

*Knowledge Economies in India and China:
Challenges and Prospects in Pharmaceuticals and
Biotechnology*

*Jayan Jose Thomas**

Research Fellow

Institute of South Asian Studies

National University of Singapore

Email: jayanjthomas@gmail.com

* *The author is thankful to the Institute of South Asian Studies, National University of Singapore for providing a research grant to carry out this study. Different versions of this study were presented at the Conference on China, India, and the International Economic Order organized by the Faculty of Law, National University of Singapore, June 23-24, 2006; a seminar at the Centre for Technology, Innovation and Culture, University of Oslo, September 25, 2006; Conference on New Asian Dynamics in Science, Technology and Innovation, Copenhagen, September 27-29, 2006; and the fourth annual conference of GLOBELICS (Global Network for Economics of Learning, Innovation, and Competence Building Systems) held at Thiruvananthapuram, India, October 4-7, 2006. The author is grateful to the participants at the different conferences/seminar, and to Anthony D'Costa and Govindan Parayil for their comments on this study. A special word of thanks goes to Joe C. Mathew for his generous help in the field study and collection of research material.*

Knowledge Economies in India and China: Challenges and Prospects in Pharmaceuticals and Biotechnology

Jayan Jose Thomas

1. INTRODUCTION

Recent news reports have frequently described India and China as “rivals and partners.”¹ India and China are today experiencing some of the fastest rates of economic expansion in their recent histories. The two countries are often seen as rivals, racing with each other on the basis of their most visible source of competence: abundance and low cost of labour.² However, economic advantages arising out of low labour costs are short lived, likely to last only until snatched away by a competitor country offering still lower wages. The real source of competence in the world economy lies in innovation. Therefore, for both India and China, performance in technology-intensive or knowledge-intensive industries will be the crucial test for long-term success.

The United Nations’ World Investment Report 2005 points out that there is now a new wave of R&D investments by multinational companies (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

¹ *“Rivals and Partners” is the title of an article on India and China published in the Economist on 3 March, 2005. See also the article by Nicholas Kristoff on economic growth prospects of India and China: ‘They’re Rounding the First Turn! And the Favourite Is’, New York Times, 17 January, 2006, p.19.*

² *A good example is this report by Andrew Taylor: ‘Study warns of China/India wage gap’, Financial Times, 15 November, 2005, p.10.*

was the third most attractive location, behind the United States.³ Foreign direct investment (FDI), especially in technology-intensive industries, used to be circulated largely within developed countries. R&D activities of MNCs in developing countries were restricted 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 is likely to mark the beginning of a new phase of globalization of R&D.

There are many factors behind Asia's growing prominence as an R&D location. The large supply of skilled professionals at relatively low costs in India and China is a major attraction. The two countries have made huge public investments in science and technology over the past decades, and this is a strong base for future growth. In addition, China and India have, in recent years, introduced new 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 provided further incentives for MNC investments.

However, the challenges unfolding are many as India and China increasingly become centres for outsourcing of innovation by global corporations. First, there are concerns on the future supply for the vast market for innovative products within India, China and other developing countries. There is 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 the rich. With the rise of India and China as favoured destinations for R&D, the future supply of innovations for the poor in the third world is likely to receive a negative – and not positive -- impetus. TRIPS-compliant product patent rules implemented by India and China, while encouraging MNC investments, have also created constraints to growth and innovation to domestic firms in these countries. At the same time, in the

³ Singapore, Taiwan Province of China, Malaysia, South Korea and Thailand found places in the list of 20 most promising destinations for R&D investments as identified by the respondents in the survey. See UNCTAD (2005), pp.22-6.

post-TRIPS phase, there are growing opportunities for domestic firms in China and India to carry out contract research for MNCs, targeting the innovation needs of rich consumers.

Secondly, as domestic firms in India and China progressively move away from their home markets and carry out R&D for export markets, it raises questions 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 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) and this has locked this industry into a low innovation trajectory. At the same time, according to Chandrasekhar (2006), outsourcing and offshoring of business services to India are part of the strategies of US corporations to maintain their high profit levels by tapping into the global reserve army of labour.

This paper analyses the above mentioned challenges as well as fresh prospects to innovation in China and India in the context of globalization of R&D. It studies the cases of pharmaceuticals and biotechnology industries. This study will argue that rather than competing with each other by cutting wage costs, India and China must join hands and take the lead in developing products of innovation that would benefit the third world.

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 health biotechnology industries in China, and on the possibilities for India-China cooperation in these industries. Section 6 is on agricultural biotechnology, and Section 7 concludes the paper.

2. THE RISE OF INDIA AND CHINA IN THE KNOWLEDGE ECONOMY

The new interest on India and China as destinations for R&D investments is triggered, most importantly, by the large supply of highly skilled professionals in these countries. In 2000-01, the total numbers of students enrolled for tertiary education were approximately 12 million in China and 10 million in India.⁴ 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 165,610.⁵ Both China and India are today ahead of the United States with respect to tertiary technical enrolment.⁶ While the supply of skilled workers is large in India and China, the costs of employing them are relatively low. 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.⁷

Both India and China have a large population of emigrants working as skilled professionals in foreign countries. Students from India and China top the list of foreign students in the United States. In China, the number of postgraduates studying abroad has increased steadily: from 860 in 1978 to 20,381 in 1995; 38,989 in 2000; and 114,682 in 2004⁸. Indian professionals accounted for 47 per cent of all H-1 visas issued (to skilled workers) in the United States in 1999; workers from China formed the second largest group, with a share of 5.0 per cent of all the H-1 visas issued.⁹ In regard to work permits issued to emigrants from different nationalities in the United Kingdom, Indians topped the list with a share of 21.4 per cent of the total work permits issued in 2002, up from a share of 8.3 per cent only in 1995 (Findlay, 2006, p.78). Today, India and China are encouraging return migration of their highly skilled professionals to

⁴ See UNCTAD (2005), p.162.

⁵ National Bureau of Statistics of China (2005), pp. 689-95.

⁶ See UNCTAD (2005), p.162.

⁷ It may be noted that annual costs include salary, benefits, equipment, office space and other infrastructure. See Ernst (2005), p.56. Ernst's (2005) figures are based on PMC-Sierra Inc., Burnaby, Canada (for Silicon Valley, Canada and India) and interviews.

⁸ National Bureau of Statistics of China (2005), pp. 689-95.

⁹ Cited in Chanda and Sreenivasan (2006), p. 220.

energize high technology entrepreneurship back home. China is aggressively promoting a programme of “reverse brain drain”; the Chinese Academy of Sciences has many attractive schemes to woo returnee researchers (Zweig, 2006).

The state in post-independence India has actively intervened to build a strong infrastructure for science and technology, and this is another factor attracting new investments. R&D in India has been financed largely by the public sector. In the total national expenditure on R&D in India in 2002-03 (the latest year for which data was available), the share of the Central government, including public sector units under its management, was 67.1 per cent and the combined share of various State governments was another 8.5 per cent. Higher education accounted for 4.1 per cent of the total national R&D expenditure. The share of the private sector in the total national expenditure on R&D in India was only 20.3 per cent in 2002-03. India’s national R&D spending is allocated into the following broad areas (based on 2002-03 figures): defence (18.3 per cent of the total), development of agriculture, forestry and fishing (17.7 per cent), space research (13.1 per cent), promotion of industrial development (10.1 per cent) and promotion of health services (9.5 per cent) (GOI, 2006, pp.3-8).

In China, government intervention in science and technology increased significantly after 1978. The government began the “four modernizations” in the areas of agriculture, industry, national defence and science and technology. New research centres were established. A crash programme was given to 800,000 scientific research workers in China. The aim was to develop expertise in the fields of energy sources, computers, space technology, high-energy physics and genetics. Eighty-eight key universities were developed for excellence in science and technology; admissions to these universities were regulated through rigorous competitive exams. Potential students talented in science and technology were identified at an early age. Scientists who were sent to the countryside in the earlier years were called back. Collaborations with foreign universities began. In 1978, China sent 480 students to 28 countries for higher studies (Spence, 1999, pp.618-20).

In China, the 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.¹⁰ The 973 programme has identified life sciences, nano-technology, information technology, and earth sciences as frontier areas for basic research. The priority areas for R&D in China during its 10th Five-year Plan period (began in 2001) included the construction of information infrastructure for the country and the development of biological, agricultural and pharmaceutical technologies. According to Chinese government statistics for 2004, of the total funding for science and technology, 22.8 per cent came directly from the government, 64 per cent of the funds were raised by enterprises themselves, and 6.1 per cent came through loans from financial institutions (National Bureau of Statistics of China, 2005, pp. 714-7).

An important feature of R&D spending in India is the domineering role of R&D institutions and the relatively minor role of industrial units. R&D institutions at the national and State levels and the academic sector, together, accounted for 75.2 per cent of the total R&D expenditure in India in 2002-03, while industries, public and private, incurred only 24.8 per cent (GOI, 2006, pp.3-8).¹¹ In China, large and medium-scale industrial enterprises accounted for 48.5 per cent of the total national expenditure on R&D (for scientific and technological activities) in 2004; R&D institutions received 22.0 per cent and higher education accounted for 10.2 per cent of the national expenditure (National Bureau of Statistics of China, 2005, pp. 714-7). In India, within the industrial sector, the sector which received the highest priority in R&D spending was drugs and pharmaceuticals followed by transportation industries (in 2002-03) (GOI, 2006, p. 32). In China, the thrust areas within high-tech industrial sector R&D are the manufacture of electronic and telecommunication equipments, manufacture of computers, and manufacture of medical and

¹⁰ 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.

¹¹ In India, the major R&D institutions at the national level are Defence Research and Development Organization (DRDO), Department of Space (DOS), Indian Council of Agricultural Research (ICAR), Department of Atomic Energy (DAE) and the Council of Scientific and Industrial Research (CSIR).

pharmaceutical products, in that order (National Bureau of Statistics of China, 2005, p.718).

Given the low share of industrial R&D in total R&D expenditures, it is relevant to examine whether investments in science and technology have created strong 'national innovation systems' (NIS) in India?¹² D'Costa (2006) argues that NIS or 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 although there are many academic and research institutions in Bangalore, they do not have much linkages with software firms in the city (D'Costa, 2006). According to Dahlman and Utz (2005), the gulf between the academic world and industry is very high in India.

2.1 Challenges Facing India and China in High Technology Sectors

While India and China undoubtedly enjoy some advantages in science and technology on account of their highly skilled manpower, both the countries still have a long way to go in many other aspects of R&D performance. In 2002, R&D expenditure incurred by the United States was US\$276.2 billions, while the corresponding figures for China and India (in 2001) were, respectively, US\$15.6 billions and US\$3.7 billions (see Table 1). R&D expenditures as a proportion of GDP for the period 1997-2002 was 2.6 per cent for high-income OECD (Organization for Economic Cooperation and Development) countries on an average and 2.7 per cent for the United States, but only 1.2 per cent for China and 0.8 per cent for India. In other indicators of R&D performance as well, as shown in Table 1, India and, to a lesser extent, China lag behind the United States and other high-income OECD countries (see Table 1).

¹² For a discussion on 'national system of innovation', see Freeman (1995).

