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Health biotechnology in China: National, regional, and sectoral dimensions

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Marcus CONLÉ

Health Biotechnology in China: National, Regional, and Sectoral Dimensions

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Institute of East Asian Studies

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Title:

Health Biotechnology in China: National, Regional, and Sectoral Dimensions

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Abstract:
Biotechnology is one of the knowledge fields particularly targeted by China, as it is considered to open up "windows of opportunity" for catch-up to the leading economies. However, the seizing of these opportunities requires the existence of an institutional and organizational structure supportive of the introduction and usage of biotechnological knowledge. The present contribution discusses this problem in its national, regional, and sectoral dimensions. By focusing on the biopharmaceutical sector, it is shown that the regulatory environment and the capital market constitute serious bottlenecks to further development.

Keywords:
China, health biotechnology, innovation system, pharmaceutical

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1 Introduction

> Biotechnology is the priority of high-tech industries by which China will try to catch up with the developed countries, and China will strengthen the application of biotechnology to agriculture, industry, population and health.
>
> President Hu Jintao (January 9, 2006, quoted in Chen et al. 2007)

Biotechnology is expected to radically transform the organization and value creation of a broad range of industrial sectors. As a consequence, governments in leading and emerging economies alike have rendered great efforts to support the development and use of biotechnology. Specifically, emerging economies view it as an opportunity to catch up to the leading countries, as this cross-cutting technology is still in the early stage of its life cycle, which may reduce the barriers to entry (Niosi and Reid 2007). In China's "National Medium to Long-term Plan Outline for the Development of Science & Technology, 2006–2020" (15-Year Plan) this commonly held expectation is incorporated as well and biotechnology figures prominently among the technological fields targeted by the Chinese government. While biotechnology may be employed in several industries, the pharmaceutical industry – a high-tech industry according to OECD classification – has received particular attention among China's policymakers (Yu 2007).

The desire of China's policymakers to occupy a leading position in the race for biotechnological innovation mirrors in the size of inputs devoted to research and development (R&D) in this technological field. While general expenditure for R&D (GERD) has surged over the last years, the Chinese government's investment into biotechnological research constitutes a major share of overall government appropriations for science & technology (Conlé and Taube, forthcoming). However, the introduction of biotechnology may arguably require a reconfiguration of existing institutional and organizational structures in order to increase the efficiency of input usage. Technologies are not introduced in a void. On the contrary, they are often, or even usually, applied in domains other than those in which they have emerged. These other domains have generally evolved over rather long periods of time. As a consequence, the introduction of new technologies entails a process of co-adaptation of technologies and domains, which is constrained by historical circumstances. This also holds for biotechnology, which comprises a (still rising) number of cross-cutting processes and techniques. In line with received research on innovation systems, we define the relevant domains according to the analytic dimension determining a domain's extent: nations (Freeman 1995, Lundvall 2007, Nelson 1993 etc.), regions (Cooke et al. 1997, Asheim and Gertler 2005), and sectors (Malerba 2005).[1] The domains shape and are shaped by the improvement and use of biotechnological knowledge.

In order to assess China's biotechnological readiness, this contribution analyzes the domains singled out above for their relevance with regard to the development of biotechnology. The next chapter 2 discusses the three dimensions – sectors, nations, regions – that constitute the problem space. While the sectoral dimension is of a general nature, both of the latter are specific to certain societies. Consistent with the emphasis of the Chinese government, we focus on the pharmaceutical sector and do not consider other industrial sectors. In chapter 3, we analyze China's biopharmaceutical sector. First of all, we provide a short overview of the most important output indicators including industrial as well as scientific output data. The following sections attempt to place China's output in context highlighting the national and regional dimensions of biotechnological development. Chapter 4 concludes.

2 Biotechnology: Sectoral, National, and Regional Dimensions

Research on innovation systems has diversified in recent years to encompass approaches, which differ in their emphasis. In general, regional, sectoral, and technological systems approaches have been added to the original nationally confined systems approach (see above). These approaches share the concept of

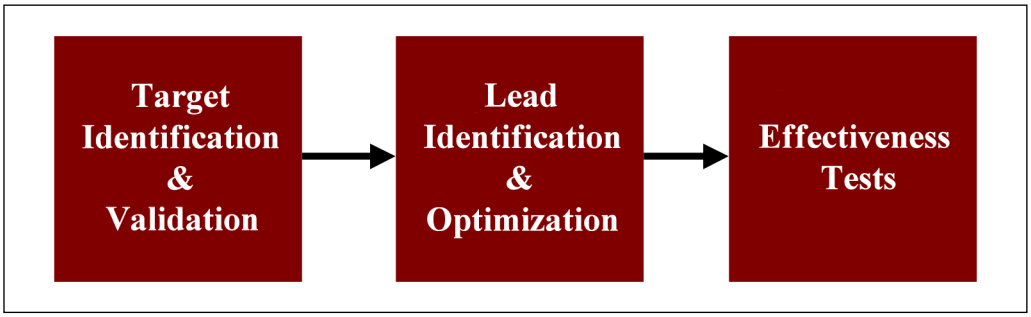
1 Besides research on national, regional, and sectoral innovation systems, another approach is to focus on technological systems (Carlsson 1997, Carlsson et al. 2002). Instead of focusing on one industrial sector (as we do in this contribution), the technological systems approach generally includes all industrial uses of a particular generic technology.

(open) "system" and are quite similar in their classification of components and relationships the respective systems are composed of. Differences, in turn, are mainly due to other definitions of a system's boundaries. Hence, all of these approaches are rather complementary than substitutive and contain an important intersection of components, i.e. individuals, organizations and institutions. For our purposes, it is not necessary to choose between any of the approaches. Rather, as we are interested in the problem of introducing a particular technology, or a "knowledge field" (Carlsson et al. 2002), it is more interesting to see these approaches as alternative dimensions of our problem space. Therefore, we henceforth use the term "domain" instead of "system" in order to indicate that these domains are open and interlinked. In principle, we are only interested in the intersection of these domains. But as the domains need to be understood as integral wholes, we cannot leave aside those areas of a domain thought to be not directly relevant to the problem. In the next sections, we generally discuss the problem of introducing, developing, and utilizing knowledge foreign to any of three domains defined according the analytic dimension defining their extent: the sectoral, national, and regional dimension.

2.1 The Sectoral Dimension

Cross-cutting technologies are relevant for a number of existing industries. These industrial sectors already feature an established knowledge base, incumbent actors, and customary routines. New technologies may bring about disruptive change to a sector's knowledge base and organization or merely add to received knowledge in a complementary manner. In the pharmaceutical industry, received knowledge was mainly derived from organic chemistry and medicinal knowledge that had built up over years of learning-by-doing. Drug development is impeded by the intricacy of the human biological system. While knowledge on the working of that system is increasing rapidly, the processes leading to particular diseases are nonetheless not properly understood. The bounds of knowledge affect the way research and development (R&D) is conducted in that sector, as drugs have to be understood as components in that biological system (Pisano 2006). That is, whereas in most industries, systems are designed to perform certain tasks, the system is already given and (as yet) unchangeable. Instead, components have to be discovered, which interact with the given system in a way that leads to desired outcomes. As the biological system is highly integral, it is also impossible to modularize the system in order to reduce complexity. The same applies to the therapeutic agent (the drug), whose elements – the active ingredient and the excipient (the inactive substance used as a vehicle for the biologically active ingredient) – need to be closely adapted to each other.

