Biomedical innovation and the geopolitics of patenting:

China and the struggle for future territory

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Introduction

In pursuit of the People's Republic of China's grand strategy of 'independent innovation' (*zi-zhu-chuang-xin*), on 5th June 2008 its State Council published the *Outline of the National Intellectual Property Strategy* (State Intellectual Property Office (SIPO), 2008). Within this document there is a clear statement of global political intent based on a particular understanding of the contribution intellectual property (IP) ownership can, and should, make to innovation and thus to China's position in the knowledge economy. Given economic globalisation, it argues, 'intellectual property is becoming increasingly a strategic resource in national development and a core element in international competitiveness, an important supporting force in building an innovative country and the key to hold the initiative in development'. Developed countries, the Strategy notes, 'make full use of the intellectual property system to maintain their competitive advantages'. If developing countries are to compete effectively on the global stage they must do likewise (SIPO, 2008).

IP therefore forms a key part of the ambition vigorously stated by President Hu Jintao at the opening of China's Fourth National Conference on Science and Technology in January 2006, where he emphasised China's need to 'adhere to a new path of innovation with Chinese characteristics and strive to build an innovation-oriented country' (China.org.cn, 2006a). His message was clear. In a rapidly changing global market, China could no longer rely on the economic advantages afforded by a cheap labour force which exploited the inventions of others. Instead, if it is to retain its international competitive advantage in the context of the economies of the developed world, China must rapidly develop an indigenous science and technology platform with the capacity to establish its own innovative directions, exploit its own intellectual capital and establish its own new industries. President Hu's message was subsequently incorporated into the 11th Five Year Plan 2006-2010 and the range of policies flowing from it (China.org.cn, 2006b). Biomedicine and the development of new health technologies are a key feature of that Plan.

Developed countries are similarly preoccupied with the requirements of successful innovation. From their perspective it is a question of how to respond to the challenge posed by the emerging economies of countries such as China to their traditional leadership of scientific innovation. Thus the United Kingdom's (UK's) White Paper *Innovation Nation* analyses the global nature of science and innovation, the international trend toward open innovation where new knowledge and ideas are shared, commercialised, capitalised and traded and the policies that will enable the UK to access the 'global value chain' from basic science to commercial product (Department of Innovation, Universities and Skills, 2008). The report is particularly exercised by how the intellectual property system can enable businesses to 'capture value from innovation' (DIUS, 2008: para 4.35). Meanwhile, in the United States (US) the Obama Administration's 2009 *Strategy for American Innovation* recognises that 'the greatest job and value creators of the future will be activities, jobs, and even industries that don't exist yet today.' It observes: 'The countries that catalyze their development will reap the greatest rewards.' (Executive Office of the President, 2009)

The common political concern of developed and developing states alike is the policies that will provide them with the platform for negotiating a strong position in the knowledge economies of the future. As states respond to this concern, so a new geopolitics of resource control is being born partly based on speculative calculations regarding the nature and value

of the future knowledge territories and the resources within their boundaries. While the traditional global competition between nations for the control of resources necessary for industrial development such as energy supplies and raw materials is based on a reasonably sound understanding of their geographical location, value, and accessibility, little such information is available about the knowledge economy territories that lie in the future of scientific and technological development. Whilst it may be confidently asserted, for example, that the life sciences in general constitute one such economy, precisely which of the current streams of life sciences research will produce sustainable biovalue through commercialisation cannot be predicted with any certainty. In this situation the direct targeting of future territories takes on the character of a political gamble. States involved in the futures competition therefore seek to hedge their bets by generating an innovation capacity capable of adapting to opportunities as they arise.

Patenting policy is a central part of this approach because without intellectual property ownership the ability of any state to exploit the value of the future knowledge economy will be limited. In an era of globalisation, state boundaries are inherently porous to flows of knowledge and finance and the capture of the value generated by innovation is heavily dependent on ownership. In this context, the question this paper addresses is how far China's strategy on patenting will enable it to achieve its ambition of challenging the global hegemony of the US in the field of biomedical innovation to achieve competitive advantage. It begins by examining the politics that underpin the globalised system of patenting and patenting governance within which China's strategy is necessarily located. What is the balance of power in that system and to what extent does it restrict or facilitate China's ability to manoeuvre in its own interests? Secondly, the paper analyses the nature of US dominance in the patenting domain in general and of biomedical innovation in particular. Thirdly, it explores the basis for China's challenge in this domain and its implications for the control of future health technologies.

States, globalisation and the governance of invention

Innovation in biomedicine is a global enterprise. As governments of all persuasions search for ways of fostering innovation, so they are obliged to recognise that governance intervention at the level of the individual state is but one component in the political equation, one that needs to be matched by policies that deal with the international and collaborative character of biomedical innovation. Research materials (such as oocytes and embryos) are part of a global tissue economy (Andrews and Nelkin 2001; Waldby and Mitchell 2006); clinical trials are increasingly outsourced as part of the pharmaceutical industry's global strategy (Cooper, 2009; Petryana, 2006); financial institutions make their investment decisions on a global basis (Kenney *et al* 2007); industrial interests are continually prospecting for new information on human and non-human biological material that can be commodified and traded (Parry 2005); and definitions of international intellectual property rights in biomedicine are frequently challenged at political sites such as the World Intellectual Property Organisation (WIPO) and the European Patent Office (EPO) (May and Sell 2005; Salter 2009a). State level governance must therefore engage with international and global forms of governance in its search for efficient modes of improving access to the innovation value chain.

However, historically some types of states are better prepared than others for the political task of influencing the composition and implementation of these transnational governance forms and the rules they embody. In the advanced economies of the North America and

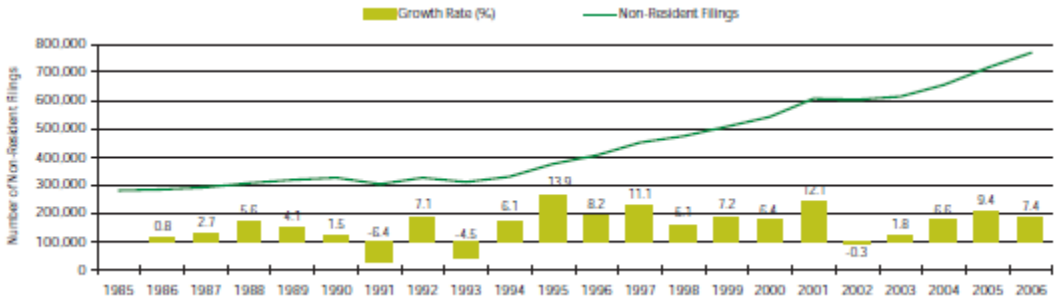
Europe, the general uncertainties accompanying the shift from Fordist to post-Fordist modes of mass production and consumption is seen to have been met by the rise of the 'competition' state as the vehicle for the pursuit of national advantage in a globalised world (Cerny, 1990, 1997; Hay, 2004; Hirsch 1991). Rather than concerning themselves with government interventions to ensure full employment and respond to market failures, states began to focus their attention instead on the neo-liberal supply-side policies that would give a sharp edge to their competitiveness in the global knowledge economy. Particularly in the case of the knowledge driven bio-industries, this meant a concentration not only on the infrastructures of innovation but also on 'agglomeration and network economies and the mobilisation of social as well as economic sources of flexibility and entrepreneurialism' (Jessop, 2002). In contrast to this, shaped by a different historical experience and lacking the scientific critical mass and innovation infrastructures of competition states, the states of the developing world chose a different approach. Focusing in the main on South Korea, Taiwan, Japan, and to some extent Singapore, in the 1980s and early 1990s, the earlier work on the 'developmental state' highlights its role in the promotion of rapid economic development through the targeting of particular industries with large global markets. The markets were already there. The political task was to penetrate them. To achieve this goal, the state protected its chosen industries using a range of policies such as import and credit controls, promoted them through state investment, guided private capital through incentive schemes, and measured their progress in terms of export achievements (Applebaum and Hendersen, 1992; Hawes and Liu, 1993; Onis, 1991). In essence, their commonality is that they sought to challenge the control exercised by the developed world over the dynamic of globalisation.

