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Health Biotechnology Innovation for Social Sustainability – A Perspective from China

Yantai Chen and Adrian Ely

Biotechnology

Health Biotechnology Innovation for Social Sustainability - A Perspective from China

China is not only becoming a significant player in the production of high-tech products, but also an increasingly important contributor of ideas and influence in the global knowledge economy. This paper identifies the promises and the pathologies of the biotech innovation system from the perspective of social sustainability in China, looking at the governance of the system and beyond. Based on The STEPS Centre's 'Innovation, Sustainability, Development: A New Manifesto', a '3D' approach has been adopted, bringing together social, technological and policy dynamics, and focusing on the directions of biotechnological innovation, the distribution of its benefits, costs and risks and the diversity of innovations evolving within it and alongside it.

This is one of a series of Working Papers from the STEPS Centre

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Today's world is experiencing rapid social, technological and environmental change, yet poverty and inequality are growing. Linking environmental sustainability with poverty reduction and social justice, and making science and technology work for the poor, have become central challenges of our times.

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1. Introduction: Progress and Challenges for (Health) Innovation in China

Beyond the often-celebrated impacts on economic growth, China's opening up since the 1980s has also helped it to contribute more than any other country to the successful realization of the Millennium Development Goals. China's recent development has delivered millions out of poverty, and the current reforms to its health system have the potential to bring about the most significant single national increase in the provision of basic healthcare in the history of the world. The achievements are among the embodiment of the current administration's concept of the 'scientific outlook on development' (科学发展观), which hopes to link socially equitable and environmentally sustainable development goals. Premier Wen described the principles behind this concept in an interview in 2008:

> The number-one principle is to put people first. The second is comprehensive development, the integration of economic development with social development, the integration of economic reform with political reform, the integration of an opening-up and inclusive approach with independent innovation, and the integration of advanced civilization with traditional Chinese culture. Thirdly, we need to resolve the disparities - rich-poor disparity, regional disparity, and urban-rural disparity - in our country's developmental process. Fourthly, sustainable development: that is, to meet the challenges of population, resources, and environmental protection faced by a population of 1.3 billion in its modernization process (Wen 2008: 363).

The 'scientific outlook on development' has been understood as a Chinese version of 'inclusive development' by other Chinese authors working in the innovation studies field (Gu *et al*. 2010). This paper investigates the ways in which innovation studies can contribute to informing solutions to the challenge of inclusive development, focussing on the health sector, in which exclusion and inequity are particularly severe (Tang, S. *et al*. 2008).

Alongside its gradual integration into the world economy, China has not only accumulated a large stock of Foreign Direct Investment (FDI), delivered breathtaking growth over a sustained period and grown to become a leading force in global governance (as illustrated by the recent appointment of Chinese nationals to a number of top positions in intergovernmental organisations, including the World Health Organisation), but is also emerging as a key international player in Research and Development (R&D). Gross domestic expenditure on R&D in China has increased at an accelerating rate since 1995, and in 2006, it invested the third largest national sum in R&D (PPP) in the world after the US and Japan (OECD 2008). In 2010, China's GERD represented 1.75% of GDP (MoST 2011), and by 2020, the country aims to dedicate 2.5% of GDP to research and development (State Council 2006). At the same time, China's authorship of scientific publications also surged from 4% between 1999 and 2003 to 10% between 2004 and 2008 (Royal Society 2011) and now ranks second in the world (MoST 2011). In the biotech industry, a typical knowledge-intensive industry, there are also signs of fast growth. China has a long history in health biotechnology, being the only 'developing country' that participated in the human genome project. Recent growth in its global share of world publications in various fields related to health innovation are illustrated in Table 1 below (Adams *et al*. 2009).

The question remains, however, whether emerging innovation activities, largely led by foreign investment, will translate into longer-term indigenous innovation-led industrial development of a form consistent with China's objectives of a fair and moderately well-off (shaokang) society. In addition, the surge of innovation in China has great significance, not only for the benefit of its own large population, but also for sustainability and development in other parts of the world. For example, the country exports inexpensive pharmaceuticals around the world, and China's role in providing medical aid and support to sub-Saharan Africa is increasing (Ruger and Ng 2010). Have China's biotechnology advances to date had a positive influence on reducing poverty and disparities between rich and poor areas? To what extent might the country's newfound innovation capabilities contribute to solving these widely-recognised national problems and similar 'social sustainability' challenges at a global level? In this paper, we would like to make a brief exploration of these questions, drawing on data and case studies from China's biotechnology sector.

	1999-2003		2004-2008	
Field	Count	World Share (%)	Count	World Share (%)
Pharmacology and toxicology	2,259	3.11	6,614	7.28
Biology and biochemistry	6,697	2.66	15,971	5.86
Microbiology	921	1.38	3,863	4.74
Molecular biology and genetics	1,642	1.43	6,210	4.49
Immunology	493	0.87	2,114	3.51

Table 1. China's world share of publications in fields relevant to health innovation (1999-2008) (Adams *et al*. 2009).

The paper is organized as follows: In Section 2, a research framework for biotechnology innovation, sustainability and governance is put forward, which focuses on the idea of social sustainability and the global governance of biotechnology innovation. We then focus on the development of China's biotechnology sector and question its economic and institutional sustainability in Section 3. In Section 4, we turn to discuss the impact of biotechnology innovation on broader notions of social sustainability, focusing on the importance of health equity in China and adopting a '3D' approach. Then, in the final section, we try to explore the roots of the obstacles which prevent biotechnology innovation from contributing more to social sustainability objectives, and raise questions about how the governance of (biotechnology) innovation at national and international levels might be reorganized to overcome these obstacles.

2. Biotechnology, Sustainability and 3D Innovation Governance

2.1 Characteristics of the Biotechnology Innovation System

Studies of innovation systems at national and regional levels have pointed to the roles of specific institutions (and the linkages between them) in fostering the development, deployment and diffusion of innovations (Lundvall 1992; Nelson 1993, Freeman 2002). Similar ideas have been applied to the study of innovation systems at the level of sectors (Malerba 2004: 13-17). Biotechnology innovation systems possess certain characteristics that distinguish them from those of other sectors. This section describes these properties, and then introduces the concepts of social sustainability and innovation governance, providing the theoretical framework for this paper. The biotechnology sector is marked by extended linkages and networks between private entities, including relationships between pharmaceutical firms and smaller biotech companies. Research partnerships, alliances between private and public institutions and regional networks all incorporating network and knowledge links are essential elements (Preverzer and Tang 2006; Preverzer 2008). The EU-funded EPOHITE project distinguished four categories of actors within biotechnology innovation systems in Europe (Lacasa *et al*. 2004). Within each of these, linkages to other actors - both domestic and international – formed an important contributor to innovation capabilities in different countries. According to the report, the major players in biotech include:

• The public sector research organizations, including universities and research institutions.

• Biotechnology companies including domestic firms and overseas firms

• Venture capitalists (VCs)

• Government Agencies, including central, provisional and local levels

• Users: including the rich, middle-income and the poor

These interact within the biotechnology innovation system represented in Figure 1 below. This will act as the analytical framework for subsequent sections of the paper.

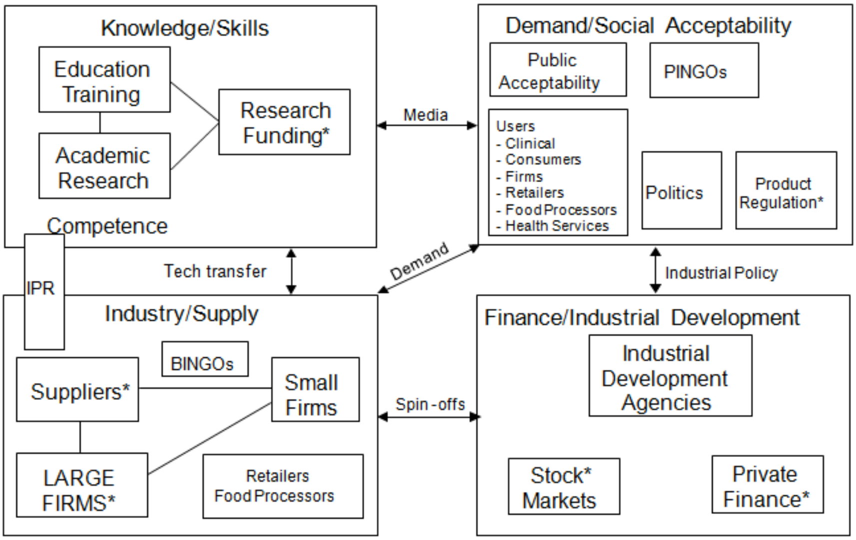

Figure 1. Research Framework of the Biotech Innovation System (Lacasa *et al*. 2004). * denotes international influences

A second fundamental characteristic of the biotech industry is its close link to basic science (McMillan *et al*. 2000). Scientists at biotech research institutes, universities and private companies regularly publish in leading scientific journals and file key patents (Murray 2002). Studies of the geography of biotech show a tight distribution of innovative small firms around star scientists (Zucker *et al*. 1998). Biotechnology start-ups often tend to cluster around research institutions, especially universities (Prevezer and Swann 1996).

