Biotechnology in China

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Introduction

Biotechnology will be among the emerging science and technology (S&T) fields that will have the most significant global impact in the decades to come. Experts forecast that better drugs, devices and treatments for diseases, advancements in stem cell and genetically modified organisms (GMO) technology, and exciting developments in genome sequencing for personalized medicine will materialize in the next 20 to 30 years. Developing economies are emerging as important players in these fields in part because of advances in information and communication technologies (ICTs), sustained economic growth and strong government support. Governments are increasing their investments in research and development (R&D), providing support for the next generation of life scientists, enabling institutionalized knowledge transfer from academia to industry and encouraging the expansion of the private sector's role in all aspects of development. Moreover, scientists from developed and developing countries are increasing collaborations to tackle global problems, creating deeply-intertwined international networks to create, share and acquire knowledge produced at the frontiers of various S&T areas.

Within the context of these encouraging developments, China is charting a trajectory in the next few decades that casts itself as a major global biotechnology player. This field is one of the government's seven strategic S&T areas identified to provide solutions to some of China's pressing societal problems, underpin long-term economic growth and serve as a pathway for building indigenous innovation ("*zizhu chuangxin*") capability. China's rise in biotechnology seems predictable, but the path is fraught with serious challenges. In this paper, I will provide a brief summary of China's biotechnology development focusing primarily on the pivotal role of the government, and then discuss some of its major challenges that, if left unresolved, could retard China's quest to become a global biotechnology leader.

Understanding the Trajectory

China's interest and significant contributions in biotechnology began decades earlier primarily as part of its S&T efforts to catch up with the West.[1] A glance at some of the country's life science/biotech accomplishments during this time reveals that these initiatives focused on discoveries and innovations with high societal relevance. In the early 1960s, Chinese life scientists successfully synthesized the "world's first" bovine insulin believed to be a major accomplishment that could have earned China a Nobel Prize.[2] Sustained government R&D support in the subsequent decades led to another milestone at the end of the 1990s when – alongside the U.S., Germany, the United Kingdom, France and Japan – China became part of the international research effort to map the human genes known as the Human Genome Project. Although its contribution amounted to just one percent of the total sequencing of the human genome, China was the only developing country participating in this consortium. In late 2003, it became the first country to approve a drug license for a recombinant gene therapy to treat head and neck cancers.[3] Today, it is one of the leaders in research on genetically modified (GM) food. The government's recent approval of a strain of genetically engineered rice and corn puts the country in position to be first in the world to produce these GM grains on a commercial scale. In China's 12th Five-Year Plan (2011–2015), the R&D focus will be on the growth of the biotechnology industry in such areas as the development of new chemical drugs, biomedical engineering and the modernization of traditional Chinese medicines.

Governance Structure

China's current drive to become a global leader in biotechnology is a microcosm of its effort to meet the growing economic demands of its population as well as to become a major power in science and technology, i.e., to "enter the ranks of innovative countries by 2020" and become a global scientific power by mid-century.[4] These strategic objectives underpin the central government's major and transformative role in China's national innovation system. As one of seven strategic priorities for scientific and technological development identified in China's 12th Five-Year Plan (2011–2015), biotechnology provides a clear illustration of the dominant role of the government in the development of national S&T capabilities.

At the heart of China's bid to become a leader in global biotechnology is the central government, whose role is reflected in a governance structure that is highly centralized and bureaucratized. At the apex of the organizational structure is the Chinese Communist Party (CCP) Central Committee (figure 1, p. 101). The CCP Central Committee exerts influence and power through a Science, Technology and Education (STE) "Lead Group" that is organized within the State Council, which is composed of all heads of ministries directly involved in China's S&T policy process. The Lead Group is usually chaired by a vice-premier who is also a concurrent member either of the Politburo or the Standing Committee of the CCP Central Committee – China's de facto governing body. However, since the integration of S&T into the national development strategy in the mid-1990s, China's premier has chaired the STE Lead Group. This group is responsible for:

- the study and review of the nation's strategy and key policies for the development of science, technology, and education;
- the identification of major tasks and programs related to science, technology and education;
- leadership appointments; and
- the coordination of important issues of science and education involving agencies under the State Council and regional institutions.