However, having 'caught up' developmental states are now aware that their traditional modes of direct state intervention do not suit the innovation requirements of the next global wave of knowledge economies with a speculative future, an uncertain market and a difficult path to commercialisation. As a consequence, observers have noted the evolution of developmental state governance into new forms described variously as the 'adaptive state', the 'flexible state', the 'post-industrial developmental state', the 'transformative state' and the 'catalytic state' in their studies of Japan, South Korea and Taiwan (Weiss, 1998; Kim, 1999; Wu, 2004). As Wong observes of biotechnology in Taiwan, it is a case of the state identifying 'the right mix of public policies aimed at facilitating technology innovation and knowledge-based interventionist strategies' and recognising that 'cutting edge technologies can no longer be borrowed; rather they must be created' – which means a change in state direction and an investment in, or access to, basic science (Wong 2005: 169-70). In moving from borrowers to innovators, developmental states are also obliged to review the nature of their engagement with global forces.

As a key element in the generation of future knowledge economies, patenting exemplifies the globalised trends of practice and governance with which developmental states must interact. In its 2009 *Patent Statistics Manual*, the Organisation for Economic Cooperation and Development (OECD) commented on how inventive activities are increasingly organised at the international level through 'global value chains': 'Inventions made by researchers residing in one country can be funded and owned by foreign companies, companies from different countries can join their resources to sponsor research, and researchers from different countries can cooperate on inventions' (OECD, 2009b: 126). Evidence on this trend is apparent in the increasing proportion of patents in total inventions worldwide characterised by cross-border ownership (having at least two inventors located in different countries), co-invention (at least two inventors located in different countries) and co-ownership (at least two

co-applicants located in different countries) (OECD, 2009b: 129). Other data from the international Patent Cooperation Treaty (PCT) filing system confirm this globalising trend in patenting: the non-resident filings share of total patent filings increased from 35.7 per cent in 1995 to 43.6 per cent in 2006 (Figure 1 - World Intellectual Property Organisation (WIPO), 2008: 31).

Figure 1
Trends in total non-resident patent filings, 1985-2006



As the globalisation of patenting practice has become steadily more marked, so it has been matched by the development of a transnational form of patenting governance characterised by a continuing conflict between the interests of developed and developing world states. Three international bodies constitute the political sites for this conflict through their attempts to promote the international harmonisation of patenting rules: the United Nations' (UN's) World Intellectual Property Organisation (WIPO – established in 1967), the World Trade Organisation's (WTO's) Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) and the European Patent Office (EPO). The creation of TRIPS in 1994 by the Final Act of the Uruguay Round of the General Agreement on Tariffs and Trade (GATT) was in large part a response by developed countries, and in particular the United States, to the manoeuvrings of developing countries within the WIPO during the 1970s and 1980s seeking to resist international encroachments on their sovereign intellectual property rights. TRIPS drastically limited their political space in two ways. First, it tied membership of the WTO (which most developing countries wanted and needed) to agreement on TRIPS. (Currently 153 states are members of the WTO and therefore signed up to TRIPS). Second, it set detailed and mandatory harmonising standards of intellectual property law on the ownership of two major technologies: digital technology and, importantly, biotechnology (World Trade Organisation, 1994; Drahos with Braithwaite, 2002:10-17).

It is inevitable that states at different stages of economic development and consequently with their own particular approaches to the exploitation of the innovation value chain will place different political demands on global patenting governance. Thus developing nations with burgeoning health manufacture sectors, like India, Argentina, Brazil, and Turkey, initially sought to protect their own industries from the force of US and European patents embodied in the operation of TRIPS. At their insistence, TRIPS contained a 10 year delay for the

institution of pharmaceutical and agricultural chemical patent protection in developing countries. Subsequently, the arguments have continued, propelled not only by conflicting economic interest but also by the impact of HIV/AIDs on the public health needs of developing countries in terms of their need for access to inexpensive ARV drugs (Cullet, 2003). The collision between developed and developing countries on this issue was highly visible in the negotiations leading up to the 2001 Doha Declaration on the TRIPS Agreement and Public Health which, although it maintained the obligation of members to adhere to the basic TRIPS rules, also confirmed that 'the TRIPS Agreement does not, and should not prevent members from taking measures to protect public health' (Johnson and Wasunna, 2007: S16). In the years following Doha, the patenting governance debate has been marked by rival interpretations of the Declaration by developed and developing countries, each seeking the pursuit of their national advantage.

Some states are better equipped than others in their efforts to interpret and exploit the flexibilities within the transnational governance domain of TRIPS. It is not a level governance playing field. Policies to optimise the potential benefits of the complex TRIPS provisions require an investment in the appropriate legal skills training, the administrative infrastructure of patenting, and intergovernmental coordinating structures with related policy areas such as health and trade (Johnson and Wasunna, 2007: S19). Governments will also be influenced in their approach to patenting by their local political environment and, in particular, by the position within this of their domestic pharmaceutical industry: its degree of development, its capacity for innovation, its relationship with international pharma and the extent to which health activism impacts on its strategies (Shadlen, 2004a and 2004b). As a result, the way in which developing states respond to TRIPS in their formation and implementation of national patenting policies varies and to an extent undermines their ability to act as a unified political force at WTO level against the interests of developed nations. Different developing countries play different patenting games.