A third characteristic specific to biotechnology innovation systems is the sectoral ecology (Lehrer and Asakawa 2004). The variety of skills needed to develop and commercialize the life sciences includes scientific, clinical, manufacturing, legal, financial, regulatory, marketing and distribution capacities. Basic scientific research is usually carried out by publicly funded universities and research institutions, development activities by large companies, and the search for new production techniques by small innovative firms (Henderson *et al*. 1999). There is substantial venture capital involvement and an active stock market for technological start-ups (Feldman and Romanelli 2006). Legislative innovations, legal expertise, and the rule of law have also played a vital role in enabling the growth of the biotechnology sector in leading countries such as the USA and Europe (Malinowski 2004). The roles of these actors and components of the biotechnology innovation system will be a key focus of the analysis in this paper.

2.2 Sustainability and Governance

The principle of sustainable development was first articulated in Our Common Future, the report of the Brundtland Commission (1987). Sustainable development can be seen as a process of change in the way that society is organized - closely related to how human societies have sought to alter the ways science and technology, economic growth and social harmony (as well as environmental protection) co-develop (Carter 2007: 207-8). Seen as an outcome, sustainability is seen to depend not only on the materials necessary for a good life, but also on good social relations and on the relationships between individuals, societies and their natural environment (Adger and Jordan 2009).

In 1987, Brundtland's definition of sustainable development as 'development that meets the needs of the present without compromising the ability of future generations to meet their own needs' (WCED 1987: 43), focused on two further concepts: 'the concept of needs, in particular the needs of the world's poor, to whom priority should be given', and 'the idea of limitations imposed by the state of technology on social organization and the environment's ability to meet present needs and cultivate further development' (WCED 1987:43). Whilst it did not separate out 'social sustainability', this term has been used since as shorthand for the two 'pillars' of sustainable development (other than environmental protection) highlighted at the 2005 World Summit (United Nations 2005). For the purposes of this paper, social sustainability relates to the goals of equity, cultural integrity and the preservation or provision of social support structures, including through just political systems that support human capabilities for social and economic development in the long-term.

Whilst many have tried to reduce (social) sustainability to simple indicators or metrics, this paper, does not see sustainability as an objectively determinate quantity, but as a concept that maintains 'the creative tension between a few core principles and openness to re-interpretation and adaptation to different technological, social and ecological contexts' (Kates *et al*. 2005). Sustainability is therefore an outcome of universal appeal but needs to be carefully thought about and deliberated upon (Adger and Jordan 2009).

Governance refers to those social activities which seek to 'guide, steer, control or manage' these activities (Kooiman 2003). Western literature describes the patterns that emerge from the governing activities of diverse actors in what is deemed acceptable norms of behaviour and divergent institutional forms (Ostrom 2005), the contributions of government, non-state actors such as businesses and non-governmental organizations (NGOs) involved in societal steering (Lemos and Agrawal 2006), aspects of governance at different spatial scales—international, national and sub-national (Cash *et al*. 2006). As such, governance for sustainability and development should be an interactive and reflexive process of debate and dialogue, which is equipped to deal with dilemma, disputable struggles and the risk of serious conflicts (Meadowcroft *et al*. 2005: 6-8). At the international level, scholars have focussed on international agreements, multi-lateral organizations and private organizations such MNEs as well as the UN system (Stiglitz 2004 2006; Michie 2003; Levy and Newell 2004; Glasbergen *et al*. 2007; Xue 2007; Adger and Jordan 2009)

2.3 Globalization and the Governance of STI for Sustainability

Globalization is characterized by the systematic reduction in the barriers to the cross-border flow of factors (labour, capital), products, technology, knowledge, information, as well as belief systems, ideas and values. Globalization arises alongside the growing complexity and reach of scientific and technological advances, and leads individuals, institutions and nations to widen their activities across national boundaries (Kaplinsky 2005). The process of globalization is affecting the production, distribution and transfer of technology (Bartlett and Ghoshal 1989; Dunning 1992; Ely and Scoones 2009). Technological globalization can be divided into three categories: the global exploitation of technology, global technological collaboration, and global generation of technology (Archibugi and Michie 1997), and the strategies developed by both government and business institutions to generate knowledge and technologies are extending beyond single country borders (Archibugi and Michie 1995). However, the majority of the world's new technologies are still primarily developed and utilized in industrialized countries. Mobilizing this knowledge to meet the agriculture, health, communication and environmental needs of developing countries will continue to be one of the most important issues in international relations (Juma *et al*. 2001). Globalization thus represents a major challenge to governance. Public institutions are traditionally held accountable to their nation-based citizens, while business firms are in theory accountable to stateless shareholders. Alongside continuing globalization, changes have occurred in social, cultural and political life, impacting local communities including nation-states, and lowering ties of national identity, citizenship and political sovereignty (Robertson 2003).

In the domain of health biotechnology, issues of 'social sustainability' have received a great deal of scholarly attention as new, emerging technologies raise different debates and political responses in various jurisdictions across the world. Without an overt focus on 'sustainability', Gottweis (1998) and Jasanoff (2005) have compared the political and regulatory debates around health and agricultural biotechnology in the USA and Europe. On the other hand, Torgersen and Seifert (1997) have focused directly on 'social sustainability' debates in relation to genetic technologies and the concept of 'sozialverträglichkeit' (social unsustainability or unbalanced burden on society or social groups) in Austria's Genetic Engineering Act.

At international levels, scholars have studied the role of existing and new biotechnologies in promoting international development (Daar *et al*. 2003), analysed innovation approaches aimed at groups not served by market mechanisms (Chataway and Smith 2006), and made arguments for further global health research on the basis of human rights (Pogge 2005). In the general area of science, technology and innovation, the STEPS Centre's New Manifesto (STEPS Centre 2010) has advocated institutional approaches to ensuring that science and technology contribute to social (and other forms of) sustainability through increasing transparency and accountability in STI funding, enabling broader participation in decision-making around support for research and development and for wider innovation policies.

Social sustainability concerns are at least as pressing to the Chinese Communist Party as environmental impacts of the current form of growth. Some international commentators, like Will Hutton, have argued that China's authoritarian approach to capitalism risks social unrest (Hutton 2011), echoing calls for significant constitutional reform from senior academics within China (Yu 2007a: 3). There are signals to indicate that these pleas are being heeded, at least in that the central committee intends the policy making culture to move to a more consultative mode (in addition to expanding the formal role of the Chinese Peoples' Political Consultative Conference). However, in the field of science and technology, fundamental deficits in transparency (for example around R&D funding decisions) and problems of public accountability remain. Although authors such as Sleeboom-Faulkner (2009; 2010) have discussed the ethical debates that have been witnessed in China around the governance of new medical technologies such as biobanks and stem-cell lines, and other scholars (e.g. Tang, S. *et al*. 2008) have discussed the challenges of health equity, the link between the country's health biotech innovation system and concerns of social sustainability have so far been relatively neglected in the scholarly literature. Even less studied are the policy processes and governance arrangements that relate to these areas.

From the 1990s 'global governance' emerged as the key term for international reform as well as a conceptual tool in political research such as environmental standard-setting, health and the reform of international institutions (Rosenau 1997; Held and McGrew 2002; Stiglitz 2003; Cogburn 2003; Dhar and Gopakumar 2006; Xue 2007). Institutionalist perspectives on international governance suggest that international institutions can deeply affect how states behave towards each other and stress the importance of international regimes - sets of principles, norms, rules and decision-making procedures around which actor expectations converge in a given area of international relations (Krasner 1983; Koenig-Archibugi 2002). Non-state actors, especially NGOs, business entities, and the staff of intergovernmental organizations (IGOs) can work together towards the resolution of public problems (Rosenau 2000). Regulations on global business follow industry self-regulatory practice more than the reverse, and multilateral IGOs can exercise influence by forging alliances, sponsoring research, mobilizing technical expertise, raising public awareness and playing a leadership role in negotiation (Archibugi and Pietrobelli 2003).

A typical example in the global governance of the science and technology domain is the World Trade Organization Agreement on Trade Related Aspects of Intellectual Property (WTO TRIPs), whose rules increasingly determine the health, agriculture, environmental, food safety rules of communities (Guzman 2004; Guzman and Simmons 2005) and to which we return later in this paper.

The STEPS Centre's 'New Manifesto' outlines a number of 'areas for action' for the global governance of innovation for sustainability, social justice and equitable development, focusing on what it calls a '3D' agenda. This agenda argues that current political debates around science, technology and innovation pay insufficient attention to the following (Stirling 2009):

- Direction – the direction in which science, technology and innovation are moving, rather than the scale (e.g. volumes of funding support) or the rate (e.g. publications or patents per year) of change;

- Distribution – the more equitable distribution of the costs, benefits and risks associated with innovations; and

- Diversity – maintaining or enhancing diversity in STI approaches to sustainability and development challenges, in order to avoid lock-in to unsustainable pathways, cater for seemingly irreconcilable perspectives and priorities and build resilience in the face of uncertainty.

In the remainder of this paper, we will draw upon the theoretical ideas outlined above, especially the characteristics of biotechnology innovation systems and the 3D agenda for innovation governance, in our analysis of China's health biotechnology sector.

3. China's Biotechnology Innovation System: Achievements and Challenges

Before discussing the social sustainability impacts of China's health biotechnology innovation system, we review some of the achievements that have been reached and challenges faced over the past thirty years in which it has emerged.

