Innovation in India and China: Challenges and Prospects in Pharmaceuticals and Biotechnology

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Abstract

India and China are important players in an evolving process of globalization of research and development (R&D). Focusing on pharmaceuticals and biotechnology industries, this paper analyses the challenges and prospects facing the two countries in global innovation. Large supplies of highly skilled professionals and well-established science and technology infrastructures are important assets for India and China in the era of globalization of R&D. At the same time, however, there is a concern that as globalization of R&D gathers steam, the poor in India, China and other developing countries are likely to be left out of the new innovations. A good example is the case of India's pharmaceuticals industry. The leading Indian pharmaceutical firms have responded well to the challenge of a strict intellectual property rights (IPR) regime by increasing their R&D spending and, simultaneously, targeting their sales to the generic drugs markets in North America and Europe. But even as India's top drug firms have been growing in technological capabilities and taking part in the globalization of pharmaceuticals R&D, they have also been shifting their focus away from the market for medicines for poor patients.

Keywords: India, China, innovation, pharmaceuticals, biotechnology

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1. Introduction

India and China are important players in an evolving process of globalization of research and development (R&D). Focusing on pharmaceuticals and biotechnology industries, this paper analyses the challenges and prospects facing the two countries in global innovation.

World Investment Report 2005 points out that there is now a fresh wave of R&D investments by multinational corporations (MNCs) in developing countries, particularly China and India. In a survey of the world's largest R&D spending MNCs conducted by the United Nations Conference on Trade and Development (UNCTAD) in 2004-05, China was identified by the respondents as the most attractive location for future investments in R&D. India was the third most attractive location, behind the United States (US) (UNCTAD, pp.22-6). The *Economist* described India and China as 'high-tech hopefuls' in a special report on technology in the two countries in its November 2007 issue.[1] Foreign direct investment (FDI), especially in technology-intensive industries, used to be circulated largely within developed countries. MNCs restricted their R&D activities in developing countries mostly to the adaptation of technologies for local markets (Kleinknecht and Wengel, 1998). Therefore, the recent interest shown by MNCs in shifting some of their core innovation activities to China and India marks the blossoming of a process of globalization of R&D.

There are many factors behind the growing prominence of India and China as R&D locations. The large supply of skilled professionals in

[1] See 'High-tech Hopefuls: A Special Report on Technology in India and China', *The Economist*, November 10, 2007.

these countries at relatively low costs is a highly crucial one. India and China have made significant public investments in science and technology over the past decades, and this provides a strong base for future growth. Also, both countries have, in recent years, introduced rules ensuring greater protection to intellectual property rights (IPRs), in compliance with World Trade Organization (WTO)'s Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS). Assurance of IPR protection has been an important incentive for MNC investments. Furthermore, the expanding numbers of middle class consumers in India and China promises a booming market for high-tech products, and this raises interest levels among multinational corporations.

At the same time, the challenges unfolding are many as outsourcing of innovation by global corporations picks up speed. First, there are concerns on the future supply for the vast market for innovative products for the poor in developing countries. There exists demand for cheap medicines for poor patients, demand for biotechnological innovations that ensure food security in the third world, demand for novel telecommunication devices for rural areas, and so on. Leading corporations in the West have so far given a low priority to this market, focusing instead on the market for innovations for rich consumers. It appears that the rise of India and China as favoured destinations for outsourcing of R&D is not likely to give any positive impetus to innovations targeting the poor. The IPR rules implemented by India and China encourage MNC investments, but also create new constraints for domestic firms in these countries. Many of the top domestic firms in China and

India will benefit from the growing opportunities for contract research, but in the process they might concentrate their efforts to the innovation needs of the rich.

Secondly, as domestic firms in India and China progressively move away from their home markets and carry out R&D for export markets, questions are raised on their long-term growth prospects vis-à-vis Western MNCs. Will they grow capable of challenging Western MNCs, or remain as junior partners in a global chain of innovation? Evidence from India's software industry indicates that its extreme reliance on export markets is likely to be a constraint on future growth. D'Costa (2002, 2004) argues that India's software industry is overly dependent on a single export market (the US market), locking the industry into a low innovation trajectory. According to Chandrasekhar (2006), outsourcing and offshoring of business services to India aid the strategies of US corporations to maintain their high profit levels by tapping into the global supply of cheap labour.

This chapter discusses current and future trends in innovation in China and India in the context of globalization of R&D, with a focus on pharmaceuticals and biotechnology industries. The next section discusses in greater detail the rise of India and China in the knowledge economy. Section 3 outlines some of the features of the demand for pharmaceutical and biotechnology innovations for the third world. Section 4 shows how India's pharmaceuticals industry could meet the demand for affordable medicines, and discusses the challenges facing the industry in the post-TRIPS phase. Section 5 is on pharmaceuticals and biotechnology industries in China, and Section 6 concludes the paper.

2. The Rise of India and China in the Knowledge Economy

The most important factor that triggers the new wave of investments in R&D in India and China is the large supply of highly skilled professionals in these countries. Both China and India are now ahead of the United States with respect to tertiary technical enrolment. In 2000-01, the total numbers of students enrolled for tertiary education were approximately 12 million in China and 10 million in India (UNCTAD, 2005, p.162). In China, in 2004, 13.3 million students were enrolled as undergraduates, while those enrolled for a Master's degree and Doctor's degree were, respectively, 654,286 and 165,610 (National Bureau of Statistics of China, 2005, pp. 689-95). At the same time, the costs of employing skilled workers are relatively low in India and China. The annual cost of hiring a chip design engineer, in 2002, was found to be $28,000 in China (Shanghai province) and $30,000 in India compared to $300,000 in Silicon Valley in the United States (Ernst, 2005, p.56).

Both India and China have a large population of emigrants working as skilled professionals in foreign countries. Indian professionals accounted for 47 percent of all H-1 visas issued (to skilled workers) in the United States in 1999; professionals from China formed the second largest group, with a share of 5.0 per cent (cited in Chanda and Sreenivasan, 2006, p. 220). With regard to work permits issued to emigrants from different nationalities in the United Kingdom (UK), Indians topped the list with a share of 21.4 percent of the total work permits issued in 2002 (Findlay, 2006, p.78). The number of postgraduates studying abroad has steadily increased in the case of China: from 860 in

1978 to 20,381 in 1995, and 114,682 in 2004 (National Bureau of Statistics of China, 2005, pp. 689-95). Today, India and China are encouraging return migration of their skilled professionals to energize high technology entrepreneurship back home. The Chinese Academy of Sciences has introduced many attractive schemes to woo returnee researchers as part of a programme of 'reverse brain drain' currently promoted in that country (Zweig, 2006).

The state in post-independence India actively intervened to build a strong infrastructure for science and technology. R&D in India has been financed largely by the public sector. The combined share of the Central and State governments (including public sector units under their management) in the total national expenditure on R&D in India in 2002-03 (the latest year for which data was available) was 75.6 per cent. The share of the private sector was only 20.3 percent while higher education accounted for the remaining 4.1 percent (GOI, 2006, pp.3-8). In China, science and technology was a major plank in the 'four modernizations' the government embarked on after 1978 (Spence, 1999, pp.618-20). Today, the Chinese government promotes R&D through two major national initiatives: the national high-tech R&D Programme or the 863 programme and the national programme on key basic research or the 973 programme.[2] The 973 programme has identified life sciences, nano-technology, information technology, and earth sciences as frontier areas for basic research. In 2004, of the total funding for science and technology enterprises in China, 22.8 percent came directly from the

[2] See the Ministry of Science and Technology of the People's Republic of China, at <www.most.gov.cn/eng/programmes/programmes1.htm> accessed 18 January 2006.

government, 64 percent of the funds were raised by enterprises themselves, and 6.1 percent came through loans from financial institutions (National Bureau of Statistics of China, 2005, pp. 714-7).

