

India and China in the Knowledge Economy: Rivals or Allies? Case Studies of Pharmaceuticals and Biotechnology

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I. INTRODUCTION

A recent news report described India and China as “rivals and partners.” China and India are today experiencing one of the fastest rates of economic growth in their recent histories, and many studies speculate which among these two economies will outperform the other.¹ The abundance and low costs of labour, not only of foremen and call centre operators but also of research scientists and engineers give China and India the edge in the world economy. In this context, China and India are often seen as rivals, racing with each other on the basis of their most visible source of competence: low wages.² However, economic advantages arising out of low labour costs are ephemeral, 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 knowledge-intensive industries will be the crucial test for success.

India and China offer exciting potential for growth of knowledge industries largely because of the strong base in science and technology built in these countries by public investment in the earlier decades. There are, however, several challenges. As will be shown in

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

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

this paper, the provisions of the Trade Related Aspects of Intellectual Property Rights (TRIPS) agreement are forcing changes in the nature of innovation emerging from firms in developing countries, including India and China. A vast market for innovative products exists within developing countries. There is, for example, demand for innovative drugs for poor patients; demand for biotechnological innovations that ensure food security in Africa and other parts of the third world; and demand for new products that meet telecommunication needs of rural areas. However, it appears that this market is given a low priority by innovative firms in developed and developing countries. This paper will argue that rather than competing with each other by cutting wage costs, India and China must join hands to develop products of innovation that would benefit the poor in their countries.

There are seven sections in this paper. The next section discusses the major features of the rise of India and China in high-technology industries. Section 3 tries to highlight the importance of pharmaceutical innovations to developing countries. Section 4 is about India's pharmaceutical industry; section 5 about China's pharmaceutical industry; and section 6 presents certain aspects of biotechnology sector in India and China. Section 7 concludes the paper.

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

Some Asian countries, particularly China, India, Singapore and South Korea, are making rapid advances in the field of research and development.³ China, Singapore and South Korea are investing hugely in biological sciences, just as India is making impressive progress in the pharmaceutical industry.⁴ China and India are racing with the west in space research.⁵ And, of course, India's expertise in information technology (IT) software and Chinese skills in IT hardware are well known.

Research and development (R&D) activities in these Asian countries are building up in two different directions. Firstly, as a consequence of state-directed efforts in R&D. Post-colonial governments in many Asian countries have been making planned investments over

³ The *Financial Times* published a series of articles in June 2005 on the emergence of Asia as a global centre for science and technology. See Cookson (2005a; 2005b; 2005c; and 2005d).

⁴ A *Financial Times* article referred to these developments as the "eastern rebirth of the life sciences." See Cookson (2005b).

⁵ "India and China reach for the moon", says Cookson (2005d).

the past several decades, with the aim of becoming self-sufficient in science and technology. Investments in the previous decades have created strong ‘national innovation systems’ in these countries, which is a solid platform for future progress.⁶

Secondly, in recent years, multinational companies (MNCs) have started making large investments in R&D in a few developing countries, including China, India, Singapore, Brazil, and Thailand. Foreign direct investment (FDI), especially in technology-intensive industries, used to be largely circulated within the developed countries.⁷ R&D activities of MNCs in developing countries were restricted mostly to adaptation of technologies for local markets. However, as the United Nations’ *World Investment Report 2005* points out, there is now a new wave of R&D investments in developing countries by the MNCs, and more importantly, these investments are part of the core innovation activities of MNCs (UNCTAD, 2005). In a survey of the world’s largest R&D spending MNCs conducted by the United Nations Conference on Trade and Development (UNCTAD) during 2004-05, China was identified by the respondents as the most attractive location for future investments in R&D. India was the third most attractive location, behind United States. Singapore, Taiwan, 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 (UNCTAD, 2005, pp.22-26).⁸

For MNCs, the new-found interest in Asian countries as a destination for R&D investments is precipitated by several factors. The most important one is the large supply of highly skilled professionals in these countries, particularly in India and China. In 2000-01, the total numbers of students enrolled in tertiary education were approximately 12 million in China and 10 million in India.⁹ 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 165,610.¹⁰ Both China and India are today ahead of the United States with respect to tertiary technical enrolment (UNCTAD, 2005, p.162). While the supply of skilled workers is thus 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

⁶ For a discussion on ‘national system of innovation’, see Freeman (1995)

⁷ See Kleinknecht and Wengel (1998) on this.

⁸ Among the notable R&D investments in Asia by the MNCs include Motorola’s R&D network in China, global research centres by General Electric and Microsoft in Bangalore, India, and the Toyota Technical Centre Asia Pacific in Thailand (UNCTAD, 2005).

⁹ UNCTAD, 2005, p.162.

¹⁰ National Bureau of Statistics of China, 2005, pp. 689-695.

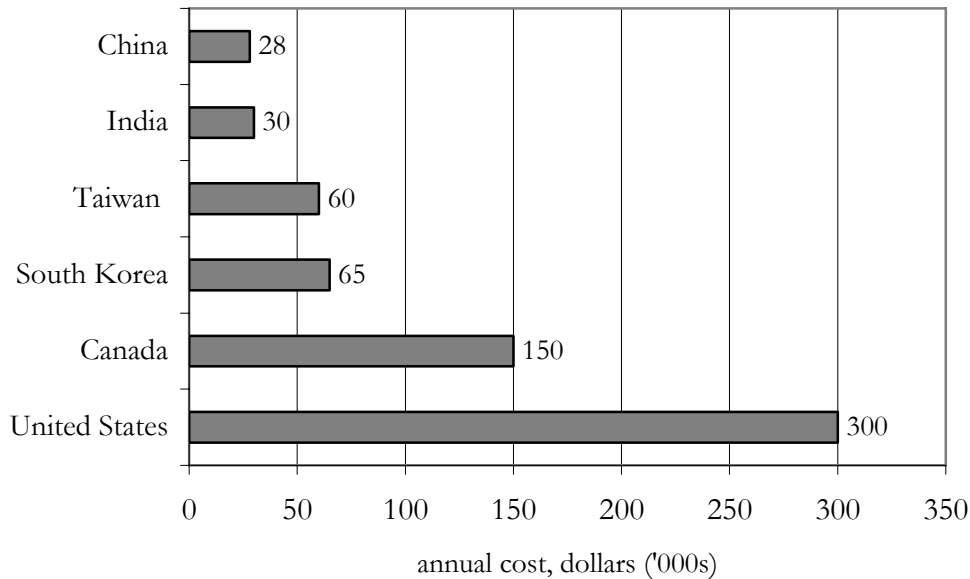
\$28,000 in China (Shanghai province) and \$30,000 in India compared to \$300,000 in Silicon Valley in the United States (see Figure 1).

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 2004¹¹. Indian nationals accounted for 47 per cent of all H-1 visas issued in the United States in 1999; China, a distant second, had a share of 5 per cent of the visas issued.¹² In regard to work permits issued to emigrants from different nationalities in United Kingdom, Indians topped the list with a share of 21.4 per cent of the total work permits issued, up from a share of 8.3 per cent only in 1995 (Findlay, 2006, Table 6). Today, India and China are encouraging return migration of their highly skilled professionals to 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).