3.1 Achievements of China's Health Biotechnology Innovation System

China has experienced rapid growth in the biotech industry since 1996 when the Chinese government announced its policy of prosperity for the country through scientific and educational advances (Fang and Mu 2008). China's investment in research and development in the agricultural field has raised the question of whether it can be described as a 'biotech developmental state' (Keeley 2003), drawing on earlier analyses of East Asian industrialisation (White 1988). Extending their analysis to health and environmental sectors, Zhang *et al*. (2010) have also used the 'developmental state' model, contrasting it with public-private partnership and entrepreneurial models (drawing from Cook and Kwon's 2007 typology). They argue that the country has adopted a hybrid model, providing large amounts of funding to support public sector R&D, fostering cooperation between academia and enterprises, and gradually liberalising markets to generate internationally competitive biotechnology firms. The story of the evolution of China's (health) biotechnology innovation system is re-told here.

The modern Chinese biotechnology industry came into existence around the 1970s. From the beginning stage until the end of the 1980s, it was mainly based on research activities in the public institutions, and some biopharmaceutical firms were founded as spin-offs of universities and public research institutions (MoST 2008). From 1981 to 1985, government funding for biological research increased more than 25-fold, and new mechanisms were introduced to allocate resources by competitive peer-reviewed grants. During the seventh 5-Year Plan (1986-1990), the level and scope of biotech funding also increased rapidly. The State Council launched the ‘The National High Technology Research and Development Program of China’ (referred to as the ‘863 Plan’) in March 1986 (Fang and Mu 2008). A small number of academics established firms in this phase, contributing to linkages between research and industry.

From the mid-1990s China’s biotech industry policy shifted towards an entrepreneurial system. The policies included support for start-ups, drawing ‘returnees’ back from abroad (Chun Hui Programme of 1996) to create new ventures, stimulating science parks and industrial clusters, and establishing a venture capital industry. As the following section suggests, these processes are still in progress.

Research was driven by National Basic Science (973) and other programmes. Instead of merely transplanting Western science, China began to make use of modern biotechnology to solve national problems and to promote indigenous innovation (Chen *et al*. 2011). International biotech firms, attracted by China’s 1.3 billion consumer-markets and its low labour costs, rushed into China for manufacturing and acquired local knowledge, legislated patents, and set up R&D centres (Liu and An 2008).

Since China joined the World Trade Organization (WTO) in 2001, it has integrated more completely into the global economy. Accession to the WTO binds China to various principles, such as improved transparency and the strengthening of commercial legal procedures. China’s WTO commitments include the tightening of intellectual property protection, tariff concessions, and market access of non-Chinese service suppliers engaging in the distribution of biotech pharmaceuticals and other biotech products (Grace 2004). At this stage, biotechnology research and industry development in China entered a new era with the creation of a national biotechnology leadership group. Funding for biotechnology research came from two sources: government and enterprises. From 2001 to 2005, the Chinese government spent a total of about 10 billion CNY (approx 1.2 billion USD) on biotechnology research mainly through the Ministry of Science and Technology (MoST), National Science Foundation of China (NSFC), China Academy of Science (CAS) and relevant local governments (NDRC 2008). Among these, MoST administrated more than half of the government funding (Lakhan 2006).

The achievements of China’s biotech innovation system can be partially illustrated below in Table 2, which gives indicators of biotech innovation, including the number of SCI papers published, global patents and the growth rate of biotech patents in modern biotechnology. China’s number of global (PCT) patents accumulated from 1995-2006 is still tiny at only 1.7% of the world total, compared with USA (43.3%), Japan (14.1%), Germany (9.6%). But the annual growth rate of China’s global biotech patents is substantial (49.3%), much higher than leading countries, and even higher than other emergent countries such as India (30.4%), Russia

(19.6%) (NDRC 2008).

Country	Number of SCI Papers in Biotech Fields		Number of Global Patents in Biotech Fields		Annual Growth Rate of Biotech Patents from 1995-2006	
	Number	Ranking	Percentage (%)	Ranking	Growth Rate (%)	Ranking
USA	37,822	1	43.3	1	1.5	20
UK	7,565	2	5.3	4	2.8	19
Germany	7,497	3	9.6	3	10.1	6
Japan	6,298	4	14.1	2	8.2	9
France	5,172	5	3.6	5	6.3	14
Canada	4,194	6	2.7	6	5.2	16
China	1,481	13	1.7	9	49.3	1
Russia	1,019	17	0.2	19	19.6	4
India	789	20	0.8	16	30.4	2

Table 2. Publication and patenting of leading countries in the biotech industry, 1995-2006

Source:

(1) SCI paper data source: China Ministry of Science and Technology (2009)

(2) Patent data source is from OECD, PCT database, from: http://www.oecd.org/document/41/0,3746,en_2649_34451_40813225_1_1_1_1,00.html

(3) The data are accumulated numbers from 1995 to 2006

The number of biotech firms has also been increasing, thanks in part to the Chinese government's encouragement of entrepreneurship and attraction of Chinese returnees into the nascent biotech industry since 2002. In 2003, there were around 500 biotech firms in China according to an Association of German Biotechnology Company report (Tang, 2004, p.24). According to an OECD report, there are 158 biotech firms, 31 R&D institutions and 22 higher education in Shanghai alone (OECD 2006). However, the true size of the Chinese biotech industry (especially innovation-based biotech firms) is difficult to gauge due to two reasons: firstly, many companies label themselves as 'biotech firms' or are labeled as such since they are located in the high-tech park, but actually they are only involved in the processing of chemical components for pharmaceutical companies; secondly, most industry reports do not differentiate between 'pharmaceutical' and 'biotech' industries (Sternberg and Müller 2005). Numbers are further complicated by the emergence of the contract research organisation (CRO) phenomenon in the global biotech and pharmaceutical industry. With the increasing specialization and modularity of R&D, transnational biotech pharmaceutical firms have begun to outsource their R&D or clinical experimental work to these private organizations, which provide full-service pre-clinical testing and clinical trials. Proximity to these partners has been highlighted as one of the reasons for European MNEs to move R&D offshore (Ujjual *et al*. 2011). China attracted negligible outsourcing activities of this kind before 2000, but in 2001 it took 0.4% of the global proportion of clinical trials, and in 2006 it reached nearly 1% (NDRC 2008).

China's biotechnology industry has maintained relatively steady growth in outputs since 1995. The total value of outputs of the biotech sector increased rapidly and reached around 60 billion RMB in 2007 (nearly 8 billion USD) after expanding at around 19% from 2002 to 2007 per year based on the national statistics data (NDRC 2008). Value added and profits followed a similar growth pattern, as illustrated in Figure 2 below. Industry analysts have argued that the market for 'genetic biotechnology products' is due to increase enormously because of growing demand for medicine, consumer preference for lower costs, forthcoming patent expiries and regulatory reforms to promote bio-generics (Festel 2007).

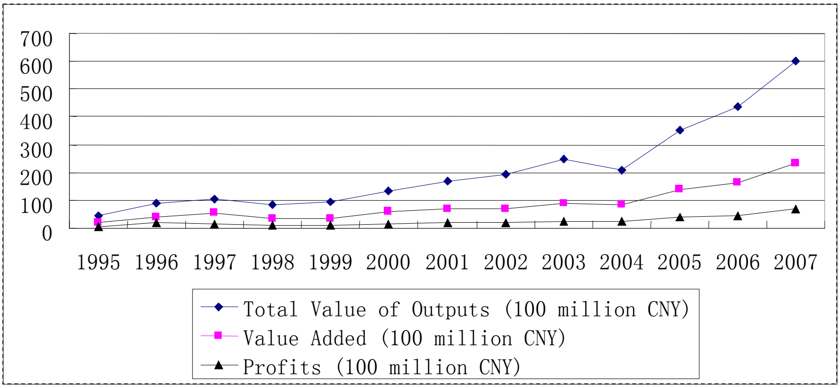

Figure 2. Total Value of Outputs, Value Added and Profits of Biotechnology Companies in China (1995-2007), source: China Statistics Yearbook on High Technology Industry (2001-2008)

3.2. The Challenges to (Sustained) Innovation in Biotechnology

China has been building capabilities for ‘indigenous innovation’ in biotechnology and other sectors, however there remain potential stumbling blocks to sustaining this process. On the basis of the system of innovation framework outlined above, these include challenges in the domain of creating truly innovative firms and providing ongoing finance to the industry. In addition, we briefly discuss issues relating to the demand side and social acceptability.

The history of China’s biotechnology/ pharmaceutical industry has been based around the production of generic medicines and to a large extent this continues. Liberalisation has led the number of firms in pharmaceutical production to increase substantially, although only a small minority of the firms produce anything other than copies or similars. The biotech market segment (which includes genetically engineered drugs, vaccines, antibodies and blood products) represents only 7.4% of China’s entire pharmaceutical industry, for which there are an estimated 130 million daily consumers. Total revenues of the entire Chinese biotech industry amounted to 5.62 USD billion in 2006, which is only 10% of US biotech industry revenues (53.5 USD billion) in the same period (NDRC 2008).