2.1 Challenges Facing India and China in High Technology Sectors

While India and China enjoy some advantages in science and technology as noted above, both countries still have a long way to go. Table 1 shows that China and India lag clearly behind the United States in many national-level indicators such as R&D expenditure and researchers and patents granted per resident population. The evolving relationship between multinational companies, on the one hand, and the state and domestic firms in India and China, on the other, will also be highly crucial. Dicken (1998) points out that the relationship between MNCs and states is conflictual as well as cooperative — with each trying to gain bargaining power over the other. In fact, according to Stopford and Strange (1991) (cited in Dicken, 1998), the 'balance of power' has moved over time from governments as a group to the multinationals. MNCs in the United States and Western Europe continue to reign supreme in high technology industries, their R&D expenditures exceeding the national R&D expenditures in many developing countries. For instance, R&D spending by Pfzier of the United States in 2002 was US$4.8 billion, while the national R&D expenditure of India in 2001 was $3.7 billion (UNCTAD, 2005, p. 120). Given their dominant position, MNCs' investments in India, China and other developing countries will not be necessarily beneficial to the host country. Local R&D firms may be taken over by MNCs; local firms and universities may not receive fair compensation as they enter into

partnerships with MNCs; and talented researchers in local firms may move into better paying jobs in MNCs (UNCTAD, 2005, pp.190-3).

Table 1: Selected indicators of performance in research and development (R&D): India, China and the United States

	India	China	United States
R&D expenditure, billions of US dollars, 2002	3.7*	15.6	276.2
R&D expenditure as % of gross domestic product, 2000-2005	0.8	1.4	2.7
Researchers in R&D, per million people, 1990-2005	119	708	4605
High technology exports as % of manufactured exports, 2005	4.9	30.6	31.8
Patents granted to residents, per million people, 2000-05	1	16	244

Notes: *2001 data.
Sources: UNDP (2007), Tables 13 and 16; UNCTAD (2005), p.105

Studies have pointed to several areas of weaknesses in the nature of growth of developing country firms, including China's high-technology firms. Lardy (2002) and Steinfeld (2004) argue that China's integration with the global economy has been a shallow one. In an ongoing process of modularization in global manufacturing – in which component manufacturing processes are spread out across locations and firms all over the globe — Chinese firms derive weak advantages on the basis of low costs and high volumes. China exports high-technology products but the country's role in these exports is limited largely to that of an assembler of high value added components (Steinfeld, 2004). According to Branstetter and Lardy (2006), domestic value added accounts for only 15 per cent of the value of China's exports of electronic and information technology products. For instance, in the case of an Apple iPod,

manufactured in China by a Taiwanese company and sold for $224 (in 2005), the value captured by China was just a few dollars, whereas Apple, an American company, claimed the largest share of profits (Linden et al., 2007). Based on an analysis of firms in the aerospace, oil and pharmaceuticals industries, Nolan and Zhang (2002) found that Chinese firms were weak vis-à-vis a few leading, mostly oligopolistic, global giants, which have emerged as core "systems integrators" in their respective sectors. The relative weakness of Chinese firms was more marked in high-technology sectors (Nolan and Zhang, 2002). Despite such challenges, however, Naughton (2007) has expressed some amount of optimism on the future of technological development in Chinese firms.

One of the important challenges to the growth of high-technology firms in India is the limited degree of interconnection between institutional and industrial R&D in the country. With respect to total national R&D expenditure, government owned R&D institutions account for the major chunk while the industrial sector's share is small (GOI, 2006). It is debatable whether public investments in science and technology have created strong 'national innovation systems' (NIS) in India.[3] D'Costa (2006) argues that the triple helix model, which refers to thick institutional linkages between industry, academia and government, has not taken deep roots in India. Bangalore's software industry, for example, is characterised by high degree of inter-firm competition — not cooperation – and limited degree of interaction with academic and research institutions in the city (D'Costa, 2006). According to Dahlman and Utz (2005), there exists a deep gulf

[3] For a discussion on 'national system of innovation', see Freeman (1995).

between the academic world and industry in India. However, there are indications of positive changes occurring. A recent study by Basant and Chandra (2007) pointed to the gradual emergence of linkages between academia and industry in the Indian cities of Bangalore and Pune. The study also noted that these linkages are deepening: from interactions in the labour market to knowledge-based linkages (Basant and Chandra, 2007).

Lastly, some of the provisions of the TRIPS agreement are creating hurdles to and, as we shall see in this chapter, altering the nature of innovation in developing countries, especially India and China. Drahos with Braithwaite (2002) has shown that an alliance between a small group of United States (US) corporations and the US state was the driver of the sequence of events linking trade and intellectual property and culminating in the genesis of TRIPS. Representatives of US corporations, importantly of the pharmaceutical giant Pfizer, which stood to gain enormously from new rules on intellectual property, played an important role in setting the government agenda on intellectual property rights in the US. The US state took forward this agenda and, employing a range of measures including the threat of trade sanctions through Section 301, succeeded in bringing other developed and developing countries into compliance on TRIPS (Drahos with Braithwaite, 2002). The United States' advocacy of strict patent rules in developing countries in recent times must be seen against the fact that the IPR regimes in advanced countries including the US during their periods of industrialization until the early 20th century were characterized by laxity and frequent violations (Chang, 2003). The rest of the chapter focuses on the changes

in the nature of innovation in the pharmaceuticals and biotechnology industries in India and China, brought about to a large extent by the TRIPS agreement.

3. Demand from Developing Countries for Innovations in Pharmaceuticals and Biotechnology

Extreme disparities exist between the developed and developing countries with respect to achievements in health and other human development indicators. Majority of the world's population living in developing countries suffer from food shortage and lack of access to medical facilities. A person born in Sub-Saharan Africa in 2000-05 could be expected to live for only 49 years, whereas a person born in a high income OECD country in the same year has a life expectancy of 79 years (see Table 2). As Table 2 shows, significantly large proportion of the population in Sub-Saharan Africa and South Asia are undernourished. Tuberculosis is still highly prevalent in least-developed and developing countries (see Table 2). Malaria cases of more than 15 per 100 population were reported in the year 2000 in several African countries including Botswana, Burundi, Zambia and Malawi, whereas none of the countries in Western Europe or North America reported incidence of Malaria in that year (UNDP, 2005).

Table 2: Selected indicators of achievements in health and human development, different regions of the world

	Population, millions	Life expectancy at birth, years	Population under-nourished, %	HIV prevalence, ages 15-49, %	TB cases, per 100,000 persons
	2005	2000-05	2002-04	2003	2003
LDCs	766	53	35	3.2	452
Developing Countries	5215	66	17	1.3	289
Sub-Saharan Africa	723	49	32	7.3	487
South Asia	1587	63	21	0.7	306
India	1134	63	20	0.4 – 1.3	287
China	1313	72	12	0.1	245
High Income OECD	932	79	—	0.4	18

Note: LDCs = Least developed countries; OECD = Organisation for Economic Cooperation and Development.