¹¹ National Bureau of Statistics of China, 2005, pp. 689-695.

¹² Cited in Chanda and Sreenivasan, 2006, p.220.

Figure 1: Annual Cost of Employing a Chip Design Engineer, 2002, thousands of dollars



Notes: Annual costs include salary, benefits, equipment, office space and other infrastructure.

Source: Based on PMC-Sierra Inc., Burnaby, Canada (for Silicon Valley, Canada and India) and interviews. See Ernst (2005), p.56.

National Programmes for R&D in India and China

The state in post-independence India has actively intervened to build a strong infrastructure for science and technology. R&D in India is financed largely by the public sector. In the total national expenditure on R&D in India in 1998-99 (the latest year for which data was available), the share of the Central government, including public sector units under its management, was 67.5 per cent and the combined share of various State governments was another 8 per cent. The share of the private sector in the total national expenditure on R&D in India was only 21.6 per cent in 1998-99 (GOI, 2002, p.3). Another feature is the domineering role of R&D institutions and the relatively minor role of industrial units in R&D spending in India. R&D institutions at the national and State levels accounted for 73.4 per cent of the total R&D expenditure in India, while industries, public and private, incurred only 26.6 per cent of the total national R&D expenditure. 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). The broad areas into which India's national R&D spending are allocated are (based on 1998-99 figures): defence (21.1 per cent of the total), development of agriculture, forestry and fishing (21.2 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, 2002, 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. Training programmes were instituted, which involved 800,000 scientific professionals in China. The aim was to develop expertise in the fields of energy sources, computers, laser and space technology, high-energy physics and genetics. Eighty-eight key universities were developed for excellence in science and technology; students were admitted to these universities only through rigorous competitive exams. Potential students talented in science and technology were identified at an early age. Scientists who were sent to the countryside were called back. Collaborations with foreign universities began. During 1978, 480 students were sent 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.¹³ 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. The 863 programme attaches special importance to several areas, some of which are the development of new materials, aviation, and the development of advanced integrated manufacturing systems. The 973 programme has identified life sciences, nano-technology, information technology, and earth sciences as frontier areas for basic research. According to Chinese government statistics for 2004, of the total funding for science and technology, only 22.8 per cent came from the government; 64 per cent of the funds were raised by enterprises themselves and 6.1 per cent came through loans from

¹³ Downloaded from the Ministry of Science and Technology of the People's Republic of China (<<http://www.most.gov.cn/eng/programmes/programmes1.htm>> downloaded on 18 January 2006)

financial institutions. Large and medium-scale industrial enterprises received 48.5 per cent of the total national funding for science and technology in 2004; R&D institutions received 18.2 per cent (National Bureau of Statistics of China, 2005, pp. 714-17).

What are the priority areas for R&D investment within the industrial sector (that includes R&D investment by public and private industrial enterprises but excludes R&D investment by R&D institutions)? Table 1 shows the relevant details for India for the year 1998-99 (the latest year for which data was available) and for China for the year 2004. As shown in Table 1, in India, the two major areas of spending in the case of industrial sector R&D are biotechnology and pharmaceuticals. In China, the thrust areas within high-tech industrial sector R&D are the manufacture of electronic and telecommunication equipments and the manufacture of computers (see Table 1).

Table 1: *Major Industries Ranked in Descending Order of Their Shares in Total Industrial R&D Expenditure of the Country, India and China*

		India, 1998-99	China, 2004	
Rank	Industries	Share in total R&D expenditure %	Industries	Share in total R&D expenditure %
1	Biotechnology	20.6	Electronics and communication equipment	64.5
2	Pharmaceuticals	15.0	Electronic computers and office equipments	13.6
3	Defence industries	8.7	Medical and pharmaceutical products	9.6
4	Electrical and electronic equipment	7.9	Aviation and aircraft manufacturing	8.6
5	Chemicals	7.7	Medical instruments	3.6
	Total industrial sector	100	Total industrial sector	100

Notes: Indian Statistics refer to R&D expenditure incurred by industrial sector. Chinese statistics refer to R&D expenditure of large-scale and medium-scale industrial enterprises in high-tech industry.

Sources: GOI (2002), Table 5.3, p. 31 and National Bureau of Statistics of China (2005), Table 21-40, p.718.

Challenges Facing India and China in High Technology Sectors

While India and China undoubtedly enjoy an edge over the rest of the world in science and technology on account of their highly skilled manpower, both the countries 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 \$276.2 billions, while the corresponding figures for China and India (in 2001) were, respectively, \$15.6 billions and \$3.7 billions (see Table 2). 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 2, China, and more so India, lag far behind the United States and other high-income OECD countries (see Table 2; see also UNDP, 2005, pp. 262-5).

Table 2: Some Indicators of Performance in Research and Development: India, China and Other Selected Countries

	India	China	Singapore	United States
R&D Expenditure, billions of dollars, 2002	3.7*	15.6	1.9	276.2
R&D as % share of GDP, 1997-2002	0.8	1.2	2.2	2.7
Researchers in R&D, per million people, 1990-2003	120	633	4352	4526
High technology exports as a % share of manufactured exports, 2003	5	27	59	31
Patents granted to residents, per million people, 2002	0	5	58	302

Notes: *2001 data

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

Countries in North America and Europe are closely monitoring, with some alarm, the emerging threat from Asia against their prominence in high technology. For all these, however, multinational high-tech companies in the United States and Western Europe continue to reign supreme in the field of innovation. 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). High-tech MNCs in the west will certainly try to foreclose the possibility of falling behind in innovation and thereby losing their leadership role in global business. In their pursuit to maintain upper hand in knowledge-intensive industries, companies in the United States and the European Union are helped by some of the provisions in the TRIPS agreement. As the following case studies will show, the TRIPS agreement can indeed dampen the prospects of India, China and other Asian countries in technology-intensive industries.

The arrival of high-tech MNCs can deplete, rather than replenish, the domestic innovation capabilities of the host developing country. Local R&D firms may be taken over by MNCs; local firms and universities may not receive fair compensation as they enter into partnerships with MNCs; and talented researchers in local firms may move into better paying jobs in MNCs (UNCTAD, 2005, pp.190-193). 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 innovation needs of developed country markets, as will be shown in the case of Indian pharmaceutical industry.

III. INNOVATIONS IN PHARMACEUTICALS: HOW IMPORTANT ARE THEY TO DEVELOPING COUNTRIES?

Extreme disparities exist between developed and developing countries with respect to achievements in health and other indicators of human development. 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 3). In 2000-02, 30 per cent of the population in Sub-Saharan Africa, 21 per cent of the population in South Asia and 19 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 and 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 less-developed countries, 289 in developing countries and 18 in high-income OECD countries (See Table3).

