ISAS Working Paper

No. 18 – Date: 26 January 2007 (All rights reserved)

Institute of South Asian Studies
469A Tower Block
Bukit Timah Road #07-01 (259770)
Tel : 65164239 Fax: 67767505
Email : isasijie@nus.edu.sg
Website: www.isas.nus.edu.sg

KNOWLEDGE ECONOMIES IN INDIA, CHINA AND SINGAPORE

Issues and Prospects

Case Studies of Pharmaceuticals and Biotechnology

Jayan Jose Thomas*
Research Fellow
Institute of South Asian Studies
National University of Singapore

* The author is thankful to the Institute of South Asian Studies, autonomous research institute in the 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 Govindan Parayil, Anthony D'Costa, and Maathai K. Mathiayazhagan 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.

Chapter 1
INTRODUCTION:
RESEARCH AND DEVELOPMENT IN INDIA AND CHINA

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 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 technology-intensive or knowledge-intensive industries will be the crucial test for long-term success.

India and China offer exciting potential for growth of knowledge industries because of their large supply of highly skilled professionals and the strong base in science and technology built in these countries by public investment over the earlier decades. Also, technology firms in India and China can cater to the vast market for innovative products that exist 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. This market has so far been given a low priority by the leading innovative firms in developed countries.

There are, however, several challenges. Some of the provisions of the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) are forcing changes in the nature of innovation emerging from firms in India, China and other developing countries. In the post-TRIPS phase, firms in developed countries are increasingly outsourcing research and development (R&D) to firms in India and China. There are indeed instances of Indian and Chinese technology firms competing with each other to obtain a larger share of the market for contract research. Such trends could lead to a reorientation in the research and development (R&D) activities of Indian and Chinese firms to the innovation needs of rich consumers in developed and developing countries. In turn, this will undermine the goal of producing innovation for the third world.

---

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 Favourite 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 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. Singapore can play an important role as a facilitator of India-China cooperation in knowledge-intensive industries, in pharmaceuticals and biotechnology, for example. Government spending and policy attention on the biotechnology industry is very high in Singapore. The Biopolis in Singapore is emerging as a leading global centre in biomedical sciences research. Singapore can act as a hub where talents from India and China interact. Singapore can also focus its attention on biomedical innovations targeted at the large markets of Southeast Asia, South Asia and China.

1.1 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. First, as a consequence of state-directed efforts in R&D. Post-colonial governments in many Asian countries have been making planned investments over 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

---

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).

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

7 See Kleinknecht and Wengel (1998) on this.

United Nations' *World Investment Report 2005* points out, there is now a new wave of R&D investments by the MNCs in developing countries, 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 (See Table 1.1; also see UNCTAD, 2005, pp.22-26).[8]

Table 1.1: Attractive Future Destinations for R&D Investments, 2005-09, according to the UNCTAD Survey of world's largest R&D spending MNCs

Rank	Country	% of respondents who expressed interest in R&D investments in the country
1	China	61.8
2	United States	41.2
3	India	29.4
4	Japan	14.7
5	United Kingdom	13.2
6	Russia	10.3
7	France	8.8
8	Germany	5.9
9	Singapore	4.4
9	Taiwan Province of China	4.4
13	Malaysia	2.9
13	Republic of Korea	2.9
13	Thailand	2.9
18	Brazil	1.5
18	Vietnam	1.5

Notes: Ranked in descending order of attractiveness as an investment destination
Source: UNCTAD (2005), p.153.

[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).