Brazil and Mexico, for example, manifest marked differences in their approach to IP management and in their actual and threatened use of compulsory licences (where a government compels the patent owner to license the exclusive rights of production, importation, and distribution) as a tactical political instrument in support of their domestic pharma industries and public health needs (Shadlen, 2009). In India, meanwhile, the introduction of TRIPS has been treated as an opportunity rather than a threat with the well established drug industry increasing its investment in R and D, and planning for innovation as a vehicle for expanding its global markets (Chaudhuri, 2005). Indian firms have focused in particular on reverse engineering drugs that are nearing the end of their patent terms, obtaining United States Food and Drugs Administration (FDA) approval for their products and increasing their exports to the US and other regulated markets in the developed world (Chaudhuri, 2008: Sampath, 2005). However, it is worth noting that the reason India's indigenous pharma were able to take this aggressive approach to the exploitation of the opportunities offered by TRIPS was because of the long term and continuing government support for India's scientific infrastructure. Many developing countries lack the resources to adopt this approach and so benefit from TRIPS.

What they do have in abundance are genetic resources capable of providing the platform for research and subsequent commercial exploitation. Given the appetite of Western biotechnology for access to such resources, from the perspective of developing countries it is important that they should be able to establish and protect their ownership of these resources

in order to benefit from them. This natural imperative then impacts on the transnational politics of patenting governance and the already existing tensions between developed and developing countries. The primary governance vehicle for this imperative is the Convention on Biological Diversity (CBD) which came into effect in 1993. Although the CBD's original purpose was the preservation of biological diversity, its provisions include the protection of states from 'biopiracy' by international biotechnology and pharmaceutical companies. With regard to genetic resources, the CBD stipulates that each country has sovereign rights over its natural resources (Article 15, Paragraph 1), that access to genetic resources requires the prior informed consent of the contracting state providing the resources (Article 15 paragraph 5), and that measures shall be taken with the aim of sharing in a fair and equitable way the results of research and development based on genetic resources, and the benefits arising from the commercial and other use of genetic resources, with the contracting state (Article 15, Paragraph 7) (United Nations Environment Programme, 1993). However, as a mechanism for the governance of transnational knowledge ownership, it lacks the political clout of TRIPS, backed as that is by the authority and sanctions of the WTO. As of January 2010, 193 states are parties to the Convention but the United States, despite having signed the CBD in 1993, is not one of them because, it can be assumed, it is not in the interest of its biotechnology industry to become so aligned. Nor does the Convention provide any specific mechanisms to enable benefit sharing to take place. Attempts by developing nations to inject Convention thinking into the operation of TRIPS (for example through the imposition of a requirement for patent specifications to specify country of origin of their knowledge base) have met with a frosty response from the Japan Patent Organisation (JPO) and the US Patent and Trademark Office (USPTO) in the corridors of the WIPO (Shimbo *et al*, 2008: 646).

In the absence of effective transnational governance to protect the biomedical knowledge resources of developing countries, some states have made their own interventions at national level. Thus the Indian Biological Diversity Act 2002 renders the access of foreign companies to biological resources, or to the results of research on biological resources, in India dependent on the approval of the National Biodiversity Authority (NBA). Furthermore, the NBA's approval is also required for the filing of any intellectual property rights derived from such resources and the Authority can impose benefit sharing and royalty conditions including requirements for the sharing of benefits arising from the commercial use of intellectual property rights (NBA, 2010).

Hegemony and challenge in biomedical innovation

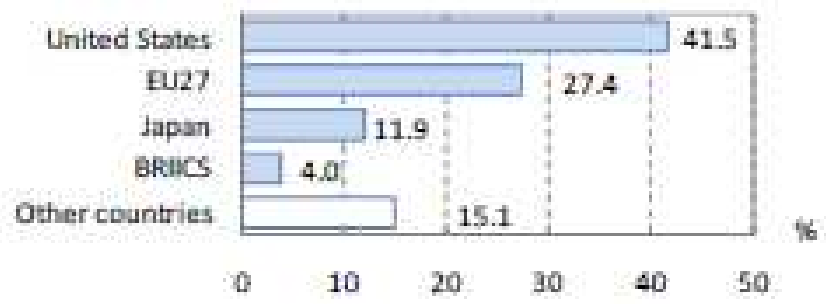
The drive by some developing countries to establish a patenting governance platform for a competitive entry into the global biomedical economy collides with the reality of US hegemony in biomedical innovation. So, for example, in announcing his Executive Order on 9th March 2009 removing the rules limiting research on human embryonic stem cells funded by the National Institutes of Health (NIH), President Obama was at pains to emphasise that in terms of the national interest his intervention was designed to enable 'America to lead the world in the discoveries it [stem cell science] may one day yield' and counter the fear that other 'countries may surge ahead of ours in the advances that transform our lives' (The Oval 2009). US dominance in global biomedical innovation, it would seem, is not to be challenged. It is a view predicated upon a particular neo-liberal model of innovation underpinned by an infrastructure of supporting domestic policies for the governance of science, society and the market: policies that need to be continuously translated into transnational form if the hegemony of the US in the world bioeconomy is to be maintained

(Cooke 2001). The US approach to patenting forms an important part of that transnational enterprise.

America's powerful mix of federal, state and private funding for biomedical science resonates easily with its dominant model of how the governance of innovation in the biotechnology industry facilitates the movement from basic science to commercial product (Salter 2010). In place of a federal led programme there is instead a market emphasis on the facilitation of a close engagement between academy and industry (Shorrett *et al*, 2003). Beginning in 1980 with the Bayh-Dole Act and the Stevenson-Wydler Act, the US government permitted universities, non-profit organisations and SMEs to appropriate knowledge resulting from research financed with public Federal funds. This then encouraged commercial enterprises to invest venture capital directly in university-based biotechnology research via sympathetic university-based intellectual property regimes and public-private partnership research funding (Mowery and Sampat, 2004). In the same year, in its decision on *Diamond v Chakrabarty*, the US Supreme Court ruled that a living organism (in this case a bacterium of the genus pseudomonas modified using molecular techniques) could be patented. In general, it commented, patents could be granted for 'anything under the sun that is made by man' and in this respect living organisms are not exceptional as long as they are made by man. Through these two actions, the US state created a permissive patenting regime with the capacity to support and enhance its ambitions for a global biomedical industry (Rai and Eisenberg, 2004). As a result, university technology transfer offices in the US focus on helping their scientists to patent their findings, identify private investment opportunities and negotiate advantageous intellectual property agreements with their scientific partners in developing countries (Forero-Pineda 2006).

The global effect of an approach that encourages existing knowledge production to adjust to the uncertainties of future commercialisation in biomedicine is clearly evident across a spectrum of what might be termed 'hegemony indicators'. In terms of knowledge ownership, first of all, in 2006 the US submitted 41.5 per cent of all biotechnology patent applications filed under the international Patent Cooperation Treaty (PCT) with Japan and Germany following with respective shares of 12 and 7 per cent. (Figure 2 – OECD 2009a: 71). In stark comparison to these figures, the combined emerging economies of the BRIICS countries (Brazil, Russian Federation, India, Indonesia, China and South Africa) produced a mere 4 per cent of PCT biotech applications. Within the US, four regions (California, Boston, New York City and Washington) account for nearly 18 per cent of the PCT total, demonstrating the critical mass density of the country's innovation capacity in biotechnology.