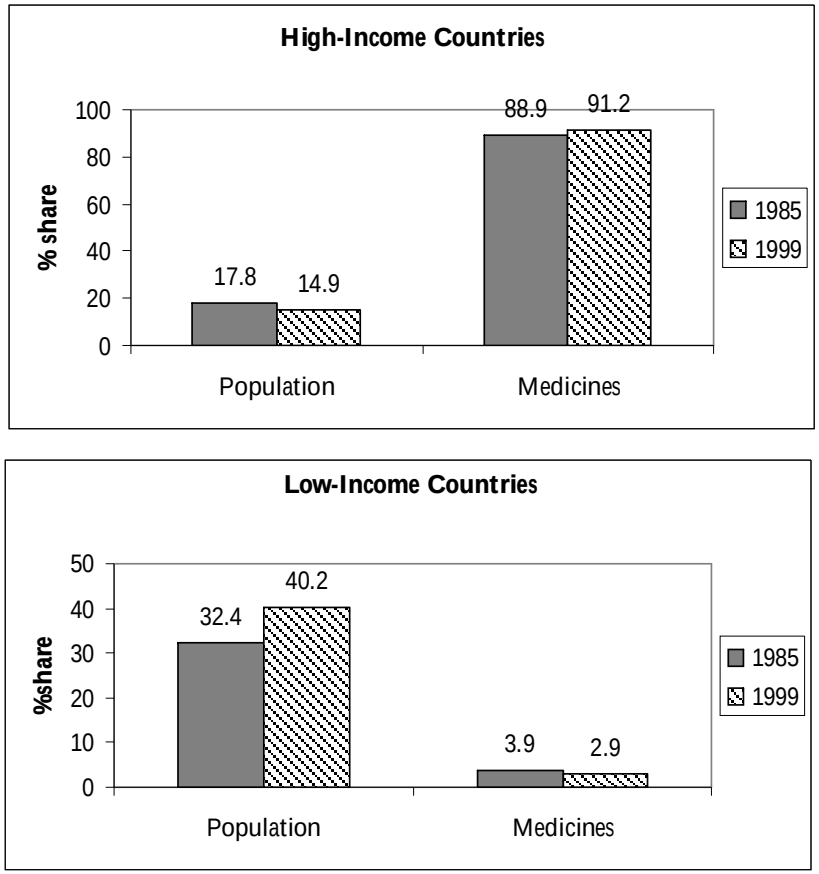
Source: UNDP (2005), Table 9; UNDP (2007), Tables, 5, 7 and 10.

Technological advances in pharmaceuticals and biotechnology open up tremendous opportunities for solving the problems of ill health and malnutrition in the developing world. However, while majority of the world's population in need of medicines live in developing countries, pharmaceuticals industry is effectively controlled by a small number of MNCs headquartered in the developed world. In 1999, the share of high income countries (according to World Bank definition) in global pharmaceutical production was 92.9 percent, middle and low income countries accounting for only the remaining 7.1 percent. Research and development in pharmaceuticals is carried out largely in developed countries. Of the total global spending on health R&D, 42 percent is

privately funded, 47 percent is funded by the public sector in high-income and transition countries, and only 3 percent is financed by the public sector in low- and middle-income countries (WHO, 2004, pp. 5-13). Not surprisingly, R&D activities are overwhelmingly directed toward the health needs of the rich in industrialized countries, toward lifestyle-related and convenience medicines. There are many 'tropical diseases' (also referred to as 'neglected diseases') such as dengue, diphtheria and malaria, which primarily affect people in poorer countries, but these diseases are given very low priority in pharmaceutical R&D (Lanjouw and MacLeod, 2005). It is pointed out that only 10 percent of the worldwide spending on pharmaceutical R&D is directed toward 90 percent of the global disease burden (WHO, 2004, pp.18-19).

Such unevenness in pharmaceuticals research and production capabilities gets reflected in the statistics on consumption of medicines. In 1999, low-income countries, accounting for 40.2 percent of world population, had a share of just 2.9 percent in global consumption (in value terms) of medicines. Imbalances between high- and low-income countries in consumption of medicines have been worsening, as shown through the data for the years 1985 and 1999 in Figure 1. It is reported that over one-third of world's population purchased less than one percent of the pharmaceuticals sold worldwide. In 1999, 1725 million people in the world, including 649 million in India, 267 million in Africa and 191 million in China, were without access to essential medicines (WHO, 2004, pp.31-3 and 62).

Figure 1: Shares of high-income and low-income countries in world population and global consumption (in value) of medicines, 1985 and 1999, in percent



Source: WHO (2004).

With the advent of biotechnology, healthcare and pharmaceutical industries are undergoing fundamental changes. The core scientific principles underlying pharmaceutical innovations are shifting 'from fine chemistry towards molecular biology' (Cooke, 2005, p.333). Rather than

waiting for 'chance discoveries', pharmaceutical innovation today is increasingly characterized by 'rational drug design' in which dedicated biotech firms play a prominent role (Cooke, 2005). However, dedicated biotech firms operate under the shadow of big pharmaceutical corporations. The therapeutic products they develop are licensed out to the big corporations. Biotech firms are located in clusters, and most of the leading clusters in biomedical sciences are in North America and Western Europe.

Advances in biotechnology also raise hopes for dramatic improvements in agricultural productivity, which are essential to meet the food supply requirements of a growing world population. However, research on agricultural applications of genetic engineering, including Genetically Modified (GM) crops, is carried out almost entirely by US-based MNCs. This is in contrast to the case of earlier innovations in agriculture including those of non-GM hybrid crop varieties, which were born out of publicly funded research. The extreme dominance of US multinationals in GM research as well as concerns regarding biological safety and biopiracy largely explains the unpopularity of GM crops in Europe and in a majority of developing countries (Bernauer, 2003). GM research has so far covered only a limited number of crops, importantly, soybeans, maize and cotton, while it has almost neglected tropical subsistence crops such as cassava, millet and cowpeas grown by poor farmers in developing countries. Similarly, while GM research focuses almost exclusively on pest resistance and herbicide tolerance, some of the issues pertinent to developing country agriculture such as drought resistance have not been on its agenda (Paarlberg, 2001). Thus, the

general picture in pharmaceuticals and biotechnology industries is one of neglect of developing country needs. It is against this general context that the case studies of pharmaceuticals and biotechnology industries in India and China presented in the following sections assumes relevance.

4. Pharmaceuticals Industry in India

India's pharmaceuticals industry has been growing at a remarkably fast pace. India supplies 8 percent of the world's output (in volume) of drugs, and 22 percent of the world's output of generic drugs (Sampath, 2005, p.15; Grace, 2004). As per the latest available statistics (for 2007), there were 75 manufacturing units in India approved by the United States Food and Drug Administration (FDA); India has the largest number of FDA approved manufacturing facilities in any country other than the United States. Recent reports indicate that the Indian pharmaceutical industry consists of 300 large to moderate firms; the number of firms rises to 24,000 if small firms are also included.[4] In 2005-06, India exported drugs, pharmaceuticals and fine chemicals worth US$4.9 billion to a large number of countries including the United States, United Kingdom, Germany, Russia and China (CMIE, 2006).

4.1 State Intervention and Growth of Pharmaceuticals Industry in India

State intervention has been an essential feature in the development and growth of the Indian pharmaceutical industry

[4] See the report 'Pharma Industry Aims High: Headed for a Place in the Global Top 10: Country Focus: India', *Chemical Week*, November 21, 2007, p. 38. See also Grace (2005), p.8.