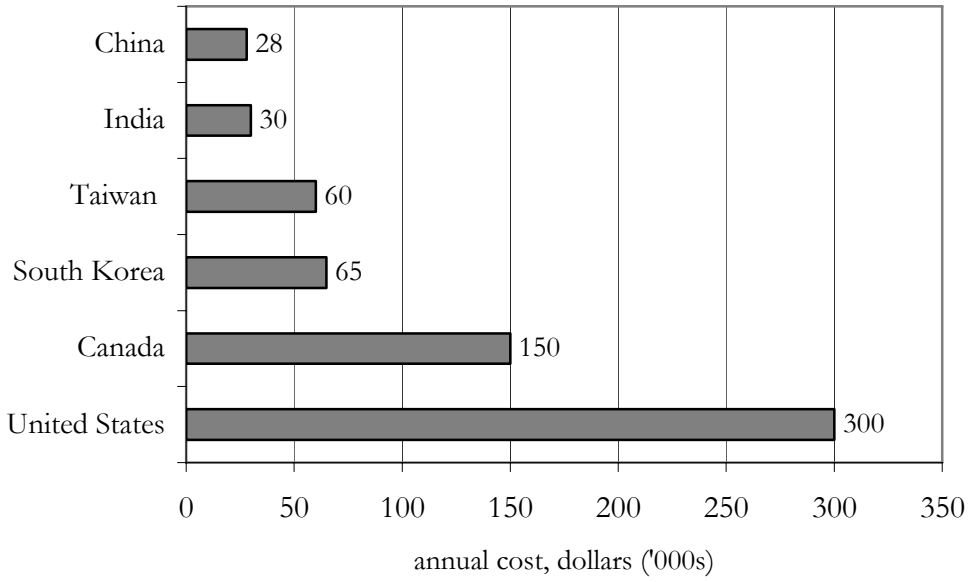
1.1.1 R&D Investments and Supply of Highly Skilled Labour in India and China

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 for 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 $28,000 in China (Shanghai province) and $30,000 in India compared to $300,000 in Silicon Valley in the United States (see Figure 1.1).[11]

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 2004[12]. 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.[13] 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).

9 UNCTAD (2005), p.162.
10 National Bureau of Statistics of China (2005), pp. 689-695.
11 UNCTAD (2005, Table V.1, p.174).
12 National Bureau of Statistics of China (2005), pp. 689-695.
13 Cited in Chanda and Sreenivasan (2006), p.220.

Figure 1.1: 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: Ernst (2005), p.56. Ernst's (2005) figures are based on PMC-Sierra Inc., Burnaby, Canada (for Silicon Valley, Canada and India) and interviews.

1.2 NATIONAL PROGRAMMES FOR R&D IN INDIA AND CHINA

1.2.1 The State and R&D in India

The state in post-independence India has actively intervened to build a strong infrastructure for science and technology. 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 (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 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. 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 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, 2002, pp.3-8).

1.2.2 The State and R&D in China

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, laser and space technology, high-energy physics and genetics. Eighty-eight key universities were developed for excellence in science and technology; admissions to these universities were done 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. 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.[14] 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

[14] 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)

came through loans from financial institutions. 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 China 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. 714-17).

1.2.3 Research and Development in the Industrial Sectors of India and China

What are the priority areas for R&D expenditure within the industrial sector? It may be noted that this includes R&D expenditure by public and private industrial enterprises but excludes R&D expenditure by R&D institutions. It may also be noted that R&D expenditure by industrial enterprises as a share of total national R&D expenditure was only 24.8 per cent in India in 2002-03 and 48.5 per cent in China in 2004. The rest of the national R&D expenditures in India and China were incurred by R&D institutions. Table 1.2 shows the distribution of industrial R&D expenditure by India for the year 2002-03 (the latest year for which data was available) and for China for the year 2004.

As shown in Table 1.2, in India, the two major areas of spending within industrial sector R&D are drugs and pharmaceuticals and transportation industries. 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 1.2). In India, 93 public sector units, together, had a share of 18.1 per cent in the total industrial R&D expenditure in the country. The rest 81.9 per cent of industrial R&D expenditure in India was incurred by the private sector, consisting of 1554 in-house R&D units and 248 scientific and industrial research organizations. For India, industrial R&D expenditure under the title 'defence industries' includes, mainly, R&D expenditures by five public sector industrial units; it does not include R&D expenditure by defence research institutions such as DRDO, which are the bigger spenders of defence R&D in India. In drugs and pharmaceuticals and transportation industries in India, the private sector dominated in R&D spending. The numbers of R&D spending units in the private and public sectors were 153 and six respectively in drugs and pharmaceuticals, and 94 and one, respectively, in transportation industries (GOI, 2006, pp.30-32).