Figure 2
Share of countries in biotechnology PCT applications, 2006

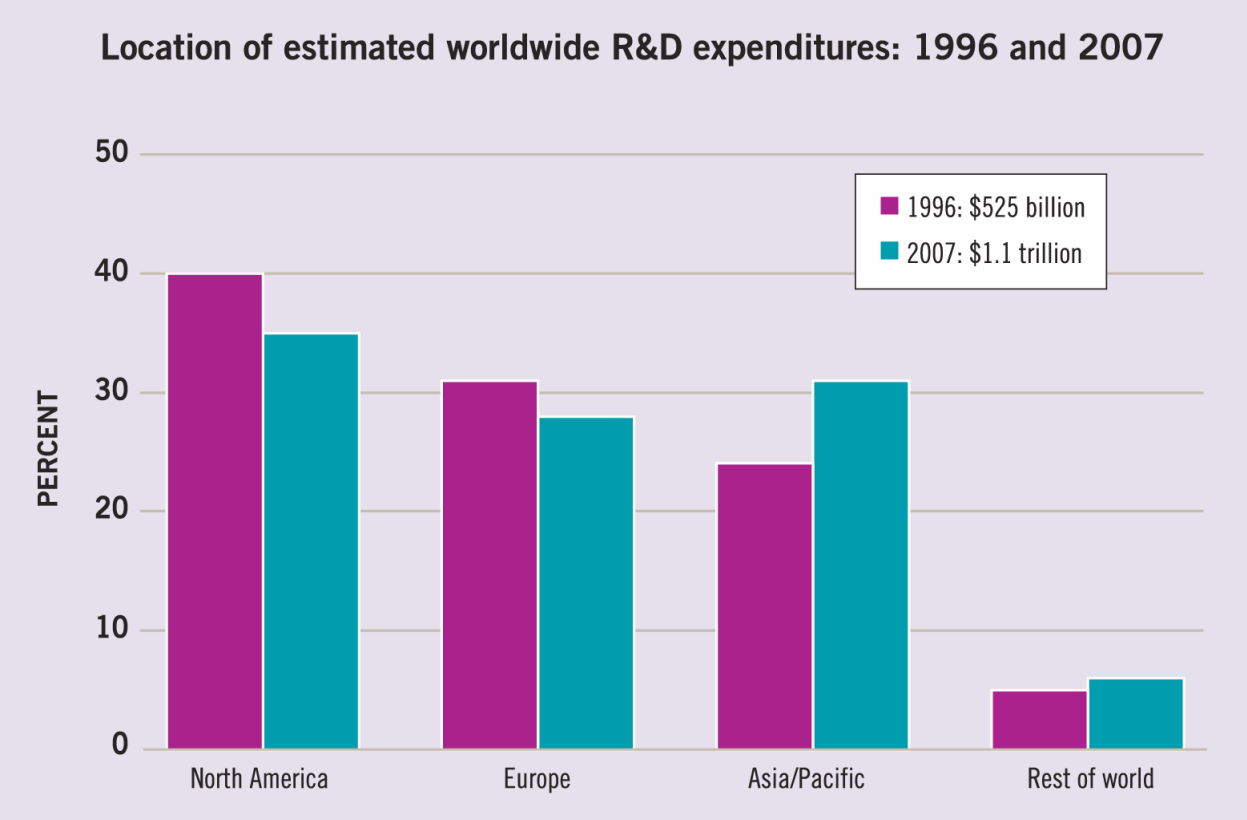


Refining the focus, we can look at data on bio-therapeutics[1] as an indicator of which states are dominating the global competition at the leading edge of health biotechnology. In the two decades between January 1989 and January 2009, firms based in the US developed 66.3 per cent of biotherapies that received marketing approval. European firms developed 15.6 per cent and Japanese firms 7.6 per cent of the approved bio-therapies. Again the contrast with developing countries is stark with China and South Korea both achieving only 3 per cent (OECD 2009: 84). A very similar picture emerges if we examine 2007 data on the clinical trials of new molecular entities (NMEs)[2] as indicators that measure current research investments to develop future products. Here the US leads all other countries with 55.9 per cent of all clinical trials of bio-NMEs and 62.6 per cent of all clinical trials of experimental bio-NMEs (OECD 2009: 86). America's dominance in the early commercialisation of biomedical science is thus overwhelming and reflected in the destination of venture capital investment (seed, start-up, early development, and expansion stages) in the life sciences. Data on the 25 OECD countries show the United States receiving a commanding 68.3 per cent of the total VC invested in the life sciences in 2007 (OECD 2009: 96).

If the US model of biomedical innovation is so comprehensively effective in maintaining America's leadership when measured against these hegemonic indicators, how is one to assess the possible contribution of the patenting governance of an emerging economy such as China to any challenge to that hegemony? In response it can be said that the infrastructure requirements of innovation span a number of policy fields, of which patenting is one, and that each of these fields makes its own contribution to a state's innovative capacity through its governance of science (funding, workforce, organisation), society (maintenance of public trust through regulation) and the market (private/public collaborations, intellectual property, venture capital support). Through the exercise of this governance, a state makes speculative choices about the areas of innovation in the knowledge economy it wishes to support and the markets it anticipates will constitute the future bioeconomy (Salter 2009b). In very crude terms, it can be seen that through such governance measures the innovation capacity of the South-East Asia states in general, and of China in particular, is increasing to the point where a possible platform for challenge to the US hegemony in biomedical innovation is being constructed. In the last decade, the R and D expenditure of the Asia/Pacific states as a proportion of the global total has increased whereas that of North America and Europe has correspondingly decreased (Table 1); the annual growth rates in the number of researchers of the South-East Asia states has been between 6 and 11 per cent whereas that of the US and Europe has been 3 per cent (Table 2); and the science and engineering publications of Asia's states have increased at a higher rate than that of the rest of the world (Table 3). In 2008, China's rapidly developing science base produced 8% of the world's research publications, becoming the second largest single-country producer, having been ranked 14th in 1995 with 2