Although China’s R&D capabilities are now well-developed, challenges still remain in terms of converting knowledge to value through the activities of innovative firms. China needs to generate a much greater intensity and diversity of indigenous innovation. Discussing ‘developing countries’ in general, Bell (2009) points to the importance of complementarities between local innovation capabilities (especially design and engineering-focused capabilities) and both local R&D and technology imports. From the history of China’s biotech industry (as discussed above), it is clear that public policies have focussed on fostering R&D capabilities organized in central and usually public institutes like national centres and leading universities, with less attention given to strengthening the creation and use of complementary capabilities in production enterprises. In addition there has been a heavy concentration within firms on acquiring technology/ knowledge (or human resources in the form of overseas students returning to China) via imports from advanced economies, and less focus on creating and using their own complementary innovation capabilities. The government’s ‘Torch’ programme was initiated in 1989 to promote high-tech development, but was restructured as part of the Medium-Long Term Plan by integrating the functions of the government’s innovation fund for technology-based SMEs, and the China Technology Market Management and Promotion Centre. The new Torch Centre (Technology Transfer Market Administration Centre) now plays the role of making policies and providing ‘angel investment’ to firms, taking forward research from the country’s mega-research projects and 863 programme, through the ‘valley of death’ (the period between R&D and deployment where funding is traditionally very difficult to obtain) and towards commercialisation.

Patenting, as mentioned earlier, has been much slower to develop than the knowledge base itself, and, notwithstanding the limitations of patent statistics (Li 2008), this may be indicative of a time-lag in 'new to country' and 'new to world' innovations. Part of the reason for this lag in innovative performance is the poor linkages between firms and the research institutions that have excelled over past years. The country is trying to overcome this by promoting entrepreneurship amongst academics, with some successful results. In addition, various provincial governments have attempted to build 'high-tech clusters' by encouraging the geographical proximity of research institutions and firms in the same sector, however with limited success. Zhang *et al*. (2010) attribute the weakness of these initiatives to the state-sponsored R&D model, which promotes vertical rather than horizontal linkages.

For the Chinese health biotechnology innovation system to successfully deliver products and services contributing to social development, the availability of finance (including from private venture capital, industrial development agencies and stock markets) is vital. From a global perspective, whilst the 'knowledge/skills' component of the system appears well-developed, the Chinese venture capital investment in biotech companies is quite small. In China, venture capital invested in life sciences was only 315.8 million USD in 2007. This is less than 6% of that invested in USA in the same year and compares to a total of 8,064 million USD PPP venture capital investments in the life sciences for all 25 reporting OECD countries in 2007 (OECD 2009). In terms of products on the market, China's offerings are also dwarfed by activities in the larger markets. Until recently, the Chinese biotechnology industry's total product sales only accounted for less than half those of the major biotechnology firm Amgen in the United States (Zhang *et al*. 2010).

The financial strategies of China biotech companies are different from those of western biotech counterparts (Chen *et al*. 2011). The evolution of the US biotech trajectory has shown that venture capital plays a key role in financing biotech (Etzkowitz and Leydesdorff 2000). However, the stock market in China is relatively young and focussed on low-risk investments, so in general venture capital (VC) is difficult to come by. Most Chinese biotech firms receive funds from state-owned enterprises or government at different levels, ranging from central (e.g. the Ministry of Science and Technology often provides some initial funds through its 863 and 973 programmes) to provincial and local, or indeed from entrepreneurs themselves. Di Masi *et al*. (2003) estimated that the cost of developing a new drug and bringing it to market in the USA would average approximately USD 800 million over 12 years, necessitating huge long-term investment that government is incapable of delivering.

Looking beyond biotechnology, the pattern of total venture capital sourcing in China is illustrated below. Financial sources from government are limited and cannot ensure sustained investment over the longer-term (beyond the early R&D stage through to development and testing of drugs). Moreover, the government officials usually lack professional experience in VC activities, limiting their understanding of growth in the biotech industry and their ability to invest wisely. Private venture capital may even be afraid of government over-intervention in the future development of biotech companies.

Because China's private venture capital sector is still at an embryonic stage, Chinese biotech companies often adopt a 'hybrid business model', which means that these companies survive on selling biogenerics in order to develop profits that can be invested in R&D. This kind of hybrid business model can dilute entrepreneurial and financial resources, and is not necessarily favorable to overseas or domestic venture capital.

	Year	2003	2004	2005	2006	2007	2008	2009
Domestic Financial Resources (%) of which:		95	n.a.	66.1	56.3	44.4	50.6	53.9
	Government (%)	26.3	n.a.	31.9	33.6	24.1	25.2	21.8
	Financial Institutions (%)	6.3	n.a.	14.8	13.0	7.0	10.7	9.5
	Firms (%)	52.6	n.a.	46.4	44.9	53.5	39.7	44.7
	Individuals (%)	10.5	n.a.	3.0	5.7	10.5	19.3	23.5
	Other (%)	5.3	n.a.	3.8	2.7	4.0	5.1	0.9
Overseas Capital (%)		5	n.a.	33.9	43.7	55.6	49.4	46.1

Table 3. Financial Sources of Venture Capital in China 2003-2009. Source: Yearbook of China's Venture Capital Investment 2010 (Cheng 2010).

Table 3 illustrates that overseas sources of venture capital played an important role in China from 2005 and grew steadily before falling again around the time of the downturn in Western economies. Government's share of domestic venture capital began to fall after 2005, with venture capital from individuals showing a steady increase. Although we have no specific data on VC in the biotech industry, we have no reason to believe that the general trends seen throughout the VC sector are not similar to those seen within biotech. We will later discuss the possible impacts of these trends with respect to the directions of innovation. Firms and financial institutions have increased their share since 2005, but a strong trend is not visible over the period for which data are available, suggesting that up until that point the venture capital industry in China was still in an emergent phase, unable to provide the kinds of support that allowed the growth of the sector in leading countries. Whilst VC from individual sources has increased steadily, due to the short-history of the biotech industry in China, domestic venture capital is generally inexperienced and only able to provide funds, in the absence of the managerial support offered by angel investors and VC in more developed markets.

The size of China provides great potential for domestic firms, but the market is yet to be exploited. China accounts for 20% of the world's population but only 1.5% of the global drug market (Griesar 2011). China's changing health-care environment is designed to extend basic health insurance to a larger portion of the population and give individuals greater access to products and services. The creation of wealth (and generation of purchasing power) in rural areas is recognized as part of a broader need - acknowledged internationally as well as at home – for China to shift growth towards a model based on domestic consumption rather than inward investment and export.

One barrier to demand for the biotech products in China is the weak health system across the entire country. According to the Chinese Ministry of Health, there are only 1.5 doctors per 1,000 people (Ministry of Health 2007). The coverage of medical insurance has decreased from 90% in the early 1980s to less than 10% in rural areas, making it difficult for patients to afford cheap, generic drugs, let-alone biotech products, which have a higher price due to patent protection for pharmaceuticals – a relatively recent change in China's health system (Liu 2004). Until the early 1990s there was no patent protection for drugs and domestic pharmaceutical companies could legally copy drugs developed and patented in other countries. In 1993 China amended its patent law, added pharmaceuticals to the list of patentable subjects and passed another law that gave foreign companies seven and a half years of marketing exclusivity for pharmaceuticals that had been patented abroad over the previous six years, but had not yet been marketed in China (Van Zwanenberg *et al*. 2011). Protection of this kind has raised the price of biotech drugs for Chinese patients. Recent developments in the patent system are discussed in the final section of this paper.

Alongside these challenges related to the unaffordable price of biotech drugs for China's masses, China's domestically-produced products suffer from low levels of trust amongst consumers, who view overseas medicines as safer and of higher quality. The current regulatory framework for pharmaceuticals in China is a product of a series of reforms dating from the late 1990s and early 2000s, driven largely by accession to the WTO and by a desire for further global integration. A series of counterfeit drug scandals through the 1980s and 1990s (Dong *et al*. 1999) as well a number of scandals in recent years relating to cases of bribery or drug contamination (Jia 2008) have led to high profile responses. The former director of the State Food and Drug Administration was executed (Nature 2007) and in February 2007, top officials ordered an investigation into the functioning of the SFDA, including a review of over 170,000 production licenses issued by the agency over the past decade, particularly those issued between 1999 and 2002 (Barboza 2007). Concern within export markets has been great, and has led to the USA establishing offices of the Food and Drug Administration in China itself (Jacobs and McDonald 2008). Regulatory capacity and improved governance (including increased accountability and strengthening of the rule of law) are -

alongside the diversification of sources of finance and generation of a strong, domestic market – key ingredients in building an innovation system that leads to sustained benefits.

4. Addressing Social Sustainability Goals in China's Dynamic Health Biotechnology Innovation System

In this Section we turn to discuss social sustainability issues related to China's health biotechnology innovation system, focusing on the role of poverty reduction and health equity in China. We use the 3D agenda from the STEPS Centre's New Manifesto (described in section 2) – a focus on direction, distribution and diversity - to consider the social sustainability, impacts and implications of China's current health biotechnology and innovation system. This discussion focuses on the various components of systems of innovation as outlined in section 2 – knowledge/skills, industry/supply, finance/industrial development and demand/ social acceptability.

4.1 Direction – Biotech innovation for poverty alleviation

The first 'D' highlighted in the New Manifesto is that of direction – the direction in which science, technology and innovation are moving, rather than the scale (e.g. volumes of funding support) or the rate (e.g. publications or patents per year) of change. Taking the social sustainability focus adopted in this paper, the key issue here is whether the technologies that are emerging from China's biotechnology innovation system are directed at the alleviation of poverty in the country and the reduction of inequalities so prominent in political discourse.