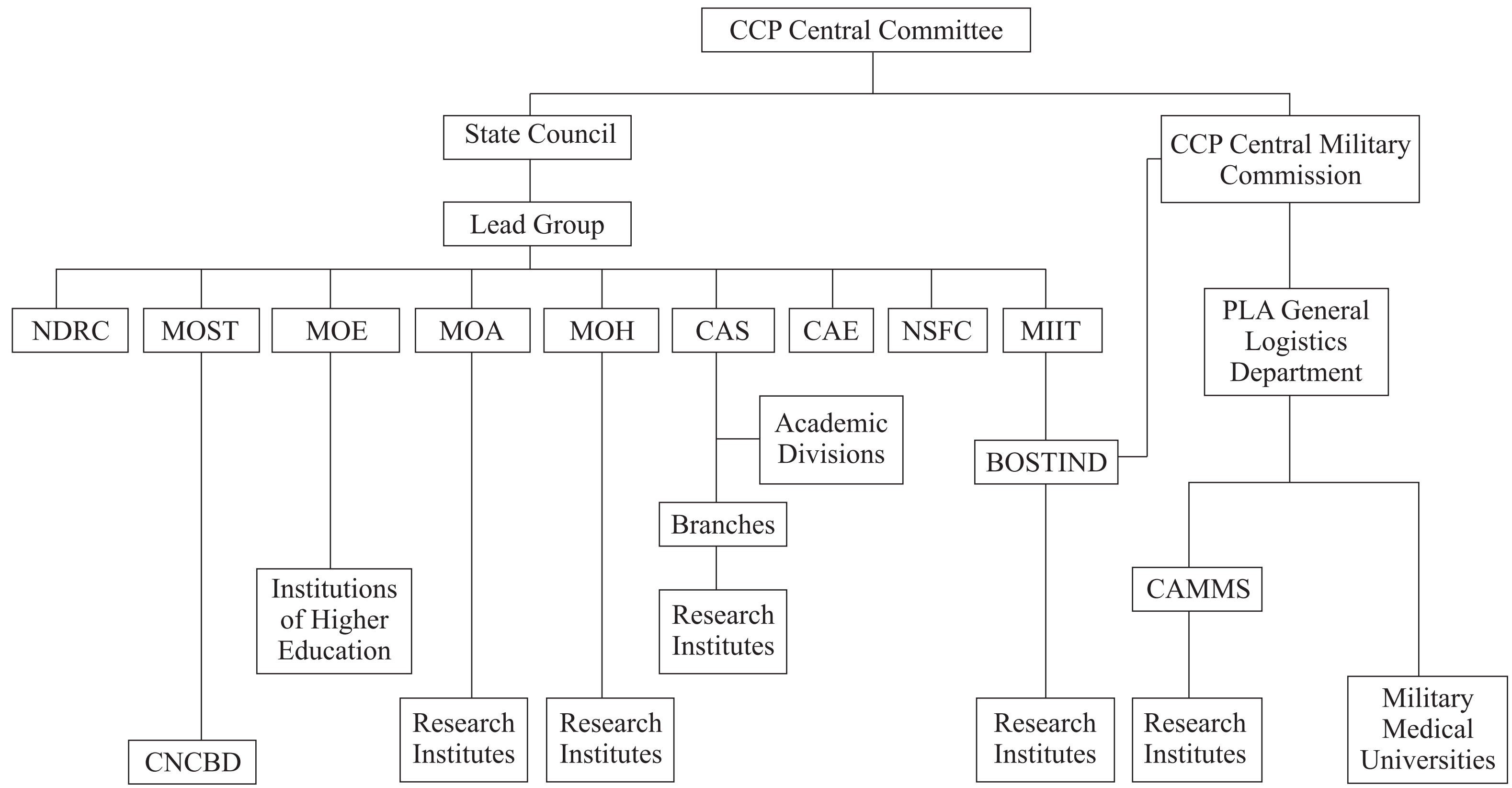

FIGURE 1 China's Organizational Structure for Life Science/Biotechnology. **SOURCE** Author's own.