Table 1.2: *Major Industries Ranked in Descending Order of Their Shares in Total Industrial R&D Expenditure of the Country, India and China*

	India, 2002-03		China, 2004	
Rank	Industries	Share in total R&D expenditure %	Industries	Share in total R&D expenditure %
1	Drugs & pharmaceuticals	22.9	Electronics and communication equipment	64.5
2	Transportation	16.8	Electronic computers and office equipments	13.6
3	Defence industries	8.8	Medical and pharmaceutical products	9.6
4	Electrical and electronic equipment	8.3	Aviation and aircraft manufacturing	8.6
5	Chemicals (excluding fertilizers)	6.2	Medical instruments	3.6
	Total industrial sector	100	Total industrial sector	100
	Industrial sector R&D as % of total national R&D	24.8	Industrial sector R&D as % of total national R&D	48.5

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.
In India, R&D spending by 'defence industries' shown in the Table does not include R&D spending by R&D institutions such as DRDO.
Sources: GOI (2006), Table 5.3, p. 32 and National Bureau of Statistics of China (2005), Table 21-40, p.718.

1.3 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 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 1.3). 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 1.3, China, and more so India, lag far behind the United States and other high-income OECD countries (see Table 1.3; see also UNDP, 2005, pp. 262-5).

Table 1.3: *Selected Indicators of Performance in Research and Development: India, China, Singapore and the United States*

	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

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 Pfzier 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). In their pursuit to maintain upper hand in innovation and knowledge-intensive industries, companies in the United States and western Europe are helped 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.190-193). 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 innovations needs of developed country markets, as will be shown in the case of Indian pharmaceutical industry.

CHAPTER 2

PHARMACEUTICAL INDUSTRY AND INTELLECTUAL PROPERTY RIGHTS REGIME IN INDIA AND CHINA

2.1. DEMAND FROM DEVELPING COUNTRIES FOR NEW PHARMACEUTICAL INNOVATIONS

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 (Organization for Economic Cooperation and Development) country in the same year could possibly live for 79 years (see Table 2.1). 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 Table 2.1).

Table 2.1: *Selected Indicators of Achievements in Health and Human Development, Different Regions of the World*

	Population, millions	Life expectancy at birth, years	Population under-nourished, %	HIV prevalence, % ages 15-49	TB cases, per 100,000 persons
	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

Note: LDCs = Less 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 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.[15] 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 2.1). It is reported that over one-third of world's population purchased less than one per cent of the pharmaceuticals sold worldwide.[16] China and India, the two most populous countries on the globe, did not figure in the list of top ten countries in the world in pharmaceutical sales (by value) in 2000.[17] As Table 2.2 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. India, 65 per cent of whose population were without access to essential medicines in 1999, Africa and many parts of the developing world faces the enormous challenge of ensuring the health needs of their population (see Table 2.2).

---

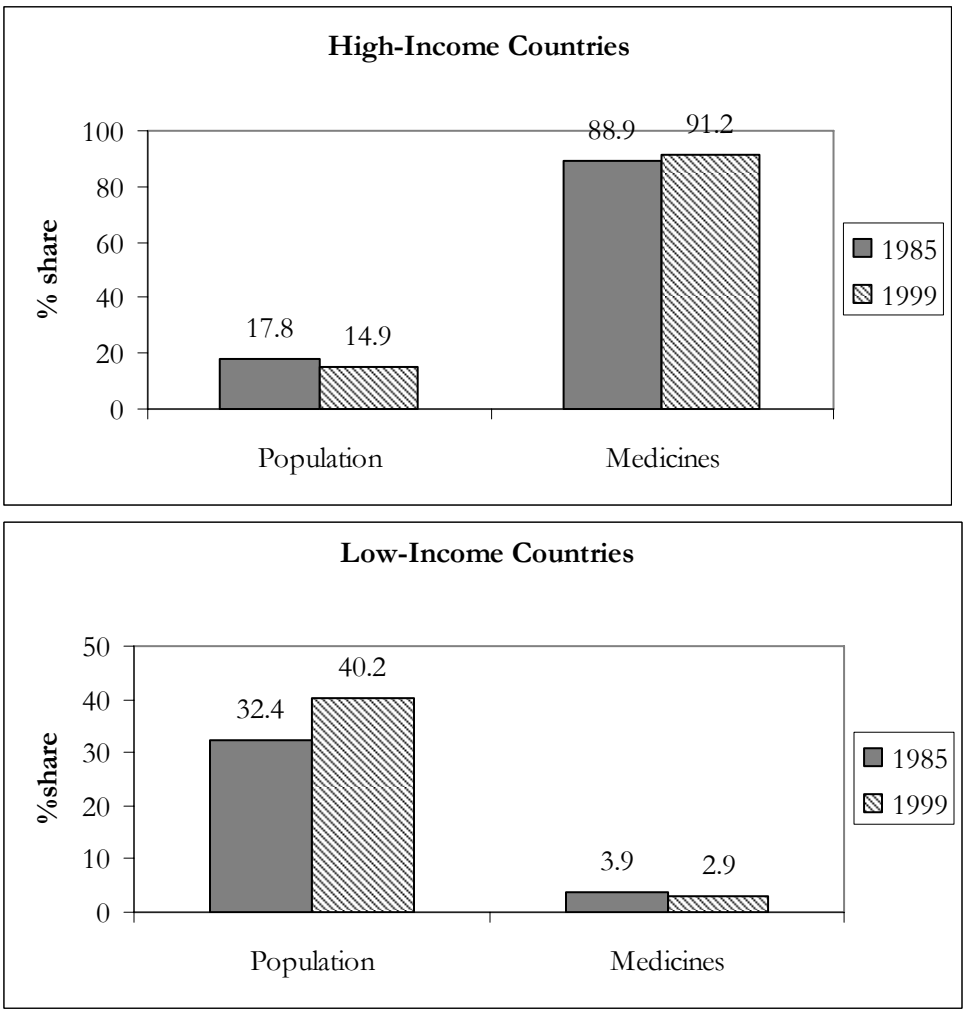
15 See Lanjouw and MacLeod (2005), p.4234.
16 WHO (2004), pp.31-33.
17 WHO (2004), p.34.