Figure 1: The Process of Drug Development



Own illustration

In general, the process of drug R&D can be broken down into three stages (Figure 1). One of the central tasks is to identify the molecular structures, usually proteins, that are involved in the pathology of a disease. These structures act as targets to which the drug to be developed binds in order to cause a therapeutic effect. Target validation, in turn, indicates the analysis of information that has accumulated on a target – e.g. through prior drug development – to verify whether the target indeed performs the hypothesized function. If a suitable target is identified, a molecule, i.e. the drug, has to be found that acts selectively on that target without interfering with other processes in the body. Until biosynthesis could be employed, the candidate compounds were solely small molecules isolated and synthesized from na-

tural resources. By means of screening for the biological activity against the target, a compound with the highest fit, the so-called lead compound, is selected and some chemical modifications are performed in order to optimize its potency, selectivity and pharmacokinetic properties.[2] Due to the complexity of the human body, the drug thus obtained is however merely a hypothesis. Eventually, the drug has to be tested for its effectiveness.

At least so far, the use of biotechnology does not change the stages of drug development that have been described simplistically above. Rather, the new knowledge is augmenting the activities at the first two stages without rendering useless the knowledge accumulated before (Pisano 2006). New knowledge attained in the scientific fields of genomics and proteomics serve to detect new drug targets. These scientific advances have not only increased the number of proteins that may act as potential targets but have also identified other molecules as prospective sites for intervention. For example, the knowledge about how a certain molecule – messenger RNA (mRNA) – carries coding information of the DNA to the ribosomes, i.e. the cell components that are responsible for protein synthesis, renders mRNA a possible target candidate. On the other hand, an increasing number of techniques subsumed under the umbrella term "biotechnology" is vastly escalating the amount of potential drug candidates. Genetic engineering with the recombinant DNA (rDNA) technique enables the synthesis of proteins, i.e. larger molecules than could be produced with organic chemistry. The hybridoma technique allows for the synthesis of monoclonal antibodies (mAbs), i.e. "magic bullets", which can be used against viruses and bacteria, if the body cannot produce these antibodies itself. Furthermore, the gene silencing technique (RNA interference, RNAi) sets to destroy the messenger RNA and hence prevents the synthesis of certain proteins involved in a disease. By means of gene therapy techniques, genetic material is inserted in living cells in order to change the processes of protein synthesis.

All of these new techniques have vastly contributed to the knowledge base in the pharmaceutical sector. There are now more targets and more therapeutic agents, which are expected to be involved respectively to interfere positively in pathologies. High Throughput Screening (HTS) allows for the concurrent testing of myriad potential agents for their biological activity against a particular target, thus economizing on the process of selecting lead compounds. However, since this has so far not led to a change in the essential structure of drug discovery, "old" knowledge on molecular compounds and their effects are not superseded. New fields of research and new techniques have considerably raised the opportunities for discovering remedies for hitherto incurable diseases. But, as Pisano (2006) argues forcefully, the strong increase in opportunities has also substantially increased uncertainty. The lead compounds that are identified by old and new techniques are still merely hypotheses, whose validity have to be checked by conducting a range of effectiveness tests.[3] According to several studies (e.g., CBO 2006), the number of new molecular entities (NMEs) that failed these tests have actually increased in recent years. The nature of drug development – that is, the art of discovering a component that can be administered to a complex given system – remains one of trial and error, which affects the organization of the pharmaceutical sector. In particular, the risk associated with incurring the costs of drug development and the need for bringing together the diverse stocks of knowledge require to be mitigated by adequate organizational means.

2.2 The National Dimension

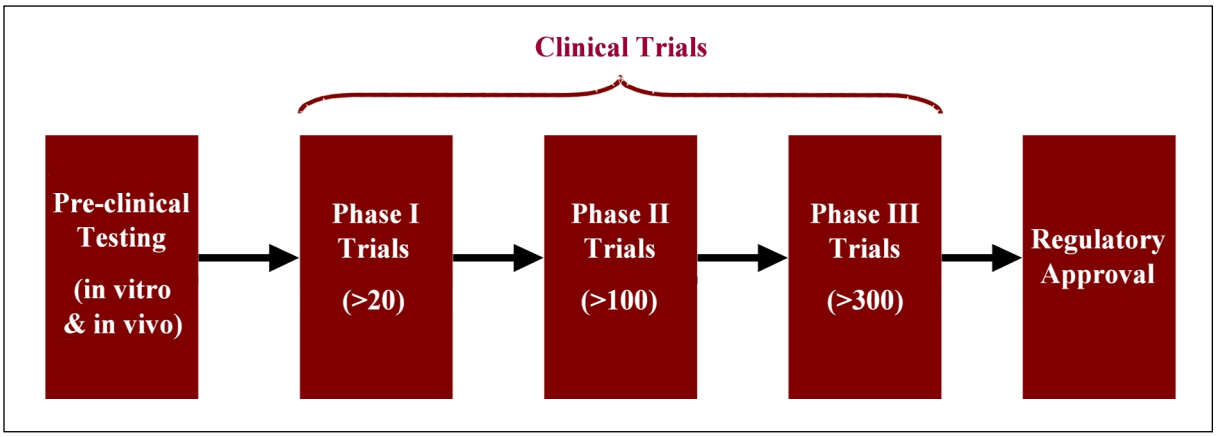
Nations distinguish themselves through sets of dominant (ethical) values that shape political discourse and translate into particular institutional configurations, i.e. norms, habits, legal rules etc. (North 2005). Especially in the case of medicine, which directly concerns the physical integrity of the human body, values determine how new technologies are to be used and where advances in knowledge are to be

2 Potency refers to the level of biological activity of the drug, selectivity to its interference with other processes beyond those relevant for the pathology of interest, pharmacokinetic properties to the way the body affects the drug after it is administered to it.

3 Consider, for example, the Phase I clinical trial for a humanized monoclonal antibody (TGN 1412) conducted in Great Britain in 2006 leading to systemic organ failure and death of several voluntary subjects. Although the pre-clinical trials involved a dose in the order of magnitude higher than those applied to the human subjects, they showed no signs of potential hazards. Until now, it is not clear what caused this serious and unpredicted difference in biological action in humans.

directed. This applies to research conduct – consider, for example, the national discourses on stem cell research and therapeutic cloning – as well as to drug approval. Since drug development remains a trial and error process, institutions are most salient with regard to regulation relating to the exposure of humans (and possibly animals) to new therapies. The design of the effectiveness tests mentioned above are here important. In general, most countries have adopted an approval process, which is structured in five phases (Figure 2): Initially, some pre-clinical trials are conducted in vitro (test tubes) and in vivo (cell cultures or animals). These trials can be used to optimize the lead compound and investigate the toxic effects of the drug. After that, clinical tests are carried out with an escalating number of human subjects. The tests are meant to determine the appropriate dosage, the examination of side effects, and the analysis of the effectiveness of the active ingredient on the pathology of an illness. If these tests are conducted successfully, the process is ended by approval through a regulatory agency.[4] Although, on the surface, the approval process is similar, the actual implementation often differs across nations. On the one hand, regulatory requirements may be applied more or less strictly. Alternative paths (e.g., fast-track reviews) may be established and used more or less frequently. Moreover, a different number of organizations – e.g. ethics committees, social pressure groups etc. – may be involved in the process.