Table 1: Selected indicators of performance in research and development: India, China and the United States

	<i>India</i>	<i>China</i>	<i>United States</i>
<i>R&D Expenditure, billions of US dollars, 2002</i>	<i>3.7*</i>	<i>15.6</i>	<i>276.2</i>
<i>R&D as % share of GDP, 1997-2002</i>	<i>0.8</i>	<i>1.2</i>	<i>2.7</i>
<i>Researchers in R&D, per million people, 1990-2003</i>	<i>120</i>	<i>633</i>	<i>4526</i>
<i>High technology exports as a % share of manufactured exports, 2003</i>	<i>5</i>	<i>27</i>	<i>31</i>
<i>Patents granted to residents, per million people, 2002</i>	<i>0</i>	<i>5</i>	<i>302</i>

*Notes: *2001 data*

Sources: UNDP (2005), Table 13, pp. 262-65 and Table 16, pp. 274-77; UNCTAD (2005), p.105

The evolving relationship between multinational companies, the state in India and China, and domestic firms in these two countries will 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. In the case of high technology industries, MNCs in the United States and Western Europe continue to reign supreme. R&D

expenditures by some Western MNCs have exceeded the national R&D expenditures in countries including India, Brazil and Singapore. For instance, R&D spending by Pfizer of the United States in 2002 was US\$4.8 billion; the national R&D expenditure of Singapore in the same year was \$1.9 billion and that of India in 2001 was \$3.7 billion (UNCTAD, 2005, p. 120). Further, in their pursuit to maintain upper hand in innovation and knowledge-intensive industries, multinational companies in the United States and Western Europe are assisted by some of the provisions in the TRIPS agreement (Drahos with Braithwaite, 2002).

It is possible that as high-tech MNCs invest in a developing country, the domestic innovation capabilities of the host country are depleted, rather than replenished. 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). More importantly, as a consequence of the above mentioned trends, the nature of R&D in developing countries may undergo changes. The nature of R&D may be tilted towards the innovations needs of developed country markets, as will be shown in the case of Indian pharmaceutical industry.

3. DEMAND FROM DEVELOPING COUNTRIES FOR INNOVATIONS IN PHARMACEUTICALS AND BIOTECHNOLOGY

With respect to achievements in health and other human development indicators, extreme disparities exist between developed and developing countries. 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 2003 could be expected to live for only 46 years whereas a person born into a high income OECD country in the same year could possibly live for 79 years (see Table 2). In 2000-02, 30 per cent of the population in Sub-Saharan Africa, 21 per cent of the population in South Asia and 16 percent of the population in developing countries as a whole were

undernourished. 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. None of the countries in Western Europe or North America reported cases of Malaria in that year (UNDP, 2005). Reported cases of tuberculosis in the year 2003 were, per 100,000 persons, 452 in least developed countries, 289 in developing countries and 18 only in high-income OECD countries (See Table 2).

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

	<i>Population, millions</i>	<i>Life expectancy at birth, years</i>	<i>Population under-nourished, %</i>	<i>HIV prevalence, ages 15-49, %</i>	<i>TB cases, per 100,000 persons</i>
	<i>2003</i>	<i>2003</i>	<i>2000-02</i>	<i>2003</i>	<i>2003</i>
<i>LDCs</i>	<i>723.2</i>	<i>52.2</i>	<i>33</i>	<i>3.2</i>	<i>452</i>
<i>Developing Countries</i>	<i>5022.4</i>	<i>65.0</i>	<i>16</i>	<i>1.3</i>	<i>289</i>
<i>Sub-Saharan Africa</i>	<i>674.2</i>	<i>46.1</i>	<i>30</i>	<i>7.3</i>	<i>487</i>
<i>South Asia</i>	<i>1503.4</i>	<i>63.4</i>	<i>21</i>	<i>0.7</i>	<i>306</i>
<i>India</i>	<i>1070.8</i>	<i>63.3</i>	<i>21</i>	<i>0.4 – 1.3</i>	<i>287</i>
<i>China</i>	<i>1300</i>	<i>71.6</i>	<i>11</i>	<i>0.1</i>	<i>245</i>
<i>High Income OECD</i>	<i>917.4</i>	<i>78.9</i>	<i>--</i>	<i>0.4</i>	<i>18</i>

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

Source: UNDP (2005).

Technological advances in pharmaceuticals and biotechnology open a window of opportunity to solve the severe problems of ill health and malnutrition in the third world. However, while majority the world's population who are in need of medicines live in developing countries, much of the global production of pharmaceuticals is controlled by a small number of MNCs in a few developed nations. Between 1985 and 1999, the share of high income countries (according to World Bank definition) in global pharmaceutical production increased from 89.1 per cent to 92.9 per cent, while the combined share of middle and low income countries decreased from 10.9 per cent to 7.1 per cent. United States is the world's largest producer of pharmaceutical products, with a share of 31.1 per cent of the total value of production in 1999. High income industrialized countries dominate the global trade in pharmaceuticals, with shares of 93 per cent of the total exports and 80 per cent of the total imports in 1999 (WHO, 2004, pp. 5-7).

Research and development in pharmaceuticals is carried out largely in developed countries. Of the total global spending on health R&D, 42 per cent is privately funded, 47 per cent is funded by the public sector in high-income and transition countries, and only 3 per cent is financed by the public sector in low- and middle-income countries (WHO, 2004, p.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' in this paper) such as dengue, diphtheria and malaria, which primarily affect people in the poorer countries, and these diseases are given very low priority in pharmaceutical R&D.¹³ It is pointed out that only 10 per cent of the worldwide spending on pharmaceutical R&D is directed toward 90 per cent of the global disease burden (WHO, 2004, pp.18-19).

¹³ See Lanjouw and MacLeod (2005), p.4234.

Poor persons in developing countries are greatly deprived of their medical needs. Between 1985 and 1999, the share of high-income countries in consumption (in value terms) of medicines increased from 88.9 per cent to 91.2 per cent, even though their share in world population declined from 17.8 per cent to 14.9 per cent. During the same period, the share of low-income countries in the total consumption (in value terms) of medicines in the world declined from 3.9 per cent to 2.9 per cent, even as their share in world's population increased from 32.4 per cent to 40.2 per cent (see Figure 1). It is reported that over one-third of world's population purchased less than one per cent of the pharmaceuticals sold worldwide.¹⁴ As Table 3 shows, 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. India, 65 per cent of whose population were without access to essential medicines in 1999, Africa and many parts of the developing world face enormous challenges in ensuring the health needs of their population (see Table 3).

Table 3: World's population without access to essential medicines, different World Health Organization (WHO) regions, 1999

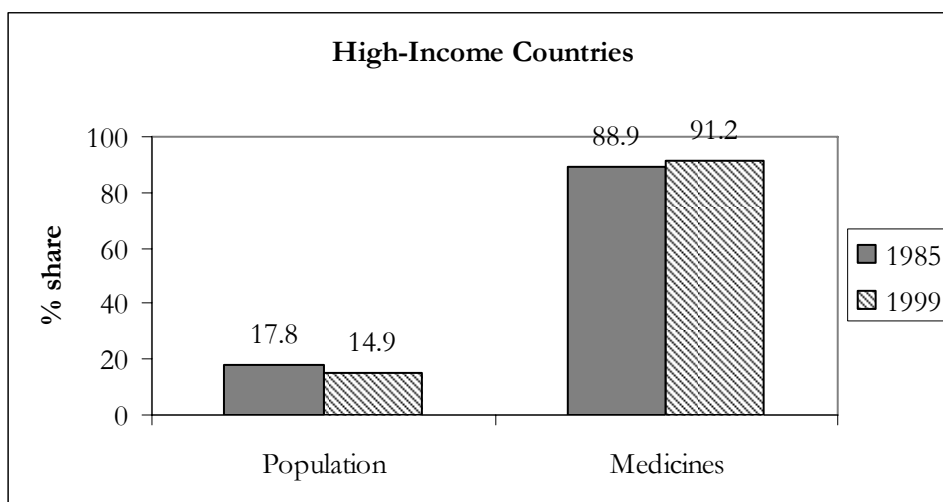
<i>WHO Region</i>	<i>Population, millions</i>	<i>Estimated population without access, millions</i>	<i>% of region's population without access</i>	<i>% share in total world population without access</i>
	<i>(i)</i>	<i>(ii)</i>	<i>(ii as % of i)</i>	<i>(ii as % of its total)</i>
<i>African</i>	<i>566</i>	<i>267</i>	<i>47</i>	<i>15</i>
<i>American</i>	<i>813</i>	<i>179</i>	<i>22</i>	<i>10</i>

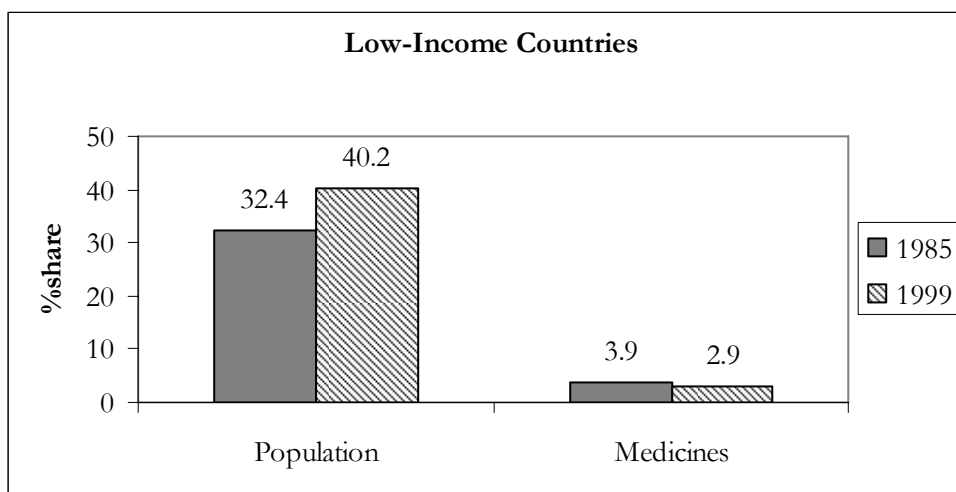
¹⁴ WHO (2004), pp.31-33.

<i>East Mediterranean</i>	<i>485</i>	<i>143</i>	<i>29</i>	<i>8</i>
<i>European</i>	<i>832</i>	<i>114</i>	<i>14</i>	<i>7</i>
<i>Southeast Asia</i>	<i>486</i>	<i>127</i>	<i>26</i>	<i>7</i>
<i>West Pacific</i>	<i>380</i>	<i>55</i>	<i>14</i>	<i>3</i>
<i>India</i>	<i>998</i>	<i>649</i>	<i>65</i>	<i>38</i>
<i>China</i>	<i>1274</i>	<i>191</i>	<i>15</i>	<i>11</i>
<i>Total</i>	<i>5334</i>	<i>1725</i>	<i>30</i>	<i>100</i>

Source: World Health Organization (2004), Table 7.2, p.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 per cent





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.

4. PHARMACEUTICALS INDUSTRY IN INDIA

India has a thriving pharmaceuticals industry. India supplies 8 per cent of the world’s output (in volume) of drugs, and 22 per cent of the world’s output of generic drugs (Sampath, 2005, p.15; Grace, 2004). In 2005, there were 84 manufacturing units in India approved by the United State’s Food and Drug Administration (FDA); this was the largest number of FDA approved

manufacturing facilities in any country outside the United States.¹⁵ As per the statistics available in 2005, Indian pharmaceutical industry consisted of 300 large to moderate firms and approximately 5000 smaller firms, and together they produced output valued at US\$10billion (Grace, 2005, p.8) (for a comparison, the combined revenues from the highly acclaimed information technology and information technology enabled services industries in India was US\$28.2 billion in 2004-05).¹⁶ In 2005-06, India exported drugs, pharmaceuticals and fine chemicals worth US\$4.9 billion. India exports pharmaceutical products to a large number of countries including the United States, United Kingdom, Germany, Russia and China (CMIE, 2006). India is a low-cost supplier of generic drugs to several less-developed countries.

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 (Chaudhuri, 2005). The most important form of state intervention was in the introduction of the Indian Patent Act of 1970 (which came into effect in 1972). The Patent Act of 1970 replaced the Patents and Design Act 1911 -- a law framed during the British colonial period which guaranteed the right to patent pharmaceutical products. Partly as a consequence of the Patent Act of 1911, 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.¹⁷

The Indian Patent Act of 1970 brought in major changes. Section 5 of the 1970 Act stipulated that in the case of drugs and food products, patenting would be allowed only on the processes of manufacturing, not on the products themselves. The period for which patents were granted was reduced from 16

¹⁵ See Knowledge@Wharton (2006).