Table 2.2: *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 total world population without access
	i	ii	ii as % of i	ii as % of its total
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.

Figure 2.1: *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 spends 33 per cent of its sales revenue on promotion compared with 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).

2.2. 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 (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.[18] As per the latest available statistics, 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 (IT) and information technology enabled services (ITES) industries in India was US$28.2 billion in 2004-05)[19]. 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 United States, United Kingdom, Germany, Russia and China (CMIE, 2005). India is a low-cost supplier of generic drugs to several less-developed countries.

---

[18] See the report 'Where will Indian Drug Companies be in Five Years? Everywhere – If They Innovate', prepared by Knowledge@Wharton in collaboration with Bain & Company, downloaded from <www.bain.com/bainweb/pdfs/cms/marketing/bain%20India%20Pharma%20FINAL%203-21-06.pdf> on 16 September 2006.

[19] See Thomas (2005).

2.2.1 State Intervention and Growth of Process Innovation Skills in India's Generic Drug Makers

State intervention has been an essential feature in the development and growth of the Indian pharmaceuticals 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 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.[20]

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).

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 was a

[20] According to the Report of the American Senate Committee. See Keayla (2005).

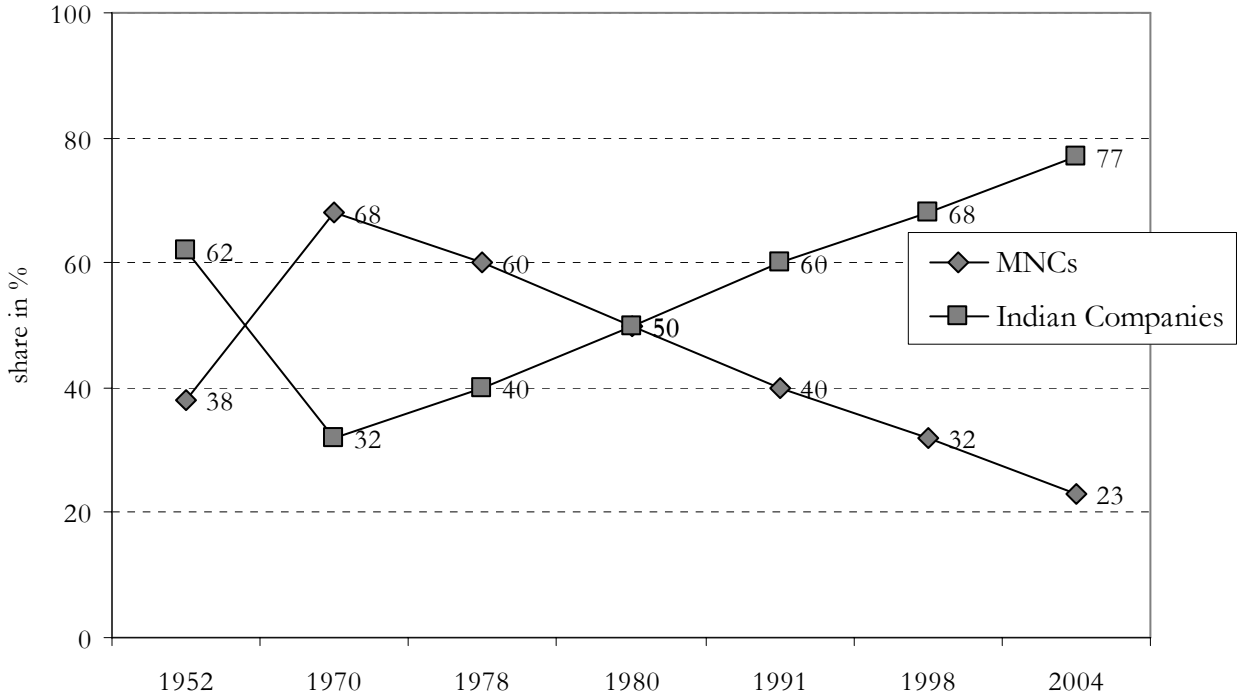
former employee of IDPL. CDRI developed a technology for manufacturing paracetamol, and this has been widely used by small-scale pharmaceutical companies in India. Top pharmaceutical companies in India have made use of the technologies developed by CSIR laboratories. For example, the technology for anti-AIDS 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 through which the state intervened in the pharmaceutical industry. NDP 1978 stipulated that pharmaceutical MNCs can hold foreign equity of more than 40 per cent only if they are locally 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 pharmaceutical prices.[21]