LEGEND: Lead Group – State Lead Group for Science, Technology, and Education; NDRC – National Development and Reform Commission; MOST – Ministry of Science and Technology; MOE – Ministry of Education; MOA – Ministry of Agriculture; MOH – Ministry of Health; CAS – Chinese Academy of Sciences; CAE – Chinese Academy of Engineering; NSFC – National Natural Science Foundation of China; MIIT – Ministry of Industry and Information Technology; CNCBD – China National Center for Biotechnology Development; BOSTIND – Bureau of Science, Technology, and Industry for National Defense; CAMMS – Chinese Academy of Military Medical Sciences

The Lead Group manages over the nine government ministries that hold S&T portfolios and carry out political functions.[5] The Ministry of Science and Technology (MOST) and the Chinese Academy of Sciences (CAS) are the prominent players in biotechnology development. MOST is by far the most powerful among the nine organizations. It is the overarching government agency overseeing the nation's S&T affairs, exercising a wide range of functions as follows:

-formulation of S&T development policies, plans, programs;
-creation of the legal framework for S&T;
-institution of reforms in government research institutes;
-management of the S&T budget and resources;
-administration of high technology programs;
-management of China's national science parks;
-establishment of programs to improve the public's scientific literacy; and
-examination of S&T's societal impacts.

The Chinese Academy of Sciences (CAS) manages around 100 research institutes and laboratories, owns at least 400 spin-off companies from its institutes,[6] and employs some 60,000 research staff – considered the best and brightest of China's S&T and engineering community. It is the premier organization leading China's innovation drive in both the civilian and defense S&T sectors, and its R&D programs are credited with producing approximately 20 percent of China's peer-reviewed scientific papers in the last ten years and around 25 percent of China's citations in scientific journals.[7]

Policy Evolution

China has been investing heavily in biotechnology in 1986 with the State High-Tech R&D Program (also known as "863"), China's first national S&T program that focused on high-technology development. The program's R&D agenda emphasized immediate outcomes and quick results over fundamental R&D. MOST awarded biotechnology the largest amount of the 863 funds. Priority areas included bioengineering technology, gene manipulation technology, bioinformatics and modern agriculture technology. This initiative was followed by the National Basic Research and Development Program ("973") in 1997. Unlike its predecessor, this program gave policy attention to the basic and mission-oriented basic R&D priorities of China to enable it to occupy an important seat (*yixi zhidi*) in international R&D communities. The 973 program supported projects that meet at least one of the following three criteria: first, provide solutions to major problems associated with China's social, economic, and scientific and technological development; second, have high relevance to major basic research problems with interdisciplinary and comprehensive significance; and third, exploit China's advantages and special characteristics, i.e., its natural, geographic and human resources.

In the last 10 years or so, these programs have evolved to conform to the latest policy guidance – the Medium and Long-Term Plan (MLP) for the Development of Science and Technology

(2006–2020). The MLP provides a roadmap of how the country – through the enhancement of indigenous innovation (*zizhu chuangxin*) capabilities – can become an innovation-oriented nation by 2020 and a world leader in S&T by 2050. It identifies biotechnology as one of the eight areas of "frontier technologies" where China is expected to make a significant global contribution in the next forty years (table 1).[8] Mega-engineering programs in biotechnology include GMO R&D, drug innovation and R&D for the prevention and control of HIV/AIDS and other major diseases. Of the original four mega-science programs, two are in the life sciences and biotechnology field: protein science, and developmental and reproductive biology.9

Key areas (11)	**Mega engineering programs (16)**
Energy	Core electronic components, high-end generic chips, and basic software
Water and mineral resources	Extra large scale IC manufacturing and technique
Environment	New generation broadband wireless mobile telecommunication
Agriculture	Advanced numeric controlled machinery and basic manufacturing technology
Manufacturing	Large-scale oil and gas exploration
Transportation	Large advanced nuclear reactor
IT industry and modern services	Water pollution control and treatment
Population and health	Genetically modified organism new variety breeding
Urbanization and urban development	Drug innovation and development
Public securities	AIDS, virus hepatitis, and other major diseases control and treatment
National defense	Large aircrafts
	High definition observation system
	Manned aerospace and lunar exploration
Frontier technology (8)	Mega science programs (4)
Biotechnology	Protein science
Information	Quantum research
New materials	Nanotechnology
Advanced manufacturing	Development and reproductive biology
Advanced energy	
Ocean	
Laser	
Aerospace and aeronautics	