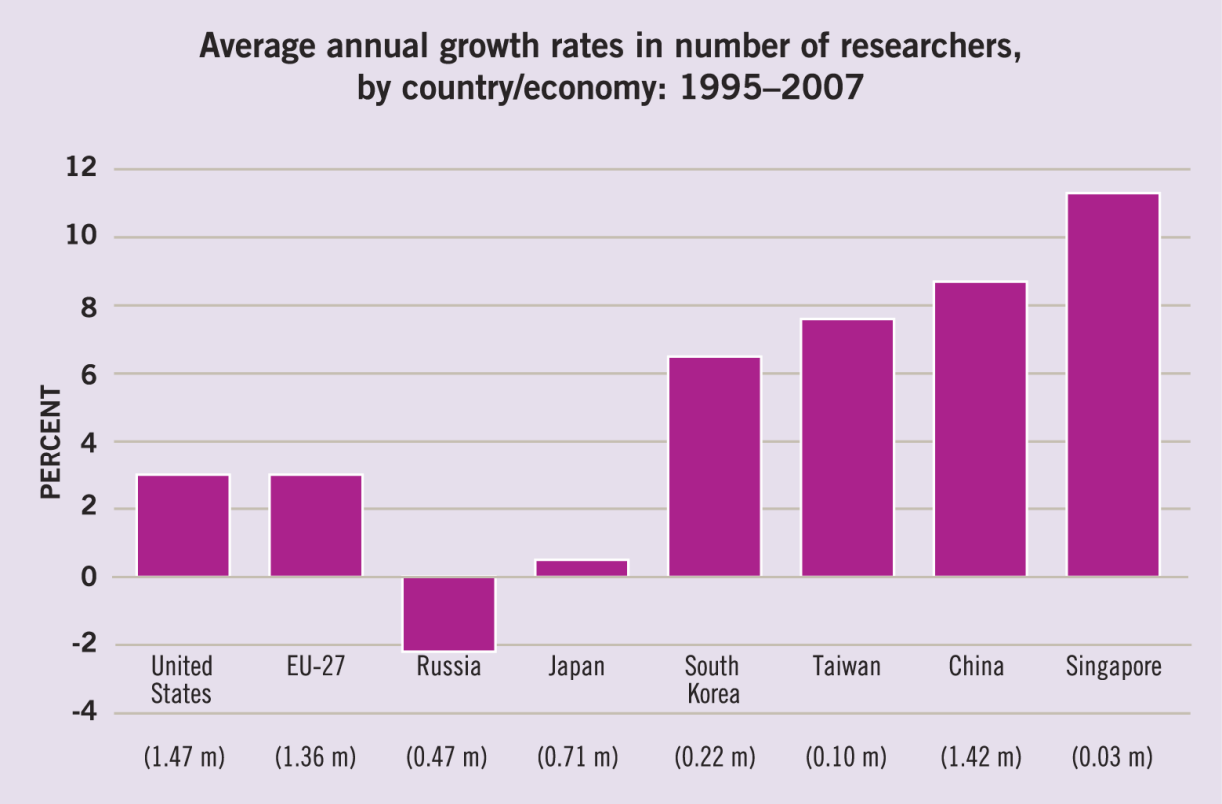
per cent of the world share (National Science Board 2010). Between 1995 and 2007, patent filings in China grew by an average of 23.9 per cent a year – far above the growth rate at the EPO and USPTO – with the result that between 2000 and 2006 Chinese residents increased their share of worldwide patent filings from 1.8 to 7.3 per cent (WIPO 2009: 15; WIPO 2008: 7). Other data across a spectrum of innovation indicators support this impression of dynamic growth in the capacity of emerging economies such as China and India to compete effectively in the global knowledge markets of the future (Salter 2008). Certainly the very steep rise in China's global position as an exporter of high technology manufactured goods between 1995 and 2008 would seem to confirm the plausibility of these indicators as measures of future economic performance (Table 4). So we can see two trends: a continuing US hegemony in biomedical innovation and an apparent challenge to that hegemony from a number of emerging economies.

Table 1



SEI 2010: **Global Patterns of R&D Expenditures,** Chapter 4.

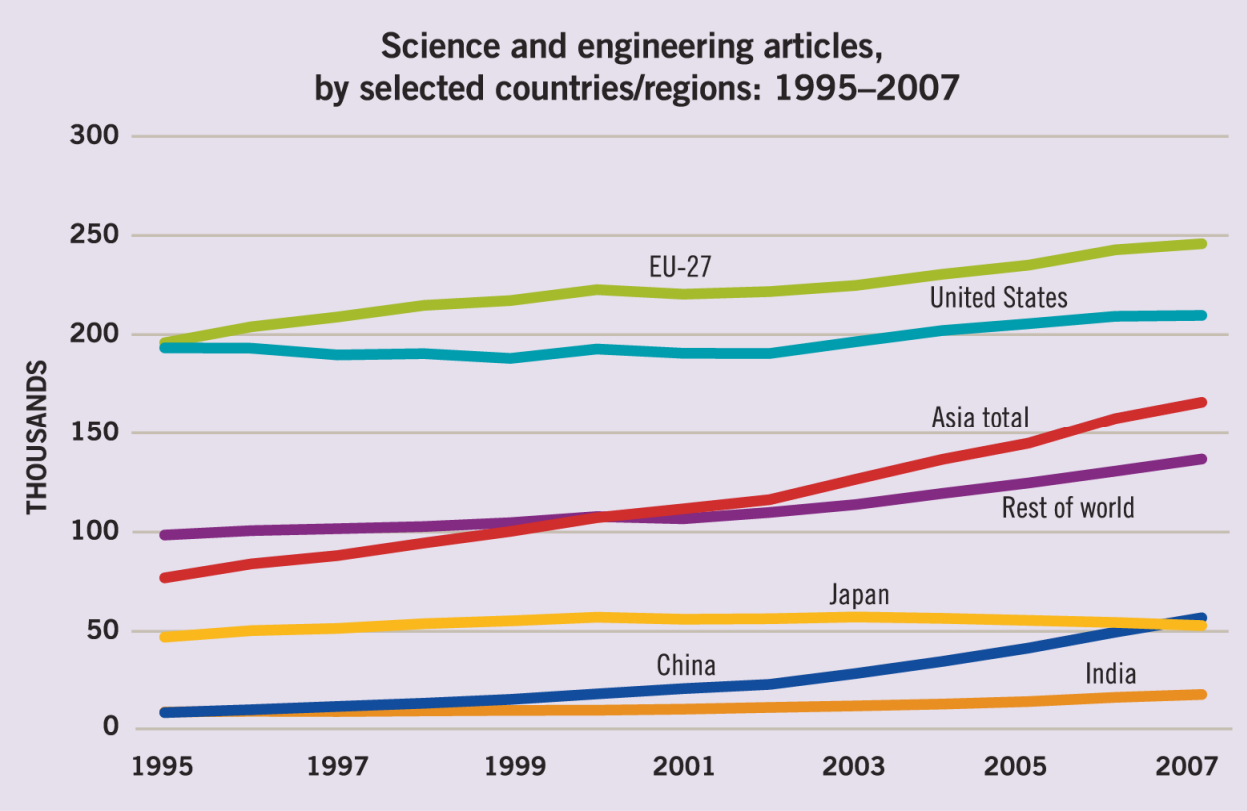
Table 2



NOTE: Estimated number of researchers (in millions) is for 2007 and shown below country/economy. U.S. 2007 estimate based on long-term growth rate.