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 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 (see Figure 2.2). 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 2.3).

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

Figure 2.2: Market Shares in India's Pharmaceutical Industry, Domestic Companies and MNCs, 1952-2004, shares in %



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).

India is a major supplier of active pharmaceutical ingredients (APIs) and finished products at cheap rates in the case of several medicines, notably vaccines and antiretrovirals (ARVs). India supplies almost the entire range of raw material for the production of ARVs by the Government Pharmaceutical Organization of Thailand and by ARV producers in South Africa. India and China are the major suppliers of raw material to ARV producers in Brazil. India supplies ARVs 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.[22] When the Indian company Ranbaxy made plans to launch the cholesterol drug atorvastatin in the U.S. and U.K., it was welcomed by the media in the U.K. as a move that would lead to substantial financial savings to the National Health Service in their country (Tomlinson, 2005).

[22] See <www.cipla.com>

Table 2.3: *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
	(1.0)	(14.6)	(13.6)	(40.9)	(81.1)
Diclofenac	3.5	84.7	59.8	61.0	674.8
	(1.0)	(24.2)	(17.1)	(17.4)	(192.8)
Rantidine	6.02	74.1	178.4	247.2	863.6
	(1.0)	(12.3)	(29.6)	(41.1)	(143.5)

Notes: Ciprofloxacin HCL is an Anti infective. Diclofenac and 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).

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

India complied with the provisions of the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) as part of its obligations as a WTO member. 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.

Implementation of TRIPS 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 introduce TRIPS compliant legislations 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; 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 contained in the TRIPS regime for developing countries. However, important concerns still persist.

Indian Legislations and Flexibilities under TRIPS

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 (Chaudhuri, 2005, pp.70-116; 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 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; Sampath, 2005; Keayla, 2005).

Another issue is regarding compulsory licensing.[23] 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. As per the revised Section 92 (A) of the 2005 Act, India can export pharmaceutical products to those LDCs which have by notification or other means allowed import of the patented pharmaceutical product from India. Also, the Act of 2005 permits the issue 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. However, as regards the objective of supplying drugs at reasonable prices for public health programmes, these provisions suffer from certain limitations. They will be ineffective in handling immediate health crises like Asian bird flue or the SAARS given that generic drug makers take some amount of time to start the manufacture of a new drug after being granted a compulsory license for it (Chaudhuri, 2005, pp.83-99; Grace, 2005).

[23] See Chaudhuri (2002) for more details.

Impact of TRIPS on Access to Medicines for Poor Patients

The changes in India's patent regime brought in by the TRIPS have important implications for growth of domestic pharmaceutical companies and, consequently, for supply of medicines to poor patients in India and the rest of 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 -- although some of the leading ones are trying to acquire these capabilities. Given this context, it is likely that 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 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 (TB) and malaria as older medicines turn ineffective with the setting in of drug resistance. In the case of combination drugs, even if only one drug in the combination is patent protected, that will escalate the cost of the entire therapy. It is also pointed out that as India has been a major supplier of essential drugs to many third world countries, patent protection of medicines in India will adversely affect the supply of medicines in other third world countries as well (Grace, 2005, pp.16-20).