Table 3: *Some Indicators of Achievements in Health and Human Development, Different Regions of the World*

	Population, millions	Life expectancy at birth, years	Population under-nourished, %	HIV prevalence, % ages 15-49	TB cases, per 100,000 persons
	2003	2003	2000-02	2003	2003
LDCs	723.2	52.2	33	3.2	452
Developing Countries	5022.4	65	16	1.3	289
Sub-Saharan Africa	674.2	46.1	30	7.3	487
South Asia	1503.4	63.4	21	0.7	306
India	1070.8	63.3	21	0.4 – 1.3	287
China	1300	71.6	11	0.1	245
High Income OECD	917.4	78.9	--	0.4	18

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 are 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. Japan, having a share of 16 per cent, and Germany, France and United Kingdom, having shares of 6- 8 per cent each, of the total value of global production in 1999 were the other major pharmaceutical producers. 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, Table 2.1, 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' such as dengue, diphtheria and malaria, which primarily affect people in poorer countries, and these diseases are given very low priority in pharmaceutical R&D.¹⁴ 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).

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 decreased 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 2). It is reported that over one-third of world's population purchased less than one per cent of the pharmaceuticals sold worldwide.¹⁵ China and India, the two most populous countries on the globe, did not figure

¹⁴ See Lanjouw and MacLeod (2005), p.4234.

¹⁵ WHO, 2004, pp.31-33.

in the list of top ten countries in the world in pharmaceutical sales in 2000.¹⁶ As Table 4 shows, 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 in 1999. For India, 65 per cent of whose population were without access to essential medicines in 1999, Africa and other less-developed regions in the world, the task ahead in ensuring health needs of their population are enormous indeed (see Table 4).

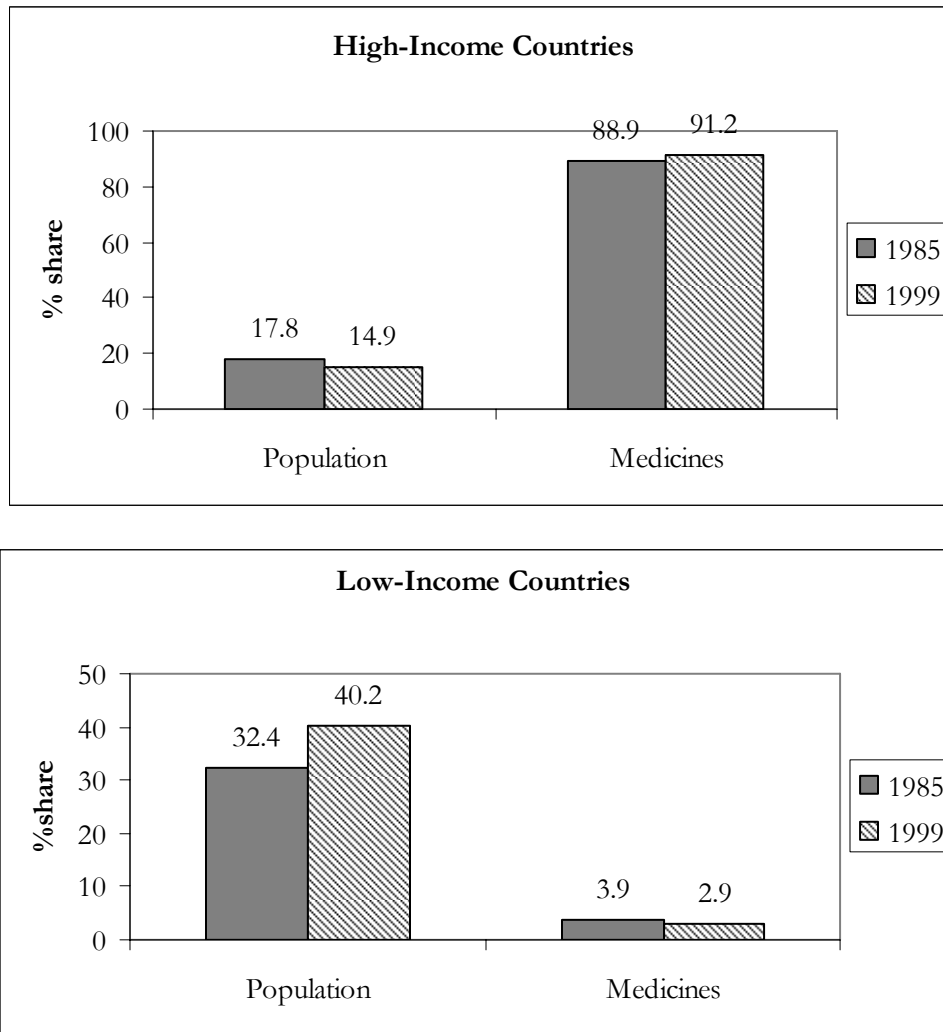
Table 4: *World's Population without Access to Essential Medicines, Different Regions, 1999*

WHO Region	Population, millions	Estimated population without access, millions	% of region's population without access	% share in world population without access
African	566	267	47	15
American	813	179	22	10
East Mediterranean	485	143	29	8
European	832	114	14	7
Southeast Asia	486	127	26	7
West Pacific	380	55	14	3
India	998	649	65	38
China	1274	191	15	11
Total	5334	1725	30	100

Source: World Health Organization (2004, Table 7.2, p.62)

¹⁶ WHO, 2004, p.34.

Figure 2: *Shares of High-income and Low-income Countries in World Population and Global Consumption of Medicines, 1985 and 1999, in per cent*



Source: WHO (2004).

A study published in 1983 noted that pharmaceuticals industry was characterized by high levels of brand competition and, as a result of this, one of the highest levels of promotion expenditure per unit of sales (Chudnovsky, 1983). Marketing and promotional activities by branded pharmaceuticals have only expanded over the past two decades. For example, Novartis reportedly spent 33 per cent of its sales revenue on promotion and only 19 per cent of its sales revenue on R&D (Economist, 2005). Branded drugs are patent protected and their prices comprise the high promotion costs involved. Branded drugs are, therefore, out of reach of poor consumers in developing countries, more so as most of these countries do

not have adequate social security systems in place. Generic drugs, the low cost versions of branded drugs which contain the same active ingredient as in the branded original, are the way out as a source of affordable medicines for the poor. The Conference of the Heads of State of non-aligned countries held in 1979 pointed out that elimination of branded drugs, adoption of generic drugs and withdrawal of patent protection on pharmaceutical products are essential steps for assuring supply of drugs to poor countries (Balasubramaniam, 1983).

IV. PHARMACEUTICAL INDUSTRY IN INDIA

India has a thriving pharmaceuticals industry. India supplies 8 per cent of the total global output (in volume) of drugs, and 22 per cent of the world's output of generic drugs. In the global pharmaceuticals industry, India is ranked 4th in volume and 13th in value of total production. In 2004, there were 65 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 (Gehl Sampath, 2005, p.15; Grace, 2004). As per the latest available statistics, Indian pharmaceutical industry consisted of 300 large to moderate companies and approximately 5000 smaller companies, 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 (IT) and information technology enabled services (ITES) industries in India was US\$28.2 billion in 2004-05)¹⁷. In 2004-05, India's export of drugs, pharmaceuticals and fine chemicals was US\$3.7billion. India exports pharmaceutical products to a large number of countries including the USA, UK, Germany, Russia and China (CMIE, 2005). India is also a low-cost supplier of generic drugs to several less-developed countries.