Figure 2: The Drug Approval Process



Own illustration

The cultural valuation of (advances in) knowledge also affect the nature of support programmes developed by governmental and non-governmental organizations. This applies to the amount of capital set aside for a particular field of research as well as for the channel through which financial capital is distributed to the relevant actors. Depending on a country's institutional configurations, government appropriations may mainly serve to finance progress in basic and applied basic science with the objective to further general (societal) knowledge. It may also be invested into the strengthening of particular actors thought important for overall (economic) development. In this regard, regulation of intellectual property rights (IPR) also matters, which can be directed towards a stronger diffusion or towards the appropriability of knowledge by particular "inventors". A move towards appropriability can include an expansion of actors involved in patenting (e.g., academic organizations, cf. Mowery and Sampat 2005) and a move towards quantifying the progress of knowledge and its effect on the country's welfare (e.g., number of patents).

The institutions mentioned so far are influencing directly the processes in the sectoral domain. However, there are also institutional configurations at the national level, which affect the sectoral conditions more indirectly. In line with the research on varieties of capitalism (Hall and Soskice 2001), labour and capital market institutions can be identified as important for the economic use of biotechnology. As has been argued above, biotechnology has not removed but has rather increased the uncertainty surrounding drug

4 Usually, post-marketing tests are required to analyze the long-term effects on patients or on particular sub-groups, e. g. pregnant women, children etc.

development. Therefore, a country's capital market needs to have mechanisms to mitigate the risk associated with financing the innovation of new molecular entities. Labour markets, in turn, can either enhance knowledge exchange by creating long-term working relationships or provide incentives for entrepreneurship in the sense of establishing new (project-oriented) firms. According to the literature on varieties of capitalism, stock market-based systems are complementary to entrepreneurship, whereas bank-based systems are supporting knowledge exchange by giving established firms the opportunity to plan in longer time horizons.

2.3 The Regional Dimension

In recent years, students of innovation have paid a renewed attention to the sub-national level. Most of this attention is due to the general observation that a country's industry is often concentrated in a limited number of regions and/or that a country's regions have developed differently in particular industrial sectors. Cooke et al. (1997) discuss the differences between regions in terms of local state capacity and social capital. Accordingly, regional administrations in different countries diverge in terms of size of own budgets, their taxation authority and degree of autonomy in regional government spending. The more autonomous regions are vis-à-vis the national governments, the more the elements that were considered above with regard to the national level play a role in regional development. Thus, local governments in federal states have the financial means to put in place an appropriate infrastructure to support innovative activities within regional boundaries. While regulation is usually performed at the national level, the sub-national level can influence economic development by e.g., establishing academic organizations, providing a communication infrastructure to facilitate exchange between organizations within the region and with knowledge bases outside the region, or helping their local economy to secure financial capital.

Another crucial variable in the structure of the regional economy is the nature and extent of inter-organizational cooperation. According to economic sociologists, dense networks of interaction between individuals and/or organizations are associated with social capital (Granovetter 2005). Regional economists and business economists (e.g., Porter 1998), in turn, have identified "clusters", i.e. regionally bounded inter-organizational networks, as an essential ingredient to regional development. Local clusters such as the fashion cluster in Italy's Emilia-Romagna are considered to be typical examples of "learning regions". Networks as "hybrid" modes of governance (Williamson 1991) are said to feature the long-term orientation and social control mechanisms amenable to the build-up of trust, while at the same time showing a higher level of adaptiveness to changes in the economic environment. Trust is vital for knowledge exchange, and spatial proximity provides sufficient opportunities to actually engage in the exchange of knowledge. Indeed, the reason for the superiority of localized networks of stable relationships is seen in the "tacitness" (in Michael Polanyi's words) of some types of knowledge. As tacit knowledge is difficult to transmit to others, it is shared more easily if frequent face-to-face interaction is possible (cf. Asheim and Gertler 2005). In this way, frequency of interaction is one determinant of learning intensity.

However, in recent years other authors have argued that knowledge in science-based industries – such as pharmaceuticals – is becoming more explicit. Therefore, spatial proximity is increasingly giving way to "cognitive" proximity (Boschma 2005). Accordingly, knowledge exchange is not so much facilitated by the opportunities of meeting frequently but rather by the "absorptive capacity" (Cohen and Levinthal 1990) of the receiver of information with regard to being able (i.e. having the complementary knowledge) to interpret the messages exchanged. Instead of regional communities, it is "epistemic communities", which are viewed as relevant for the diffusion of knowledge. Nonetheless, geographic space does not lose its importance, as agglomeration economies provide a rationale for co-location (cf. Krugman 1991; Breschi and Lissoni 2001). The main logic of agglomeration economies rests on a coordination game between specialized providers of inputs, in particular knowledge (human capital) and financial capital. Suppliers of human capital are attracted to industrial agglomerations as they are able to choose from a large number of employment opportunities, while employers can select from a larger pool of potential staff. The advantages are most pronounced for small enterprises – e.g., entrepreneurial start-ups

– as the regional availability of further employment opportunities decreases the risk of an employee with regard to accepting a job in a fledgling firm. If the local agglomeration gains a reputation for successful start-up activities, venture capitalists are lured into the region to get their share of the prospective profits. As this model is usually associated with science-based industries, Cooke (2001) calls this regional system "new economy" innovation systems.

The differences between the two types of regional domains appears to be in the nature of industrial and capital relations. Asheim and Gertler (2005) relate these differences to the approach of varieties of capitalism mentioned above. Cooke, for example, views the "new economy" system as essentially venture capital-driven. In the same vein, we could argue that the former system is based on banks or social groups tightly integrated into long-term trust relations with each other thus facilitating relationship-lending schemes. In fact, it appears as if this element provides a connection between the national and regional domains. Since regions may, however, differ with regard to local state capacity and local cultures, there is a possibility that this connection does not hold. Instead, it is likely that regional peripheries to the dominant national variety emerge with divergent complementarities between the labour and capital market. Altogether, the comparative advantage of any of these local varieties with regard to supporting the utilization of biotechnology is not yet established. All that we want to declare is that the differences at the national and local level have an impact on the organization of a given industrial sector, and that this difference matters for the use of and progress in biotechnological knowledge.