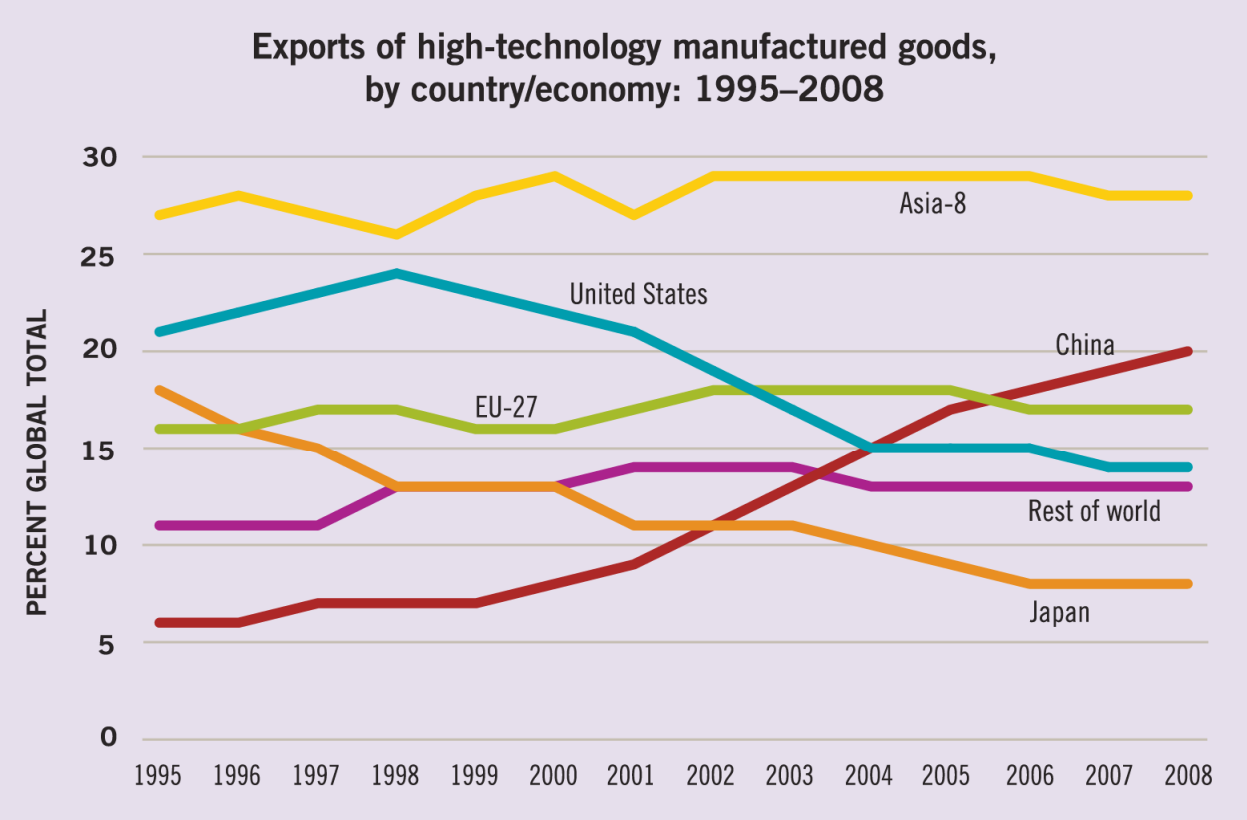
SEI 2010: **Global S&E Labor Force,** Chapter 3.

Table 3



SEI 2010: **S&E Article Output,** Chapter 5.

Table 4



NOTES: China includes Hong Kong. Excludes intra-EU trade.
SEI 2010: **Trade of High-Technology Goods,** Chapter 6.

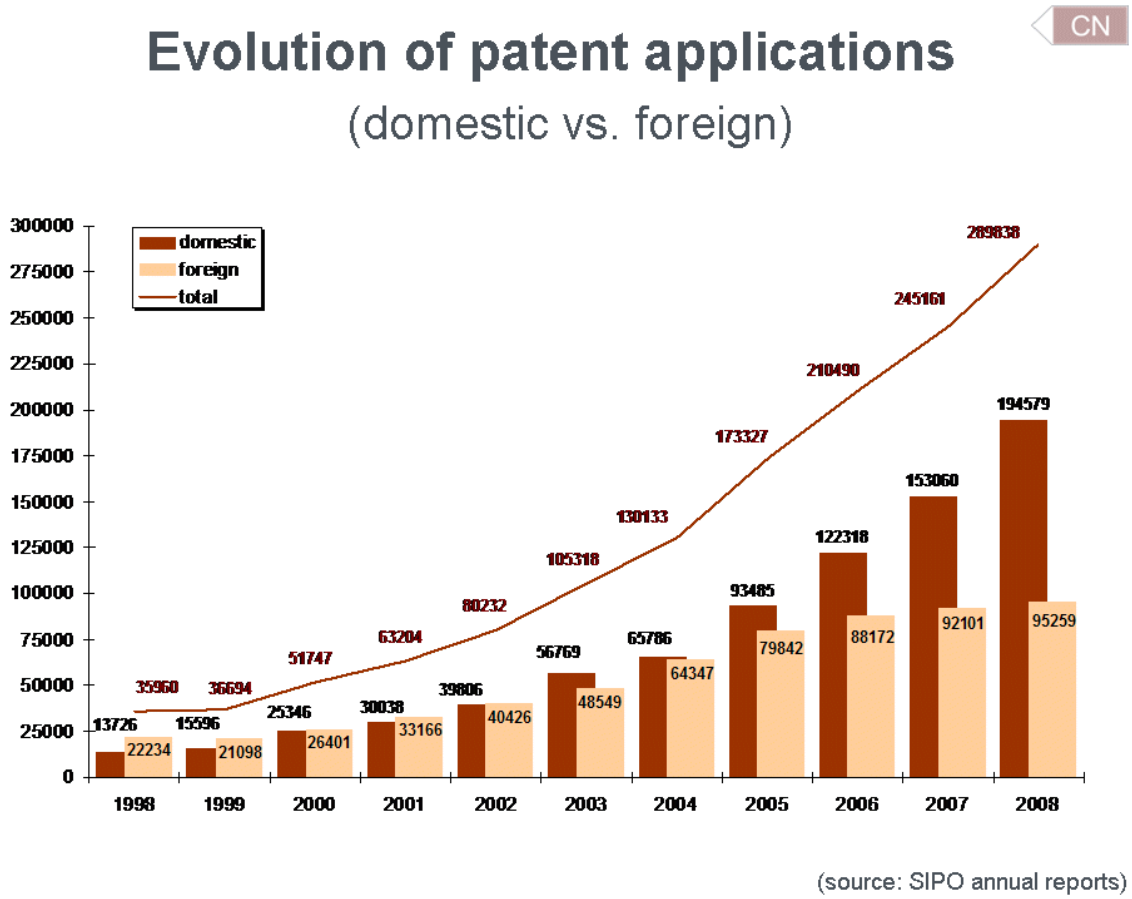
How can we reconcile these two trends? It can be argued that a state's innovation capacity, and hence its ability to challenge, only becomes meaningful when considered in terms of the interaction of this capacity with the global knowledge economy rather than in terms of its purely domestic applications. At the formal policy level, China is working hard to try to ensure that its global ambitions quoted at the beginning of this article are supported by the appropriate patenting infrastructure to enable such interaction. With its accession to the World Trade Organisation (WTO) in 2001, China agreed to conform to the requirements of the Trade Related Aspects of Intellectual Property Rights (TRIPS) agreement and passed its 'Patent law of the People's Republic of China' supported by the 'Implementing regulations of the patent law of the People's Republic of China' in July of that year (MOST 2001). In the following years, China cooperated frequently with World Intellectual Property Organisation (WIPO) and the European Patent Office (EPO) on personnel training and promoted IPR teaching and research in over 70 universities (Huang *et al* 2004: 377). More recently, China has accelerated the development of its IP infrastructure in pursuit of the innovation agenda. This agenda has high level support: for example, in his speech on the world economy at the 2009 Summer Davos, Premier Wen Jiabao re-emphasised the familiar theme that, in China's approach to the world economy, 'IPR protection is vital to driving innovation and development. To safeguard IPR is to safeguard the source strength of innovation.' (Premier Wen Jiabao 2009). In December 2008, China's Patent Law was amended with the aim, according to Chen Guangjun, a senior official with the National Peoples Congress's (NPC's)