State Intervention and Development of Innovative Skills in India's Generic Drug Makers

¹⁷ See Thomas (2005).

State intervention has been an essential feature in the development and growth of the Indian pharmaceuticals industry (Chaudhuri, 2005; Sampath, 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 period, which upheld the rights of pharmaceutical companies 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.¹⁸

The Indian Patent Act of 1970 brought in major changes. Section 5 of the 1970 Act stipulated that the patent coverage on drugs, food and other products manufactured by chemical processes would be completely removed. Patenting would henceforth be allowed only on methods or processes to manufacture these products. The period for which patents were granted was reduced from 16 years to five years (from the date of patent granting or seven years from the date of patent application). The 1970 Act also ruled that once a local patent was granted to any pharmaceutical process, the patent holder was obliged to commence domestic production using the patented process within three years from the date of sealing of the patent. After three years from the date of sealing of a patent, a local manufacturer was automatically entitled to obtain a license from the patent holder for a royalty not exceeding 4 per cent (of ex-factory price in bulk form) (Lanjouw, 1998, p.51; Chaudhuri, 2002; Chaudhuri, 2005, pp.36-38; Gehl Sampath, 2005, p. 24).

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 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 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

¹⁸ According to the Report of the American Senate Committee. See Keayla (2005)

companies in India have made use of the technologies developed by CSIR laboratories. For example, the technology for anti-AIDS drugs marketed by CIPLA has been developed jointly by CIPLA and IICT (Chaudhuri, 2005, pp.30-36).

Foreign Exchange Regulation Act (FERA) 1973 and New Drug Policy (NDP) 1978 were the other important instruments of state involvement in pharmaceutical industry. NDP 1978 stipulated that pharmaceutical MNCs can hold foreign equity of more than 40 per cent only if they are manufacturing bulk drugs involving high technology. Government discouraged MNC presence in drug formulations or 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 the prices of medicines.¹⁹

Under the protective cover of state support, the domestic industry developed reverse engineering capabilities in chemicals-based processes for pharmaceutical production, and evolved into 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, 1998, p.3). Over the years after 1970, the domestic pharmaceutical industry grew capable of supplying medicines for the Indian market, and correspondingly the dependence on multinational pharmaceutical companies declined. The proportion of domestic firms to foreign firms in the Indian pharmaceutical industry steadily increased: from 15:85 in 1970 to 50:50 in 1982 and 61:39 in 1999 (Gehl Sampath, 2005, p. 21-22). The share of domestic firms in India's pharmaceutical market 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 (Chaudhuri, 2005). Most importantly, domestic pharmaceutical companies were able to manufacture and sell generic versions of medicines at very low prices in India, which were much lower than the prices of similar drugs in several other countries including United States, United Kingdom and also Pakistan and Indonesia. As Table 5 shows, prices of several drugs in Pakistan and Indonesia, in 2002-03, were 12 – 30 times higher than the corresponding prices in India (see Table 5).

¹⁹ The DPCO, which underwent several modifications, was finally replaced by the National Pharmaceuticals Policy of 2002.

India is a major supplier of active pharmaceutical ingredients (APIs) and finished products at low rates in the case of several medicines, notably vaccines and antiretrovirals (ARVs). Grace (2004) reports that for the production of ARVs by the Government Pharmaceutical Organization of Thailand and by ARV producers in South Africa, almost the entire supply of raw material comes from India. India and China are the major suppliers of raw materials to ARV producers in Brazil. India supplies ARV finished product to countries like Malawi and Kenya (Grace, 2004, pp.13-5). The Indian pharmaceutical company CIPLA supplies ARVs to over 250,000 HIV patients in poor countries, claims the company website.²⁰ When another Indian company Ranbaxy made plans to launch the cholesterol drug atorvastatin in the US and UK, it was welcomed by the media in the UK as a move that would lead to substantial financial savings to the National Health Service in their country (Tomlinson, 2005).

Table 5: *Prices of Selected Drugs in India and Selected Countries, in Indian Rupees, 2002-2003*

Drug	India	Pakistan	Indonesia	UK	USA
Ciprofloxacin HCL	29	423.9	393.0	1185.7	2352.4
	1	14.6	13.6	40.9	81.1
Diclofenac	3.5	84.7	59.8	61.0	674.8
	1	24.2	17.1	17.4	192.8
Rantidine	6.02	74.1	178.4	247.2	863.6
	1	12.3	29.6	41.1	143.5

Notes: Ciprofloxacin HCL is an Anti infective. Diclofenac and Rantidine are anti-ulcerants: 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)

TRIPS Agreement, Changes in India's Patent Laws and their Impact on Domestic Pharmaceutical Industry

India had to comply with the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) as part of its obligations as a WTO member. This implied that a series of

²⁰ See <www.cipla.com>

important changes would have to be made to India's Patent Act of 1970, leading eventually 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, India had to comply with the TRIPS by 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 (Chaudhuri, 2005).

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 patent term to 20 years. It made the alleged infringer of patent responsible for the burden of proof; this responsibility lay with the patent holder earlier. To introduce product patent provisions, the government issued the Indian Patent Ordinance of 2004 in December 2004. The Ordinance was criticized in India and abroad for its strict product patenting regulations. Finally, the Ordinance was replaced with the Indian Patent (Amendment) Act of 2005 passed by the Parliament in March 2005 (Chaudhuri, 2005; Gehl Sampath, 2005, pp. 33-35; Grace, 2005, p.3).

With the legislative changes effected, the future growth of the domestic generic drugs industry is uncertain. It is argued that 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 offered by the TRIPS regime for developing countries. However, important concerns still persist.

The criteria of patentability (section 3) and the grounds on which a patent can be revoked (section 64) defined by the Ordinance of 2004 were very unfavourable to the interests of the domestic industry. Section 3 of the Ordinance allowed combination patents and patents on crystalline versions of known molecules, as in developed countries. Patent owners could use these provisions to obtain secondary patents, leading to what is described as 'evergreening of patents'. Patents Amendments Act of 2005 rectified some of the

drawbacks in the Ordinance. Section 3 of the 2004 ordinance was amended, and as per the amendment, combinations, crystalline and other derivatives of an original substance will not be considered as a new, patentable substance unless they are significantly different in properties from the original substance. There were nine grounds on which a patent could be opposed during the pre-grant period, as per the Act of 1970. Patent Ordinance of 2004 reduced that to two, and this was a major setback. The 2005 Amendment removed this drawback by retaining the nine original grounds and enlisting two additional grounds for pre-grant opposition (Gehl Sampath, 2005, pp.34-36).