(Chaudhuri, 2005). A major component of this state intervention relates to the introduction of the Indian Patents Act of 1970 (which came into effect in 1972). Until 1970, the Patents and Design Act 1911 — a law framed during the British colonial period which guaranteed product patenting rights to drug companies – was a serious drag on the growth of domestic pharmaceutical firms in India. Production and distribution of medicines in India was almost fully under the control of MNCs, and prices of medicines sold in India by the MNCs were reported to be one of the highest in the world.[5] The Indian Patents Act of 1970 brought in major changes. Section 5 of the 1970 Act disallowed product patenting in the case of drugs and food products; only the processes for manufacturing these products were eligible for patents, according to the Act. The period for which patents were granted was reduced from sixteen years to five years (from the date of patent granting or seven years from the date of patent application). The 1970 Act made it mandatory for the patent holder to start domestic manufacturing using the patented process within three years from the date of sealing of the patent as well as to issue licenses to local manufacturers (for a royalty) after the three-year period (Lanjouw, 1997, p.51; Chaudhuri, 2005, pp.36-8).

Pharmaceutical manufacturing and research organizations set up by the Indian government from the 1950s created a supportive environment for the growth of the domestic industry. Hyderabad's emergence as a centre for bulk drug manufacturing was aided by the early establishment of public sector units such as Indian Institute of

[5] According to Kefauver Committee of the United States, cited in Keayla (2005).

Chemical Technology (IICT) and Indian Drugs and Pharmaceuticals Limited (IDPL) (inaugurated in 1956 and 1961 respectively) in the city. India's Council of Scientific and Industrial Research (CSIR) developed many technologies that were used by even the top pharmaceutical firms in India. At the same time, through a number of regulations in the 1970s, the government discouraged MNCs presence in low technology areas, leaving these sectors for domestic firms (Chaudhuri, 2005). In addition, the government's Drug Price Control Order (DPCO) of 1970 took steps to check the unwarranted escalation of pharmaceutical prices.[6]

Under the protective cover of state support, domestic firms developed reverse engineering capabilities in chemicals-based processes for pharmaceutical production. Many of them grew to become leading producers of generic drugs and started supplying medicines for the Indian market. In 1970, of the top ten pharmaceutical firms by retail sales in the Indian market, only two were Indian firms while the rest eight were subsidiaries of multinational companies (Lanjouw, 1997, p.3). The shares of domestic firms and MNCs in India's pharmaceuticals market by sales were 32 per cent and 68 per cent respectively in 1970. By 2004, these shares were altered upside down: the share of domestic firms rose to 77 percent while the share of MNCs correspondingly declined to 33 percent (see Table 3).

More importantly, domestic pharmaceutical companies were able to manufacture and sell generic versions of medicines at very low prices

[6] The DPCO, which underwent several modifications, was finally replaced by the National Pharmaceuticals Policy of 2002.

in India. Drug prices in India are much lower than the prices of similar drugs in several countries including the United States and United Kingdom as well as Pakistan and Indonesia (see Table 4). India has been a major exporter of relatively cheap active pharmaceutical ingredients (APIs) and pharmaceutical formulations of several medicines, notably vaccines and anti-retrovirals (ARVs) (Grace, 2004, pp.13-5). The Indian pharmaceutical firm CIPLA supplies ARVs to over 250,000 HIV patients in poor countries.[7] When Ranbaxy, another leading Indian pharmaceutical firm, announced plans to launch the cholesterol drug atorvastatin in the US and UK, the media in the UK welcomed it as a move that would result in substantial financial savings to that country's National Health Service (Tomlinson, 2005).

Table 3: Selected Indicators of Growth of Domestic Firms in India's Pharmaceuticals Industry, 1970-2004

	1970	1998	2004
Share in % of domestic firms in India's pharmaceuticals market by sales	32	60	77
Number of domestic firms among top 20 firms by pharmaceutical sales in India	6*	12*	15

Notes: *Statistics refer to the years 1971 and 1996 respectively.

Sources: Chaudhuri (2005), p.18 and Lanjouw (1997), p.39. The statistics cited in Chaudhuri (2005) are based on the following: for 1970, Ministry of Petroleum and Chemicals (1971), p.1; for 1998, Kalsekar (2003); for 2004, Sudip Chaudhuri's calculation using ORG-MARG (2004). The statistics relating to top 20 firms by pharmaceutical sales was cited in Lanjouw (1997) and was sourced from ORG, Mumbai.

[7] See <www.cipla.com>, accessed 15 January 2006.

Table 4: Prices of selected drugs in India and other countries, in Indian Rupees, 2002-2003

Drugs and dosage	India	Pakistan	Indonesia	UK	US
Ciprofloxacin HCL, 500 mg	29	423.9	393.0	1185.7	2352.4
	(1.0)	(14.6)	(13.6)	(40.9)	(81.1)
Diclofenac Sodium, 50 mg	3.5	84.7	59.8	61.0	674.8
	(1.0)	(24.2)	(17.1)	(17.4)	(192.8)
Ranitidine, 150 mg	6.02	74.1	178.4	247.2	863.6
	(1.0)	(12.3)	(29.6)	(41.1)	(143.5)

Notes: Ciprofloxacin HCL is an Anti-infective. Diclofenac and Ranitidine are anti-ulcerants.
Figures in brackets show prices as indices with price in India = 1
Drug prices refer to the following years: for India, 2003; for Pakistan 2002-03; for US, 2002; and for UK February 2004.
Retail prices in India and wholesale prices in other countries were considered. All prices were converted to Indian Rupees.

Source: Centre for Study of Global Trade System and Development (2004) and Keayla (2005).

4.2 The TRIPS Agreement and Changes in India's Patent Laws

The WTO's Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) came into effect on 1 January 1995. As WTO members, India and other developing countries were obliged to bring in legislations in line with the TRIPS provisions over a ten-year period. 'Mail box' facilities and exclusive marketing rights were to be introduced from 1 January 1995 itself; provisions regarding rights of patentee, term of patent protection, compulsory licensing and reversal of burden of proof had to be legislated before 1 January 2000; and laws protecting product patents had to be legislated before the end of the ten-year transition period (therefore, before 1 January 2005).

The Indian Parliament debated the TRIPS provisions intensely, in the process delaying the introduction of obligatory legislations in several instances. The Parliament passed the Patents (Amendments) Act 1999, the Patents (Amendment) Act 2002, the Indian Patents Ordinance of 2004, and the Indian Patents (Amendment) Act of 2005. India's patent rules were made less liberal over the years with the introduction of these legislations. The Patents (Amendment) Act 2002 had made 64 changes to the Patents Act of 1970. There were criticisms that some of the new legislations had not even made full use of the flexibilities that the TRIPS regime had allowed for developing countries; there were also widespread concerns on the implications of these laws for public health. The Indian Patents Ordinance of 2004 had allowed patents on combinations and crystalline versions of known molecules; reduced the grounds on which a patent could be opposed during the pre-grant period; and required least developed countries (LDCs) to issue compulsory licenses for importing generic drugs from India. All these provisions generated strong criticisms as being unduly favourable to patent owners. The Indian Patents (Amendment) Act of 2005, which introduced product patent rules, rectified some of the drawbacks contained in the Ordinance of 2004 (Chaudhuri, 2005, pp.70-116; Grace, 2005).