3 China's Biopharmaceutical Industry

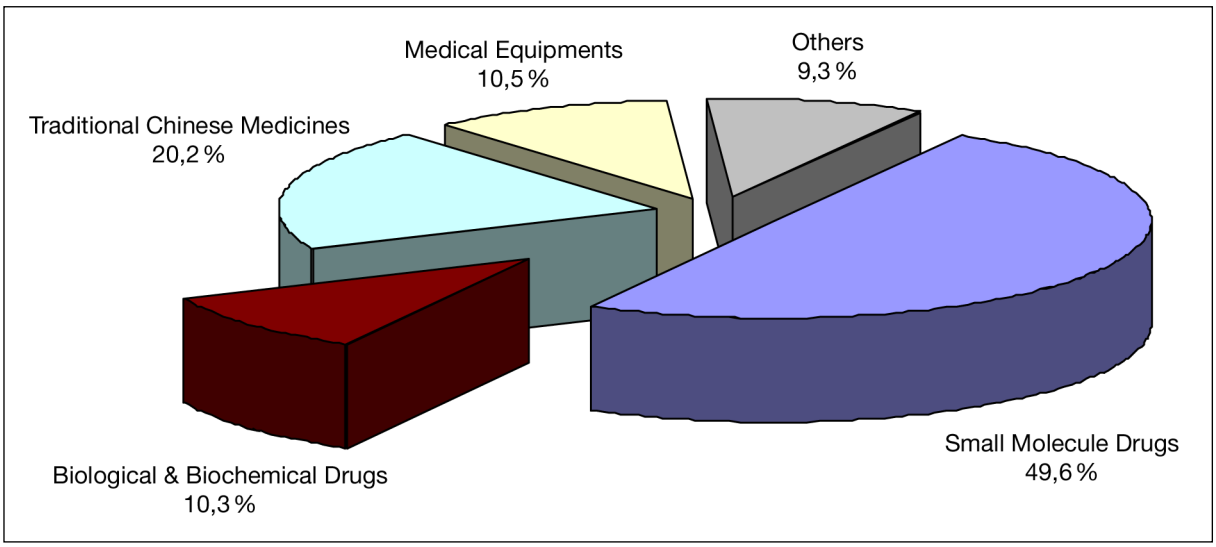
In the preceding chapter, the introduction of biotechnology was explained as a problem along sectoral, national, and regional dimensions. While the sectoral dimension is general and applies to all countries alike, the national and regional dimensions are specific to certain societies. The differences between countries along these dimensions, in turn, are to a different degree advantageous to further progress in biotechnological knowledge. As these domains build on cultural disparities, a lacking fit between these dimensions are not easily superseded. In this section, we analyze China's health biotech sector. Before we discuss the national and regional dimensions of that sector, we give a short overview over the main (quantifiable) output indicators. These include industrial output, introduction of new drugs as well as scientific performance as can be discerned from the analysis of patents and scientific papers.

3.1 The Output of the Biopharmaceutical Segment: An Overview

Development of (Western) pharmaceuticals is rather recent in China. Until the late 1970s, the country has however managed to substitute medical imports of the most essential pharmaceuticals by domestically reengineered and manufactured drugs (Shen 2008). An acceleration of growth in that industrial sector can be observed since the early 1990s. Between 1995 and 2008, gross sectoral output has increased eight-fold (Conlé and Taube, forthcoming). This increase also includes a rise in the biopharmaceutical segment, i.e. the biological and biochemical segment according to Chinese statistical classification. Although it has featured above-average growth rates, the segment is, as of 2008, still only comprising 10 % of the whole pharmaceutical sector (Figure 3). In contrast, Western-style chemical (small molecule) drugs and traditional Chinese medicines (TCM) account for the largest share in drug manufacturing, covering 50 % and 20 % respectively. The differences in output shares is also reflected in the number of new drugs. According to the data search engine of China's State Food and Drug Administration (SFDA),[5] which apparently contains all the drugs approved since 2000, small molecule drugs dwarf biopharmaceutical products in numbers (Table 1). Nonetheless, biological drug manufacturing is clearly on the rise. As many observers however suggest, most of these products are generics (Frew et al. 2008). Hu et al. (2006) list the main reasons for the boom of biogenerics in China: Firstly, many of the products innovated in the West have lost their patent protection, and Chinese companies can exploit their superior knowledge of the Chinese market. In fact, Chinese companies are predominately focused on the do-

5 http://app1.sfda.gov.cn/datasearch/face3/dir.html (accessed June 6, 2010).

Figure 3: China's Pharmaceutical Industry by Market Segment (2008)



Data: MIIT (2009)

mestic market, while exports account for only a minority of total sales volume. China's pharmaceutical exports, in turn, primarily comprise raw materials used for chemical drugs (MIIT 2009). Secondly, the domestic health system presently puts a premium on affordable drugs, which creates a market environment that is mainly based on price competition. As Hu et al. (2006) note, several drugs are produced by tens of companies, which are predominately small-scale operations attracted by easy profits. Thirdly, mature expression systems vastly simplify the manufacturing of biological products. Hence, the technological barriers to entry are low enough to enable market entry even for companies without strong scientific capabilities.

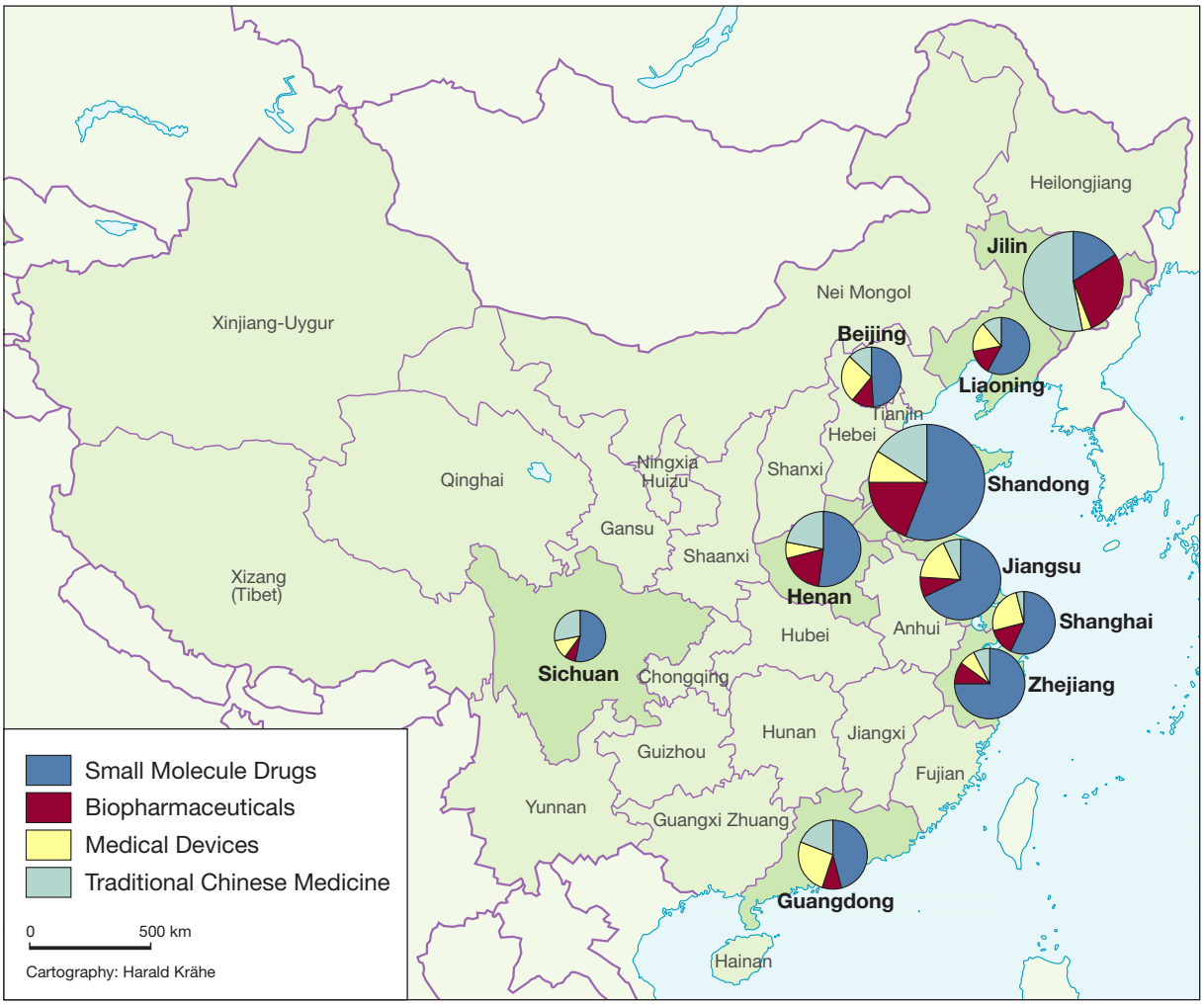
Table 1: Domestically produced drugs approved by SFDA (2000–June 6th 2010)