¹⁶ See Thomas (2005).

¹⁷ See the Report of the American Senate Committee, cited in Keayla (2005).

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. After three years, the patent holder was also obliged to issue licenses to local manufacturers (for a royalty not exceeding 4 per cent of ex-factory price in bulk form) (Lanjouw, 1997, p.51; Chaudhuri, 2002; Chaudhuri, 2005, pp.36-8).

The government set up pharmaceutical manufacturing and research organizations in the public sector. Hindustan Antibiotics Limited (HAL) and Indian Drugs and Pharmaceuticals Limited (IDPL) were inaugurated in 1954 and 1961 respectively. India's Council of Scientific and Industrial Research (CSIR) set up Central Drug Research Institute in Lucknow in 1951 and Indian Institute of Chemical Technology (IICT) in Hyderabad in 1956. All these created a supportive environment for the growth of private pharmaceutical firms. Hyderabad, where IDPL's synthetic drug plant and IICT are located, evolved as a centre for bulk drug manufacturing firms. The founder of Dr. Reddy's Laboratories (a major pharmaceutical company in the private sector) was a former employee of IDPL. CDRI developed a technology for manufacturing paracetamol, and this has been widely used by small-scale pharmaceutical companies in India. Top pharmaceutical companies in India have made use of the technologies developed by CSIR laboratories (Chaudhuri, 2005, pp.30-6).

Foreign Exchange Regulation Act (FERA) 1973 and New Drug Policy (NDP) 1978 were two other important instruments through which the state intervened in the pharmaceuticals industry. With NDP 1978, foreign companies were allowed to hold more than 40 per cent equity in Indian pharmaceutical firms only if they were bringing in high technology. The government discouraged MNC presence in drug formulations and bulk drug manufacturing involving easily available technologies, 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.¹⁸

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. In 1970, of the top 10 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). Over the years after 1970, the domestic pharmaceutical industry grew capable of supplying medicines for the Indian market; correspondingly, the dependence on multinational pharmaceutical companies declined. The share of domestic firms in India's pharmaceuticals market by sales increased from 32 per cent in 1970 to 77 per cent in 2004; and the share of MNCs correspondingly declined from 68 per cent to 33 per cent during this period of time (see Figure 2).

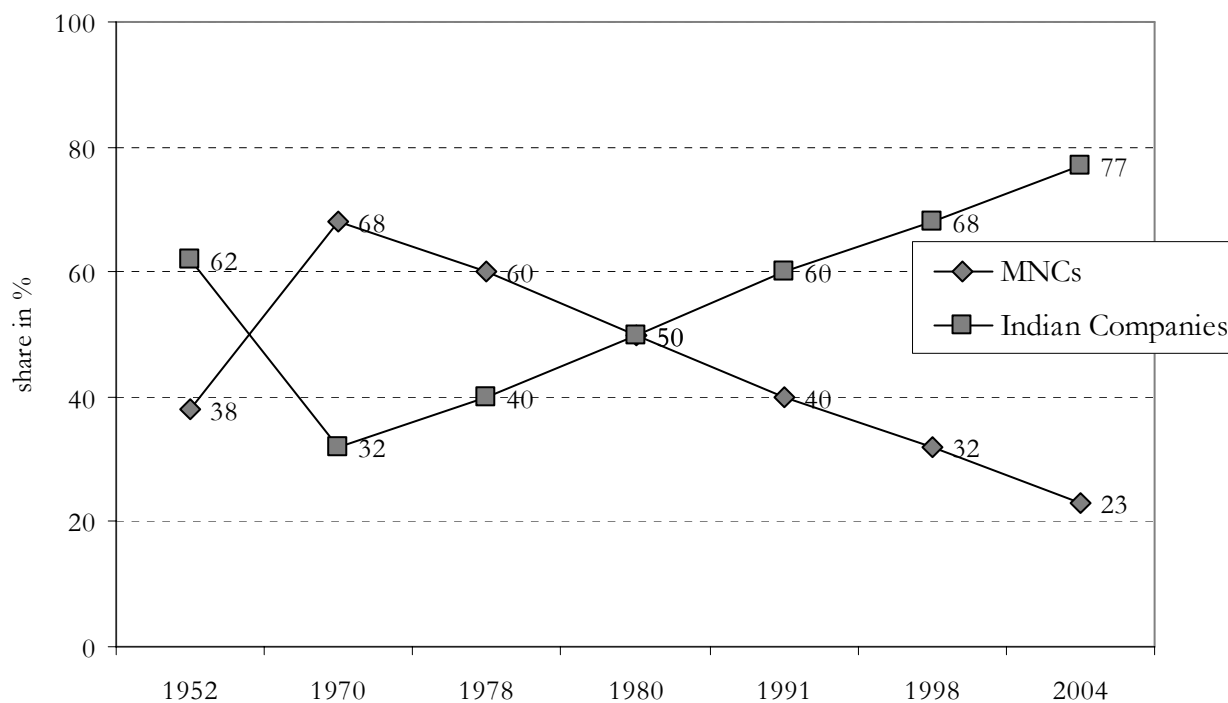
More importantly, domestic pharmaceutical companies were able to manufacture and sell generic versions of medicines at very low prices in India. Drug prices in India are much lower than the prices of similar drugs in several countries including the United States and United Kingdom as well as Pakistan and Indonesia. As Table 4 shows, prices of some selected drugs in Pakistan and Indonesia were, in 2002-03, 12 – 30 times higher than the corresponding prices in India (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 antiretrovirals (ARVs) (Grace, 2004, pp.13-5). The cost of antiretroviral drugs for HIV/AIDS treatment was US\$10,000 per patient per year; Indian pharmaceutical company CIPLA could offer this drug at US\$350 per patient per year. CIPLA supplies ARVs to over 250,000 HIV patients in poor countries, according to the company website.¹⁹ When Ranbaxy, another leading Indian pharmaceutical company, made plans to launch the cholesterol drug atorvastatin in the US and UK, the media in the UK welcomed it as a move

¹⁸ The DPCO, which underwent several modifications, was finally replaced by the National Pharmaceuticals Policy of 2002.

¹⁹ See <www.cipla.com>, accessed 15 January 2006.

that would lead to substantial financial savings to the National Health Service in their country (Tomlinson, 2005).

Figure 2: Shares in India's pharmaceuticals market by sales, domestic companies and multinational companies (MNCs), 1952-2004, shares in per cent



Source: Chaudhuri, Sudip (2005), p.18. The sources cited in Chaudhuri (2005) are the following: for 1952, Pharmaceutical Enquiry Committee (1954), pp. 20-1, 61-6; for 1970, Ministry of Petroleum and Chemicals (1971), p.1; for 1978, Chaudhuri (1984), p. 176; for 1980, 1991, and 1998, Kalsekar (2003); for 2004, Sudip Chaudhuri's calculation using ORG-MARG (2004).

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

<i>Drug</i>	<i>India</i>	<i>Pakistan</i>	<i>Indonesi a</i>	<i>UK</i>	<i>USA</i>
<i>Ciprofloxacin HCL</i>	29 (1.0)	423.9 (14.6)	393.0 (13.6)	1185.7 (40.9)	2352.4 (81.1)
<i>Diclofenac</i>	3.5 (1.0)	84.7 (24.2)	59.8 (17.1)	61.0 (17.4)	674.8 (192.8)
<i>Rantidine</i>	6.02 (1.0)	74.1 (12.3)	178.4 (29.6)	247.2 (41.1)	863.6 (143.5)

Notes: Ciprofloxacin HCL is an Anti infective. Diclofenac and Rantidine 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 USA, 2002, and for UK February 2004.

Source: Keayla (2005).

4.2 TRIPS Agreement and Changes in India's Patent Laws

India became a member of the World Trade Organization (WTO) in 1995. As part of its obligations as a WTO member, India was required to bring in

legislations in line with the provisions of the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS). A series of important changes were made to India's Patent Act of 1970, which eventually led to the introduction of product patenting in India.

The TRIPS came into effect on 1 January 1995. India and other developing countries were required to introduce 'mail box' facilities and exclusive marketing rights from 1 January 1995 itself. In the case of provisions other than product patenting such as rights of patentee, term of patent protection, compulsory licensing and reversal of burden of proof, TRIPS- compliant rules had to be legislated before 1 January 2000. As a developing country which did not have a product patenting regime, India was given a transition period of 10 years (therefore, until 1 January 2005) to fully introduce product patenting provisions.

Introduction of legislative changes in accordance with the requirements set by the TRIPS met with several hurdles in the Indian Parliament. The Patents (Amendments) Act 1999 passed by the Indian Parliament introduced the mail box system and the system of exclusive marketing rights (EMRs) retrospective from 1 January 1995. The Patent (Amendment) Act, 2002, which came into force on 20 May 2003, made 64 changes to the Patent Act of 1970, including extension of the patent term to 20 years and reversal of burden of proof (from the patent holder to the alleged infringer of patents). To introduce product patenting as required by the TRIPS, the government issued the Indian Patent Ordinance of 2004 in December 2004. The strict provisions of the Ordinance were criticized in India and abroad as being detrimental to public health concerns. Finally, the Ordinance was replaced with the Indian Patent (Amendment) Act of 2005 passed by the Indian Parliament in March 2005 (Chaudhuri, 2005; Grace, 2005, p.3).

Compared to the Indian Patent Ordinance of 2004, the Indian Patent (Amendment) Act of 2005, which replaced the Ordinance, has made better use of several flexibilities for developing countries contained in the TRIPS regime. The Indian Patent Ordinance of 2004 had allowed patents on combinations and crystalline versions of known molecules, which the patent owners could use to lengthen their period of patent claims. The Patents Amendments Act of 2005 rectified this drawback by ruling that combinations and crystalline versions of an

originally known molecule will not be considered as new (and patentable) unless they are significantly different in properties from the known molecule. Patent Ordinance of 2004 had reduced the grounds on which a patent could be opposed during the pre-grant period from nine to two; the 2005 Amendment retained the nine original grounds and enlisted two additional grounds for pre-grant opposition (Chaudhuri, 2005, pp.70-116).

As per the Indian Patent Ordinance of 2004 (Section 92 (A)), least developed countries (LDCs) were required to issue compulsory licenses for importing generic drugs from India. This stipulation was clearly unnecessary as LDCs were exempted from the introduction of product patents until 2016. The Patent (Amendments) Act 2005 relaxed the requirement: as per the revised Section 92 (A) of the 2005 Act, LDCs can import pharmaceutical products from India by notification or other means. Also, the Act of 2005 permits the issue of compulsory licenses to local manufacturers after three years from the date of grant of a patent and in cases when a patent holder indulges in anti-competitive practices. However, these provisions still suffer from many limitations, which the patent holders might take advantage of. In particular, compulsory licensing provisions are not equipped to handle immediate health crises like Asian bird flu or the SAARS (Chaudhuri, 2005, pp.83-99; Grace, 2005).