The battle on patent rules is still going on in India. Multinational pharma corporationss lobby for stricter patent laws and their stricter implementation. On the other side are a number of activists and international organizations raising concerns on public health. Currently, there is strong pressure particularly from the MNCs to bring in new provisions that allow data exclusivity in India. Data exclusivity specifies

that the test data submitted by the patentee to the regulatory agencies will not be disclosed to the public. Generic drug firms, which need to prove bioequivalence of their generic versions of drugs, will be affected by this rule. Also data exclusivity allows the patent holders to extend their monopoly rights even after the expiry of the patent term (Chaudhuri, 2005, pp.80-3; Keayla, 2005).[8] At the same time, in August 2007, an Indian Court dismissed an appeal from the pharmaceuticals giant Novartis regarding patent cover for its drug Gilvec; the Court pointed out that incremental innovations will not be eligible for patent protection. This ruling has raised the hopes for health activists worldwide who argue that a strict patent regime is a deterrent to the supply of affordable medicines (Cookson and Yee, 2007).

4.3 TRIPS and Strategies of Indian Pharmaceutical Firms

With the introduction of TRIPS-compliant product patent rules in 2005, Indian pharmaceutical industry can no longer rely on its reverse engineering skills alone for future growth. India's domestic pharmaceutical firms have been growing in technological capabilities, and this enabled them to make two fundamental changes to their business models during the years of TRIPS implementation (1995-2005).[9] First, leading pharmaceutical firms in India have been making higher allocations for R&D spending and trying to acquire patents abroad. In the case of Dr. Reddy's Laboratories, an Indian firm, R&D charges as a proportion of

[8] See also Dhar and Gopakumar (2006).

[9] See Lanjouw (1997), Sampath (2005), and Chaturvedi et al. (2007) (which provides a detailed update on the strategies of Indian pharmaceutical firms before and after TRIPS). See also Ramanna (2005) on the emergence of a strong pro-patent lobby in the country prior to 2005.

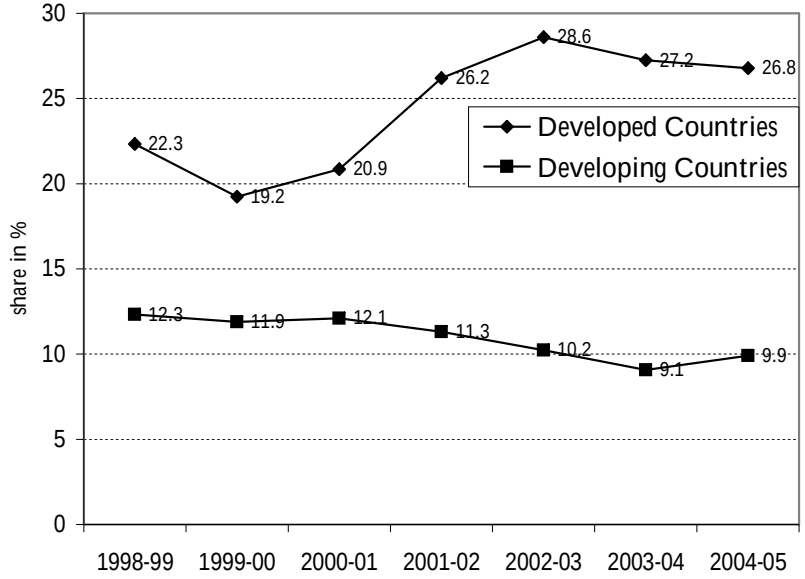
sales revenue were 0.6 percent and 2.8 per cent respectively in the three year periods ending in 1987 and 1994-95. The proportion rose to 11.0 percent in the three year period ending in 2005-06.[10] Ranbaxy made 698 patent filings in the first nine months of 2005 compared to 428 patent filings in the first nine months of 2004.[11] Secondly, rising R&D intensity went hand in hand with export orientation, notably to the regulated markets of North America and Europe. For instance, in 2005, United States and Europe, together, accounted for 45.2 percent of Ranbaxy's total global sales (of US$1178 million).[12] The preference shown by Indian pharmaceutical firms to developed country markets is evident in Figure 2.

[10] See Dr. Reddy's Laboratories Ltd. Annual Reports, various years.

[11] See <www.ranbaxy.com>, accessed 15 January 2006.

[12] See *Ranbaxy Annual Report 2005*, downloaded from <http://www.ranbaxy.com>, accessed on 17 January 2007.

Figure 2: **Exports of drugs, pharmaceuticals and fine chemicals by India to selected developed and developing countries, 1998-99 to 2004-05, shares in India's total exports in percent**



Notes: Selected developed countries: United States, Germany, United Kingdom and Canada.
Selected developing countries: Nigeria, Viet Nam, Sri Lanka, Pakistan, Bangladesh and Nepal.
These 10 countries have figured in the list of 21 leading destinations for India's exports of drugs, pharmaceuticals and fine chemicals throughout the period under study.

Source: Calculations based on CMIE (2005), p.69.

Indian pharmaceutical industry's international ambitions have received a boost also from the changing nature of the global pharmaceutical business. The discovery of a new drug is an extremely lengthy and financially-risky process. Bringing an experimental drug into the United States market takes an average of 12 years. According to some reports, of the 5000 drug compounds that are evaluated at the

preclinical stage, five compounds enter the phase of clinical trials, and only one compound ultimately gets the approval for marketing from the US Food and Drug Administration (FDA).[13] Reports in 2006 indicate that the cost of development and subsequent introduction into the market of a new drug compound range between US$ 0.8 to 1.7 billion (McKinnell, 2006). To reduce the cost of new drug discovery, pharmaceutical MNCs are entering into strategic alliances with smaller pharmaceutical firms, biotech companies and academic centres. Novartis, for instance, claims to have more than 400 collaborations in over 20 countries.[14] India's cost advantages in pharmaceuticals R&D are encouraging global corporations to form research partnerships with Indian firms. Outsourcing of clinical trials to India has witnessed an especially fast growth; the number of ongoing clinical trials in India has risen to 270 in 2007 (Yee, 2007).

The strategies pursued by India's leading drug makers today consist of collaboration as well as, in some cases, competition with Western pharmaceutical MNCs. Even the leading Indian drug firms are much smaller compared to pharmaceutical corporations, and they do not possess the skills or the resources to carry out the entire process of new drug discovery.[15] Therefore, Indian pharmaceutical companies conduct research and develop new molecules, but instead of proceeding further into the long and financially risky clinical trial and regulatory stages, they

[13] According to information given at the Website of Alliance Pharmaceutical Corporation. See <www.allp.com/drug_dev.htm>, accessed 15 July 2006.

[14] See <www.allp.com/drug_dev.htm> and <www.nibr.novartis.com/OurScience/drug_development.html> , accessed 16 September 2006.

[15] For example, in 2005, sales revenue of the Indian company Ranbaxy was US$1.17 billion and that of Pfizer was US$51.3 billion. See Knowledge@Wharton (2006).

license out the molecule to bigger pharmaceutical MNCs (Chaudhury, 2005). At the same time, the high returns in the generic drugs market in North America and Western Europe is highly attractive to Indian drug firms. They have challenged big pharmaceutical corporations in the market for generic drugs in the West. Also, to consolidate their generic drugs business, many Indian drug firms have been pursuing an aggressive strategy of overseas acquisitions over the past several months.[16]

Success, however, is not guaranteed for India's leading drug makers in the generic business. Originator drug companies, some of which have launched their own branded generics, unleash long and expensive legal battles against their generic competitors (Rai, 2003; Jack, 2005). For originator drug companies, patent litigation to delay the entry of generic competitors even by a few months is a high return-zero risk strategy, whereas for generic drug firms, patent related legal battles involve high returns as well as high risks (Chaudhuri, 2005, pp.205-6). Many of the top Indian drug firms are fighting IPR-related legal battles, incurring heavy costs. Ranbaxy has been engaged in a legal wrangle over its generic version of atorvastatin calcium, an anti-cholesterol drug, which Pfizer claims has violated its patent on Lipitor. Ranbaxy's fortunes have waxed and waned in this long-drawn-out litigation that is still being fought in the courts of several countries. Reports suggest that Ranbaxy spent US$30million on legal expenses in the year 2005, while the company's R&D expenditure, for the year 2004, was US$75.1 million.[17]

[16] Information obtained from various issues of *Indian Industry: A Monthly Review* for the year 2007, published by Centre for Monitoring Indian Economy, Mumbai.