Article 39 (3) of the TRIPS agreement stipulates that the test data submitted by pharmaceutical companies to regulatory agencies is not disclosed to the public. This stipulation, which is known as data exclusivity, is detrimental to the interests of generic drug makers. Without access to test data, generic competitors will not be able to prove bioequivalence of their generic versions of drugs. Data exclusivity is granted from the date of introduction of a drug in a particular market, and not from the date for which the drug is granted a patent. This will create the following problem. 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 its monopoly rights, even after the expiry of the patent term, through the years for which it is granted data exclusivity (Gehl Sampath, 2005; Keayla, 2005).

Another issue is regarding compulsory licensing.²¹ Section 92 (A) of the Ordinance of 2004 stipulated that even less-developed countries (LDCs) had to issue compulsory licenses in order that they could import pharmaceutical products from India. As LDCs have been granted exemption from introduction of patents on pharmaceutical products until 2016 under the WTO, this stipulation in the Ordinance of 2004 was clearly unnecessary. The Patent (Amendments) Act 2005 made better use of the flexibility allowed under the TRIPS agreement, and the revised Section 92 (A) of the 2005 Act allowed India's export of pharmaceutical products to those LDCs, which has "by notification, or otherwise, allowed importation of the patented pharmaceutical products from India". Also, the Act of 2005 permits the issuing of a compulsory license anytime after three years from the date of grant of a patent and in cases when a patent holder indulges in anti-competitive practices. These provisions, targeted to meet the demand for drugs at reasonable prices for public health programmes, however, suffer from certain limitations. It will be ineffective in handling

²¹ See Chaudhuri (2002) for more details

immediate health crises like Asian bird flue or the SAARS as generic drug makers take some time to synthesize new drugs even after being granted a compulsory license (Gehl Sampath, 2005, p.38; Grace, 2005).

Impact on Domestic Firms and on Access to Medicines for Poor Patients in India and the Third World

With the introduction of product patenting rules, domestic pharmaceutical companies will no longer be able to reverse engineer and commence domestic production of new, patented drugs using process innovations. At the same time, none of the Indian companies today possesses the skills or financial resources to carry out the whole process of new drug innovation (Chaudhuri, 2005, ch.5). Therefore, India's new patent laws will eventually affect the supply of medicines in India and the rest of third world.

Grace (2005), after examining previous studies, concluded that the share of patented medicines in the current market value of medicines supplied in India would be approximately 10 - 15 per cent. However, over time as new medicines are invented, a greater proportion of the overall market for medicines in the country will be under the patent cover. New medicines are necessary in the treatment of most diseases including TB and malaria as older medicines turn ineffective over the years with the onset of drug resistance. In the case of combination drugs, even if only one drug in the combination is patent protected, that would escalate the cost of the entire therapy. As India has been a major supplier of essential drugs to many third world countries, patent protection of medicines in India would adversely affect the supply of medicines in other third world countries as well (Grace, 2005, pp.16-20). CIPLA, the Indian pharmaceutical company that has been an important supplier of medicines for tropical diseases, has expressed great concerns about India's new patent legislation. Dr. Y. K. Hamied, Chairman and Managing Director of CIPLA, had this to say:

“I have no doubt that this 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”²².

It is important to note that Indian domestic pharmaceutical firms have been readying themselves in anticipation of tighter patent rules, and making increased allocations for R&D spending (Lanjouw, 1997; Gehl Sampath, 2005). In fact, Ramanna (2005) argued that in recent years 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. However, given their paucity of skills and resources, and, more importantly, the difficulty of going through the entire new drug development process, domestic pharmaceutical firms are increasingly adopting a new strategy. They conduct research and develop new molecules, but instead of proceeding further into the financially risky and time-consuming clinical trial and regulatory stages, they license out the molecule to pharmaceutical MNCs. In this manner, rather than targeting their research into neglected diseases prevalent in third world countries, Indian pharmaceutical firms are increasingly catering to global diseases, which pharmaceutical MNCs are keen to develop further (Chaudhuri, 2005).

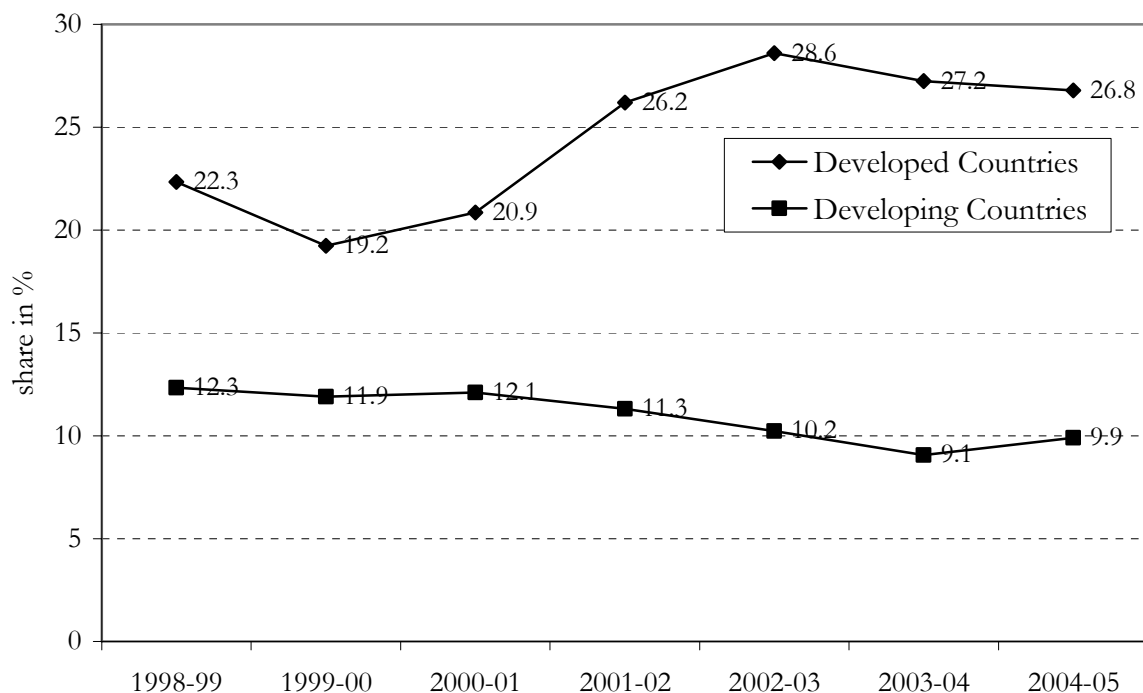
Ranbaxy, the Indian pharmaceutical company that aims to become “one of the top five generic drug makers in the world by 2012”, spends approximately 7 per cent of its global revenue on R&D, low by the standards of western pharmaceutical MNCs, but high for an Indian company. The company website says that, globally, Ranbaxy made 698 patent filings in the first nine months of 2005 compared to 428 patent filings in the first nine months of 2004. Today, Ranbaxy’s marketing strategies are oriented to the western markets, which offer higher returns. North America and Europe, together, accounted for 44.3 per cent of the company’s total global sales of (US\$868million) for the first nine months of 2005; India along with Brazil, Russia and China accounted for only 29 per cent.²³ In a survey of 31 large pharmaceutical companies operating in India (which included companies under Indian ownership and MNC subsidiaries), Lanjouw and MacLeod (2005) found that only 10 per cent of the entire R&D investments by these companies in 2003-04 were targeted at developing country markets and at tropical diseases.