TABLE 1 Areas and Programs Identified in China's Medium and Long-Term Plan (MLP) for the Development of Science and Technology, 2006-2020

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In the wake of the global financial crisis that started in 2007, the State Council promulgated the "Policies for Expediting the Development of Biotech Industry" (2009) requiring government ministries and regional governments to formulate concrete implementation policies for biotechnology. The government identified biotechnology as a new, post-crisis engine for economic growth with a focus in five areas: biomedicine, agricultural biotechnology, energy biotechnology, biotech manufacturing and environmental biotechnology. Currently, the government is preparing to release a plan for the rejuvenation of the (NDRC)-led biomedicine industry that will focus R&D efforts in the areas of gene medicine, protein medicine, monoclonal antibody medicine, therapeutic vaccines and small molecule chemical drugs. A new element to this initiative is NRDC's calls for unprecedented interagency collaboration with MOST, the Ministry of Health, and the State Food and Drug Administration (SFDA). It is hoped that this institutional innovation will pave the way for more coordination across ministries holding biotechnology portfolios.

Funding

The government continues to invest heavily in biotechnology. It committed over $238M in life sciences and biotechnology from 1996 to 2000, and significantly increased this amount to $795M from 2001 to 2005. In the Twelfth Five-Year Plan period (2011–2015), biotechnology is set to receive $1.7 Trillion in government funding, and at least $1.5B for new drug development alone.[10] Development priorities will include biopharmacy, bioengineering, bioagriculture and biomanufacturing.[11]

In terms of biotechnology industrial output value targets, data show that China is well on its way to achieving its Twelfth Five-Year Plan target of $253.6B by 2015, with a current industrial output value in the areas of gene engineering drugs, vaccines and diagnostic test kits already reaching $159B.[12] By 2020, the goal is to reach an industrial output value of around $318B – $477B, to include the development of new biotechnology industries such as biomedicine and GM plants.[13, 14] Life sciences and biotechnology now account for about 20% ($27B) of the total investments in R&D ($135B). In terms of human resources, China currently has approximately 30,000 scientists employed in around 200 publicly-funded labs in biotechnology, and an estimated 50,000 workers in some 500 biotechnology companies.[15] From 2011 to 2015, biotechnology is expected to create one million jobs, improve life expectancies by one year, reduce infant mortality rate to 12 percent, and reduce carbon emissions of the most common pollutants by 10 percent.[16]

Government-Sponsored Science and Industrial Development

Beyond providing the strategic direction and the primary funding source, government support for biotechnology is manifest in other ways. First, it identifies specific sites for biotech industrial development. NDRC granted approval for the establishment of nine national biotechnology bases in Beijing, Shanghai, Guangzhou, Changsha, Chongqing, Qingdao, Chengdu, Kunming and Wuhan, following the construction of three such bases in Shijiazhuang, Shenzhen and Changchun. Selection of these cities were based on the presence of infrastructure suitable for biotechnology development, a relatively perfect market environment, and the existence of a cluster of related industries that facilitates the integration of large biotechnology groups and the development of small and medium-sized enterprises. In addition, NDRC also approved the creation of ten national biotechnology industrialization bases in Xi'an, Tianjin, Taizhou, Tonghua, Dezhou, Zhengzhou, Nanning, Harbin, Hangzhou and Nanchang. In these cases, the government seeks to promote new clustered areas for biotechnology development, create an industry with regional characteristics and redistribute economic and social resources to other areas of China.