Currently, there is strong pressure particularly from the MNCs to bring in laws that allow data exclusivity in India. Data exclusivity, guaranteed under Article 39 (3) of the TRIPS, stipulates that test data submitted by pharmaceutical companies to regulatory agencies will not be disclosed to the public. Without access to test data, generic competitors will find it difficult to prove bioequivalence of their generic versions of drugs. Another problem associated with data exclusivity is that it is granted from the date of introduction of a drug in a particular market, and not from the date on which the drug is granted a patent. This implies that if a drug is introduced in the Indian market a few years after it was granted a patent, the patent holder will be able to hold on to her monopoly rights even after the expiry of the patent term, through the years for

which the drug is granted data exclusivity (Chaudhuri, 2005, pp.80-3; Keayla, 2005).²⁰

4.3 TRIPS and Strategies of Indian Pharmaceutical Firms

With the introduction of TRIPS-compliant product patenting rules, Indian pharmaceutical firms will no longer be able to reverse engineer using process innovations and start domestic manufacturing of new, patented drugs. During the years of TRIPS implementation (1995-2005) and after, India's domestic pharmaceutical firms have been devising new strategies in anticipation of product patent rules.²¹ The strategies they adopted attest to the growing technological maturity in India's pharmaceutical industry. 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, R&D charges as a proportion of sales revenue increased from 0.6 per cent in the three year period ending in 1987 to 2.8 per cent and 11.0 per cent respectively in the three year periods ending in 1994-95 and 2005-06.²² Ranbaxy made 698 patent filings in the first nine months of 2005 compared to 428 patent filings in the first nine months of 2004.²³ Secondly, leading Indian pharmaceutical companies have been orienting their sales increasingly to the export markets of North America and Europe. Correspondingly, the proportion of their sales in the domestic market declined. Ranbaxy made its entry into the US generic drugs market in the mid-1990s. In 2005, United States and Europe, together, accounted for 45.2 per cent of Ranbaxy's total global sales (of US\$1178 million).²⁴

²⁰ See also Dhar and Gopakumar (2006).

²¹ See Lanjouw (1997) and Sampath (2005). See also Ramanna (2005) who argued that prior to 2005 there emerged a strong pro-patent lobby in the country, constituted not only by domestic firms and MNCs but also by a few public sector research institutes.

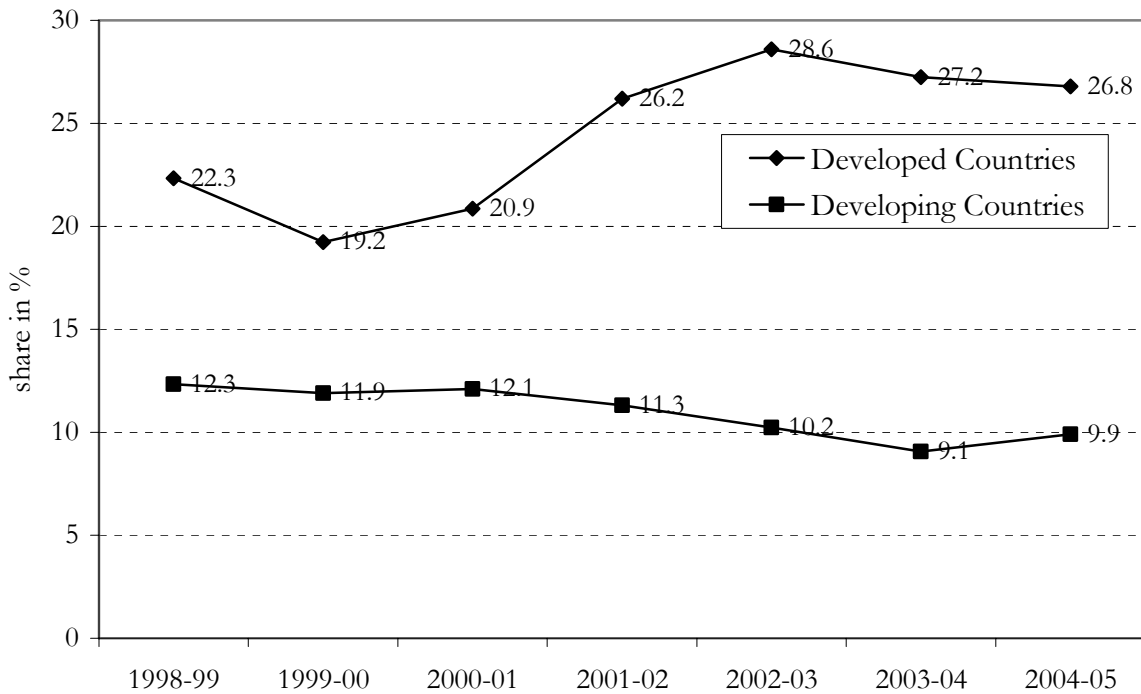
²² See Dr. Reddy's Laboratories Ltd. Annual Reports, various years.

²³ See <www.ranbaxy.com>, accessed 15 January 2005.

²⁴ See Ranbaxy Annual Report 2005, downloaded from <<http://www.ranbaxy.com>> accessed on 17-1 -2007.

The growing orientation of Indian pharmaceutical industry to developed country markets is evident in Figure 3. The figure shows the combined share of four developed countries and the combined share of six developing countries as destinations for India's exports of drugs, pharmaceuticals and fine chemicals. These four developed countries --United States, Germany, United Kingdom and Canada -- and the six developing countries -- Nigeria, Viet Nam, Sri Lanka, Pakistan, Bangladesh and Nepal -- have figured in the list of 21 leading destinations for India's exports of drugs, pharmaceuticals and fine chemicals throughout the period under study. Between 1998-99 and 2004-05, the combined share of the four developed countries increased from 22.3 per cent to 26.8 per cent, while the combined share of the six developing countries declined from 12.3 per cent to 9.9 per cent.

Figure 3: 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 per cent



*Notes: Developed countries: United States, Germany, United Kingdom and Canada
 Developing countries: Nigeria, Viet Nam, Sri Lanka, Pakistan, Bangladesh and Nepal
 Source: CMIE (2005), p.69.*

4.4 Indian Pharmaceutical Firms and Pharmaceutical MNCs: Collaboration and Competition

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).²⁵ Reports indicate that in 2001, US \$1 billion was spent on R&D costs for bringing a new drug compound into the market (Griffith, 2002, cited in Cooke, 2005). To reduce the cost of new

²⁵ According to information given at the Website of Alliance Pharmaceutical Corporation. See <www.allp.com/drug_dev.htm>, accessed 15 July 2006.

*drug discovery, pharmaceutical MNCs are entering into strategic alliances with smaller pharmaceutical firms, biotech companies and academic centres. Novartis, for instance, claims that it has more than 400 collaborations in over 20 countries.*²⁶

*Indian pharmaceutical firms do not possess the skills and the resources to carry out the entire process of new drug discovery. Even the leading Indian firms are much smaller compared to Western pharmaceutical MNCs.*²⁷ *Given such a scenario, the response of India's leading pharmaceutical firms has been to collaborate and, in some cases, compete with Western pharmaceutical MNCs. 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 license out the molecule to bigger pharmaceutical MNCs. As part of this strategy, Indian pharmaceutical firms carry out R&D on global diseases, which suit the business interests of big pharmaceutical MNCs they collaborate with. At the same time, as a consequence of this strategy, Indian firms' research focus on neglected diseases prevalent in third world countries is likely to be reduced considerably (Chaudhuri, 2005).*

*Indian drug firms have also challenged big pharmaceutical corporations in the market for generic drugs in the West. The high returns in the generic drugs market in North America and Western Europe is highly attractive for Indian companies. In the US market, a generic drug company which successfully challenges a secondary patent held by an originator drug company (mostly a Western MNC) will obtain Para IV ANDA or market exclusivity for 180 days, and this assures a profit of US\$2 billion and more. The possibility of reaping such huge profits encourages Indian companies like Ranbaxy to spend as high as US\$13 million on a single patent challenge.*²⁸ *Originator drug companies, some*

²⁶ See <www.allp.com/drug_dev.htm> and <www.nibr.novartis.com/OurScience/drug_development.html> , accessed 16 September 2006.

²⁷ 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).

²⁸ See Knowledge@Wharton (2006).

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 competition from generic drug firms is a high return-zero risk strategy, as they would gain greatly even by delaying the entry of generic competitors by a few months. On the other hand, for generic drug firms, challenging the patents held by originator drug company is a high return-high risk strategy (Chaudhuri, 2005, pp.205-6).

There are many instances of IPR-related legal battles involving Indian companies. Ranbaxy and Pfizer have been engaged in a legal wrangle over Ranbaxy's generic version of atorvastatin calcium, an anti-cholesterol drug. Pfizer claimed that Ranbaxy's drug violated its patent on Lipitor.²⁹ The rulings by the London High Court in October 2005 and by a US Federal Court in December 2005 went against Ranbaxy. Reports suggest that Ranbaxy spent US\$30million on legal expenses in the year 2005.³⁰ This must be compared to Ranbaxy's R&D expenditure, which was US\$75.1 million in 2004.³¹ Eventually, however, Ranbaxy invalidated Pfizer's patent claim. Dr. Reddy's Laboratories had obtained US FDA approval for AmVaz, a hypertension drug, in October 2002. However, with Pfizer's successful challenge in a US court, Dr. Reddy's had to delay its manufacturing plans (Krishna, 2004; Rai, 2003). 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 Indian Pharmaceutical Industry and Supply of Affordable Medicines to the Poor

Only the leading Indian pharmaceutical firms have so far been able to take advantage of the opportunities to export generic drugs to developed country markets. At the same time, a large number of relatively small pharmaceutical

²⁹ See Economist (2005) and Tomlinson (2005) for reports on the legal battle between Ranbaxy and Pfizer.

³⁰ See Mahapatra (2006).

³¹ According to Ranbaxy's website <www.ranbaxy.com>, accessed 14 December 2005.

firms in India are facing grim growth prospects in export and domestic markets in the post-TRIPS phase.

To begin with, the regulatory barriers to entry into developed country markets, particularly the US market is very high. For instance, getting an approval for Abbreviated New Drug Application (ANDA) – a prerequisite for marketing a drug formulation in the US -- takes upto five years and costs as high as US \$1 million. The market for generic drugs opened up in the United States since the late 1980s. Indian companies like Ranbaxy and Dr. Reddy's, which are today successful as exporters of generic drugs, have the advantage of early entry into the US market. The going will be tough for the relatively small Indian pharmaceutical firms as they try to enter the regulated markets of United States and Europe (Chaudhuri, 2005).

The implementation of product patent legislations will eventually affect the growth and expansion of India's small pharmaceutical firms in the domestic market. Manufacturing drugs for the domestic market using process innovations, which was a strategy for the leading Indian drug makers of today in their formative years, is not possible any longer.³² In addition, competition in the domestic market is tightening. The Indian pharmaceuticals industry has witnessed a significant increase in mergers and acquisitions (M&As), and this has further weakened the smaller Indian companies.³³ 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.³⁴

It is argued by the advocates of a strict patent regime 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

³² Interview with Mr. B. K. Keayla, 11 December 2006.

³³ Concentration ratios of the largest four and largest eight firms in Indian pharmaceutical industry increased after 1995-96. See Chadha (2006).

³⁴ Interview with Mr. Lalit Kumar Jain, a spokesperson for small scale pharmaceutical industry in India, New Delhi, December 10, 2006. See also Chaudhuri (2005).

(which included companies under Indian ownership and MNC subsidiaries), Lanjouw and MacLeod (2005) found that only 10 per cent of the entire R&D investments by these companies in 2003-04 were targeted at developing country markets and tropical diseases. Multinational pharmaceutical companies are readying to take advantage of the market opportunity arising from India's large middle class population with high prevalence of global diseases such as cancer and cardiovascular diseases. Yet their investments in the manufacture of bulk drugs have not gone up. Also, the share of pharmaceuticals in the total inflow of foreign direct investment (FDI) into India has been very limited in the years after 1991 (the period when India adopted a more liberal policy regime towards FDI investments).³⁵ During the same period, import of drug formulations into India has shown a substantial increase.³⁶ Multinational companies have started outsourcing of clinical trials to India as the cost reduction involved is substantial. However, this could entail many dangers to poor patients in India if proper regulations are not put in place (Nundy and Gulhati, 2005).