Education, Science, Culture and Health Committee, of 'encouraging innovation and improving China's "international competitiveness". One of the revisions rather belatedly designed to enhance international engagement was: 'the removal of the requirement for all Chinese individuals and entities to first file applications in China for inventions made in China. The revision allowed Chinese individuals and entities to file their patents for the first time in other countries, not necessarily China.' (China Daily 2009) That China's biotech entrepreneurs had to wait until 2008 until they were allowed to first file in the national market of their choice is an indicator of the reluctance of China's policy makers on innovation to move from the domestic to the global agenda.

In theory, the drive towards an innovation supporting IP system is propelled by annual action plans implemented by China's State Intellectual Property Office (SIPO). Thus *China's action plan on IPR protection 2009* details 170 measure in 9 areas: enforcement, trials, institutional building, publicity, training and education, international exchanges and cooperation, corporate IP protection and services to right holders (SIPO 2009). In addition, at the local level, some provinces and municipalities have established IPR bureaus to coordinate public awareness campaigns and, to a more limited extent, enforcement. However, against this optimistic agenda have to be set the several constraints on effective enforcement. These include: a reliance on administrative instead of criminal measures to combat IPR infringements, corruption and local protectionism, limited resources and training available to local enforcement officials, and a lack of public education regarding the economic and social impact of counterfeiting and piracy – hitherto endemic features of Chinese society (Hane 2008). It is also likely that the costs of using China's IP system still remain prohibitively expensive for many small innovative companies despite government subsidies for patent applications and maintenance (Frew *et al* 2008: 45).

Within China, the net effect of these tensions in its IP infrastructure has been to encourage the expansion of patenting between 1998 and 2008 but to limit the rate of expansion of the non-resident element particularly, one suspects, with regard to the smaller, high risk enterprises of health biotechnology (Table 5 – EPO 2009). A recent report from the European Chamber of Commerce in Beijing shows that European companies operating in China remain concerned that confidential data submitted by them during filing, product registration and other stages of business development are leaked to their Chinese competitors This combined with concerns over a draft new patent law which requires innovative companies to submit inventions to the Chinese authorities for 'confidentiality examinations' prior to filing patent applications abroad is likely to make EU companies less willing to place their R and D activities at Chinese plants (EurActiv 2009). Such externally-linked knowledge based activities are precisely the kind that China needs to encourage if its global ambitions regarding the future bioeconomy are to be realised.

Table 5

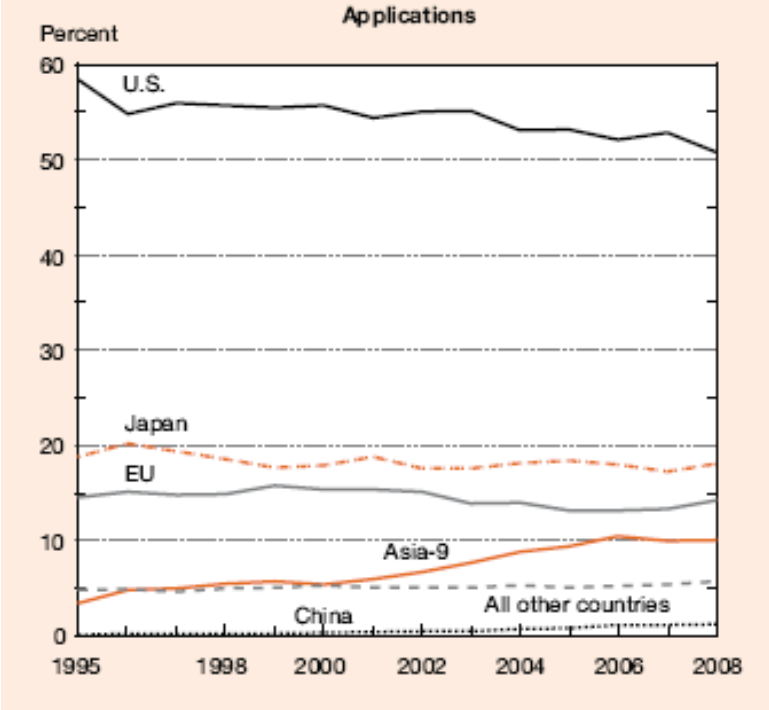


If there are difficulties associated with China's internal ability to attract the international IP required for biomedical innovation, it is also questionable whether China's engagement with external patenting regimes and opportunities is increasing its global innovation capacity. States with global ambitions need to use non-resident filings to protect their IP rights outside their domestic markets. Although as we have seen, globalisation of knowledge ownership is increasing when measured in terms of non-resident filings, in geopolitical terms this globalisation is characterised by a very skewed distribution of non-resident filings in favour of a small number of countries in the developed world led by the United States (21.9% of non-resident filings worldwide in 2006), Japan (21.7%) and Germany (10.8%). Furthermore it is a continuing trend. Between 2000 and 2006 the 8 largest countries of origin increased their share of worldwide non-resident patent filings from 66% to 74%. Applicants from emerging economies, including China, filed relatively few patent applications outside their own countries (WIPO, 2008). This is not to say that China's non-resident filings are not increasing, and increasing rapidly, but that they are starting from such a low base that their global impact is very small. In 2007, China filed 7643 non-resident applications: a mere 5 per cent of the US total of 168,605 (WIPO 2009: 17). In the biotechnology field, this disparity is perfectly reflected in PCT patent applications in 2004/06 where China recorded 423 applications – 4 per cent of the US figure of 11,474 applications (OECD 2009a: 75).

Any state planning to build global capacity in biomedical innovation has to factor the US into its calculations about the location of its knowledge ownership because America is both the largest health care market in the world and the main source of venture capital for early stage

biotech development. Between 1996 and 2008, the US resident share of USPTO applications fell from 55 to 51 per cent. In the same period applications from the Asia-9[3] (not including China) rose at more than twice the average rate, driven by increases in South Korea and Taiwan, moving from 5 to 10 per cent. China's share quadrupled, but from such a low base that in 2008 it was still only 1 per cent (Table 6 – National Science Board 2010: 6-47). Compare this with the share of Japan and the EU countries which remained roughly constant in the 1996-2008 period at around 20 and 15 per cent respectively.