²² Address by Dr. Y. K. Hamied, Chairman and Managing Director, CIPLA, Sixty-Ninth Annual General Meeting – Tuesday, 6th September 2005, Downloaded from <<http://www.cipla.com/corporateprofile/financial/cm69.htm>> (accessed on 14-12-05)

²³ See <<http://www.ranbaxy.com>> accessed on 14-12-05.

The increasingly growing orientation of Indian pharmaceutical industry to developed country markets is evident from Figure 3. The figure shows the combined share of four developed countries and the combined share of six developing countries as destinations to India's total exports of drugs, pharmaceuticals and fine chemicals. These four developed countries --United States, Germany, UK 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 almost continuously 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 (see Figure 3).

Figure 3: Exports of Drugs, Pharmaceuticals and Fine Chemicals by India to Four Selected Developed Countries and Six Selected Developing Countries, 1998-99 to 2004-05, Shares in India's Total Exports of Drugs, Pharmaceuticals and Fine Chemicals in %



Notes: Developed countries: United States, Germany, UK and Canada

Developing countries: Nigeria, Viet Nam, Sri Lanka, Pakistan, Bangladesh and Nepal

Source: CMIE (2005), p.69.

India's domestic pharmaceutical companies are trying to enter the pharmaceutical markets in North America and Europe not only as collaborators of MNCs (by licensing out molecules to them) but also as competitors. Indian firms such as Ranbaxy and Dr. Reddy's have directly challenged product patents held by MNCs. However, originator drug companies employ several strategies to ward off competition from generic rivals. Many originator drug companies have launched their own branded generics (Jack, 2005). They also unleash long and expensive legal battles against their generic competitors (Rai, 2003). A good example is the ongoing legal battle between Ranbaxy and Pfizer over Ranbaxy's generic version of atorvastatin calcium, an anti-cholesterol drug. Pfizer claimed that Ranbaxy's drug violated its patent on Lipitor (with global sales \$12bn in 2004, it is the highest selling medicine in the world). Ranbaxy fought legal battles against Pfizer in the US and UK.²⁴ However, the rulings so far, by London High Court in October 2005 and by a US Federal Court in mid-December, have gone against Ranbaxy. The financial burden of waging the legal war has been very high for Ranbaxy. As per reports in January 2006, Ranbaxy spent \$30million in the last one year as legal expenses.²⁵ At the same time, it must be seen that the R&D expenditure by Ranbaxy for the year 2004, according to the company website, was \$75.1 million.²⁶ Dr. Reddy's Laboratories had a similarly long legal war with Pfizer over the right to market AmVaz, a hypertension drug, in the US. Pfizer went to court alleging that AmVaz was infringing on the patent rights of Pfizer's drug, Norvasc. Dr. Reddy's had obtained United States' FDA approval for AmVaz in October 2002, but with Pfizer's challenge in a US court, Dr. Reddy's had to shelve its manufacturing plans (Krishna, 2004; Rai, 2003). All these came at a huge cost as, reportedly, Dr. Reddy's spent \$12m on legal bills in 2004, which was equivalent to a quarter of the company's R&D budget (Economist, 2005).

Has the implementation of product patent rules led to increased presence of pharmaceutical MNCs in the Indian market? India's large middle class population, among whom there is high prevalence of global diseases such as cancer and cardiovascular diseases, is an attractive market for pharmaceutical MNCs. However, MNCs investing in India do not appear to be interested in the manufacture of bulk drugs; nor are they allocating funds for

²⁴ See Economist (2005) and Tomlinson (2005) for reports on the legal battle between Ranbaxy and Pfizer.

²⁵ Mahapatra (2006)

²⁶ Downloaded from <http://www.ranbaxy.com> on 14-12-05

R&D for neglected diseases in India. With liberalization and removal of restrictions on foreign investment in pharmaceuticals, MNCs are free to import drug formulations into the country. Between 1 August 1991 and 31 December 2000, the share of drugs and pharmaceuticals in total inflow of foreign direct investment (FDI) into India was only 1.01 per cent. At the same time, imports of formulations into India have been rising quickly after 1994-95 (Chaudhuri, 2005, pp. 138-9). Pharmaceutical MNCs have also been entering into marketing agreements with Indian pharmaceutical firms.

Another feature of Indian pharmaceutical industry's growing orientation to the west is an increase in outsourcing of clinical research. Expenses on clinical trials account for 40 per cent of the total cost of drug development. Multinational companies are keen to outsource clinical trial to India due to the cost reduction involved and also due to the tightening of patent rules after the new patent legislations. That India has a large, ethnically diverse population, majority of them having never been exposed to much medications before, is an added advantage. While outsourcing of clinical trials promises some business opportunities, there are several dangers if investments in this sector are left unregulated. The poor and the illiterate are very likely to be victims of illegal and unethical trials. These are risky trials conducted without their informed consent, either through financial inducements or simply by enrolling the patients in trials as if on a medication programme. At the same time, clinical trial participants who respond positively to the dosage of tested medicine are not guaranteed free supply of medicines after the trials (Nundy and Gulhati, 2005).

V. PHARMACEUTICAL INDUSTRY IN CHINA

Pharmaceutical industry is expanding fast in China too. There were 4296 pharmaceutical manufacturing facilities in China in 2003. Domestic pharmaceutical industry supplies almost 70 per cent of the Chinese market for pharmaceutical products. In pharmaceuticals, Chinese expertise is in the manufacture of bulk drugs or active pharmaceutical ingredients (APIs), not in finished dosage forms or formulations production as it is in the case of India. China is the second largest producer of pharmaceutical ingredients in the world; annual output of pharmaceutical ingredients from China was 800,000 tonnes in 2003. 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.13-14). 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.10-11).

Significant steps towards the building of a patent regime began in China only after the late 1970s.²⁷ Chinese government's gradual implementation of an intellectual property rights (IPR) policy was determined by two factors: one, a commitment to 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, and this 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. Only those foreign inventors with whose countries China enjoyed reciprocity were eligible to obtain patents. These restrictions helped to ensure that foreign investments into China came along with technology transfer. In turn, these contributed to building domestic invention capability in China (Kong, 2005).