Therefore, the emerging post-TRIPS scenario in India is the following: leading domestic drug firms are increasingly targeting the export markets in developed countries, while smaller Indian drug firms are encountering problems to growth and expansion. MNCs, while interested in the Indian market, are not entering into drug manufacturing or research on tropical diseases. All these will have implications for the supply of affordable medicines to the poor in India and the rest of the third world. 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 per cent. 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

³⁵ *The share of drugs and pharmaceuticals in total foreign direct investment (FDI) inflows into India was only 1.01 per cent for the period between 1 August 1991 and 31 December 2000; the share increased to 3.57 per cent during the period 2000-04, and jumped to as high as 9.1 per cent in 2004 but fell to 2.64 per cent in 2005. See Chaudhuri (2005), pp.138-9 and Chadha (2006).*

³⁶ *See Chaudhuri (2005).*

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). To summarise the situation 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”³⁷.

5. PHARMACEUTICALS AND HEALTH BIOTECHNOLOGY IN CHINA

Pharmaceuticals industry is expanding fast in China. There were 4296 pharmaceutical manufacturing facilities in China in 2003. Domestic industry supplies almost 70 per cent of the Chinese market for pharmaceutical products. Chinese firms have acquired great expertise in the manufacture of bulk drugs or active pharmaceutical ingredients (APIs), just as Indian pharmaceutical firms have gained a reputation in finished dosage forms or formulations. China is the second largest producer of pharmaceutical ingredients in the world. China is the world’s largest producer of many pharmaceutical products including penicillin (producing 60 per cent of world output), vitamin C (50 per cent of world output), terramycin (65 per cent of world output), doxycycline hydrochloride and cephalosporins (Grace, 2004, pp.13-4). China is carrying out 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).

³⁷ 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.

5.1. Pharmaceuticals Industry and the Evolution of Intellectual Property Rights Regime in China

Significant steps towards the building of a patent regime began in China only after the late 1970s. ³⁸ Chinese government's gradual implementation of an intellectual property rights (IPR) policy was determined by two factors: one, a commitment to the development of domestic capabilities in science and technology, and, two, international pressure, particularly from the United States, pushing China to a strict patent regime. China entered the World Intellectual Property Organization (WIPO) in March 1980 and the Paris Convention for the Protection of Industrial Property in March 1985. A Trademark Law was implemented in China in 1982 (Kong, 2005).

China implemented its first Patent Law in 1984, which came into effect on 1 April, 1985. This law 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 Patent Act of 1970). The law also had certain discriminatory clauses against foreign inventors. These restrictions ensured that foreign investments into China came along with technology transfer and that they contributed to the building of domestic invention capability in China (Kong, 2005).

China introduced a stricter patent regime in 1992. In the early 1990s, China was integrating itself with the world economy, and a strict patent regime was believed to aid China's plans to attract foreign investments. Also, from being an importer of technologies, China was slowly emerging as an exporter of technology-intensive products (Kong, 2005). Grace (2005) points out that China's patenting policies were greatly influenced by the bilateral negotiations between China and the United States. Product patenting rules came into effect in China in 1993 – more than ten years before TRIPS would have required it to. As per the agreement between China and the United States in 1999 on China's accession to the WTO, China was required to implement IPR rules that were TRIPS-compliant.

³⁸ See <<http://www.china.org.cn/e-white/20050421/index.htm>>, accessed 15 January 2006.

China joined the WTO in 2001, and the country brought in patent laws that incorporated 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 third world. China is an important producer of a wide variety of raw materials for second-line antiretrovirals (ARVs).³⁹ One of the means through which China bypasses 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 including India where it is processed into APIs and finished products. In fact, between 2001 and 2005 (when China had implemented product patent legislations and India had not do so), there have been instances of Indian and Chinese firms partnering to produce essential medicines (Grace, 2005, pp.23-5).

However, pharmaceuticals industry in China is today facing challenges from the patent regime. The United States continuously pressurize China to improve its record on IPR enforcement.⁴⁰ In December 2006, on the occasion of the fifth anniversary of China's entry into the WTO, the US Trade Representative,

³⁹ *In the treatment of HIV/AIDS, second line ARVs become necessary once the patient develops resistance to first-line treatment. Treatment using second-line ARVs is much costlier than first-line treatment. 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.*

⁴⁰ *For example, in a news release on 29 April 2005, the Office of the US Trade Representative (USTR) remarked that IPR infringement levels "remain unacceptably high throughout China, in spite of Beijing's efforts to reduce them." See <<http://usinfo.state.gov/usinfo/Archive/2005/Apr/29-580129.html>>, accessed 7 October, 2005.*

Susan C. Schwab, slammed China's record in implementation of IPR rules. In a 100-page report submitted to the US Congress, the US Trade Representative accused that piracy of software, videos, pharmaceuticals and other goods was rampant in China, and that the Chinese government did very little to curb this practice (Weisman, 2006). Reports suggest that after the implementation of the TRIPS agreement, patent related litigations between multinational pharmaceutical companies and their Chinese rivals have shot up (Hepeng, 2004).

Western multinational pharmaceutical companies are rushing to invest in China. To them, China's large middle class population is a potentially huge market. It is no wonder, therefore, that pharmaceutical companies are attracted to China's eastern region, in particular the Yangtze River Delta, which enjoys higher levels of purchasing power. China's pharmaceutical market is estimated to be worth US\$20 billion and it is expected to grow at double digit rates until 2010.⁴¹ With the introduction of product patent legislations, many multinational pharmaceutical companies are outsourcing pharmaceutical research and clinical trials to China. Companies like Novo Nordisk and Novartis set up R&D facilities in China to conduct research on global diseases, making use of China's cost advantage. They are equally keen to make inroads into the Chinese market for pharmaceuticals.⁴²

5.2 Health Biotechnology in China

China has embarked on an ambitious programme in biotechnology, greatly supported by the government. This initiative generates much optimism for new pharmaceutical innovations. Life sciences became an important focus area in China as the government began encouraging science and technology from the late 1970s. 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;

⁴¹ 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.

⁴² See the report 'A Novel Prescription' in the *Economist*, November 11, 2006; also see *Kjersem and Gammeltoft (2006)*.

Chervenak, 2005). By 1992, the government established 17 national biotechnology laboratories that were open to both domestic and foreign scientists. In 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\$180million) in biotechnology (Economist, 2002). Local governments also supported biotechnology research. The Central and local governments channeled money into quasi-venture capital funds, which promoted technology start ups (Chervenak, 2005). The government encouraged Chinese firms to establish links with Western biotechnology companies (Chervenak, 2005).

After 2000, the government enhanced allocation of funds for the biotechnology sector in China. According to 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). According to estimates by China's Science Ministry, 20,000 researchers were working in the life sciences in China in 2002; 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 same year. It is expected that their eventual return to the country will give a further boost to the biotechnology industry in China (Economist, 2002).

Today, the major centres of China's biotechnology industry are 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).

5.3 India and China in Pharmaceuticals and Biotechnology: Possibilities for Cooperation

Over the past few years, there has been a growing engagement between India and China in the economic sphere. Interactions between the two countries are on the rise in the pharmaceuticals industry. India's leading pharmaceutical companies are important players in pharmaceutical formulations and finished dosage forms, while many Chinese firms have built expertise in the production of active pharmaceutical ingredients (APIs) and a wide range of raw materials for drugs. Major Indian pharmaceutical companies have set up joint ventures and production facilities in China. Ranbaxy's joint venture in China – Ranbaxy Guangzhou China Limited – was incorporated in 1993.⁴³ China is a very important source of APIs and bulk drugs for pharmaceutical companies in India. As a source of India's imports of medicinal and pharmaceutical products, China's share has been continuously increasing: from 6.2 per cent in 1993-94 to 34.6 per cent in 2005-06. China is today the largest exporter of medicinal and pharmaceutical products to India. Correspondingly, as a destination for India's exports of drugs, pharmaceuticals and fine chemicals, China's share increased from 0.4 per cent in 1993-94 to 3.5 per cent in 2005-06 (see Figure 4).

It may be noted that import of bulk drugs and APIs from China is seen as a threat by many small-scale bulk drug manufacturers in India. As discussed earlier, small-scale drug firms in India have been encountering constraints to growth due to a variety of reasons. Competition from Chinese bulk drug makers is aggravating their growth challenges. China is a large-scale producer of many of the intermediates for bulk drug manufacturing, and this gives the Chinese companies a significant advantage. At the same time, India possesses superior technology and skills in pharmaceutical formulations. A representative of small-

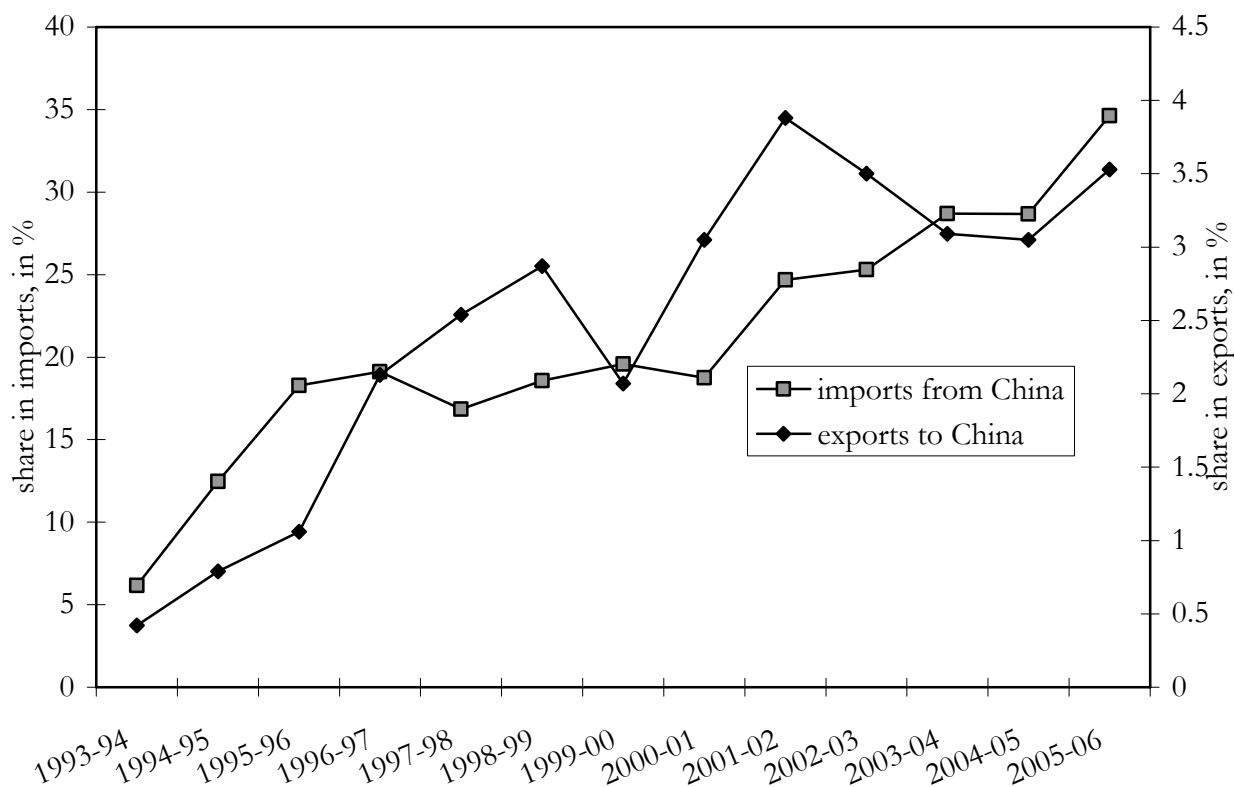
⁴³ See <www.ranbaxy.com/china.htm>, accessed 5 February 2007.

scale pharmaceutical industry in India expressed fears about Indian drug companies transferring technological skills to their Chinese counterparts.⁴⁴

While some of the genuine growth concerns of small-scale drug makers in India need to be addressed, they should not be a reason to stall greater positive interaction between pharmaceuticals industries of the two countries. 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 pharmaceuticals industry should feed into each other's expertise. Together, they should strive for pharmaceutical innovations that address the health needs of the poor in the third world.