[17] See Mahapatra (2006) and Ranbaxy's website <www.ranbaxy.com>, accessed 14 December 2005.

Similarly, Dr. Reddy's reportedly spent US$12m on legal bills in 2004, which was equivalent to a quarter of the company's R&D budget (Economist, 2005).

4.5 The Future of the Industry and the Supply of Affordable Medicines

It is doubtful whether the leading Indian pharmaceutical firms will ever grow to match the levels of Western pharmaceutical MNCs, given the hurdles posed by the IPR-regime and the disparities between the two in financial and research capabilities. No Indian firm has, so far, been able to fully develop an original drug, although some firms are close to achieving this feat. More crucially, a large number of relatively small Indian pharmaceutical firms are facing grim growth prospects in the post-TRIPS phase, and this is raising important questions for the future of the industry in India. It will be difficult for these small Indian firms to repeat the successes of their bigger counterparts in the export markets for generics: the regulatory barriers to entry and the stiff competition in the generic drugs markets in developed countries are important road blocks (Chaudhuri, 2005). In the domestic market, product patent legislations will eventually rein in the growth of small Indian firms. Manufacturing drugs for the domestic market using process innovations, the strategy that helped leading Indian drugs makers during their formative years, is not possible any longer.[18] Furthermore, there is growingly intense competition in India's pharmaceutical markets, raising the costs of entry to smaller firms. In recent years, the Indian

[18] Interview with Mr. B. K. Keayla, 11 December 2006.

pharmaceuticals industry has witnessed a significant increase in mergers and acquisitions (M&As) and a consequent rise in concentration ratios.[19] Smaller Indian pharmaceutical firms are also affected by the tightening of regulatory restrictions in the Indian market as well as in the export markets of countries such as Brazil and Korea.[20]

A bigger concern arising from the recent developments in the pharmaceuticals industry relates to their implications for the supply of medicines to poor patients. The advocates of a strict patent regime have argued that with the implementation of product patent rules, MNCs will step up investment in research on neglected diseases. However, this does not appear to have occurred in India. In a survey of 31 large pharmaceutical companies operating in India (which included companies under Indian ownership and MNC subsidiaries), Lanjouw and MacLeod (2005) found that only 10 percent of the entire R&D investments by these companies in 2003-04 were targeted at developing country markets and tropical diseases. At the same time, multinational pharmaceutical corporations are sensing a major market opportunity for the supply of medicines for global diseases such as cancer and cardiovascular diseases prevalent among India's large middle class population. It appears that MNCs' interests in India are limited to its growing pharmaceuticals market, and not so much in the country's potential as a pharmaceuticals manufacturer. MNC investments in India in the manufacture of bulk drugs have not recorded any appreciable increase in recent years (Chaudhury, 2005). Meanwhile, worries are surfacing about the outsourcing of clinical trials to India.

[19] Concentration ratios of the largest four and largest eight firms in Indian pharmaceutical industry increased after 1995-96. See Chadha (2006).

[20] Interview with Mr. Lalit Kumar Jain, an entrepreneur having long association with small-scale pharmaceutical industry in India, New Delhi, 10 December, 2006.

Terming it as 'a new colonialism', Nundy and Gulhati (2005) have discussed some of the dangers of conducting clinical trials among poor and illiterate patients without putting in place a proper regulatory system.

The problems emerging as part of a post-TRIPS scenario are likely to become more severe in the future. Grace (2005), after examining previous studies, concluded that the share of patented drugs in the market value of medicines supplied in India in 2005 was in the range of 10 to 15 percent. However, over time, as new medicines are invented, a greater proportion of the overall Indian market for medicines will come under the patent cover. New medicines are necessary in the treatment of most diseases including tuberculosis and malaria as older medicines turn ineffective with the setting in of drug resistance. In the case of combination drugs, even if only one drug in the combination is patent protected, that will escalate the cost of the entire therapy (Grace, 2005, pp.16-20). The pressures on the supply of affordable medicines brought about by changes in patent rules are reflected in the words of Dr. Y. K. Hamied of CIPLA, an Indian company that is an important supplier of medicines for tropical diseases:

> ".....[India's product patent legislation implemented in 2005] will deprive the poor of India and also third world countries dependent on India, of the vital medicines they need to survive....It will lead to a systematic denial of drugs to the three billion in the poorer nations, an act tantamount to selective genocide by the year 2015".[21]

[21] Address by Dr. Y. K. Hamied, Chairman and Managing Director, CIPLA, Sixty-Ninth Annual General Meeting, 6 September 2005, at <http://www.cipla.com/corporateprofile/financial/cm69.htm>, accessed 14 December 2005.

5. Pharmaceuticals and Biotechnology in China

Pharmaceuticals industry is expanding fast in China. According to Nolan and Yeung (2001), China's pharmaceuticals industry picked up in growth after the mid-1980s. This was a period when the government relaxed state controls over the industry and generated competition among the suppliers. The structure of ownership was gradually liberalized as well, and raising funds on the stock market and mergers and acquisitions became instruments through which the pharma industry further consolidated its position in China (Nolan and Yeong, 2001). There were 4296 pharmaceutical manufacturing facilities in China in 2003. Domestic industry supplies almost 70 percent of the Chinese market for pharmaceutical products. Chinese firms have acquired great expertise in the manufacture of bulk drugs and active pharmaceutical ingredients (APIs). China is the world's second largest producer of pharmaceutical ingredients, and the largest producer of many pharmaceutical products including penicillin (producing 60 percent of world output), vitamin C (50 percent of world output), terramycin (65 percent of world output), doxycycline hydrochloride and cephalosporins (Grace, 2004, pp.13-4). The countrty is promoting innovative research in the area of traditional Chinese medicine; in April 2004, Chinese authorities approved the first HIV/AIDS treatment derived from traditional Chinese medicine (Grace, 2005, p.10-1).

At the same time, however, the strength of China's domestic pharmaceuticals industry should not be overstated. Nolan (2002), while making a note of the impressive growth of the Chinese pharmaceutical firm Sanjiu during the 1990s, was quick to add that firms like Sanjiu

would face massive hurdles as they compete with multinational pharmaceutical giants. Nolan (2002) points out that China's pharmaceuticals industry is "relatively small and highly fragmented", and that the revenues and research capabilities of Chinese firms are only a tiny fraction of multinational companies (Nolan, 2002: 123).