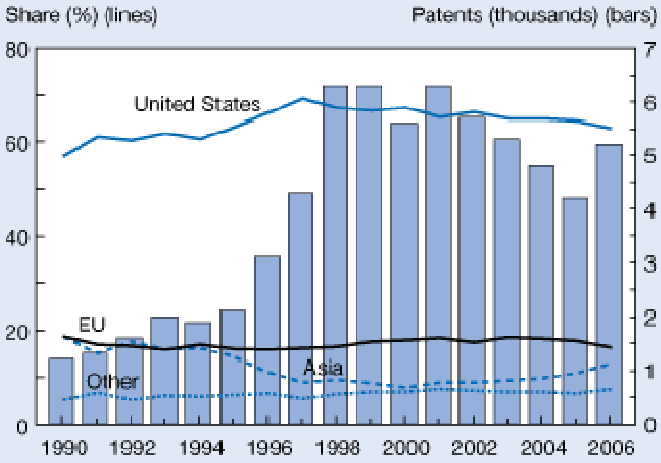
Table 6
Region/country/economy share of USPTO patent applications 1995-2008



If we look now at biotechnology patents in particular, we find that the resident US patenting activity in this innovation field is more intense than in other technology areas, thus safeguarding its global hegemony in this field. Since 1990, the US dominance is clearly maintained at about 60 per cent of the total with the EU ranked second and Asia third (including China in this data) (Table 7 – National Science Foundation 2008: 6-37). China's share for biotechnology patents has remained at the same level as its overall USPTO share - 1 per cent.

Table 7

Figure 6-37
USPTO biotechnology patents granted and share of total, by inventors from selected regions/ countries: 1990–2006



EU = European Union; USPTO = U.S. Patent and Trademark Office

NOTES: Biotechnology patents defined by Organisation for Economic Co-operation and Development (OECD). Patent counts on fractional-count basis. For patent grants with multiple inventors from different countries, each country receives fractional credit on basis of proportion of its participating inventors. Asia includes China, India, Indonesia, Japan, Malaysia, Philippines, Singapore, South Korea, Taiwan, and Thailand. China includes Hong Kong.

SOURCE: OECD, Patent database, http://stats.oecd.org/wbos/default.aspx?DatasetCode=PATS_IPC, accessed 15 February 2007. See appendix tables 6-46 and 6-47.

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Conclusions

Patenting governance is one strand in China's geopolitical bid to position itself as a strong global competitor in biomedical innovation. In conjunction with policies on R and D investment and research organisation, the scientific workforce, regulation, foreign direct investment and venture capital, China's approach to patenting is designed to help access the future markets of biomedicine, wherever they are to be found. In so doing, China must

inevitably seek to challenge the US hegemony in the life sciences and the historic US ability to identify and exploit new biotechnological opportunities faster and more comprehensively than any other state.

In embarking on this mission, China is apparently building on its proven ability to compete effectively in the high technology field and in terms of such measures as research investment and scientific publications would seem to be developing a sound platform from which the challenge can be launched. However, whether this potential can be translated into the acquisition of future biomedical territory given the uncertainties of innovation, on the one hand, and the dominating presence of the US, on the other, is questionable. On all the measures of hegemony in early stage biomedicine be these biotechnology patents, clinical trials or biotherapeutic marketing approvals, the US lead over the last decade remains secure with no indication so far that any other state .

At the national level it can be argued that China's drive for a global biomedical innovation capacity is reflected in its preparedness to accept the transnational governance of knowledge ownership through its membership of TRIPS, reforms of its patenting laws to attract inward flows of biomedical knowledge, a continuing emphasis on improving the coherence and administration of its IPR infrastructure and a rapid rise in resident and non-resident patent applications to its State Intellectual Property Office. However, when this optimistic domestic scenario is related to the balance of power in the global ownership of new knowledge a different picture emerges. With the exception of South Korea and, to an extent, Thailand, China and the other emerging economies of South and East Asia have yet to make any impact on the developed world's traditional dominance of an increasingly globalised knowledge ownership market. The majority of non-resident filings, both generally and in the specific biotechnology case, remain in the hands of the developed economies: in terms of future knowledge territories, the West and Japan continue to be very much in control. Furthermore, any state with aspirations in the future of biomedicine must at some point address the issue of knowledge ownership in the current home of biomedical innovation and largest biomedical market: the US. This China has signally failed to do with its penetration of US biotechnology patenting stagnating at a lowly 1 per cent.

The problems faced by China in metamorphosing from a significant player in established high technology markets to a potentially significant player in future health technology markets is one faced by developmental states in general. The infrastructure requirements for the handling of the uncertainties and risks inherent in biomedical innovation cannot be created overnight by ambitious state intervention since these requirements depend as much on the embedded expertise of informal flexible networks established over time in transnational space as they do on the provision of the kinds of formal structures and resources in which developmental states have traditionally specialised. In this context the national construction of the apparatus of patenting governance is merely a first step in persuading the global sources of biomedical knowledge that China knows how to manage the complex and difficult process of translating that knowledge into biomedical therapies. Biotech companies have lagged far behind financial services, pharma and technology-based services (including telecommunications and information technology) in making China, India and other emerging markets part of the global value chain. Offshore outsourcing in biotech to countries such as China is currently at only 1 to 3 per cent of the industry's potential owing principally to apprehension over IP laws and their implementation (Ernst and Young 2008: 14). In a risky

business no-one wants to expose their knowledge base to the uncertainty of unreliable patenting governance.

It may be that awareness of these issues lies behind the visits of Chinese industrialists to the US to find out why healthcare/biotech companies have not emerged from their innovation 'pipelines' in the way that high tech companies have and to investigate whether they can simply buy the necessary IP (Ratner 2008). For the Chinese, the perplexities of patenting governance and its contribution to biomedical innovation parallel those of venture capital where the state sponsored support for VC involvement in the life sciences has had equally limited impact (Salter 2009c). China is discovering that the geopolitics of knowledge resource control and the capturing of future biomedical value is a new kind of political game; one less susceptible to the direct forms of state intervention that have served China's move into new industries so well in the past.

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[1] 'Bio-therapeutics include large molecule recombinant proteins such as enzymes and hormones and monoclonal antibodies. Experimental bio-therapeutics cover tissue engineering, therapeutic vaccines, stem cell research, lytic viruses, and gene, antisense, and RNAi therapies. They are defined as "experimental" because only a few of them have received marketing approval in one or more jurisdictions.' (OECD 2009a: 84)

[2] An NME contains an active ingredient that has never received marketing approval in a specific jurisdiction such as the Food and Drug Administration in the United States.

[3] Asia 9 includes India, Indonesia, Malaysia, Philippines, Singapore, South Korea, Taiwan, Thailand and Vietnam.