Figure 4: China as a source of imports for and destination for exports of India's pharmaceuticals industry, shares in per cent

⁴⁴ *Interview with Mr. Lalit Kumar Jain, a spokesperson for small-scale pharmaceutical industry in India, New Delhi, December 10, 2006. See also Chaudhuri (2005).*



Notes: China's shares as a destination for India's total exports of drugs, pharmaceuticals and fine chemicals and as a source of India's total imports of medicinal and pharmaceutical products.

Source: CMIE (1997), CMIE (2006).

6. AGRICULTURAL BIOTECHNOLOGY IN INDIA AND CHINA

The world's population is expected to reach 7 billion by 2015, and more than two-thirds of this population will be in developing countries. Meeting the food supply requirements of an increasing world population without endangering the natural environment is an important challenge. To give an indication of the magnitude of this challenge, it is estimated that the yield of cereal cultivation will have to increase from 2.9 tons per hectare in 1999 to 4.1 tons per hectare in 2025 (Bernauer, 2003).⁴⁵ Research in biotechnology offers the hope for dramatic increases in agricultural productivity.

⁴⁵ Cited in Bernauer (2003), Table 2.1.

In 1973, scientists discovered a technique to obtain recombinant DNA (DNA or deoxyribo nucleic acid are molecules that comprise genes, and genes are the carriers of specific traits). Using this technique, which is called genetic engineering (GE) or genetic modification (GM), it is possible to combine specific genes from different organisms. This technique has several applications including the breeding of new, superior quality agricultural crops (Paarlberg, 2001). Consider, for instance, the case of insect resistant GM crops. Insecticidal proteins such as Cry1Ac and Cry2Ab, derived from naturally occurring soil bacterium Bacillus thuringiensis (Bt), has the power to kill certain pests in crops. Once the gene that generates Bt protein is incorporated into the DNA of a cotton variety, then the resultant plant itself will produce the pest resistant protein (Rao, 2006).

The potential benefits arising from GM research are many. Golden rice, a genetically modified rice variety that accumulates β -carotene, is rich in Vitamin A. Rice can also be genetically engineered to be enriched in iron. Genetically modified rice varieties will be beneficial to the more than 100 million Vitamin A deficient children and 400 million women suffering from iron deficiency worldwide (according to estimates by World Health Organization) (Taverne, 2005). Genetically engineered tomatoes and bananas can be used as oral vaccines. Currently, research is conducted to develop tomatoes that thrive on salty water and rice that can resist cold, drought or high salinity (Taverne, 2005).

Global Spread of GM Crop Cultivation

Since 1994, when commercial cultivation of GM crops was first given approval, the spread of GM crops has been limited to only a few countries. United States, Argentina, Canada, Brazil and China have witnessed the fastest expansion of area under GM crop cultivation (See Table 5).⁴⁶ Globally, area under cultivation of GM crops increased from 2.8 million hectares in 1995 to 90 million hectares in 2005 (see Table 5). So far, GM techniques have been employed only in the case

⁴⁶ *In 2000, United States, Argentina, and Canada, together, accounted for more than 98 per cent of the total acreage in the world under GM crops (Paarlberg, 2001).*

of a few crops: importantly, maize, cotton, soybean, and potato. Most of the new GM crops carry only one new agronomic trait, that is, resistance to insects or to specific herbicides (Paarlberg, 2001).

Cultivation of GM cotton is expanding fast. Countries that commercially cultivate GM cotton include the United States, Mexico, Argentina, South Africa, China, India, Australia, Indonesia and Columbia. It is reported that in the cotton growing season in 2005-06, 54 per cent of cotton crops grown in the United States, 76 per cent grown in China and 80 per cent of cotton grown in Australia used single or multiple Bt genes (Rao, 2006).

Opposition against GM Crops

At the same time, cultivation of GM crops is met with resistance from various quarters. Europe and several developing countries have not been welcoming of GM crops. Cultivation of GM crops was stopped in Indonesia and Bulgaria in 2004. Cultivation of Bt maize had been banned in France and Portugal though it is resumed now.⁴⁷ Globally, there are several non-governmental organizations (NGOs) campaigning against the dangers of GM crop cultivation.

Research on agricultural applications of genetic engineering is carried out almost entirely by US multinational companies. 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. Agricultural biotechnology industry is characterised by high degree of concentration. In the late 1990s, six firms, Novartis, Monsanto, DuPont, Zeneca, AgrEvo, and Rhône-Poulenc (the latter two firms merged to form Aventis), controlled almost the entire world market for GM seeds. It is pointed out that the extreme dominance of US multinationals in GM research is an important reason behind the unpopularity of GM crops in Europe and in a majority of developing countries (Bernauer, 2003). There are also concerns regarding biological safety and

⁴⁷ See the report 'Transgenic Crops Catching Up, Claims Pro-GM Agency', *Financial Express*, January 15, 2006.

biopiracy (the latter refers to the threat of MNCs acquiring patents on seed varieties, which the local farmers have used and improved over for generations).

Multinational seed companies direct their research and development (R&D) activities specifically towards the lucrative markets for GM seeds among the rich farmers in the United States, Argentina and Canada. Only a limited number of crops, importantly, soybeans, maize and cotton, are covered by the GM research. At the same time, tropical subsistence crops such as cassava, millet and cowpeas grown by poor farmers in developing countries have been neglected by GM research. Similarly, while GM research focuses almost exclusively on pest resistance and herbicide tolerance, some of the concerns of developing country agriculture such as drought resistance have not been on its agenda. In India, where 67 per cent of the cultivated area falls under non-irrigated dry-land, the GM technologies currently available do not offer much help (Paarlberg, 2001). Future research will possibly lead to the development of GM crops including GM rice that give very high yields even in marginal lands under testing conditions like drought.⁴⁸

6.1 Agricultural Biotechnology in India

The early proposals for cultivation of genetically modified (GM) crops were met with considerable resistance in India. The US multinational giant Monsanto in alliance with Maharashtra Hybrid Seed Company (Mahyco) was one of the first firms to venture into development of genetically modified cotton in India. Mahyco-Monsanto obtained permission for conducting Bt cotton trials in India in 1998. There were immediate protests from farmer's organisations, environmental groups, and sections of agricultural scientists. Bt cotton trial fields were set on fire in Karnataka in 1998 by activists of the Karnataka Rajya Raitha Sangha. Mahyco-Monsanto conducted a second round of large-scale Bt cotton field trials in 2000. The results of these tests were not satisfactory to India's Genetic Engineering Approval Committee (GEAC).⁴⁹ GEAC held a 'public dialogue' in

⁴⁸ See McFadden (2005).

⁴⁹ Genetic Engineering Approval Committee (GEAC) is part of the Ministry of Environment and Forests, Government of India.

June 2001 in which scientists and environmental activists expressed strong concerns about GM crop cultivation. Consequently, GEAC rejected Mahyco-Monsanto's proposals for environmental clearance for large scale cultivation of Bt cotton (Menon, 2001).

*However, a year later in 2002, GEAC gave approval for commercial sale of three Bt cotton hybrids – MECH 12 Bt, MECH 162 Bt and MECH 184 Bt – in India for a period of three years. Today, India's Genetic Engineering Approval Committee (GEAC) has given approvals for commercial sale for 12 varieties of Bt cotton hybrids. All the 12 varieties carry the Bt cry 1 ac gene, derived from the naturally occurring bacterium *Bacillus thuringiensis* (Bt), developed by Monsanto. These Bt cotton hybrids are marketed in India by Mahyco-Monsanto as well as other seed companies which are sub-licensees of Monsanto's technology, including Raasi seeds, Ankur seeds, and Nuzhivedu seeds, (Chaturvedi, 2005). Total area under cultivation of Bt cotton showed significant increase in India over the last three years. In India, of the more than 9 million hectares under cotton cultivation, 1.3 million hectares were cultivated using Bt cotton in 2005 (see Table 5).*

The Record of Biotechnology in Indian Farms

Reports about the benefits of using Bt technology, coming from different districts in Andhra Pradesh, are not very encouraging. They showed that GM cotton crops sold in the State by Mahyco-Monsanto were a failure in all the three years after the crop's introduction. The Bt cotton seeds sold by Monsanto-Mahyco were approximately four times costlier than the usual hybrid variety, yet it did not perform any better in crop yields or pest resistance (Venkateshwarlu, 2006). Many farmers in Andhra Pradesh who took loans to buy GM seeds fell into huge debt-traps. Mahyco-Monsanto refused to compensate the farmers. Similarly, reports from Madhya Pradesh's Nimar region indicated that Bt cotton farmers faced heavy losses. Seed companies, all of which have licensed seeds from Monsanto, refused to pay compensation, claiming that the crop losses were on account of lack of rainfall (Zaidi, 2006).

Eventually, in 2005, the Government of Andhra Pradesh revoked the approval for Monsanto-Mahyco Bt cotton in the State. Further, the Government

took the battle against Monsanto to Monopolies and Restrictive Trade Practices Commission (MRTPC). According to the Government of Andhra Pradesh, for each 450 gm packet of Bt cotton seeds purchased by the farmer at a cost of Rs.1850, Rs.1250 (or 67.6 per cent of the cost) was royalty payments to Monsanto.⁵⁰ Andhra Pradesh Government brought this to the attention of MRTPC. The State Government pointed out that Monsanto was charging only Rs.90 per kg of GM cotton seeds in China as well as in the United States, Brazil, and Australia. MRTPC directed Monsanto to make substantial reduction in the price of GM seeds that it sells in India. In the wake of widespread criticism, Monsanto reduced royalty fees by 30 per cent to Rs.900 per 450 gm of GM seeds in March 2006. The Company also challenged the MRTPC order in the Supreme Court. However, India's Supreme Court upheld the order by Andhra Pradesh State government and asked Monsanto not to charge more than Rs.750 per 450 gm of cotton seeds.⁵¹

Recently, there have been some positive steps in the direction of developing indigenous GM technologies in India. Swarna Bharat Biotechnics Private Limited (SBBPL), a consortium of seven Indian seed companies, is expected to commercialize indigenously developed GM crops by 2007-08. The consortium has procured technology licenses from various public laboratories. It obtained licenses for 'lectin' gene (LEcGNA 2), which produces a protein that destroys sucking pests, from the Centre for Plant Molecular Biology (CPMB) at the Osmania University, Hyderabad; and for genes that protect cotton from pests from the National Botanical Research Institute (NBRI), Lucknow. With the development of indigenous GM crop technology, GM crops can be made accessible to small farmers at relatively low costs. Royalties from sale of indigenous seeds should be channelled back into future research.⁵² It may be

⁵⁰ 'Andhra Pradesh plans to drag Monsanto to Monopolies and Restrictive Trade Practices Commission over Bt cotton royalty', Business Line, December 29, 2005.

⁵¹ See the reports 'Monsanto Loses India Court Appeal over Genetically-Modified Seeds Price', AFX International Focus, June 6, 2006 and 'Monsanto Challenges MRTPC Order before Supreme Court' The Statesman, May 17, 2006.

⁵² Agricultural Biotechnology Task Force led by Professor M.S. Swaminathan in its report submitted in 2004 recommended that Indian government should invest US\$264.9 million for ensuring food security; it also suggested the establishment of a new apex regulatory body for biotechnology (Raja, 2004).

noted here that almost 70 per cent of royalties from seeds sales of Indian subsidiaries of Monsanto are ploughed back into the parent US company (Jayaraman, 2004).