CIPLA, the Indian pharmaceutical company that is an important supplier of medicines for tropical diseases, has expressed great concerns about India's product patent legislation implemented in 2005. 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"[24].

2.2.3 TRIPS and the Future of Indian Pharmaceutical Industry

Indian domestic pharmaceutical firms have been readying themselves in anticipation of product patent rules, and making increased allocations for R&D spending (Lanjouw, 1997; Sampath, 2005). In fact, Ramanna (2005) 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. At the same time, leading Indian pharmaceutical companies have been orienting their sales increasingly to the export markets of North America and Europe.

Ranbaxy, the Indian pharmaceutical company that has set itself the target of becoming "one of the top five generic drug makers in the world by 2012", spends approximately 7 per cent of its global revenue on research and development -- 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. [25] Ranbaxy made its entry into the U.S. generic drugs market in the mid-1990s. Today, bulk of Ranbaxy's revenues comes from developed country markets in the west. United States and Europe, together, accounted for 45.2 per cent of the company's total global sales of (US$1178 million) in 2005.[26] 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 tropical diseases.

---

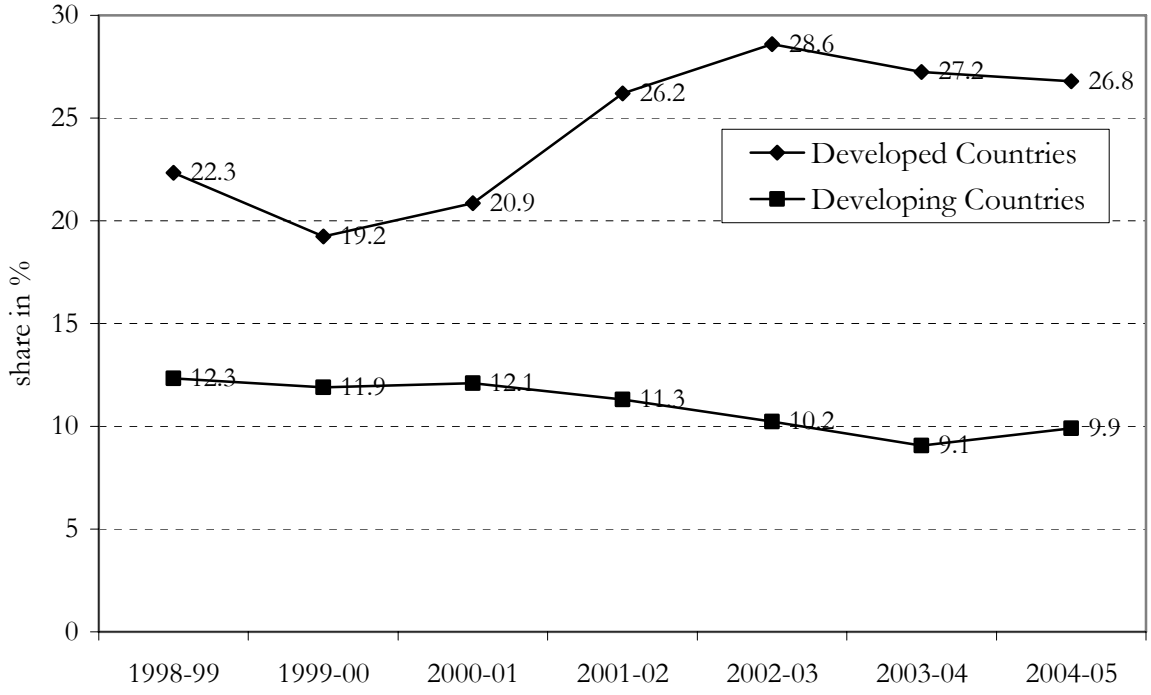
[24] Address by Dr. Y. K. Hamied, Chairman and Managing Director**,** CIPLA, Sixty-Ninth Annual General Meeting – Tuesday, 6th September 2005, Downloaded from <http://www.cipla.com/corporateprofile/financial/cm69.htm> (accessed on 14-12-05)

[25] See <www.ranbaxy.com>

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

The increasingly growing orientation of Indian pharmaceutical industry to developed country markets is evident in Figure 2.3. 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, 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 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 2.3: *Exports of Drugs, Pharmaceuticals and Fine Chemicals by India to Selected Developed Countries and 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.