The rapid progress in poverty alleviation in the two decades following opening-up and reform was uneven over time and across provinces (Ravallion and Chen 2007). Since that time, the GINI index of the country as a whole (measuring the degree of inequality in income distribution) has fluctuated, but the overall trend shows an increase of around 7% per decade, and the index is expected to reach 50% (implying high inequality) by around 2015 (Ferreira and Ravallion 2008). Disparities in health exist between urban and rural areas, between the costal and western regions, and between different households. Wealth has been shown to be a strong predictor of health-system coverage in China, and the inequalities in

GDP link closely to the availability of health services in different provinces (Liu *et al*. 2008). Box 1 provides more details of health equity issues in China.

Box 1. Equity issues in China's dynamic healthcare system

At the outset of the reform period in 1979, the Chinese government eliminated free primary healthcare (which had often been provided, although imperfectly, through the communes), leading most to purchase their own health insurance (unaffordable for many). Some have argued that an established right to social assistance could not have been so easily—and so swiftly—dropped in a functioning democratic society (Sen 2011). Official figures suggest that the life expectancy of developed regions such as Shanghai in 2000 was around 77 years, but 10 years lower in the poorest provinces (State Statistics Bureau 2006). Indicators for children's health also show substantial disparities. Rural infant mortality rates in poor areas are 123 versus 26 per 1000 livebirths in the wealthiest regions (Tang, J. *et al*. 2008).

These inequalities have risen to become a major political issue in China. The Ministry of Health issued a new policy in 2008 stating that 'Health is the cornerstone of comprehensive human development…assurance of health equity is now regarded as the key parameter for the social justice and fairness in the country. ...Accessibility of basic medical and health care services is a basic right of the people' (Tang, S. *et al*. 2008). In response to the spiralling cost of healthcare in the wake of market reforms, insurance-based support, or direct support for the poorest patients, has emerged. In the rural Chinese context the primary insurance scheme for rural residents is the New Cooperative Medical Scheme (NCMS) administered by the Bureau of Health. The NCMS was launched in 2002, with combined financing from both government and individuals, and provides a fixed annual sum that families can draw upon to pay for healthcare at village and township healthcare facilities. Any remaining costs are paid for out of pocket, however research has suggested that the scheme has not reduced out-of-pocket expenses, and has pointed to remaining problems with the NCMS, especially for the poorest or chronically ill families (which show lower enrolment) (Wagstaff *et al*. 2007). However, reforms are continuing, with the NCMS and a parallel urban insurance scheme aiming to achieve universal coverage by 2020 (Dong 2008).

Directions of health innovation in the West, and more generally in liberalized economies, tend to suffer from the 90/10 gap – 'where 90% of all medical research is targeted at problems affecting only 10% of the world's population' (Chataway and Smith 2006). Innovation directions are thus profit-driven, largely focusing on the needs of wealthier markets and treatment (of diseases of consumption) rather than prevention. It is worth evaluating whether the experience of China since reform and opening up suggests alternative directions of research and innovation that might be better-equipped to respond to the needs of China's enormous rural (and urban poor) populations, who continue to suffer from high levels of infectious disease, among other complaints.

In discussing directions within the context of China's heavy investment in research, it is worth understanding how the state has come to set the R&D priorities for biotechnology in China. Government and scientists have dominant roles in the decision-making, with the State Council setting overall priorities, the Ministry of Science and Technology (MoST) (through various research programmes), National Science Foundation of China (NSFC) and Chinese Academy of Sciences (CAS) setting programmatic themes for research and selecting projects for funding support. The approach of priority-setting in China thus follows what appears to be a top-down, directive format, as illustrated in Figure 3 below (Zhang *et al*. 2010). Yet, at the same time, the Chinese government has reportedly made some efforts to encourage public engagement in science and technology, including in policy-making. These include suggestions through the internet on how the country should rebuild its science and technology by 2020 (Jing 2003) and similar consultations on the reform of the health system (Van Zwanenberg *et al*. 2011).

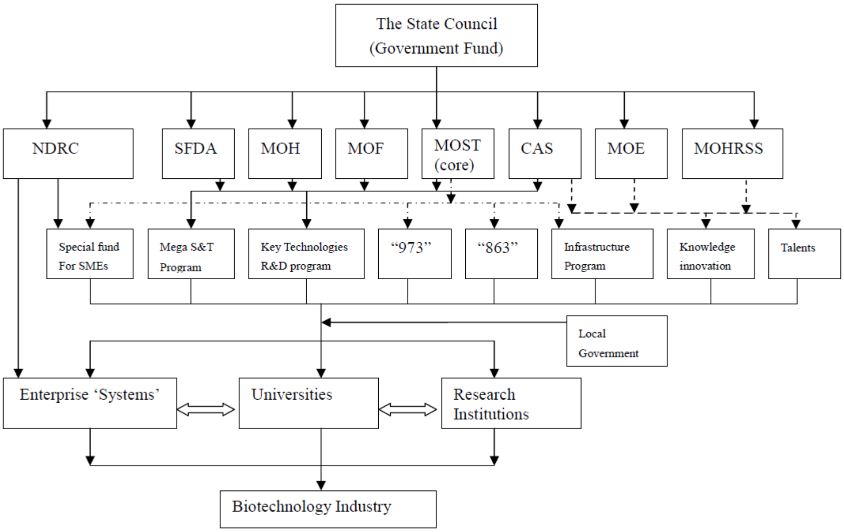

Figure 3. Biotechnology and development management system in China adapted from Zhang *et al*. 2010, based on data from the China National Centre for Biotechnology Development (see http://www.cncbd.org.cn) and interview with MOST official, 25/8/2011.

Note: within China's national biotechnology investment system, the State Council has overall responsibility for the distribution of funds. The Ministry of Science and Technology (MOST) plays the dominant role in guiding research priorities through supporting national programs including the 973 and 863 infrastructure programmes and Special Fund for SMEs. In some national programs (e.g. the Mega Science and Technology Program and Key Technologies R&D Program), MOST works as the dominant ministry alongside Ministry of Health (MOH), State

Food and Drug Adiministration (SFDA), China Academy of Sciences (CAS). The Chinese Academy of Sciences (CAS), Ministry of Education (MOE) and Ministry of Human Resource and Social Security (MOHRSS) work together with MOST to support the Knowledge Innovation program and to cultivate talents. The National Development and Reform Commission (NDRC) plays an important role in enhancing the commercialization of research within the biotechnology industry through its support of SMEs and enterprise systems at different levels.

The government itself has dedicated significant resources to research into health challenges faced by the poorer sections of the country's population. The Guidelines on National Medium- and Long-term Program for S&T Development (2006–2020) include drug innovation and control of major emerging infectious diseases within a broader portfolio (State Council 2006). Biotechnology is identified as one of eight frontier technologies identified in the plan, and five strategic areas within it are illustrated in the table 4 below (Yu 2007b, p. 136, as cited in Zhang *et al*. 2010).

Strategic area	Details
Drug target discovery	Functional characteristics of key and disease-related genes: drug target screening and validation
Animal and plant models and drug design	Analysis and integration of bio-information drug design and metabolism; computer-assisted designs, syntheses, and screening of compound libraries based on combinatory chemistry
Gene manipulation and protein engineering	Chromosome structure and site-directed integration; design and manipulation of protein-coding genes; polypeptide chain modification; structure solving; scaled protein purification
Stem cell-based human tissue engineering	Therapeutic cloning, directional differentiation; in vitro construction of structural organs and production; construction and damage repair of complex organs with multiple cell types
New generational industrial biotechnology	Scaled screening of functional microbes; modification of bio-catalysts and industrial production; bio-conversion media and systems for industrial operation

Table 4. Strategic areas of biotechnology specified by the Medium- and Long-term Science and Technology Development Plan (compiled from Yu 2007b, taken from Zhang *et al*. 2010)

Prevention and control of HIV/AIDS which together affected nearly a million Chinese in 2007 (Zhang *et al*. 2008), viral hepatitis, which afflicts 20-30 million patients in China (Zhang *et al*. 2010) and other major infectious diseases are a key priority for the government (Wang *et al*. 2008). As such, their inclusion in two of the 'Megaprojects' emerging from the Medium to Long-term Science and Technology Development Plan (Cyranoski 2008) was no great surprise (even if the process of eliciting proposals was rushed). The key question is whether these investments in research will enable the required directions of innovation in firms across the country – one which, again, requires a systemic view.

Linkages between research institutions and firms in China have often been described as weak, creating difficulties for knowledge generated in universities or academies to be commercialized (Prezever 2008). The government has implemented a number of reforms to try to overcome these obstacles, including incentivizing entrepreneurial activities within research institutions through enabling them to patent their inventions (Liu and An 2008). However, aside from the funding offered under the 863 programme, the government offers little support for taking products to the market, and pro-poor research struggles to generate interest from the private sector (hampering commercialization). At the same time, linkages between firms are limited as well. Interactions between small 'dedicated biotechnology firms' and large (pharmaceutical) firms have been shown to be key to the emergence of a mature biotechnology sector in other country contexts (Kenney 1986; Saviotti 1998). Currently, China is devoid of large pharmaceutical firms with the finance and focus necessary to purchase or forge strategic alliances with small biotech start-ups, leading to a continued dominance of innovation directions set by multinational firms.

The trends outlined in the section above on 'challenges' show that VC investment in China has begun to move away from that provided by government towards the private sector. Without a mandate to serve equity objectives, it appears more likely that this sustained funding will contribute to a 90/10 gap similar to that seen in other parts of the world. As outlined above, much of China's biotechnology industry exists in the form of contract research organisations. By definition, it is unlikely that the priority focus of these organisations relates to locally-determined health challenges, and more likely that their efforts have been dedicated to innovation serving overseas markets (in what has been described as 'internal brain drain' - Singer *et al*. 1970) or, if they are contracted by large domestic firms, wealthy markets within China. In a study of MNEs carrying out R&D in China, Ujjual *et al*. (2011) found that some of them were using these centres to develop products specifically for the Chinese market, however by-and-large for diseases of the wealthy.