Biopiracy and Threats to Biodiversity

Farmers in India and many other parts of the world have a long tradition of saving seeds and freely exchanging seeds among other farmers. This has greatly contributed to biodiversity and food security in India. However, this tradition is today threatened by the introduction of intellectual property rights over seeds through the TRIPS agreement.⁵³ As per the Indian Patent Act of 1970, plants and agricultural practices were not patentable. However, this has changed with the introduction of two amendments to Section 3 (j) of the Act of 1970. Processes for treatment or processes adding economic value of plants were not patentable earlier, but are patentable now, as per the first amendment. Seeds and “biological processes for production or propagation of plants and animals” will be counted as inventions and are patentable, as per the second amendment (Siva, 2005). With these amendments, Siva (2005) contends, Section 3 (j) of the Indian law has fully incorporated Article 27.3 (b) of the TRIPS agreement. The above-mentioned changes in the Indian law imply that multinational seed companies like Monsanto can obtain monopoly rights over seeds. Also, Monsanto and other seed companies have developed new seed varieties that do not germinate, using terminator technologies, and this will compel Indian farmers to buy seeds every new season. All these are an affront on farmers’ right to save, exchange and improve seeds (Siva, 2005).

There have been demands from developing countries to make changes in Article 27.3 (b) of the TRIPS agreement, but very little progress has been achieved. In the WTO Ministerial Conference in Hong Kong held in December 2005, India proposed amendments to Article 27.3 (b) or Article 29 of the TRIPS agreement. India demanded that while making patent applications for inventions

⁵³ See Shiva (2001).

that used any form of traditional knowledge, the information relating to the traditional knowledge used should be disclosed. There have been several instances of 'biopiracy' in the developing world: that is, instances where MNCs claim ownership rights over traditionally held knowledge through patents. The proposed amendment by India was an essential, but only a preliminary, step in the direction of countering biopiracy. However, the proposal did not go through due to opposition from the United States.⁵⁴

6.2 Agricultural Biotechnology in China

China is making rapid advances in the field of agricultural biotechnology. In China, the policy focus on agricultural biotechnology began in the late 1980s. This was a response to the enormous challenges of feeding a large population and of improving productivity in China's small farms. Reports suggest that the government under Premier Zhu Rongji was highly concerned at the growing dominance of US biotechnology firms in Chinese agriculture. That the seeds improved over several decades by Chinese farmers could be appropriated by US biotech companies was a worrying prospect to policy makers in China.⁵⁵ In fact, in the late 1990s, Chinese firms were competing with US multinationals such as Monsanto to be the leading supplier of transgenic crops in the various Chinese provinces (Chen, 1999).⁵⁶ Chinese policy makers took note of the growing alliances between seed companies and biotechnology companies in western countries. Monsanto, which was originally a chemical engineering company, seized the new opportunities in biotechnology, and emerged as a major player in agricultural biotechnology. Links between seed companies and biotech companies were non-existent in China, and this was perceived to be a major

⁵⁴ See Subramaniam (2005).

⁵⁵ 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 on the US MNC's dominance in Chinese agriculture after a visit to the north-eastern province of Jilin.

⁵⁶ In the late 1990s, the US biotech companies were in a dominant position in Shijiazhuang, Hebei and Langfang area. Chinese biotech firms had the upper hand in Henan and Anhui Provinces. See Chen (1999).

weakness. It was under these circumstances that the government under Zhu Rongji allocated RMB 500 million for five years for agricultural biotechnology (Chen, 1999).

In China, research in agricultural biotechnology is funded largely by the public sector -- unlike in the case of developed countries where private sector dominates agricultural biotechnology research. Government funded research in China is targeted at developing 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 1999, although it was still considerably smaller than the US\$1-2 billion that the United States spent in 1999 on plant biotechnology research. Outside North America, China's is the largest programme for agricultural 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, research institutes in China are developing genetically modified tomatoes that take longer to rot (which helps in their transportation, processing and storage); and vitamin C enriched rice that will help improve nutrition in many parts of the developing world. In the early 1990s, China began commercial cultivation of virus-resistant tobacco, thus becoming the first country to plant a GM crop on a commercial basis. China recorded great success in developing Bt cotton. Chinese research laboratories developed 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 (see Table 5). In 2001, over 4 million small-scale farmers were involved in Bt cotton cultivation in China (Karplus, 2003).

However, the opposition against GM crops in Europe and many parts of Asia is a factor that slows down China's agricultural biotechnology programme. China worries that its agricultural exports to Europe will be affected because of its cultivation of GM crops (Karplus, 2003). There are other concerns too. There are reports of illegal planting of GM rice in China. Experts warn that GM rice

cultivation without instituting a proper regulatory mechanism and agricultural management could result in an environmental disaster (Xun, 2005).

Table 5: Area under Cultivation of Genetically Modified (GM) Crops, 1996 to 2005, in million hectares

	1996	1997	1998	1999	2000	2001	2002	2003	2004	2005
<i>United States</i>	1.5	8.1	20.5	28.7	30.3	35.7	39	42.8	47.6	49.8
<i>Argentina</i>	0.1	1.4	4.3	6.7	10.0	11.8	13.5	13.9	16.2	17.1
<i>Brazil</i>	--	--	--	--	--	--	3.5	3.0	5.0	9.4
<i>Canada</i>	0.1	1.3	2.8	4.0	3.0	3.2	--	4.4	5.4	5.8
<i>China</i>	1.1	1.8	n.a.	0.3	0.5	1.5	2.1	2.8	3.7	3.3
<i>India</i>	--	--	--	--	--	--	<0.1	0.1	0.5	1.3
<i>Australia</i>	--	0.1	0.1	--	0.1	0.2	--	0.1	0.2	0.3
<i>Mexico</i>	--	--	<0.1	<0.1	--	<0.1	<0.1	<0.1	0.1	0.1
<i>Spain</i>	--	--	<0.1	<0.1	--	<0.1	<0.1	<0.1	0.1	0.1
<i>Germany</i>	--	--	--	--	--	<0.1	<0.1	<0.1	<0.1	<0.1
<i>Portugal</i>	--	--	--	<0.1	--	--	--	--	--	<0.1
<i>France</i>	--	--	<0.1	<0.1	--	--	--	--	--	<0.1
<i>Czech Republic</i>	--	--	--	--	--	--	--	--	--	<0.1
<i>Others</i>	--	--	--	--	--	--	--	--	--	2.8
<i>Total</i>	2.8	12.7	27.8	39.9	44.2	52.6	58.7	67.7	81	90

Source: James (1997, 1999, 2004, 2005) cited in van Beuzekon and Arundel (2006), p.54.

There have been certain steps recently in the direction of India-China cooperation in agriculture. Agriculture Ministers of the two countries signed an agreement in March 2006 and identified a number of areas for cooperation. They

*include crop production, agriculture biotechnology, farm mechanisation, exchange of plant and animal germplasm and collaborative research.*⁵⁷

7. CONCLUSIONS

Globalization picks its winners and losers. As Hoogvelt (2001) shows, populations and countries in the periphery of the global economy progressively lose out while those who are part of the core strengthen their positions. Global rules on intellectual property rights enshrined in the TRIPS and imposed on developing countries are bringing in fundamental changes to the geography and nature of innovation in the world economy. India and China, which possess large supplies of highly skilled professionals and well-established science and technology infrastructures, have emerged as important destinations for global R&D. However, even as globalization of R&D gathers steam, the poor in India, China and the rest of the third world are likely to be left out of the new innovations, while big corporations in the West are likely to consolidate their strengths.

The evidence from India's pharmaceuticals industry presented in this paper gives credence to such apprehensions. India's pharmaceuticals industry has been a major supplier of generic drugs at affordable prices within the country and outside. By 2005, India fully implemented product patenting legislations in compliance with the TRIPS as part of its WTO obligations. Leading Indian pharmaceutical firms have responded well to the challenge of a strict IPR regime. They have increased their R&D spending and, simultaneously, targeted the market for generic drugs in North America and Europe. At the same time, there has been a corresponding decline in their production for the domestic

⁵⁷ See the report 'India, China Sign Agriculture Cooperation Pact', *Financial Times*, March 30, 2006.

market and research on neglected diseases. The entry of small pharmaceutical firms into India's domestic market as makers of generic drugs has been made difficult by the implementation of product patent rules. MNCs have increased their presence in India, conducting contract research and clinical trials on global diseases, eyeing the market of rich patients in India and abroad. As a cumulative effect of these trends, there are growing uncertainties on the future supply of affordable medicines in India and the rest of the third world.

China has been an important supplier of raw materials and active pharmaceutical ingredients (APIs) for the manufacture of several essential drugs, including anti-retrovirals for the treatment of HIV/AIDS. However, growth of pharmaceutical industry in China is constrained by product patent rules China implemented in 2002 as part of its joining the WTO. The United States continuously pressurize China to improve its record on enforcement of IPR rules. Western MNCs are investing in China in pharmaceutical research and clinical trials. Apart from China's cost advantage, these investments are fuelled by a desire to tap into the market for pharmaceuticals originating from the large middle class population in China. As in India, pharmaceutical research by MNCs in China is on the cure of global diseases. Contrary to expectations, implementation of TRIPS has not led to any marked increase in MNC's R&D spending on neglected diseases.

Research in agricultural biotechnology is today dominated by US multinational companies. Genetically modified (GM) crops have great potential in improving agricultural productivity and ensuring food security, but anxieties regarding GM crops are widely prevalent in Europe and many developing countries. India has approved commercial cultivation of GM cotton sold by the Indian subsidiaries of Monsanto. However, reports indicate that the Indian experience so far with GM cotton cultivation has not been much impressive.

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 energize 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. The large public investments in the biotechnology sector in China have produced many remarkable successes, raising hopes for beneficial innovations in the future. Chinese research institutes produced 141 new varieties of GM crops by 2002, including genetically modified cotton, tomato, tobacco and rice.

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 larger 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. Another area which offers high potential for collaboration between the two countries is agricultural biotechnology. China and India have the responsibility for and indeed the capabilities to lead developing countries in innovations that solve world's problems of ill health and deprivation.

References

- Bernauer, Thomas (2003) Genes, Trade, and Regulation: The Seeds of Conflict in Food Biotechnology (Princeton and Oxford: Princeton University Press).*
- Centre for Monitoring Indian Economy (CMIE) (1997) Foreign Trade (Mumbai: CMIE).*
- Centre for Monitoring Indian Economy (CMIE) (2005) Foreign Trade and Balance of Payments (Mumbai: CMIE).*
- Centre for Monitoring Indian Economy (CMIE) (2006) Foreign Trade and Balance of Payments (Mumbai: CMIE).*
- Chadha, Alka (2006) 'Destination India for the Pharmaceutical Industry', Delhi Business Review, 7 (1): 1-8.*
- Chanda, Rupa and Sreenivasan, Niranjana (2006) 'India's Experience with Skilled Migration', in Kuptsch and Pang (eds.) (2006), pp.215-56.*
- Chandrasekhar, C.P. (2006) 'The Political Economy of IT-driven Outsourcing', in Parayil, Govindan (ed.) (2006) Political Economy and Information Capitalism in India: Digital Divide, Development and Equity (Basingstoke, UK: Palgrave Macmillan).*
- Chaturvedi, Sachin (2005) 'Dynamics of Biotechnology Research and Industry in India: Statistics, Perspectives and Key Policy Issues', Directorate for Science, Technology and Industry, Organisation for Economic Cooperation and Development (OECD), at <www.oecd.org/dataoecd/43/35/34947073.pdf>, accessed 17 December 2005.*