Segment	Number of Drugs
Chemical Drugs	186,482
Chinese Medicine	62,273
Biological Drugs	2,873

Source: www.sfda.gov.cn

As with many industries in China, regional concentration in the pharmaceutical industry proceeds very slowly, because many local governments have designated this sector a "pillar" industry targeted for development. Due to the high significance assigned to the sector, most provinces feature manufacturing operations. However, provinces differ in manufacturing size, and the output share of some provinces has changed dramatically over the past two decades. In particular, Shandong province has expanded extraordinarily fast since the turn of the century. This output expansion is even more rapidly in the biopharmaceutical segment, and Shandong has accounted in 2008 for 20 % of China's gross manufacturing output in this segment. Figure 4 shows the top ten provinces in biopharmaceuticals with their output portfolios in the pharmaceutical industry. As can be seen, the provinces apparently exhibit different strengths. While most provinces have a rather large share of chemical drugs, they differ regarding their focus on other segments such as TCM or medical devices. The differences in the composition of pharmaceutical manufacturing may hint at different knowledge bases. Jilin, for example, is second in biopharmaceuticals, but its main pharmaceutical output is in the TCM segment. In fact, the province's largest biopharmaceutical firms such as Tonghua Dongbao Pharmaceutical have started with TCM products. On the other hand, the rapid surge in Guangdong province's total manufacturing output is mainly due to electronic and communication equipment producers, in particular those from Greater China. Although Guangdong has also developed into a biopharmaceutical manufacturing base, the province's particular strength is in medical devices.

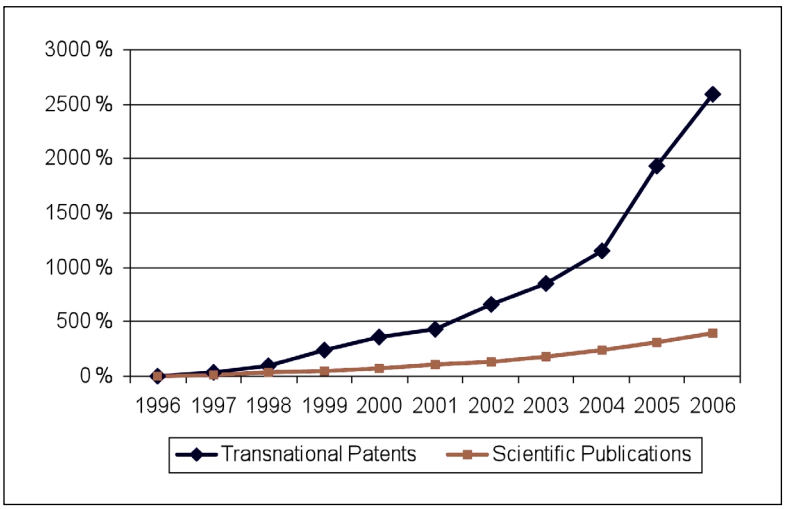
Figure 4: Top Ten Provinces by Biopharmaceutical Output (2008)



Annotation: The size of the pie charts show the relative size of the biopharmaceutical segment in relation to the country's total output in that segment.
Data: MIIT (2009)

In order to account for the future potential of China's biopharmaceutical industry, R&D output, especially patents and scientific papers, may provide a first hint. R&D output has surged since the beginning of the reform, and the increases are particularly strong since the turn of the century (Figure 5). The strong increase in patents also pertains to biotechnology patenting. Van Beuzekom and Arundel (2009) have analyzed patent applications filed under the Patent Co-operation Treaty (PCT). Accordingly, China has managed to enter the top ten list of countries with the highest share of PCT applications in the biotechnology field (Table 2). As can be seen from the comparison of data from the periods 1994–1996 and 2004–2006, the United States has kept its outstanding position, but within a decade the importance of East Asian countries has increased immensely. While Japan has passed both, the United Kingdom and Germany, as the most important pursuer of the United States, Korea and China account for the highest increases in patent applications. In the case of China, applications in the period 2004–2006 are almost twenty times as high as a decade before. Applications at China's State Intellectual Property Office (SIPO) are even higher. According to the analysis by the National Development and Reform Commission (NDRC) and the Chinese Society of Biotechnology (CSBT) (NDRC and CSBT 2008), domestic biotechnology patent applications in the period 1997–2006 mainly derived from two cities, Beijing and Shanghai. Moreover, universities and public research institutes, most notably those of the Chinese Academy of Sciences (CAS), were responsible for about 57 % of applications, while enterprises accounted for 25 %.