5.1. Pharmaceuticals Industry and the Evolution of IPR Regime in China

Significant steps in the direction of establishing a patent regime began in China only after the late 1970s.[22] Chinese government's gradual implementation of an intellectual property rights (IPR) policy was shaped by two factors: a commitment to the development of domestic capabilities in science and technology, on the one hand, and, international pressure, particularly from the United States, pushing China to a strict patent regime, on the other. China joined the World Intellectual Property Organization (WIPO) in March 1980 and the Paris Convention for the Protection of Industrial Property in March 1985. The first Patents Law was introduced in China in 1984. This law, which came into effect on 1 April, 1985, was rather narrow in its scope. It did not offer product patent protection to inventions in pharmaceuticals, chemicals, food, beverages and condiments (in much the same manner as India's Patents Act of 1970). The stipulations contained in the 1984 law ensured that foreign investments into China came along with technology transfer and contributed to the building of domestic innovative capabilities (Kong, 2005).

[22] See <http://www.china.org.cn/e-white/20050421/index.htm>, accessed 15 January 2006.

China introduced a stricter patent regime in 1992. In the early 1990s, China was integrating itself more closely with the world economy, and a commitment to IPR protection was important to attract foreign investments. Also, from being an importer of technologies, China was gradually emerging as an exporter of technology-intensive products (Kong, 2005). Grace (2005) noted that the implementation of IPR policies in China was influenced, to a great extent, by the country's bilateral negotiations with the United States on trade and investment. Product patenting rules came into effect in China in 1993 – more than ten years before TRIPS would have required the country to implement them. An agreement between China and the United States in 1999 on China's WTO accession contained proposals for early introduction of TRIPS-compliant IPR rules. China joined the WTO in 2001, and the country introduced patent laws incorporating TRIPS provisions by the end of 2002. China was not given the transition period that was granted to other developing countries (Grace, 2005, pp. 21-5; Kong, 2005). Chinese laws extend patent protection for twenty years and data exclusivity for six years (Grace, 2004).

Despite the implementation of product patent laws, China has been able to manufacture pharmaceutical ingredients that contribute to the supply of essential medicines for the developing world. China is an important producer of a wide variety of raw materials for second-line antiretrovirals (ARVs) (second-line ARVs are necessary for treatment once the patient develops resistance to first-line treatment).[23] One of the

[23] See 'India, China or Brazil — Who will Produce the Second Line ARVs?', *Health and Development Networks*, July 12, 2005, at <http://www.aidsmap.com/en/news/24B33FA6-89CB-42BA-880F-18D774FF85D6.asp>, accessed 17 September 2005.

means through which China has bypassed the limitations set by patent laws is by manufacturing intermediates only till the pre-API (active pharmaceutical ingredients) stage. Patent protection is usually applicable to APIs and finished products, and manufacturing a chemical that is one step away from formulation into an API will not be a patent violation. China then exports these intermediate pharmaceutical chemicals to other countries where it is processed into APIs and finished products (Grace, 2005, pp.23-5).

However, pharmaceuticals industry in China is now facing challenges from the patent regime. The United States continuously pressurize China to improve its record on IPR enforcement. In December 2006, on the occasion of the fifth anniversary of China's entry into the WTO, the US Trade Representative, Susan Schwab, slammed China's record in enforcement of IPR rules. In a 100-page report submitted to the US Congress, the US Trade Representative claimed that piracy of software, videos, pharmaceuticals and other goods were rampant in China and that the Chinese government did very little to curb such practices (Weisman, 2006). Reports suggest that in 2004, 2550 patent litigations were filed in Chinese courts and that the rulings in 80 per cent of these cases went in favour of the foreign patent holders (Seewald, 2006).

At the same time, Western multinational pharmaceutical companies are waking up to the tremendous market opportunities offered by China's large middle class population. Some estimates say that the Chinese pharmaceuticals market would be the fifth largest in the world by 2010.[24] It is noted that over 20 of the world's top 25 pharmaceutical

MNCs have already made their entry into China.[25] Pharmaceutical corporations are flocking especially to China's eastern region comprising the Yangtze River Delta, which enjoys high levels of purchasing power.[26] With the introduction of product patent legislations, many multinational pharmaceutical companies are outsourcing pharmaceutical research and clinical trials to China. In 2007, there were a total of 510 clinical trials – including completed and ongoing — outsourced to China (Jack and Yee, 2007). Companies like Novo Nordisk and Novartis have set up R&D facilities in China to conduct research on global diseases by making use of China's cost advantage. They are equally keen on making inroads into the Chinese market for pharmaceuticals.[27]

5.2 Health and Agricultural Biotechnology in China

China has embarked on an ambitious programme in biotechnology. Life sciences has emerged as an important focus area in China after the late 1970s, along with the state-wide promotion of science and technology in the country during this period. The National Centre for Biotechnology Development was established in 1983 under the State Science and Technology Commission (this Centre later became part of the Ministry of Science and Technology) (Gross, 1995; Chervenak, 2005). By 1992, the government established seventeen national biotechnology

[24] See 'The Chinese Pharmaceuticals Market is Forecast to Become the World's Fifth Largest by 2010', *Biotech Business Week*, July 9, 2007

[25] Information from *Biotech Business Week*, May 14, 2007

[26] See 'Pall Magnifies Focus on Asia; Brings Top Talent, More Resources to the Region to Address Growing Biopharmaceutical Market', *Business Wire Inc*, March 21, 2006.

[27] See the report 'A Novel Prescription' in the *Economist*, November 11, 2006; also see Kjersem and Gammeltoft (2006).

laboratories that were open to both domestic and foreign scientists; and by 1995, there were approximately 1,000 biotechnology projects in China employing over 10,000 scientists. According to a report in 1995, almost one-third of the funds for biotechnology research in China came from the Central Government (Gross, 1995). Between 1996 and 2000, the Central Government invested over 1.5 billion Yuan (US$180 million) in biotechnology (Economist, 2002). Local governments as well as quasi-venture capital funds set up by the Central or local governments were active in the promotion of biotechnology in China. The government also encouraged Chinese firms to establish links with Western biotechnology companies (Chervenak, 2005).

The government enhanced funding for the biotechnology sector in China after 2000. As per estimates made in 2005, the Chinese government spends more than US$600 million per year on biotechnology R&D through its various funding programmes (Chervenak, 2005). This, however, must be compared to the investment in biotechnology R&D in the United States, which was US$15.7 billion in 2001 (Economist, 2002). In 2002, according to estimates by China's Ministry of Science and Technology, 20,000 researchers were working in the field of life sciences in the country; in the same year, biotechnology industry was reported to be employing 191,000 people in the United States. Approximately another 20,000 Chinese biotechnology researchers were working abroad in the year 2002, and their eventual return to the country was expected to give a further boost to the biotechnology industry in China (Economist, 2002).

The major centres of China's biotechnology industry include Shenzhen, Shanghai and Beijing. Beijing Genomics Institute (BGI), which

was established as a state-sponsored research centre in 1999, took part in the Human Genome Project; China was the only developing country to participate in this project. Fudan University's Human Genome Laboratory in Shanghai is involved in the mapping and sequencing the human X chromosome (Gross, 1995; Chervenak, 2005).

China is making rapid advances in the field of agricultural biotechnology as well. Agricultural biotechnology began to receive considerable policy attention in China from the late 1980s, as part of a response to the enormous challenges of feeding a large population and improving productivity in China's small farms. Reports suggest that the government under the former Prime Minister Zhu Rongji was highly concerned about the growing dominance of US biotechnology firms in Chinese agriculture.[28] That the seeds improved over decades by Chinese farmers could be appropriated by a few large US biotech corporations was a worrying prospect to policy makers in China (Chen, 1999).[29] Under these circumstances, the government stepped up funding for research on GM crops that are highly suited to local growing conditions. In 1999, government expenditure on agricultural biotechnology research in China was US$112 million. This figure was nearly ten times the agricultural biotechnology research budgets of India and Brazil in the same year,

[28] In the late 1990s, the US biotechnology companies were in a dominant position in Shijiazhuang, Hebei and Langfang area. Chinese biotechnology firms had the upper hand in Henan and Anhui Provinces. See Chen (1999).