Domestic Chinese firms may play a more significant role in innovating for poorer markets in China. The Chinese-educated entrepreneurs and returnees who often lead these firms illustrate that 'brain drain' is not the whole story. It is estimated that over 1.3 million Chinese students have gone abroad to study since 1978, over 30% of which have been in the field of biotechnology or related areas (MoE 2010), suggesting that this 'brain circulation' may have a continued role to play in the longer term. Returnees (especially from USA and EU) have played a significant role in contributing to the development of modern biotechnology innovation in China since the year 2000. There has been a favorable environment for returnees to set up their own business in returnee parks (high-tech zones set up deliberately to attract back Chinese talent that had worked overseas) or to work in universities and public research institutions (People's Daily 2011). The Chinese government launched the 'Thousand Talents' programme in 2008, and attracting returnees is still a high priority for the top leadership (Royal Society 2011). From the perspective of 'direction', however, it can be argued that the skills and specialisms that are brought over to China from abroad focus, again, on the treatment of diseases that are most prevalent in wealthier markets overseas. Public health benefits as a result of preventative approaches are a direction that the returnee trend is unlikely to enhance.

4.2 Distribution – Geographical and between Social Groups

The second 'D' highlighted in the New Manifesto (STEPS Centre 2010) concerns the equitable distribution of benefits, costs and risks associated with new innovations. We have already discussed the distribution of healthcare and health equity across China, however there is no data available (to our knowledge) that allows us to ascertain the distribution of impacts from China's innovation activities. Instead, we use some of the data available to investigate the distribution of different parts of the health biotechnology innovation system across the country as a way of understanding the country's approach to fostering equitable distribution of benefits from biotechnology innovation.

In political documents, the focus is clear. The 12th Five Year Plan for Science and Technology (MoST 2011) includes a section devoted to strengthening technology for the people's livelihoods, in which it focuses the first part on accelerating the development of health technology, and enhancing the capacity of national health protection. A number of traditionally marginalized groups (women, children, the elderly and the disabled) are highlighted in particular, as is a focus on the prevention of common diseases and appropriate technologies for healthcare in rural areas (MoST 2011). But beyond the rhetoric, to what extent is the innovation system configured in a way that is likely to serve these innovation goals?

As discussed above, linkages between research institutions, firms, finance and markets are all key to effective biotechnology innovation systems. In investigating whether China is likely to generate more equitably-distributed health innovations than those seen in the West, it is therefore worth looking at current patterns of innovative activity (imperfectly recorded through patent-metrics) across different parts of the country. Since 2000, the number of all the biotechnology inventions patents applications filed in China increased from more than 414 applications in 2000 to 2482 in 2007. Empirical evidence shows that innovative activities are not distributed evenly across the country, with Eastern China being highly innovative while other areas demonstrate comparatively less patenting activities (see Figure 4).

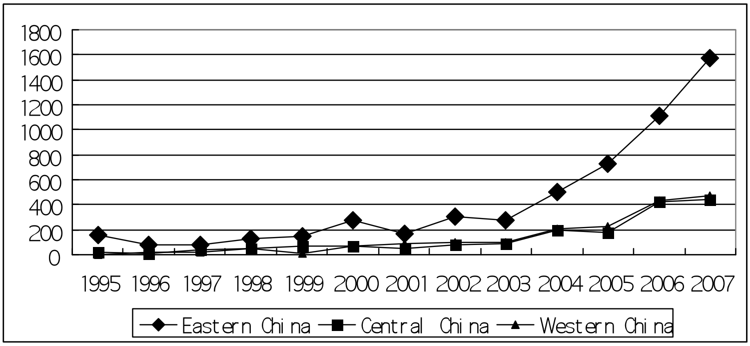

Figure 4. Number of Inventions Patents Owned by Pharmaceuticals Firms in China (1995-2007), source: China Statistics Yearbook on High Technology Industry (2001-2008).

In the Yangtze River delta, Shanghai, Jiangsu and Zhejiang contributed to 20.3% of all medicine invention patents for the 1995-2007 period: Shanghai (4.62%), Jiangsu (9.64%) and Zhejiang (6.02%). In China, these three regions accounted for nearly 34.75% of all medicine invention patents in biotechnology according to the Chinese statistics on high-technology (MoST 2008). According to the Chinese Patent document retrieval system (http://www.patent.com.cn), the top five geographic regions by number of applications - Beijing, Shanghai, Guangdong, Jiangsu and Zhejiang - account for around 60% of all the Chinese biotechnology applications by all types and respective categories (see Table 5)

Location	Biotechnology Applications in General	Biotechnology Pharmaceutical Applications	Biotechnology Fermentation Applications	Biotechnology Diagnosis Applications
Beijing	3543	949	425	1130
Shanghai	2903	792	496	1204
Guangdong	1938	464	207	544
Jiangsu	1792	321	297	644
Zhejiang	1162	213	239	417
Top five regions (Total applications)	59.7%	60%	56.7%	63%

Table 5. Geographic Distribution of Patent Applications in Biotech in China (2003-2007), source: SIPO, Chinese Patent Document Retrieval System. From: http://www.patent.com.cn

Note: With regard to biotechnology patent typology, the main International Patent Classification (IPC) classes selected from SIPO databases were A61K (pharmaceuticals), C12N, C07K (microbiology, gene and enzyme), C12Q, G01N33 (biotech diagnosis), C12P (biotechnology fermentation), C10G3, C12P7 (biotech energy), (MoST 2008).

As well as ownership being distributed unevenly across the country, there is a changing balance between domestic application and foreign applications. Between 2002 and 2007, domestic inventions patent applications grew rapidly, while foreign inventions patent applications showed a more stable pattern (see Table 6), suggesting that relative control over the technology was moving slowly towards domestic firms. Within the international patent category IPC A61 (biotechnology), one of the most important sub-categories (A61K - pharmaceuticals) showed a high concentration of patenting activity for both domestic and foreign patents applications.

	Year					In total
	2003	2004	2005	2006	2007	
Total Application	5642	5885	6988	7951	8707	35173
Domestic Application	3287	3353	4285	4826	5502	21253
Foreign Application	2355	2532	2703	3025	3205	13920
Patents granted	2280	1897	1685	2676	3213	11751
Among them: Biotechnology Pharmaceutical (A61K)						
Domestic Application	865	863	1110	1091	1663	5592
Foreign Application	943	1008	1028	376	675	4030
Patents granted to Domestic	390	339	311	277	418	1735
Patents granted to Foreigners	157	49	38	19	29	292

Table 6. Foreign and Domestic Biotech Patent Applications in China (2003-2007), source: SIPO, Chinese Patent Document Retrieval System. From: http://www.patent.com.cn

Note: Biotechnology patents were categorized by International Patent Classification (IPC) classes selected from SIPO databases. 'Total Application' refers to all main classes of IPC: A61K (pharmaceuticals), C12N, C07K (microbiology, gene and enzyme), C12Q, G01N33 (biotech diagnosis); C12P (biotechnology fermentation); C10G3, C12P7 (biotech energy). In this analysis, we compare this total with the category of pharmaceuticals, i.e. the category of A61K from the IPC of SIPO database.

We have looked at the geographical location of investments and ownership as an indicator of whether innovation is taking place in China's poorer areas, however distribution is not just a geographical matter – huge inequalities exist between social groups within China's diverse society and urban/rural differences are acute. Market demand for biotechnology products is currently weak in China, where more than 35% of urban households and 43% of rural households are struggling to afford health care. Exacerbating this situation are remaining inefficiencies in the health system. It is estimated that most hospitals derive 40-60% of their revenue from prescription sales, hospitals remain the main outlets for distributing pharmaceuticals in China (CCID Consulting 2009). Distribution channels in the rural and marginal regions are dispersed and small-scale, making it more challenging for small-scale Chinese domestic biotech firms to reach this huge market. At the same time, current arrangements for the new health system reforms do not improve the situation. Within the insurance schemes described above, different provinces have their own essential drugs lists, but more expensive (patented) biotech drugs are rarely supported. Under the 2009–2011 Action Plan on China's Healthcare Reform (which aimed to extend free primary healthcare to rural areas), the government announced its intention to develop a national list of essential drugs that would be produced and distributed under government control and supervision and would be available at all public health facilities and retail drugstores from 2009 (The Central People's Government 2010). It is unclear whether this national list could be used as a tool for driving Chinese innovations serving poorer markets, or even serve as a tool for future problems that are likely to emerge in China before other parts of the world (e.g. through the use of advance-market commitments, discussed below). One such problem is that of antibiotic resistance amongst micro-organisms causing infectious diseases. Clearly, as discussed in Box 2 below, market signals have been insufficient to incentivize private sector R&D in this field over recent decades. In partnership with the international community, China has a role to play in incentivizing innovation in this area in order to avert a possible impending public health catastrophe.

Box 2. Case Study – Innovation for combating antimicrobial resistance in China

Widespread use and misuse exists worldwide, and increasing rates of microbial resistance to antibiotics have become a major public health problem, not only in low and middle income countries, but also in high income countries (Cars *et al*. 2008). Globally, only two new classes of antibiotics have been developed in the past 30 years, and research and development into new antibiotics is decreasing

(Infectious Diseases Society of America 2004).