Figure 5: China's Performance in Patents and Scientific Papers (1996–2006)



Annotation: Percent changes to the base year 1996
Source: Fraunhofer ISI

Table 2: Top Ten Countries by PCT Biotechnology Applications

Country	1994–1996 Number of Applications	2004–2006 Number of Applications	% of Total
United States	7,757	11,474	41.5
Japan	894	3,720	11.9
Germany	895	2,106	7.0
United Kingdom	985	1,264	4.5
France	577	991	3.6
Canada	437	809	3.2
Korea	59	653	3.0
Netherlands	273	643	2.8
Australia	297	556	2.1
China	22	423	1.9

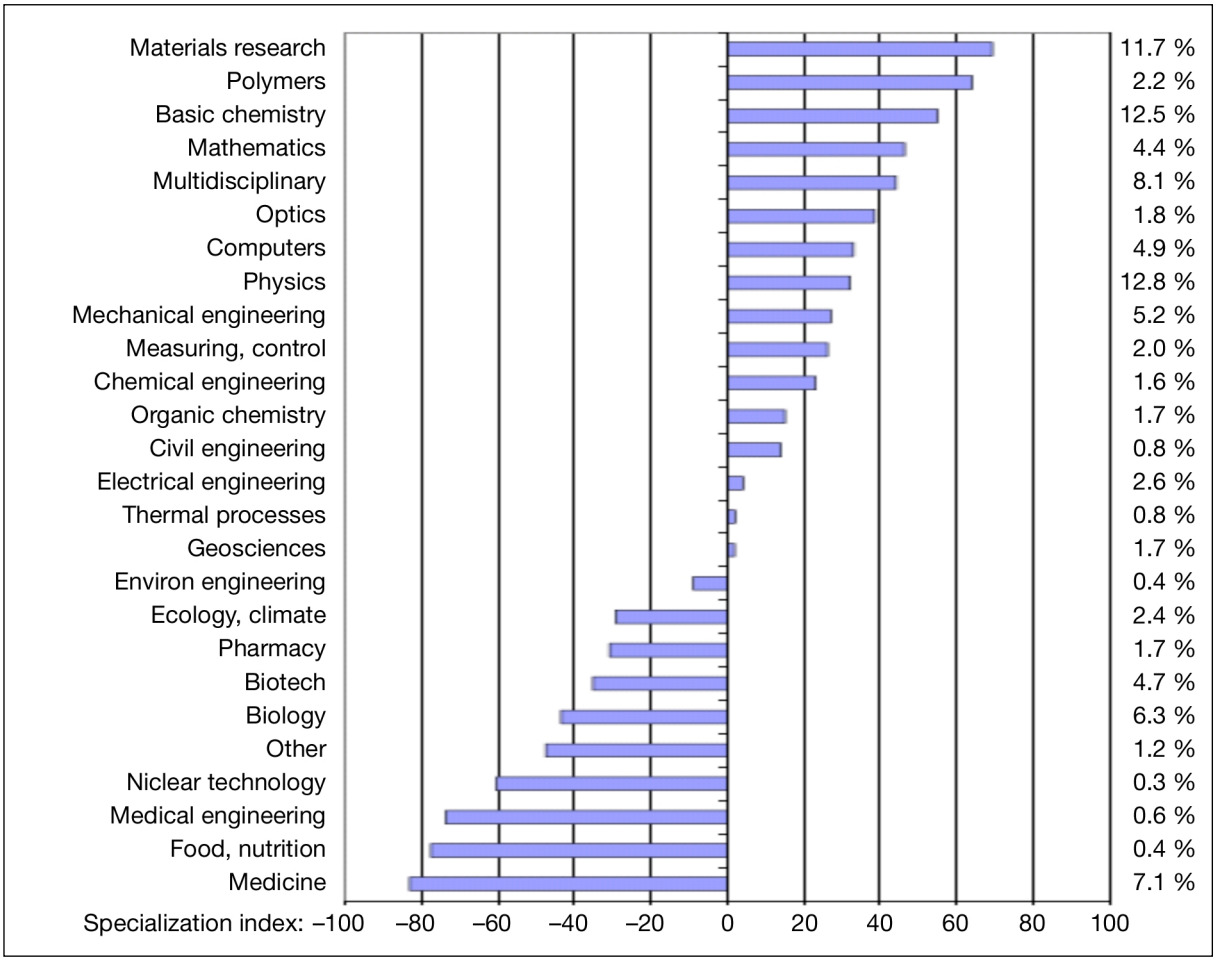
Source: van Beuzekom and Arundel (2009)

Application quantity, however, does not tell much about their quality. A look at the international patent classes (IPC), which figure prominently in Chinese patent applications, reveals that the largest share of applications pertains to genetic engineering for synthesizing proteins (C12N 15/00).[6] On the other hand, patenting with regard to antibodies (C07K 16/00) has only started in recent years. Some, however limited, patenting activity can be observed with regard to gene therapies (A61K 48/00). Besides genetic engineering, diagnostics tests – most importantly tests for nucleic acids (C12Q 1/68) to detect pathogens such as viruses (e.g., SARS, HIV) – is one of the most important fields of Chinese patenting activities. In general, diagnostics represent a less risky strategy to enter the biopharmaceutical segment than the development of new molecular entities (cp. Frew et al. 2008). The strong activity in this product category, sometimes referred to as "bread-and-butter" products (cp. Feldman et al. 2005), may reflect an immaturity of China's biopharmaceutical industry. Statistics show that China's biopharmaceutical enterprises are still of limited scale. Thus, it may make sense to innovate products that are less capital-intensive than the development of novel drugs.

Scientific journal articles have increased strongly in recent years as well. This also includes research output in the fields of biology. However, as specialization indexes show (e.g., Figure 6), China is more specialized in materials research – nanotechnology in the wider sense – than in biological research. Frietsch

6 This analysis rests on a tentative examination of a fraction of Chinese PCT applications contained in WIPO's PATENTSCOPE, backed by the analysis of applications at SIPO conducted by NDRC and CSBT (2008).

Figure 6: Scientific Profile of China (2004–2006)



The index shows the scientific specialization of a country in relation to the world average. Positive values for a research field indicate a higher weight within the country than on the international level, negative values, in turn, a lower weight. A country may feature a negative specialization in a research field, even if the numbers of SCI papers are relatively high at the national level (the percentage values on the right hand side), and vice versa.
Source: Frietsch (2008), Fraunhofer ISI

(2008) contends that Chinese researchers already belong to the world elite in materials and polymer research. In fact, it is expected that China is surpassing the USA as incumbent nanotechnology nation in the next years. Although China is negatively specialized in biological fields, Lenoir and Herron (2009) come to a surprising result in their text analysis of China's nanotechnology publications. By using citation analysis, text mining, mapping and data visualization techniques, they identify a recent surge in bionanotechnology papers, which are directly relevant to the pharmaceutical sector. Hence, it may be premature to conclude that Chinese science is weak with regard to issues of biotechnology. Rather, the nanotechnology papers work at the intersection of nanotechnology and biotechnology containing pharmaceutically relevant key words such as antibody and immunoassay.

3.2 The National Dimension of China's Biopharmaceutical Segment

The development of the biopharmaceutical segment is influenced by governmental intervention and initiatives at the national level. As has been mentioned above, the health biotechnology realm is considered in many countries as a very sensitive issue, since it directly involves the integrity of the human body and, more generally, the dignity of man. Of course, these propositions are implicitly containing ethical valuations, which may not be shared by all cultures alike. In general, Confucianism and Taoism – those religions practiced most widely in China – are mainly containing pragmatic codes of practice. In this sense, eminent Chinese researchers such as Jun Yu from the Beijing Institute of Genomics, CAS, find it not very surprising that stem cell research and therapeutic cloning have not provoked strong social

resistance (Yu 2007). The pragmatic attitude towards technological progress is mirrored in the field's regulation. China is one of the most liberal countries with regard to embryo research, although it has outlawed reproductive human (not animal) cloning. An important problem with regard to pragmatism is, however, that standards with regard to a right/wrong dichotomy are hard to establish and to defend. Combined with China's strong desire to catch up to the leading countries (see the quotation at the beginning of this contribution), it may seem to observers that ethical considerations are replaced by a strong growth imperative.