[29] These are the views expressed by Chen Zhangliang, Vice Chancellor and Professor of Beijing University, in an interview he gave in 1999. See Chen (1999). According to Chen Zhangliang, the Chinese Premier expressed his concerns regarding US multinational corporations' dominance in Chinese agriculture after a visit to the north-eastern province of Jilin.

although it was still considerably smaller than the US$1-2 billion that the United States spent in 1999 on plant biotechnology research (Karplus, 2003).

Public investment in biotechnology research in China has produced impressive results. As per reports in 2002, Chinese research institutes developed 141 types of GM crops, of which 65 were undergoing field trials. Today, China is carrying out research on genetically modified tomatoes that take longer to rot (which helps in their transportation, processing and storage); and vitamin A enriched rice that will help improve nutrition in many parts of the developing world. China has recorded great success in research on *Bt* cotton. Chinese research laboratories introduced 18 varieties of pest resistant *Bt* cotton by 2002 (Karplus, 2003). Area under *Bt* cotton cultivation in China increased from 1.5 million hectares in 2001 to 3.3 million hectares in 2005, and over 4 million small-scale farmers were involved in *Bt* cotton cultivation in China in the year 2001 (Karplus, 2003).

5.3 India and China: Interactions in Pharmaceuticals and Biotechnology

Over the past few years, there has been a growing engagement between India and China in the economic sphere, and this has extended to the pharmaceuticals and biotechnology sectors as well. While several major Indian pharmaceutical firms have set up joint ventures and production facilities in China, China has emerged as a very important supplier of APIs and bulk drugs for pharmaceuticals industry in India. As a source of India's imports of medicinal and pharmaceutical products,

China's share is the highest, at 34.6 percent in 2005-06, having risen from 6.2 percent in 1993-94. Correspondingly, as a destination for India's exports of drugs, pharmaceuticals and fine chemicals, China's share increased from 0.4 percent in 1993-94 to 3.5 percent in 2005-06 (CMIE, 1997; CMIE, 2005; CMIE, 2006).

It may be noted that the import of bulk drugs and APIs from China is viewed as a threat by many small-scale bulk drug manufacturers in India. Small-scale drug firms in India have been encountering several growth constraints (some of which have been discussed earlier), which are aggravated by competition from Chinese bulk drug makers. Chinese firms are large-scale producers of many of the intermediates for bulk drug manufacturing, enjoying clear advantages in their specific areas of production. At the same time, industry observers say that India possesses superior technology and skills in pharmaceutical formulations. Representatives of small-scale pharmaceutical industry in India have expressed fears about Indian drug companies transferring technological skills to their Chinese counterparts.[1]

While some of the genuine growth concerns of small-scale drug makers in India need to be addressed, these should not be a reason to stall greater positive interaction between pharmaceuticals industries in India and China. Rather than competing with each other, pharmaceutical firms in the two countries must seek avenues for cooperation at the higher plane of innovation. China's biotechnology sector and India's

[1] Interview with Mr. Lalit Kumar Jain, New Delhi, December 10, 2006. See also Chaudhuri (2005).

pharmaceuticals industry should feed into each other's expertise. Together, they can strive for pharmaceutical innovations that address the health needs of poor patients in the developing world.

India and China can enhance their levels of engagement in agricultural biotechnology as well. India has given approval for commercial sale of 12 varieties of *Bt* cotton hybrids, all of which carry the gene developed by the multinational giant Monsanto and marketed in India by joint ventures (Mahyco-Monsanto) or sub-licensees of Monsanto (Chaturvedi, 2005). However, reports from Andhra Pradesh indicate that genetically modified (GM) cotton crops sold by Mahyco-Monsanto were a failure in all the three years after the crop's introduction. Many farmers who took loans to buy GM seeds fell into huge debt-traps, but Mahyco-Monsanto refused to compensate the farmers for their losses (Venkateshwarlu, 2006). Given such experiences, public and private sector seed companies in India should strive to develop new GM technologies that are suitable for India's agro-climactic and socio-economic environment. Collaboration with China, which has a very successful programme in agricultural biotechnology, will be highly useful in this regard. It is indeed a positive sign that, in March 2006, Agriculture Ministers of India and China identified a number of areas for cooperation, including agriculture biotechnology and exchange of plant and animal germplasm.[30]

[30] See the report 'India, China Sign Agriculture Cooperation Pact', *Financial Times*, March 30, 2006.

6. Conclusions

Globalization picks its winners and losers. According to Hoogvelt (2001), populations and countries in the periphery of the global economy progressively lose out while those who are part of the core strengthen their positions. This chapter shows that the geography and nature of innovation in the world economy are being fundamentally altered, in part due to global rules on intellectual property rights enshrined in the TRIPS and imposed on developing countries. India and China are emerging as important destinations for global R&D on account of their large supplies of highly skilled professionals and well-established science and technology infrastructures. However, even as globalization of R&D gathers steam, the poor in India, China and other developing countries are likely to be left out of the new innovations, and big corporations in the West are likely to consolidate their strengths.

The case studies of pharmaceuticals industries in India and China presented in this chapter gives some credence to such apprehensions. India has been a major supplier of generic drugs at affordable prices within the country and outside, while China has been an important producer of raw materials and active pharmaceutical ingredients for the manufacture of several essential drugs, including anti-retrovirals for the treatment of HIV/AIDS. Product patent rules in compliance with the TRIPS were fully implemented in China by 2002 and in India by 2005 as part of the WTO obligations of these countries. The leading Indian pharmaceutical firms have responded well to the challenge of a strict IPR regime by increasing their R&D spending and, simultaneously, targeting their sales to the generic drugs markets in North America and Europe. However,

even as India's top drug firms have been growing in technological capabilities, they have also been shifting their focus away from the market for medicines for poor patients. Smaller pharmaceutical firms in India are facing several growth challenges, especially from the new IPR regime, which hinder their potential to supply drugs for the domestic market. The United States continuously pressurize China to improve its record on enforcement of IPR rules. MNCs have increased their presence in India and China, conducting contract research and clinical trials on global diseases, eyeing the market of rich patients in these countries and outside. Contrary to expectations, the implementation of TRIPS has not led to any marked increase in MNCs' R&D spending on neglected diseases. In fact, there are growing uncertainties today on the future supply of affordable medicines in the developing world.

In the light of such experiences, developing countries, importantly India and China, need to initiate strong policy measures to counter the negative effects of globalization of R&D. First, developing countries should strengthen their national programmes in science and technology to ensure that they are not overshadowed by global corporations. In this regard, China's attempt to reinvigorate the biotechnology sector is commendable. Secondly, developing countries need to cooperate in the area of innovation. Innovative firms in India and China should explore areas for complementary growth, rather than competing with each other to obtain a slice of the market for R&D outsourcing. Blending India's expertise in pharmaceutical formulations and China's growing capabilities in biotechnology could result in new drugs for neglected diseases. China and India have the responsibility for and, indeed, the capabilities to lead developing countries in innovations that could solve world's problems of ill health and deprivation.

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