Antibiotics are the most commonly prescribed medicine in China, accounting for 30–50% of all drug consumption (Xiao *et al*. 2008). Work by Zhang *et al*. (2006) indicates that China has more severe antimicrobial resistance and more rapid spread of antimicrobial resistance (22% average growth in a study spanning 1994 to 2000) than both Kuwait and the United States. Based on the surveillance results from 17 tertiary hospitals located in 15 cities in China, Xiao *et al*. (2008) concluded that antibacterial resistance in China is more serious than North America and Europe, for example stating that about 65% of the Escherichia coli strains were resistant to fluoroquinolones in 2004–2005.

Historically, antibiotics were freely available through barefoot doctors (Zhang and Unschuld 2008) or over the counter at public and private health facilities, until a notice was issued by the State Food and Drug Administration (SFDA) on 1 July 2004 which ordered that antibiotics should not be sold without prescription. Studies have shown that over-the-counter sales of antibiotics continue, and that operating under perverse incentives, private clinics still often provide unnecessary and expensive antibiotics in order to maximise profits within the privatised health system. These patterns of overuse threaten to increase medical costs and accelerate antibiotic resistance, whilst raising the risk of hospital infection with resistant strains and potentially undermining the very drugs on which so much modern medicine relies.

Research in rural Hubei and Shandong (Jin *et al*. 2011) suggests that Chinese citizens expect the government to take care of problems of antibiotic resistance. Whilst promoting (and enforcing) rational use of antibiotics is obviously an urgent and vital step in this regard, the need for international investment in a new generation of these drugs is also clear. China's growing biotechnology capabilities and large population (over-) relying on antibiotics, suggests that the country should take a more proactive role in global innovation efforts to overcome the problems of antimicrobial resistance. The application of innovative financing mechanisms to provide incentives for firms to invest in this area are a possible area for future research and policy discussion.

4.3 Diversity – TCM and public health approaches

China's unique national history as the world's oldest continuous civilization, and the country's multiple ecologies have resulted in a great diversity in health conditions and responses (Han *et al*. 2008). China's research portfolio has historically tended to focus efforts within core programmes, driven by national priorities (IDRC/SSTC

1997) and, as illustrated by some of the programmes described above, continues to current times. Diversity has not been a key consideration in the setting of these priorities, however as well as the relatively homogeneous ‘international’ directions covered in earlier sections, a considerable amount of diversity exists in the Chinese health research system.

One area that contributes to the diversity of China’s health biotechnology research system (and contributes significantly to the diversity of the global health research portfolio) is that of traditional Chinese medicine (TCM). China has, more than any other ‘developing’ country, used its rich traditional pharmacopoeia in modern research programmes. The importance and potential of TCM has been recognized since Mao’s time, when the leadership promoted the continued use of TCM, for example within the barefoot doctor system. Recent investment in research (including a number of universities dedicated to TCM and the application of modern biotechnologies to TCM treatments) have tried to take a more integrative approach, and the modernization of TCM using biotechnological methods such as high-throughput screening provides opportunities for candidate drugs to be identified faster, improving the efficiency of product development in Chinese firms working in this area (Zhang *et al*. 2010). The benefits assist not only the Chinese population, but have also made significant global impacts.

A number of examples exist, perhaps the most celebrated of which is the use of artemisinins to treat Malaria (Pandey *et al*. 1999). These drugs, developed from Artemisia annua (used for centuries in traditional Chinese medicine), are now the most common group of drugs used to treat the disease across the African continent. However, they are also threatened with resistance problems. This prompted worldwide efforts to rationalize use and improve formulations (for example through including them in combination therapies) in order to delay the obsolescence of these life-saving drugs (Arrow *et al*. 2004), although artemisinin-resistant malaria has already been identified in South East Asia. Long-term stewardship of medicines is also a challenge faced by China’s dynamic health system in respect to antibiotics (discussed below). International interest has led to the development of new drugs from TCM knowledge. The Institute of Microbiology of the Chinese Academy of Sciences has engaged in strategic alliances with international partners to develop new treatments for TB, partnering with the US-based ‘Global Alliance for TB Drug Development’ (Hille and Jack 2009).

Some argue that the focus on individual active ingredients detracts from the holistic approach that traditionally characterizes true TCM[1], which is based on a deep philosophical notion of balance (Tang, J. *et al*. 2008) and which is lost when doctor-patient interaction is reduced to prescription (or more often rendered obsolete through the availability of OTC drugs). Nevertheless formulations of

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[1] Interview with scientists from Institute of Traditional Chinese Medicine, Guangdong Pharmaceutical University, 4th August 2007.

raw materials (e.g. powdered plant material encased in capsule form), as well as pills containing isolated or synthesized active ingredients are common within different sectors of China's health system. In 2006, the TCM sector provided care for over 200 million outpatients and some 7 million inpatients, accounting for 10% - 20% of health care in China (GOSATCM 2006 cited in Tang, J. *et al*. 2008). Challenges to technological upgrading in the development of traditional medical knowledge and integration within the Chinese biotechnology industry also include the difficulties involved with trials for efficacy and side-effects (Tang, J. *et al*. 2008) and ongoing reforms in product regulation (especially with regard to internationally harmonized pharmaceutical standards). However, despite these challenges, MNE representatives have stated that they are 'just one step away from TCM-based products being launched on the global market' (Wilsdon and Keeley 2007).

Beyond the focus on high-tech, product and service innovation, China has also pioneered a number of social and organizational innovations in its health system. Reformulating incentive structures, creating new institutions and introducing new financial arrangements have taken place possibly because of the activities of different stakeholders in the co-construction of an effective health system (Bloom 2011). At the same time, infrastructural development, for example through the development of an online disease surveillance system (Han *et al*. 2008) has played an important role. Community health-workers that were refashioned as 'barefoot doctors' in rural China (Zhang and Unschuld 2008) have been used as a model for taking healthcare to the poor in other countries. The focus on capacity-building in rural settings is not so great within the new systems of healthcare being developed in China, and training local doctors remains a challenge (Zhang and Unschuld 2008).

At the same time, China has been slower to invest in public participation in the health system (e.g. through public health education). Although the government does support educational programmes/ propaganda on state-television and radio, low levels of public understanding are recognized as a challenge. Disease prevention through infant immunization was also somewhat neglected during the 1990s (Liu *et al*. 2008). This kind of preventative healthcare, which does not produce such direct impacts on GDP as sales of curative therapies, has been highlighted as lacking by scholars evaluating China's health system (Liu *et al*. 2008).

5. Opportunities for enhancing ‘3D’ health innovation in China

In drawing upon the preceding discussions and considering the future opportunities for enhancing ‘3D’ health innovation in China, this section is divided into three parts. The first part analyses the situation in China and discusses how its contribution to a ‘3D’ agenda for social sustainability might be enhanced. The second looks at the international context and discusses governance changes at the global level which may also help these domestic changes. The final section points towards innovation studies research that has analysed government and non-government approaches to enhancing pro-poor innovation, and suggests possible future research options around similar questions in China.

5.1 Enhanced participation and Market Creation for Biotechnology Innovation in China

Leach and Scoones (2006) have argued that ‘innovation should not only focus on technology itself, but also on the social, cultural and institutional relationships that will enable the technology to work.’ To make existing technologies accessible to people living under the poverty line thus requires both technical and social interventions. ‘To enable poor people to make use of technologies that may be available, but are poorly understood, often requires culturally appropriate communication strategies, improving people’s knowledge and power to make technology choices’ (Leach and Scoones 2006). When considering national innovation systems, it’s vital to extend the ‘hardware’ of R&D infrastructure and capabilities to the social and political relations among many actors, and the different interests that shape science and technology (Leach and Scoones 2006). As illustrated by the earlier discussion of governing innovation for sustainability, providing these different ‘interests’ with opportunities for an ongoing dialogue around sustainability goals and objectives forms part of the ‘process’ of sustainable development. Government-funded research, and the increasing dominance of the private sector in innovation may prevent technology from following pro-poor directions, while the involvement of a broader set of actors in the innovation system (including in the setting of research priorities and engagement in product development and commercialisation) may help to open up possibilities for alternative pathways (Stirling *et al*. 2007). More networked and inclusive forms of technology assessment can help to build capabilities throughout innovation systems and promote understanding of these different pathways (Ely *et al*. 2011). Civil society can also play a significant role in governance at national and international levels. International organizations, scientific experts, and non-governmental organizations (NGOs) can add critical and alternative voices (Scholte 2007). Emerging arrangements such as public-private partnerships (PPP), publicly-funded initiatives and private technology entrepreneurship in poor regions, as well as innovative approaches to 'inclusive regulation', for example around intellectual property, are advocated by Leach and Scoones (2006).

Increased access to information is opening up opportunities for citizen engagement around science and technology in China, whether through the formal media or through online discussions. Developing countries, like China and India, are facing challenges for building civic infrastructure and citizen engagement. They have different incentives and barriers, often suffering from a lack of a viable institutional framework, civic infrastructure, cultural differences, time pressures and poverty (Denhardt *et al*. 2009). Whilst China's traditional governance mode does not lend itself to broader participation in decision-making around directions of research and innovation, gradual political reform offers the possibility for stakeholder and citizen engagement – for example through technology assessment activities - to contribute to a '3D' agenda. Facilitating networks around biotechnology development and deployment is one way that the government can help to establish contacts and linkages between different stakeholders working in the field. Examples from elsewhere, such as the Indian-led Open Source Drug Discovery initiative (OSDD), have drawn upon public-private collaboration and the voluntary contributions of students and researchers to deliver remarkable results in the search for TB drugs (Massum *et al*. 2011), a challenge that could also benefit many of China's rural areas. Similar experiments in China have not, to date, been explored.