China has tried to refute such accusations and has entered into many international discourses in order to find proper codes of conduct (Yu 2007). In turn, the sometimes conflicting objectives of economic growth and ethical conduct pertain to all countries alike. A major difference to other countries is, however, that existing regulation is difficult to implement. One of the key problems related to enforcement is the uneasy relationship between different regulatory authorities on the national and local level, which are more thoroughly addressed in the next section. Suffice to say at this point that earlier, most of the drugs were approved by local instead of central authorities. It was only in 2001, when the new Drug Administration Law centralized approval procedures. The establishment of the State Drug Administration in 1998, and – through merger – the State Food and Drug Administration (SFDA) in 2003, contributed to a significant centralization and modernization of China's regulatory oversight over the pharmaceutical industry (cp. Jia 2007). However, the definition of "new drug" remains a very broad category. The high number of new drugs reported in the previous section is the outcome of such a loose definition. Some improvements have been made since 2005, when drugs were no longer considered to be new, if there were slight adaptations such as a change in dosage form or an improvement in production technique (Jia 2007). Even more problematic is the wide-spread corruption, which has also plagued the health sector. In July 2007, Zheng Xiaoyu, the former head of the SFDA, was executed for taking bribes in return for approving drugs, while other senior officials were put to lengthy prison terms. Apparently, some of the drugs the SFDA approved during his tenure were later found to be inferior, even resulting in some fatalities (BMI 2008).

The regulatory problems have put some doubt on the quality of China's marketed drugs, as the corruption scandal and the high number of drugs taken over from local regulatory authorities cast a cloud even on the more innovative drugs approved by the SFDA. In 2003, China granted permission to the marketing of the first gene therapy product worldwide, Shenzhen SiBiono GeneTech's Gendicine. The recombinant adenovirus was actually developed and clinically tested in the United States, but was not granted approval there.[7] Gendicine is a modified version, so that the rejection does not necessarily allow conclusions to be drawn on the effectiveness of the modified version. However, the opacity of the approval process directed towards a fast-track review and the paucity of information on clinical trials have rendered observers wary of the claims of company and regulator (Krimsky 2005). China's approval process is basically taken over from the United States and includes the stages mentioned above. Besides, a fast-track review system is in place to quickly bring to market treatments for diseases such as HIV and (advanced) cancer. All of the more contested drugs have been allowed to take the fast track, which includes a far smaller amount of trials with human subjects (cp. Hu et al. 2006, Krimsky 2005).

Problems with regulation also extends to China's intellectual property rights (IPR) regime. Initially, China viewed the enforcement of IPR in strictly developmental terms (Potter 2001). This perspective basically meant that quick knowledge diffusion (including foreign knowledge) was given priority over appropriability. As a consequence, the evolution of the regime was mainly driven by the attempt of China's policymakers to accommodate demands from countries regarded as most important with regard to trade and foreign direct investment. This applies most pronouncedly to the pharmaceutical sector, which was only included in the patent law in 1992 at the demands from the United States. Apparently, the initial rationale has however given way to a new logic, which emphasizes appropriability as a means to provide sufficient incentives for conducting R&D, especially in the high-tech industries including the

7 The same applies to the other gene therapy products approved in China. Shanghai Sunway Biotech's H101 is essentially a copy of a drug developed and abandoned by Onyx Pharmaceuticals (Hu et al. 2006). Shandong Simcere Medgenn Bio-pharmaceutical's Endostar is a modified version of EntreMed's Endostatin, the clinical trials of which were also abandoned (Jia 2007).

biopharmaceutical industry. Since the turn of the century, Chinese policymakers have initiated several changes in the regime to incentivize firms to step up their R&D activities. These initiatives include tax incentives, financial support for the application of international patents etc. (Kroll et al. 2010). Moreover, the recent third revision of the patent law, which went into effect in October 2009, has raised the penalties for patent infringements and clarified several inconsistencies in order to improve law enforcement (cf. Cheng 2009).

High-powered incentives have been applied as well to the science system comprising research universities and public research institutes. In the past years, pay schemes have been changed to include variable remunerations based on published papers and third-party funds. However, since evaluation and assessment systems are still immature, this has led to difficulties, which resemble those mentioned above. A number of misconduct cases have startled Chinese policymakers and the scientific community (Hao 2006). While most of the papers in the recent publication spurt are innovative, a number of researchers were accused of copying or fabricating data. Moreover, grants were given to well-connected researchers, since government funds for research projects are often not distributed on a peer-review, competitive basis.[8] As it appears, funds are thus often given on an ad hoc basis from high-level politicians. These issues are all the more problematic as a few government programmes account for the lion's share of government spending on innovation. One of the programmes, the National High-tech R&D Programme (863 Programme) targets the high technologies that also figure prominently in the 15-Year Plan. The Basic Research Programme (973 Programme), in turn, was initiated to improve basic research. Apparently, the fields of research outlined in the 15-Year Plan particularly considered in the review process. This, in turn, implies that a large share of the programme funds will be spent on the development and implementation of biotechnological knowledge.

3.3 The Regional Dimension

In the social sciences literature on China, China's political system has been often referred to as a quasi-federalist system (e.g., Montinola et al. 1995). Two decentralization phases during the pre-reform era (the Great Leap and the Cultural Revolution) effected a devolution of responsibilities over the local economies to lower-level governments. The fiscal reform of the early 1980s reinforced this tendency by assigning primary responsibility for revenue and expenditure to local governments (Whiting 2001). In this sense, the local state capacity discussed above is rather high in China's case. Local governments have their own fiscal income and can spend their revenue rather autonomously. Originally, even regulatory authority was devolved to the local level. But due to several problems already mentioned in the previous section, most of this authority has been recentralized in the late 1990s (Mertha 2005). The recentralization has however not led to a decline in the capacity to conduct industrial policy. Due to the local state capacity, distinct local varieties have evolved (cp. Krug and Hendrischke 2008), although institutional competition has caused some isomorphic change.

Local varieties distinguish themselves especially through local government strategy and social capital. Some of the governments – in particular those with rather small budgets at the begin of the reform era – have adopted a rather hands-off approach. This has not consistently produced positive results, because not everywhere appropriate social conditions prevailed. In local communities with a high density of personal networks, however, small enterprise clusters have evolved, which feature vibrant local markets supported by trust relationships (e.g., Walcott 2007). Due to the nature of capital markets, which are usually based on relationship lending between private individuals, the clusters are usually in less capital-intensive industries. Moreover, as most of the clusters are located in rural regions, the education level of the workers and entrepreneurs is rather low. As a consequence, entry is mostly in low-tech industries. However, possibilities to upgrade exist, as even in low-tech industries innovation is remunerated with higher profits. Some of the clusters are also interesting with regard to the biopharmaceutical industry. For example, from the TCM cluster in Tonghua (Jilin province), a few enterprises – most notably,

8 Peer-review procedures are however used with funds managed by the Natural Science Foundation of China (NSFC). These funds still account for a small share of overall appropriations for R&D.