- Chaudhuri, Sudip (1984) 'Indigenous Firms in Relation to the Transnational Corporations in the Drug Industry in India', unpublished thesis, Jawaharlal Nehru University, New Delhi.
- Chaudhuri, Sudip (2002) 'TRIPS Agreement and Amendment of Patents Act in India', *Economic and Political Weekly*, August 10.
- Chaudhuri, Sudip (2005) *The WTO and India's Pharmaceuticals Industry: Patent Protection, TRIPS, and Developing Countries* (New Delhi: Oxford University Press).
- Chen, Zhangliang (1999) 'Unlimited Prospects for Biotechnology', Interview with Chen Zhangliang, *Knowledge Economy [Zhishi Jingji]*, December, pp.22-28, at <www.usembassy-china.org.cn/sandt/biotechch.html>, accessed 15 March 2006.
- Chervenak, Mathew (2005) 'An Emerging Biotech Giant?', *China Business Review*, May-June, at <www.chinabusinessreview.com/public/0505/chervenak.html>, accessed 15 March 2006.
- Cooke, Philip (2005) 'Rational Drug Design, the Knowledge Value Chain and Bioscience Megacentres', *Cambridge Journal of Economics*, 29 (3): 325-41.
- D'Costa, Anthony P. (2002) 'Software Outsourcing and Development Policy Implications: An Indian Perspective', *International Journal of Technology Management*, 24 (7-8): 705-23.
- D'Costa, Anthony P. (2004) 'Export Growth and Path-Dependence: the Locking-in of Innovation in the Software Industry', in D'Costa, Anthony P. and Sridharan, E. (eds), *India in the Global Software Industry: Innovation, Firm Strategies and Development* (Hampshire, UK: Palgrave Macmillan).
- D'Costa, Anthony P. (2006) 'Exports, Institutional Architecture, and Innovation Challenges in Bangalore's (and India's) IT Industry', Paper presented at *New Asian Dynamics in Science, Technology and Innovation*, Gilleleje, Denmark, September 27-29, 2006.
- Dahlman, Carl and Utz, Anuja (2005) *India and the Knowledge Economy: Leveraging Strengths and Opportunities* (Washington D.C.: The World Bank).
- Dhar, Biswajit and Gopakumar, K.M (2006) 'Data Exclusivity in Pharmaceuticals: Little Basis, False Claims', *Economic and Political Weekly*, December 9.
- Dicken, Peter (1998) *Global Shift: Transforming the World Economy*, Third Edition (London: Paul Chapman Publishing Ltd).
- Drahos, Peter with Braithwaite, John (2002) *Information Feudalism: Who Owns the Knowledge Economy?* (New York: The New Press).
- Economist* (2002) 'Biotech's Yin and Yang', *Economist*, December 12, at <www.economist.com/science/displayStory.cfm?story_id=1491569>, accessed 17 December 2005.
- Economist* (2005) 'Prescription for Change: A Survey of Pharmaceuticals', *Economist*, June 18-24.

- Ernst, Dieter (2005) 'Complexity and Internationalisation of Innovation – Why is Chip Design Moving to Asia?', *International Journal of Innovation Management*, 9 (1): 47-73.
- Findlay, Allan M. (2006) 'Brain Strain and Other Social Challenges Arising from the UK's Policy of Attracting Global Talent', in Kuptsch and Pang (eds.) (2006), pp.65-86.
- Freeman, Chris (1995) 'The 'National System of Innovation' in Historical Perspective', *Cambridge Journal of Economics*, 19 (1): 5-24.
- Government of India (GOI) (2006) *Research and Development Statistics 2004-05* (New Delhi: Ministry of Science and Technology, Department of Science and Technology).
- Grace, Cheri (2004) 'The Effect of Changing Intellectual Property on Pharmaceutical Industry Prospects in India and China: Consideration for Access to Medicines', Department for International Development (DFID) Health Systems Resource Centre, London, June, at http://www.dfidhealthrc.org/shared/publications/Issues_papers/ATM/Grace2.pdf, accessed 28 December 2005.
- Grace, Cheri (2005) 'Update on China and India and Access to Medicines', DFID Health Resource Centre, London, November, at www.dfidhealthrc.org/what_new/Final%20India%20China%20Report.pdf, accessed 28 December 2005.
- Griffith, V (2002) 'Biotech Groups Stuck on a Rollercoaster Ride', *Financial Times*, 1 February.
- Gross, Ames (1995) 'Opportunities in the China Biotechnology Market', *Pacific Bridge Medical*, January-February, at www.pacificbridgemedical.com/publications/html/ChinaJanFeb1995.html, accessed 28 December 2005.
- Hepeng, Jia (2004) 'IP Litigation in China could Drive Innovation', *Nature Biotechnology*, 22 (4): 368.
- Hoogvelt, Ankie (2001) *Globalization and the Postcolonial World: The New Political Economy of Development, Second Edition* (Basingstoke, United Kingdom: Palgrave).
- Jack, Andrew (2005) 'Patently Unfair? Makers of Branded Drugs Struggle to Counter the Generic Onslaught', *Financial Times*, 22 November.
- Jayaraman, K.S. (2004) 'India Produces Homegrown GM Cotton', *Nature Biotechnology*, 22, pp.255-6.
- Kalsekar, Mahesh (2003) 'The Indian Pharmaceuticals Market – An Overview', ORG-MARG, AC Nielson, Mumbai.
- Karplus, Valerie (2003) 'Global Anti-GM Sentiment Slows China's Biotech Agenda', *YaleGlobal*, 26 September, at <http://yaleglobal.yale.edu/display.article?id=2526>, accessed 15 October 2006.
- Keayla, B.K. (2005) 'Patents (Amendment) Ordinance 2004: A Critique', *National Working Group on Patent Laws*, New Delhi.
- Kjersem, Julie Marie and Gammeltoft, Peter (2006) 'Investing in High-tech in China: the Cases of Novo Nordisk, GN Resound and BenQ Siemens Mobile',

- Paper presented at New Asian Dynamics in Science, Technology and Innovation, Gilleleje, Denmark, September 27-29, 2006.*
- Kleinknecht, Alfred and Wengel, Jan ter (1998) 'The Myth of Economic Globalization', Cambridge Journal of Economics, 22 (4): 637-647.*
- Knowledge@Wharton (2006) 'Where will Indian Drug Companies be in Five Years? Everywhere – If They Innovate', Report Prepared by Knowledge@Wharton in collaboration with Bain & Company, at <www.bain.com/bainweb/pdfs/cms/marketing/bain%20India%20Pharma%20FINAL%2003-21-06.pdf>, accessed 16 September 2006.*
- Kong, Qingjiang (2005) WTO, Internationalization and the Intellectual Property Rights Regime in China (Singapore: Marshall Cavendish Academics).*
- Krishna, Gina, S (2004) 'NORVASC: Who will Pop the Bitter Pill?', Business World, 4 March, at <www.businessworldindia.com/mar0104/indepth04.asp>, accessed 4 October 2005.*
- Kuptsch, Christiane and Pang, Eng Fong (eds.) (2006) Competing for Global Talent, International institute for Labour Studies, International Labour Organization, Geneva.*
- Lanjouw, Jean O. (1997) 'The Introduction of Pharmaceutical Product Patents in India: "Heartless Exploitation of the Poor and Suffering"?'', Yale University, Economic Growth Centre, Discussion Paper No. 775.*
- Lanjouw, Jean O. and MacLeod, Margaret (2005) 'Pharmaceutical R&D for Low Income Countries: Global Trends and Participation by Indian Firms', Economic and Political Weekly, September 24.*
- Mahapatra, Rajesh (2006) 'India's Ranbaxy Labs Blames Pricing Pressure in US market for Sharp Drop in 2005 profit', Associated Press Financial Wire, 18 January.*
- McFadden, Johnjoe (2005), 'Top of the Crops', Guardian, August 23, at <www.guardian.co.uk/gmdebate/Story/0,2763,1554374,00.html>, accessed 28 December, 2005.*
- Menon, Parvathi (2001) 'The Transgenesis Debate', Frontline, 18 (14), July 7-20.*
- Ministry of Petroleum and Chemicals (1971) 'Drugs Prices Control: Aims & Achievements', Government of India, New Delhi.*
- National Bureau of Statistics of China (2005) China Statistical Year Book 2005 (Beijing: China Statistics Press).*
- Nundy, Samiran and Gulhati, Chandra M. (2004) 'A New Colonialism: Conducting Clinical Trials in India', New England Journal of Medicine, 352 (16): 1633-6.*
- ORG-MARG (2004) 'ORG IMS Retail Store Audit for Pharmaceutical Products in India', ORG-MARG Private Limited, AC Nielson, Baroda, December.*
- Paarlberg, Robert L. (2001) The Politics of Precaution: Genetically Modified Crops in Developing Countries (Baltimore and London: International Food Policy Research Institute, Johns Hopkins University Press).*
- Pharmaceutical Enquiry Committee (1954) Report of the Pharmaceutical Enquiry Committee (New Delhi: Ministry of Commerce and Industry, Government of India).*
- Rai, Saritha (2003) 'Generic Drugs From India Prompting Turf Battles', New York Times, 26 December.*

- Raja, M (2004) 'Boost for India's Battling Biotech Business', Asia Times Online Limited, June 24, at [www.atimes.com/atimes/South Asia/FF24Df03.html](http://www.atimes.com/atimes/South_Asia/FF24Df03.html), accessed 7 October, 2005.
- Ramanna, Anitha (2005) 'India's Patent Policy and Political Economy of Development' in Parikh, Kirit S. and Radhakrishna, R. (eds.) (2005), *India Development Report 2004-05* (New Delhi: Oxford University Press) pp.112-25.
- Sampath, Padmashree Gehl (2005) 'Economic Aspects of Access to Medicines after 2005: Product Patent Protection and Emerging Firm Strategies in the Indian Pharmaceutical Industry', United Nations University-Institute for New Technologies, at www.who.int/entity/intellectualproperty/studies/PadmashreeSampathFinal.pdf, accessed 17 December 2005.
- Shiva, Vandana (2001) *Protect or Plunder? Understanding Intellectual Property Rights*, Zed Books, London.
- Spence, Jonathan D. (1999) *The Search for Modern China, Second Edition* (New York and London: W. W. Norton & Company).
- Stropford, J.M. and Strange, S. (1991) *Rival States, Rival Firms: Competition for World Market Shares* (Cambridge: Cambridge University Press).
- Subramaniam, G. Ganapathy (2006) 'India, US have a tiff over TRIPS', *Economic Times*, December 16.
- Taverne, Dick (2005) 'The New Fundamentalism', *Nature Biotechnology* 23 (6), pp. 415-16.
- Thomas, Jayan Jose (2005) 'New Technologies for India's Development', in Parikh, Kirit and Radhakrishna, R. (eds.) (2005), *India Development Report 2004-05* (New Delhi: Oxford University Press) pp.126-40.
- Tomlinson, Heather (2005) '\$12bn Battle that Pits an Indian Upstart against the Mighty Pfizer', *The Guardian*, 29 August, at www.guardian.co.uk/business/story/0,3604,1558296,00.html, accessed 20 January 2006.
- UNCTAD (2005) *World Investment Report 2005: Transnational Corporations and the Internationalization of R&D* (New York: United Nations Conference of Trade and Development) (downloadable from www.unctad.org).
- UNDP (2005) *Human Development Report 2005: International Cooperation at a Crossroads: Aid, Trade and Security in an Unequal World* (New York: United Nations Development Programme) (downloadable from <http://hdr.undp.org/>).
- van Beuzekon, Brigitte and Anthony Arundel (2006) *OECD Biotechnology Statistics-2006*, Organization for Economic Cooperation and Development, accessed from www.oecd.org/dataoecd/51/59/36760212.pdf
- Venkateshwarlu, K. (2006) 'A Saga of Failures', *Frontline*, 23 (1), January 14 – 27.
- Weisman, Steven R. (2006) 'Before Visit to China, A Rebuke', *New York Times*, 12 December.

- World Health Organization (2004) *The World Medicines Situation*, World Health Organization, at [http://w3.who.se/LinkFiles/Reports World Medicines Situation.pdf](http://w3.who.se/LinkFiles/Reports%20World%20Medicines%20Situation.pdf), accessed 7 January 2005.
- Xun Zi (2005) 'GM Rice Forges Ahead in China amid Concerns over Illegal Planting', *Nature Biotechnology*, 23 (6), p. 637.
- Zaidi, Annie (2006) 'Failure in Nimar', *Frontline*, 23 (1), January 14-27.
- Zweig, David (2006) 'Learning to Compete: China's Efforts to Encourage a "Reverse Brain Drain"' in Kuptsch and Pang (eds.) (2006), pp.187-214.