&D activities. Because biotechnology is a generic technology, it requires government support. This means that the federal government plays an important role in national innovation system for biotechnology. As we noted above, various statistics prove that the United States federal government has implemented a competent national innovation system for biotechnology.

Secondly, American governments are working hard to enhance their regional and economic competitiveness. State governments in the U.S. encourage universities to sustain education and training in disciplinary sciences, and to collaborate with industrial companies recognizing the need for communication and collaboration among disciplines. These days, their promotion, collaboration, and connection efforts have focused on biotechnology. And most states in the U.S. have engaged in promoting biotechnological capabilities through their own programs, funding, and legislation.

Thirdly, the American biotechnology industry has grown rapidly in recent years. Various materials over the past decade have shown the rapid growth of the American biotechnology industry. There has been a strong increase in sales volume, revenues, employments and R&D investments. These successful results come from capable national innovation systems for biotechnology. Fourth, the U.S. national innovation system for biotechnology includes public research institutes like NIH. For decades, the U.S. federal government has spent a large amount of money on R&D in biotechnology through public research institutions. NIH has executed not only its own intensive biotechnological research but also provided R&D grants for universities. And, NIH has plenty of programs from various institutes and centers that help biotechnology firms and universities to enhance their R&D capacity. This indicates that NIH has played an essential role in promoting interaction among innovation actors in the U.S. national innovation system for biotechnology.

Fifth, American universities play a pivotal role in R&D collaboration in U.S. national innovation systems for biotechnology. The biotechnology field requires talented people and the biotechnology industry relies on research universities as a source of technological innovation because biotechnology is a generic technology and the biotechnology industry is extremely knowledge intensive. Therefore, American universities educate and produce many well qualified research personnel through various training programs. At the same time, they advance training and career development programs in biotechnology. As a result, American universities hold a large share of biotechnology patents and properties. These supports at universities have produced various synergies in U.S. national innovation systems in biotechnology.

Finally, innovation actors which organize the U.S. national innovation system for biotechnology are closely linked by various interactions. They have high intensity in their innovation performance like collaboration, based on strong governmental support. The interlinked economy is becoming so powerful that it is pushing the nation-state towards the status of a declining industry (Ohmae, 1990). American companies, public research institutes, and universities innovate through not only themselves but also collaboration research and various cooperation programs. Through these efforts, they engage in close and flexible interaction. The federal and state governments in the U.S. support these interactions among innovation actors in the American national innovation system for biotechnology by funding various political programs. The success of the American national innovation system in biotechnology means that various innovation actors, especially the federal government, states governments, industry, public research institutes, and academia aid each other.

These implications explain why the U.S. occupies the top position in biotechnology. As discussed above, we know that innovation actors are closely linked with each other and they have active interaction. We also know that the federal government and state governments support these interactions through various political efforts and funding. Therefore, many other countries seeking to achieve technological innovation in biotechnology should learn by benchmarking the U.S. Specifically, they apply the innovative efforts of each actor in the American national innovation system for biotechnology.

However, there are wide differences between developing countries and the USA with regard to funding amounts. Consequently, situation and conditions in each country should be considered. And then, each nation should concentrate on not only government support but also need to select biotechnology sector as one of its strategic sector in the national level.

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