Tonghua Dongbao and Tonghua Yujin – emerged, which have been evaluated as important protein therapeutic products manufacturers (e.g., BioPlan 2008).

Other regions with a higher number of biopharmaceutical enterprises and start-ups share however more similarities with the "new economy"-type agglomerations. In their case, emergent firms are mostly spin-offs from local universities and public research institutes. Unsurprisingly, these agglomerations are mainly concentrated in cities with a sound academic infrastructure, which provides the number of skilled workers required to start production in technology-intensive sectors such as biopharmaceuticals. Academic spin-offs are a major constituting element of clusters in Beijing and Shanghai, but also in other secondary cities with decent research facilities, e.g. Hangzhou (Zhejiang province) or Chengdu (Sichuan province). Entrepreneurship in these cities was initially the unexpected outcome of a policy introduced in the mid-1980s. Accordingly, budget appropriations for public research institutes were cut in order to forge science-industry linkages. But for several reasons – including weak IPR and limited interest by the predominant state-owned enterprises – the research institutes eventually opted to venture into business themselves (Eun et al. 2006). Several researchers seized the opportunity, as their income was rather modest at that time (cp. Zhou 2008). The success of entrepreneurial ventures, in turn, served as a model for further entrepreneurship. In fact, the observation of opportunities has increasingly attracted Chinese professionals, who have stayed in leading countries, in particular the United States, for extended periods of time to pursue advanced studies or work at major enterprises. Returned students – so-called "sea turtles" – are an important force in the development of China's biopharmaceutical industry (Frew et al. 2008).

Local governments have supported the new ventures very early on. One of the foremost initiatives is the Torch Programme launched by the Central government in 1988, which consists of the establishment of science parks. Gradually, specialized industrial bases were added. For the present contribution, the biotechnology industrial bases established since the early 2000s are of particular importance. Until 2007, 12 such bases were founded (Table 3), but recently ten further parks were added.[9] Although the Central government is responsible for the initiation of the programme, it is local governments, which have taken over the sponsorship and management of the parks. The involvement of the local governments has its strengths and weaknesses. On the positive side, local governments have been particularly eager to support these parks, as the development of high-tech sectors can be expected to yield higher tax revenue in the future. However, this expectation has led to a strong lobbying by the local governments to open their own parks. The 22 parks established so far are scattered around the whole country. Increasingly, local governments compete against each other for resident enterprises.

Table 3: China's Biotechnology Industrial Bases (2007)

City	Gross Output Value (Bn. Yuan)	Profit (Bn. Yuan)	Enterprises
Beijing	19.2	2.8	200
Shijiazhuang (Hebei)	28.0	1.6	270
Changchun (Jilin)	21.6	1.6	175
Shanghai	29.3	2.7	370
Guangzhou (Guangdong)	22.5	4.7	350
Wuhan (Hubei)	22.0	3.3	328
Changsha (Hunan)	24.2	2.6	310
Chengdu (Sichuan)	35.1	3.7	500
Chongqing	22.6	1.9	513
Kunming (Yunnan)	4.3	0.4	155
Qingdao (Shandong)	7.3	1.2	182
Shenzhen (Guangdong)	26.6	2.3	752

Source: NDRC and CSBT (2008)

9 The other bases are located in Xi'an (Shaanxi province), Tianjin, Taizhou (Jiangsu province), Tonghua (Jilin province), Dezhou (Shandong province), Zhengzhou (Henan province), Nanning (Guangxi province), Harbin (Heilongjiang province), Hangzhou (Zhejiang province), and Nanchang (Jiangxi province).

The nature of China's capital markets is a decisive variable in this competition for development chances. While China can be characterized as a rather bank-based system, the major (state-owned) banks are mainly serving established state-owned enterprises. Starved for capital, technology-intensive enterprises in the biopharmaceutical industry have developed several strategies to cope with their situation. One of the strategies is to enter the industry with less capital-intensive products, e.g. diagnostics tests. Moreover, some of the enterprises are producing other commodities to finance the development of their core products. For example, Shanghai GENON Bio-engineering sells animal protein products (Frew et al. 2008, author's own interview in February 2010). Even if they do so, they still need to secure financial capital. Local governments are an important source of capital. The strong involvement of local governments in venture financing is one of the idiosyncrasies of China's system (cp. White et al. 2005). But this feature has important implications for China's geography of innovation. In a sense, local government finance may have caused a de-clustering of China's biopharmaceutical industry. In their search for sources of finance, domestic companies have sought the help of several governments. As a consequence, many companies – despite their rather small size – have turned into multi-regional companies, which have manufacturing bases at sites other than their headquarters. Moreover, several academic spin-offs are not established at the location of the academic organization, but rather at the place of the investor, often a local government (Conlé and Taube 2010).

4 Conclusion

China's biopharmaceutical sector has rapidly increased in size. So far, much of this growth is due to biogenerics, which are simple to produce owing to mature production processes. However, scientific output indicators also show a strong increase hinting at a rise in innovative capacity. Most of the patenting activity occurring in China comes from universities and public research institutes, but biotech enterprises account for a gradually increasing share of patents. China's academic organizations, most of all twenty to thirty research universities and the research institutes of CAS, appear to be well-suited to support the development of science-based industry, including the pharmaceutical sector. While China seems to have a negative scientific specialization in biological fields, text analyses show that nanotechnology papers – China's strongest field – actually contain a rising number of papers belonging to the emerging field of nanobiotechnology.

Scientific output appears to be encouraging, but by analysis of other dimensions relevant for the development and use of biotechnology, bottlenecks to China's further development can be identified. Whereas a part of China's academia is at or close to the scientific frontier, commercialization of knowledge is impeded by several constraints in the national and regional domains. Most of the finest companies are start-ups involving domestic research staff or "returned students", which are not burdened by the same organizational evolution as China's large state-owned pharmaceutical companies. But their development is constrained by deficiencies in regulation and capital market structure. The first of the problems concerns the payoffs for innovation. So far, the regulatory environment rewards "me too" drugs, which outcompete alternative products in a fierce price competition. Recently however, the Chinese government has attempted to counteract by improving the patent system and introducing incentives for innovations through government procurement. But since the problems are not confined to a sector but to the whole (national) domain, the limited range of interventions may not produce the desired results. On the other hand, China's capital market is geared towards the financing of traditional state-owned enterprises. Although the Chinese government has also rendered great efforts to introduce an adequate venture finance system – e.g., in October 2009 ChiNext was opened as China's first Nasdaq-like growth board – it may not yet be enough to support this new capital-intensive industry. Moreover, the involvement of local governments in venture financing can be viewed as a transitional means to improve the situation. Yet, the local government's intervention appears to have the effect of de-clustering China's pharmaceutical industry. It remains to be seen whether the regional extension of the industry is supportive enough of knowledge exchange and innovation.

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