Second, the government is also investing a total of $1.8B in biotechnology science parks. The development of these parks is orchestrated with its policy to recruit overseas Chinese-born scientists and professionals who are offered generous incentive packages to return to China to establish and lead life science-related business entities in these parks. For instance, the Suzhou Industrial Park launched a "Pioneering Talent Grant" in 2007 that carries a $158,500 award as start-up capital. This was followed up by an additional investment of up to $792,500 through the China–Singapore Suzhou Industrial Park Ventures Co. Ltd, supplemented by provisions of free laboratory space and housing subsidies for key talents.[17] The bioBay, as the Suzhou Biotech Science Park is now known, is considered one of the best biotech parks in China.[18]

Third, the government's interests in biotechnology industry are represented in the commercial sector by two types of enterprises. The first are the state-owned enterprises (SOEs). Amidst the backdrop of a favorable policy environment, SOEs are typically monopolies, receive generous government support, are well equipped and have relatively advanced technological capabilities. The second group includes top-tier state-owned research and higher education institutions that have life-science schools or departments. These institutions have institutionalized a "commercial identity," creating their own spin-off biotech firms and arranging tie-ups with local and foreign companies. In recent years, the Chinese government significantly increased R&D budgets in these institutions, especially among the elite universities and institutes under the Chinese Academy of Sciences. Since 1994, it has established at least 15 national biomedical research key laboratories.[19]

Finally, the government provides strong support to the growth of the private sector involved in the biotechnology industry through a combination of reforms and tax and legal incentives. The focus of support consists of two groups. The first are small private enterprises, often set up by returnees and to a lesser extent by former employees of public research institutes. This category also includes a small number of China-based outsourcing service providers – mainly contract research organizations (CROs). CROs provide an array of services including product development, formulation and manufacturing clinical trial management, data management, biostatistics and medical writing services for new drug applications and regulatory affairs support. Given the breadth of their functions, CROs can potentially be the main players in the development of China's pharmaceutical industry and will be critical in creating increased opportunities for international collaboration.[20] The second group – and a more recent actor in China's biotechnology R&D landscape – consists of the multinational pharmaceutical giants, e.g., Pfizer (Beijing), GlaxoSmithKline (GSK, Shanghai), Novartis (Beijing), AstraZeneca (Shanghai), and Roche (Shanghai). Aside from conducting their own R&D in China, these companies are developing collaborations with Chinese universities, research institutes and biotechnology enterprises, as well as establishing joint ventures with domestic companies.

Looking Ahead

A confluence of conditions is paving the way for China to make great strides in biotechnology: high economic growth, strong government and elite support that recognizes the strategic role of S&T in the country's rise to power and development, immense demographic, health and agricultural challenges that call for wide-scale and urgent S&T solutions, and the gradual improvement of the quality of its scientific labor force due to the increasing international exchanges and the growing number of returning S&T talent eager to become stakeholders in China's innovation drive. However, China still faces significant difficulties, and the achievement of its goal to become a global leader in biotechnology will largely be a question of the timing and extent to which it can overcome these challenges.

First are the institutional challenges rooted in the governance structure of China's national innovation system. The issue is whether a bureaucracy-centered S&T policy- and decision-making process provides the optimal arrangement for China's quest to become a global S&T leader. While the highly-centralized and bureaucratized set-up allows for extending biotechnology development across various government ministries, turf battles and bureaucratic rivalries have inhibited policy coherence and coordination. In some cases, organizational goals and funding priorities overlap, resulting in wasted resources and duplication of efforts. There have also been concerns of weak accountability with reference to new spending initiatives and monitoring expenditures. In the last decade, government-sponsored S&T institutions and programs have come under fire from some government officials, technocrats, and especially from members of the Chinese S&T community for undermining efforts to strengthen China's innovative capability.[21] The laundry list of criticisms include a corrupt and politicized process involving some national science projects, favoritism in the awarding of grant money, weak accountability for research results, intellectual property rights violations,[22] and inflexible management structures that are not conducive for innovative R&D work. A more recent institutional development – the growing role of local (provincial and municipal) governments in R&D – is yet to be examined in terms of their impact on the centralized S&T policy-making process and their role in the creation of innovative environments and domestic markets.