China introduced a stricter patent regime in 1992. China was integrating itself with the world economy. A strict patent regime was important for China to attract foreign investments. Also, from being an importer of technologies, China was slowly emerging as an exporter of technology-intensive products. Grace (2005) points out that China's patenting policies evolved largely under pressure from bilateral negotiations with the United States. Product patenting rules came into effect in China in 1993 – more than ten years before TRIPS would have forced it to – under compulsion from bilateral agreements China signed with the United States. As per the agreement between China and the United States in 1999 on China's accession to the World Trade Organization (WTO), China had to implement IPR rules that fully comply with the TRIPS. China joined the WTO in 2001, and the country had to bring in patent laws in compliance with the TRIPS by the end of 2002. It was not given

²⁷ See <<http://www.china.org.cn/e-white/20050421/index.htm>>

the transition period that was granted to other developing countries (Grace, 2005, pp. 21-25; Kong, 2005). Today, Chinese laws extend patent protection for twenty years and data exclusivity for six years.²⁸

While China has been successful in introducing patent laws, there have been questions on the effectiveness of patent implementation in China. The United States continuously pressurize China to improve its record on IPR enforcement.²⁹

Despite the implementation of product patent laws, China is able to manufacture pharmaceutical ingredients that contribute to the supply of essential medicines for the third world. One of the means through which China achieves this is by manufacturing intermediates only till the pre-API stage, whereas patent protection is usually applicable to APIs and finished products. 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, there have been instances of India and China cooperating to bypass patent restrictions and produce essential medicines (Grace, 2005, pp.23-5). China is the largest source for India's imports of medicinal and pharmaceutical products. China supplied 28.3 per cent of India's imports of medicinal and pharmaceutical products in 2004-05, up from 18.6 per cent in 1998-99 to (CMIE, 2005, p. 217).

China is expected to play a major role in the production and supply of second-line antiretrovirals (ARVs) for the third world. In the treatment of HIV/AIDS, second line ARVs become necessary once the patient develops resistance to first-line treatment. As of now, second-line treatment is much costlier than first-line treatment. As China is already a major producer of a wide variety of raw materials for second-line ARVs, it is expected that China can become a major supplier of second-line ARVs in the future.³⁰ For all these,

²⁸ See Grace (2004).

²⁹ For example, in an April 29 news release, 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> (downloaded on October 7, 2005).

³⁰ 'India, China or Brazil - who will produce the second line ARVs?', *Health and Development Networks*, key correspondent team, Tuesday, July 12, 2005, downloaded from <http://www.aidsmap.com/en/news/24B33FA6-89CB-42BA-880F-18D774FF85D6.asp> (on 17-09-2005).

however, there are limitations that the TRIPS agreement places. It is reported that after the implementation of the TRIPS agreement, there has been an increase in patent related litigations between multinational pharmaceutical companies and their Chinese rivals (Hepeng, 2004).

China is fast acquiring expertise in different areas of biotechnology, including gene mapping, transgenic technology, gene therapy technology, and stem cell research. There are a number of world-class biomedical institutions in China, including North and South Genome Centres, the Institute of Materia Medica, and Beijing University (Grace, 2004, pp.42-44). A measure of China's strengthening research capabilities in biotechnology is the number of biotech-related papers coming out from that country. In 2004, the number of biotech papers from China as appeared in a *PubMed* search was 112, better than South Korea's 92 and India's 54, although way behind the corresponding number of papers published from European Union (624) and United States (514) (Lawrence, 2005).³¹

VI. AGRICULTURAL BIOTECHNOLOGY IN INDIA AND CHINA

Biotechnology and Agriculture in Developing Countries

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. A good measure of this challenge can be seen in the required increases in yield of cereal cultivation: from 2.9 tons per hectare in 1999 to 4.1 tons per hectare in 2025 (Bernauer, 2003).³² The fast paced research in biotechnology offers hope for dramatic increases in agricultural productivity as well as major gains in the medical field. This paper looks specifically at the promises and problems of research on genetically modified crops.

In 1973, scientists discovered the technique to obtain recombinant DNA (DNA or deoxyribo nucleic acid are molecules that comprise genes, and genes are the carriers of

³¹ *PubMed* is an archive of life sciences journals maintained by the National Centre for Biotechnology Information of the United States.

³² Cited in Bernauer, 2003, Table 2.1.

specific traits). With this, it is possible to combine specific genes from one organism with the DNA of another organism. This technique is called genetic engineering (GE) or genetic modification (GM), and it can be used in several applications including the breeding of new, superior quality agricultural crops (Paarlberg, 2001). Since 1994 (the year in which commercial development of GM crop was first given approval), the spread of GM crops has been almost entirely in three countries: United States, Argentina, and Canada (Paarlberg, 2001).³³ Cultivation using GM crops is highly limited in countries in Europe and in most developing countries. So far, GM crops have been developed only in a few crops -- maize, cotton, soybean, and potato. Again, most of the new GM crops carry only one new agronomic trait, that is, resistance to insects or to specific herbicides (Paarlberg, 2001).

Research on agricultural applications of genetic engineering is carried out almost entirely by American 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 highly concentrated. 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 said that the extreme dominance of US multinationals in research in the field as well as concerns regarding biological safety are reasons behind the unpopularity of GM crops in Europe and in a majority of developing countries (Bernauer, 2003).

American multinational seed companies direct their research efforts specifically to the lucrative markets of rich farmers in the United States, Argentina and Canada, and to a very few crops, importantly, soybeans, maize and cotton. At the same time, poor farmers in developing countries growing tropical subsistence crops such as cassava, millet and cowpeas have been neglected by the 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 never 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). The potential exists to develop GM

³³ 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)

crops including GM rice that give very high yields even in marginal lands under testing conditions like drought; however, this potential is yet to be realized.³⁴

Biotechnology in India

The crucial role of biotechnology in agriculture and health sectors was recognized early on in India. India's Sixth Five Year Plan (1980-85) laid out plans to build domestic research capabilities in fields such as immunology, genetics and communicable diseases. National Biotechnology Board was set up in 1982, and this became the Department of Biotechnology (DBT) in 1986. In India, DBT is the primary agency through which the government allocates funds for research on biotechnology. Other important institutions that support biotechnology research in India are the Department of Science and Technology, the Council of Scientific and Industrial Research (CSIR), the Indian Council of Medical Research (ICMR), the Indian Council of Agriculture Research (ICAR), the University Grants Commission (UGC), and the Department of Scientific and Industrial Research (DSIR) (Chaturvedi, 2005).

Today, the private sector is also very active in the biotechnology sector in India. According to data from Biotech Consortium India Limited, there were 401 biotechnology firms in India in 2003 (Chaturvedi, 2005).³⁵ The DBT has recently unveiled plans to expand the country's biotech industry to \$5 billion in revenues per year by 2010.³⁶

In India, the areas of focus within health biotechnology are human genetics, genomics and vaccine research. Within the agricultural sector, priority is attached to development of transgenic crops, particularly for cotton, rice and wheat. A new area of interest is bioinformatics. Given India's strengths in IT and biotechnology, the country is expecting major investments in this field.

India's experience with genetically modified crops merits a detailed study. In India, as of today, cultivation of GM crops is approved only for cotton. India's Genetic Engineering Approval Committee (GEAC) has given approvals to 12 varieties of *Bt* cotton hybrids, all carrying the *Bt cry 1 ac* gene (that has been derived from the naturally occurring bacterium,

³⁴ See McFadden (2005).