Citizen engagement can enable poorer sections of society to articulate their needs more strongly than traditional market signals allow them to do so. At the same time, however, there are many ways in which facilitating inclusion in markets and supporting the institutions around them can help to improve health services (Bloom *et al*. 2009). Expanding domestic biotech product demand is an imperative for the Chinese Government (not only in health but throughout the economy). Strengthening health systems infrastructure and distribution mechanisms can form the basis for part of this demand, whilst at the same time responding to the urgent challenges around health equity described above. Government should increase support to clinicians and facilities in rural or isolated regions, and scarce-resource urban regions. As Liu *et al*.'s (2006) study on health care in China shows, the private sector or non-government providers tend to serve the low-middle income class in China, with relatively lower costs and higher consumer satisfaction. This is another channel of reaching potential consumers and expands the biotech product demand. However, this non-government solution tends to be self-organizing, and requires timely regulation – another reason to involve these kinds of stakeholders in governance processes.

Analysis of pro-poor health innovation initiatives involving the biotechnology industry in the West (only mentioning China's role in terms of CRO involvement) points to the challenges of translating promising research on neglected diseases in the lab to impactful innovations in the field (BVGH 2007). As discussed above, although research in fields of relevance to China's poorer populations is ongoing, institutional mechanisms are not necessarily in place to ensure that they will be commercialized. Market-pull incentives are urgently required.

A fundamental restructuring of the payment system, reducing the high out-of-pocket payments and expanding broad insurance coverage is already underway (Hu *et al*. 2008) and is of great significance to China's Biotech product demand. The opportunities for co-ordinating across different areas of China (e.g. through a national essential medicines list), thus linking this huge demand at the bottom of the pyramid (Prahalad 2004) to the biotechnology innovation system presents possibilities for supporting not only indigenous but also pro-poor innovation. Subsequent improvements in health amongst rural populations over the longer term could increase their capabilities to contribute to the country's development in an ongoing, virtuous cycle. Similarly, as discussed above in the case study of antibiotics, market signals need to be created to drive innovation that responds to future health needs. The possibility of extending the use of essential medicine lists to act as a tool for incentivizing innovation (for example in conjunction with advance market commitments) needs to be investigated.

5.2 Global Governance to Enhance Biotech Innovation Systems in Developing Countries

Global science and technology governance is complicated by severe coordination problems. Within a liberal multilateral trading system, these arise as nations compete to seize the perceived 'first mover' advantage and to encourage firms to locate within their borders. This leads to 'hyper-competition' which wastes money, human resources and other resources and create systemic friction (Stone 2008). Problems of co-ordination can also contribute to threats of neo-techno-nationalism, orphan public goods, and nationalistic backlashes to the accelerating emergence of global innovation networks (Ernst and Hart 2008). In the area covered by this paper, as with global innovation governance more generally, a more co-operative approach involving international collaboration networks needs to be enhanced (Chen *et al*. 2011), and institutional innovations are required in order to promote and co-ordinate research and innovation for global public goods. The STEPS Centre's New Manifesto proposes an international body - a 'global innovation commission' - which could contribute to these requirements.

At the same time, existing institutions are in need of reform in instances where they discourage innovation for social sustainability goals in developing countries. The global biotech industry is governed to a significant extent by the Agreement on Trade-Related Intellectual Property Rights (TRIPS) under the World Trade Organization (WTO). Current intellectual property arrangements are not conducive to promoting innovation in pro-poor technologies or enhancing access to these technologies in developing countries (Abdelgafar 2001; WHO 2001). After China entered the WTO in 2001, it adjusted its IP regulations to comply with the TRIPS agreement. As a result of the TRIPS regime, the need to maintain multiple patents across various countries is extremely expensive and emerging biotech firms from countries such as China struggle to access the market even in the domestic setting. Some transnational companies even set ‘patent traps’, taking advantage of their dominant international patents in developing countries like China (Frew *et al*. 2008). This creates enormous challenges for Chinese biotech firms both in the international and domestic market.

The third amendment to China’s patent law already made some innovative changes that went beyond the scope of TRIPS, for example requiring the reporting of providence when a patent relies on the use of genetic resources (Zhu *et al*. 2008). In addition, the latest amendment allows compulsory licenses for drugs protected under Chinese patents on the basis of a ‘national emergency or any extraordinary state of affairs … or where the public non-commercial use so requires’ (following the Doha Declaration) or on the basis of public health, for export to the least developed countries or countries that have insufficient capacity for the manufacture of the drug. Whilst it should not be used as a tool for unfairly supporting domestic biotechnology firms, this clause could in theory serve health equity concerns either in China or elsewhere. Under conditions of increasing antimicrobial resistance, for example, the need to prevent increasing healthcare costs might necessitate the compulsory licensing of more expensive, patented antibiotics not usually affordable to China’s poorer patients. The current patent regime creates a number of conflicting pressures, in some cases both incentivising irrational use (in order to maximize profits whilst patents are in force) and disincentivising investment in new drugs (when IP protection or license payments are in question). In this particular case, there is an urgent need for international co-ordination, beyond the current activities of the WHO to include intellectual property reform and institutions to foster innovation towards this global public good.

There are crucial challenges to fostering public health and supplying basic treatments for diseases prevalent in developing countries, but these fail to receive the resources and support that their nations urgently need (Xue 2008). For instance, only 11 out of 1,223 new pharmaceuticals developed between 1975-1996 were for the treatment of tropical diseases, according to WHO. This is partly due to perverse incentive mechanisms and partly due to the weak capability in developing countries themselves. The current global governance framework also hampers the development of biotech companies in developing countries, which are perhaps best-placed to respond to challenges faced by their populations. From a Chinese perspective, the continued dominance of multinational firms hampers efforts to provide affordable healthcare to the country's poor. More accountability and responsibility of the transnational biotech firms around providing access to basic biotech products, should be encouraged (Greve 2008) and firms that contribute proactively, for example by opening up research databases (Nature 2010) should be rewarded. Regulatory frameworks and the role of international institutions, particular the TRIPS agreement are also a key concern (Juma *et al*. 2001). Finding ways of balancing the cooperation between developed and developing countries, whilst assuring that the incentives for innovation are not undermined is key, and more research is required to understand how health equity can be promoted by global governance frameworks (Pogge 2005).

5.3 Conclusions and Future Research Possibilities

This paper identifies the opportunities and challenges of China's health biotechnology innovation system for social sustainability in China and beyond. R&D capabilities have improved significantly in China over the past decades, but with a concentration in leading universities and research institutions, and alongside insufficient collaborations and linkages between different players in the National Innovation System. Further investigation is required to better understand how pro-poor research generated in laboratories can best be translated to the market, given insufficient demand-pull incentives in many cases. Government procurement of innovative products from domestic biotech firms for the benefit of poorer patients, strengthening health system infrastructure and distribution channels to ensure the availability of innovative health-biotech products to the poorer patients, and working with non-government providers to construct supplementary distribution channels, are all relevant to harnessing China's enormous but untapped market and contributing to the growth of the domestic biotech industry. China's huge population presents not only an advantage in the marketing of drugs, but also their development and testing (Li *et al*. 2004). However, this advantage has not been leveraged to the full possible extent. The potential for linkages between the dynamic health system, currently undergoing radical reforms, and the nascent biotechnology sector, remain under-investigated. Lessons from China could contribute a great deal to our understanding of biotechnology policies, supplementing information from other developing countries around science, finance, ethics, society and culture and politics (Daar *et al*. 2007). Targetted case studies may provide a way forward – for example through investigating the economics of specific neglected diseases (or problems like antibiotic resistance) and the potential financial tools available to promote innovation towards their prevention and treatment.

Biotech innovation in China is still concentrated and depends largely on returnees and international firms – primarily in the East of the country. At the same time, multi-national firms still dominate, driving the sector towards innovations serving wealthy overseas or domestic markets and maintaining a hold over intellectual property. More research is required to document the innovation focus of domestic and international firms from different parts of the country, and to look into mechanisms for enhancing the more equitable distribution of resources to parts of China's innovation system that are currently lagging but are well-placed to serve marginalized communities. The diversity of China's investment in various health paradigms (including in traditional Chinese medicine) could be better-understood by analysis using measures of disparity and diversity metrics (Stirling 2007). Civil society groups do not currently participate in knowledge creation, technology development or policy-making for biotech research, which are largely driven by government and elite scientists. While opportunities for including such groups in decision-making are limited, more participatory forms of technology assessment might provide interesting insights to the kinds of contributions that non-governmental actors could make. New models of international science collaboration are required, but with a renewed focus on co-ordination across countries and firms to enhance the production and sharing of global public goods knowledge. As China becomes an ever more important player on the global innovation scene, collaborative social science research is also important to inform policies at national and international levels, and foster understanding across national borders. Readjusting the global governance regime, balancing the impacts of IPR regulation between developed and developing countries and making timely adjustments to domestic regulations, are of vital importance for the social sustainability impacts of biotech innovation in developing countries like China, and more globally.

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