The second challenge is the need for the biotechnology industry to parlay what has so far been an effective 'scientific and applied research catch-up' system to one that creates a culture of innovation in order to develop and commercialize indigenous products that are internationally competitive. In-house R&D activities among domestic enterprises have not kept pace due to weak research capabilities, low R&D spending, heavy reliance on foreign S&T for its innovation activities and weak academic–industrial enterprise R&D linkages. Chinese firms focus on short-term gains, e.g., from sales of generic products, rather than on the longer-term benefits accruing from innovative research. Most Chinese pharmaceutical companies that invest in R&D only aim to improve upon existing processes and modify existing formulations of drugs. Moreover, government-supported venture capital firms that experts view as critical in promoting indigenous innovation still have minimal presence in industrial biotechnology, much less private biotechnology startup companies. According to China's State Intellectual Property Office (SIPO), foreign entities filed 51 percent of the biotech patent applications and received 62 percent of the patents granted.[23] Data (table 2) also show that imports far exceed exports in the life sciences and biotechnology sector. This profile of industrial biotechnology for the most part describes the state of China's high-technology sector, and in an effort to bolster China's industrial innovation, the government – articulated through its 2006 MLP and 11th Five-Year Plan (2006–2010) – called for the development of an innovation system that strengthened the 'lab-to-market' process.[24] This is a decided shift in government S&T/industrial policy, so the challenges will lie in the implementation phase.

Year	**2003**	**2004**	**2005**	**2006**	**2007**	**2008**	**2009**	**2010**	**2011**
Exports									
Biotechnology	190	219	268	256	265	263	296	355	410
Life science	2,502	3,237	4,563	6,342	8,917	13,394	11,059	13,861	17,840
Imports									
Biotechnology	105	108	142	154	201	322	360	422	450
Life science	3,062	3,793	4,576	5,138	6,464	8,063	9,477	11,683	15,800
Balance									
Biotechnology	-85	-111	-126	-102	-64	59	64	67	40
Life science	560	556	13	-1,204	-2,453	-5,331	-1,582	-2,178	-2,040

TABLE 2 China's Trade in Biotechnology and Life Science ($ million) **SOURCE:** *www.sts.org.cn*.

The third challenge covers international aspects of China's biotechnology development. Growing numbers of multinational biotechnology and pharmaceutical companies have set up their R&D operations in the country to take advantage of the availability of a large, but as yet relatively underutilized, S&T labor force and undoubtedly transforming the landscape of China's industrial biotechnology. But the joint ventures and partnerships face a steep learning curve. On the one hand, the legal framework that governs international business collaborations still need further reform, and international partners need to educate themselves on the evolving Chinese legal system. China's biotechnology has no overall national industry association, presenting a challenge to new entrants looking for both industry information and partnerships. On the other, home-grown enterprise managements have little experience with the various aspects of the 'discovery and development' value chain. Intellectual property rights (IPR), tax, ownership and other issues often come to the fore when due diligence is conducted by their foreign counterparts. Domestic biotech enterprises that are truly international in orientation remain in the minority, so one key issue facing China will be how and to what extent the industry can be 'internationalized' and be able to stand up to global business standards.

The speed with which China will achieve its goal becoming a global S&T powerhouse will significantly hinge on its ability to defend IPRs, a vital component of the innovation system.[25] While it is making great strides in IPR reform,[26] the government is yet to create a basic and complete legal framework for IPR protection. For instance, such a framework needs to include initiatives to educate the Chinese public on the importance of intellectual property protection. For the most part, people are still unwilling to support legally copyrighted products, emboldened by the fact that the existing legal system is not effective to serve as a deterrent to commit IPR-related violations. The IPR concerns of international companies entering the China market, e.g., protection of technology that companies bring to the country, lack of legal enforcement, opacity of domestic laws, etc. also expose weaknesses of the current legal regime. Addressing these issues as soon as possible will allow China to bolster its innovation efforts, especially as more of its companies and citizens will b ecome patent holders and key players in Chinese innovation, a trend that will most likely drive the future discourse of IPR protection in China.

As one of seven strategic S&T areas identified in the government's 12th Five-Year Plan (2011–2015), biotechnology is considered a major platform for strengthening China's innovation system and primed to be a leading purveyor of high-value S&T in the future. The challenges it faces are not unique but rather typify those faced by other leading edge S&T areas in China. Because of its central role in shaping the trajectory of China's S&T development, the government is no doubt the driving force behind China's efforts to address these challenges. Competitive and strong national innovation systems however, may not necessarily require a central role for the state. It bears watching how China's government will transform itself as the drive for indigenous innovation gains momentum.