³⁵ Of these 142 firms in the area of healthcare, 132 firms in agricultural biotechnology, 42 firms in industrial biotechnology, and 16 in environmental biotechnology (Chaturvedi, 2005, p.19).

³⁶ See Jayaraman (2005).

Bacillus thuringiensis (Bt)) developed by the US multinational seed company, Monsanto. In India, *Bt* cotton hybrids are sold by Mahyco, Monsanto's partner in India, and other seed companies which are sub-licensees of Monsanto's technology -- Raasi seeds, Ankur seeds, and Nuzhivedu seeds. It is reported that while the total area under cotton cultivation in India is more than 9 million hectares, the area in which *Bt* cotton is cultivated is slightly more than half a million hectare (Chaturvedi, 2005).

Suman Sahai, a leading Indian academic on agricultural biotechnology, points out that more than 40 per cent of the research on GM crops carried out in the public and private sectors in India uses the same gene, *cry 1 Ac*, developed by Monsanto.³⁷ There have been several instances of illegal planting of *Bt* crops in India. There is also very high risk of contamination of non-GM crops by GM crops. A recent research showed that in cultivation using GM crops, excessive use of the same gene could lead to breakdown of pest resistance, the very agronomic trait they are designed for.³⁸ It could also lead to monoculture with alarming consequences on biodiversity.

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 Monsanto-Mahyco were a failure in all the three years after the crop's introduction. The *Bt* cotton sold by Monsanto-Mahyco was 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. 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.³⁹

Farmers in India and many other parts of the world have a long tradition of saving seeds and freely exchanging seeds among other farmers, and this has contributed greatly 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.⁴⁰ As

³⁷ See Krishnakumar (2002).

³⁸ Research paper by Keshav Kranthi, published in *Current Science*, 87, 1593-1597 (2004). See the report by Jayaraman *et al.* (2005).

³⁹ 'Andhra Pradesh plans to drag Monsanto to Monopolies and Restrictive Trade Practices Commission over Bt cotton royalty', *Business Line*, December 29, 2005.

⁴⁰ See Shiva (2001).

per the Indian Patent Act of 1970, plants and agricultural practices were not patentable. However, this 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 force 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 that used any form of traditional knowledge, the information relating to the traditional knowledge used might 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.⁴¹

Biotechnology in China

The Chinese state actively promoted science and technology from the late 1970s, and life sciences became an important focus area. The government set up the State Science and Technology Commission, and under the Commission, the National Centre for Biotechnology Development was established in 1983 (this Centre later became part of the

⁴¹ See Subramaniam (2005).

Ministry of Science and Technology). China's central government launched the Torch Plan in 1988 to develop and commercialize high technology products. Under the Torch Plan, China established nearly 120 high- and new-technology development zones (Gross, 1995; Chervenak, 2005). The National High-tech Research and Development Programme or the 863 Plan was the official successor to the Torch Plan. High-tech medicines and vaccines, protein engineering, and gene therapy have been among the major areas of foci in the 863 Plan (Gross, 1995; Chervenak, 2005).

The role of the Chinese government in the promotion of biotechnology sector has been crucial. By 1992, the government had 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. Government-sponsored key projects numbered around 100. According to a report in 1995, almost one-third of the funds for biotechnology research 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 encouraged technology start ups. Investments by venture capital funds in biotech firms in China, however, are typically much lower than \$500,000 to \$2 million that startups command in developed countries (Chervenak, 2005).

China is making rapid advances in the field of agricultural biotechnology. In China, the policy focus on agricultural biotechnology started in the late 1980s, and 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 U.S. biotechnology firms in Chinese agriculture. That the seeds improved over several decades by Chinese farmers could be appropriated by U.S. biotech companies was a worrying prospect to policy makers in China.⁴² In fact, in the late 1990s, Chinese firms were competing with U.S. multinationals

⁴² 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 U.S. MNC's dominance in Chinese agriculture after a visit to the north-eastern province of Jilin.

such as Monsanto to be the leading supplier of transgenic crops in the various Chinese provinces (Chen, 1999).⁴³ In western countries, seed companies and biotechnology companies were quickly forming alliances with each other. 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 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 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 has produced good results in China. As per reports in 2002, Chinese research institutes developed 141 types of GM crops, of which 65 were already undergoing field trials. Research is undergoing to develop genetically modified tomatoes 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 6). In 2001, over 4 million small-scale farmers were involved in Bt cotton cultivation in China (Karplus, 2003).

⁴³ In the late 1990s, the U.S. 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).

However, the opposition against GM crops in Europe and many parts of Asia is a factor that slows down China's agricultural biotech programme. China worries that its exports to Europe will be affected because of its cultivation of GM crops (Karplus, 2003). 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 6: *Area under Cultivation of genetically modified (GM) crops, 1996 to 2005, in million hectares*

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

VII. CONCLUSIONS

A vast market for innovative products – including affordable medicines, high yielding crops and cheap telecommunication – exist in developing countries. Some developing countries, especially China and India, possess national innovation systems built by previous public

investment; these countries have the capabilities to produce innovations targeted at the poor in the third world. For example, India's pharmaceutical industry has had an excellent record in supplying medicines at affordable prices to the poor in India and other third world countries. However, some of the provisions of the TRIPS agreement that came into effect in recent years have produced harmful impacts on the nature of innovation in developing countries. In the case of India's pharmaceutical industry, the strict patent laws, introduced under compulsions from the WTO, have considerably reduced the ability of Indian firms to manufacture generic drugs for the domestic market. In response to the introduction of product patent laws, Indian pharmaceutical firms have been stepping up their R&D spending. At the same time, they have also been increasingly orienting their research and production activities towards the lucrative pharmaceutical markets in North America and Europe. They collaborate with multinational pharmaceutical companies, which contract out research and clinical trials to India. In their attempts to enter the generic drug markets in western countries, Indian firms have also directly confronted MNCs, which have led to costly legal battles over patent violations.

Research in agricultural biotechnology is today dominated by U.S. 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 China, government is taking the lead in biotechnology research. Chinese research institutes produced many varieties of GM crops, including genetically modified cotton, tomato, tobacco and rice.

There is large potential for India and China to cooperate in pharmaceuticals and biotechnology. China is today an important player in the supply of pharmaceutical chemicals and active pharmaceutical ingredients. India has developed capabilities in the formulation of pharmaceutical dosage forms from chemical intermediates. For India, China is the largest source of imports of medical and pharmaceutical products (CMIE, 2005).⁴⁴ Both India and

⁴⁴ Matrix Laboratories of India and Mchem of China formed a strategic alliance, which helped Matrix expand its production of APIs into China (Grace, 2005, p.11).

China are investing in biotechnology. Technology-intensive firms in India and China should not be competing with each other on the basis of low wages to obtain a larger share of the market for outsourcing of innovation. Rather, they should cooperate to develop new products aimed at the poor in the third world.

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