Notes

1. Qing Vicky Xia, "Riding the Dragon Biotechnology in China: Analysis of Future Directions and Growth of Biotechnology in China," *Asia Pacific Biotech News* 12, no. 14 (2008): 1-6.

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3. Sue Pearson, Heping Jia and Keiko Kandachi, "China Approves the First Gene Therapy," *Nature Biotechnology* 22 (2004): 3-4.

4. Hu Jintao, "Hu Jintao zai zhongkeyuan gongchengyuan liang yuan yuanshi dahuishang jianghua (quanwen)," (Hu Jintao's speech at the member's conference of CAS and CAE-full text), *Xinhua*, Jun 7, 2010, *http://www,gov.cn/ldhd/2010-06/07/content_1622343.htm*.

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6. See http://english.cas.cn.

7. Fred Y. Ye, "The Two Engines that Drive Science in China," *Current Science* 98, No. 3 (February 10, 2010).

8. Cong Cao, Richard P. Suttmeier and Denis Fred Simon, "China's 15-Year Science and Technology Plan," *Physics Today* (December 2006): 38-43.

9. In 2010, two more areas were added on to the mega-science program list: stem cell and global climate change.

10. "China to Spend More Than RMB10 billion to Support Biomedicine" (in Chinese), *The Twenty-First Business Herald*, *http://www.21cbh.com/HTML/2010-8-10/5NMDAwMDE5MTE5Ng.html*.

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12. *http://www.cas.cn/xw/kjsm/gndt/20100708_2898996.shtml* (in Chinese).

13. Wang Jin, "In three steps, China wants to become a biotechnology giant," (in Chinese) *Science Times*, October 31, 2005, 1.

14. *http://www.most.gov.cn/kjbgz/200707/t20070717_51565.html* (in Chinese).

15. *http://www.china.com.cn/chinese/kuaixun/279290.htm* (in Chinese).

16. Yu and Xiang, "China placing priority," June 28, 2011.

17. *http://fjt.sipac.gov.cn/gate/big5/stipc.sipac.gov.cn/sipstipcEN/News/200704/t20070410_21446.html* (in Chinese).

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20. Yibing Zhou. *Contract Research Drives China's Pharma Sector*. (Rockville, MD: BioPlan Associates, Inc., 2006), *http://www.bioplanassociates.com/publications/Pharma_Mfg_CRO_Drives_China.pdf*.

21. Micah Springut, Stephen Schlaikjer and David Chen. *China's Program for Science and Technology Modernization: Implications for American Competitiveness*. (Arlington VA: CENTRA Technology, Inc., January 2011), 33.

22. Ibid.

23. Xia, "Riding the Dragon Biotechnology in China," 1-6.

24. Scott Kennedy, Richard P. Suttmeier and Jun Su. *Standards, Stakeholders, and Innovation: China's Evolving Role in the Global Knowledge Economy* (Seattle, WA: National Bureau of Asian Studies, 2008), *http://www.nbr.org/publications/specialreport/pdf/SR15.pdf*.

25. China's history with IPR is relatively short. The State Patent Office, the predecessor of SIPO, was only established in 1980. The country adopted its first Patent Law on March 12, 1984, coming into force on April 1, 1985. See also SIPO Legislations, *http://www.sipo.gov.cn/sipo_English/about/basicfacts/200904/t20090415_451003.html*.

26. For instance, the 1984 Patent Law has undergone numerous revisions – most recently in December 2008 – to harmonize the national legal framework with international norms as China strives to institutionalize a modern innovation system. The country also joined the World Intellectual Property Organization (WIPO) and other major IPR-related international organizations and conventions and treaties within 20 years of establishing the State Patent Office. See Lulin Gao, "China's Patent System and Globalization: China has Continuously Improved its Patent System and IP Laws Until it Now Conforms to the World Trade Organization's TRIPS Agreement," *Research-Technology Management* 34 (2008), *http://www.allbusiness.com/trade-development/economic-development-trade/11747018-1.html*.