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 situation, Indian firms compete and, in some cases, collaborate 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. With this strategy, however, Indian firms' research focus on neglected diseases prevalent in third world countries is likely to be reduced considerably (Chaudhuri, 2005).

NEW DRUG DISCOVERY

The discovery of a new drug is an extremely time-consuming and financially-risky operation. The entire process of bringing an experimental drug into the United States market takes an average of 12 years. This involves approximately 3.5 years for preclinical testing, 6 years for clinical trials and another 2.5 years for approval by the U.S. Food and Drug Administration (FDA). On an average, of the 5000 compounds that are evaluated at the preclinical stage, five compounds enter the phase of clinical trials, and only one compound ultimately gets the FDA approval for marketing (according to information given at the Website of Alliance Pharmaceutical Corporation). 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). To reduce costs of new drug discovery, pharmaceutical MNCs are entering into strategic alliances with smaller pharmaceutical firms, biotech companies and academic centres. Novartis claims in its website that the company has more than 400 collaborations in over 20 countries, including 120 collaborations with biotech companies and 280 collaborations with academic centres.

Source:<www.allp.com/drug_dev.htm> and <www.nibr.novartis.com/OurScience/drug_development.html> downloaded on 16 September 2006,

[27] For example, in 2005, sales revenues of the Indian company Ranbaxy was US$1.17 billion and that of Pfizer was US$51.3 billion. See the report 'Where will Indian Drug Companies be in Five Years? Everywhere – If They Innovate', prepared by Knowledge@Wharton in collaboration with Bain & Company, downloaded from <www.bain.com/bainweb/pdfs/cms/marketing/bain%20India%20Pharma%20FINAL%203-21-06.pdf> on 16 September 2006.

For Indian pharmaceutical companies, the high returns in the market for generic drugs in North America and Western Europe is a major attraction. However, the regulatory barriers to entry into developed country markets, particularly the U.S. market is very high. A potential exporter of bulk drugs to the United States has to file a Drug Master File (DMF), which will incur a cost of US $200,000. For an Indian company to market a drug formulation in the United States, it has to get approval for its Abbreviated New Drug Application (ANDA). Approval of ANDA takes upto five years and costs as high as US $1 million. A pharmaceutical company applying for ANDA must identify its bulk drug suppliers and DMF numbers. It is estimated that setting up a manufacturing plant meeting ANDA standards costs six times more than an ordinary manufacturing plant and three times more than a plant meeting World Health Organization (WHO)'s good manufacturing practices. Such requirements erect barriers to relatively small Indian pharmaceutical companies trying to sell generic drugs in the U.S. market (Chaudhuri, 2005).

The market for generic drugs opened up in the United States only since the late 1980s. Today, there is tough competition in the U.S. market for generic drugs. In the generic drugs market, prices fall drastically with the entry of new generic drug makers as competitors. Companies like Ranbaxy and Dr. Reddy's, which are today successful as exporters of generic drugs, have the advantage of early entry into the U.S. market. The going will be tough for the relatively small Indian pharmaceutical companies as they try to enter the regulated markets of United States and Europe (Chaudhuri, 2005). In fact, in recent months, it is reported that many of the smaller Indian pharmaceutical companies have been going through difficult times. This is because of increasing competition and the tightening of regulatory restrictions in the Indian market as well as in the export markets of countries such as Brazil and Korea (Chaudhuri, 2005). The Indian pharmaceutical industry has witnessed a significant increase in mergers and acquisitions (M&As), and this has further weakened the smaller Indian companies (Chadha, 2006).[28]

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

Indian Generic Drug Makers vs. Originator Drug Companies

The bigger pharmaceutical companies in India that are trying to enter the market for generic drugs in the west have been facing many challenges. Indian generic drug firms such as Ranbaxy and Dr. Reddy's have directly challenged product patents held by originator drug companies (mostly the big pharmaceutical MNCs), but this has led them to long and costly legal battles with the latter.

Originator drug companies try to hold on to the monopolies over drugs through secondary patents. Many originator drug companies have launched their own branded generics (Jack, 2005). Another strategy employed by originator drug companies to ward off competition is to unleash long and expensive legal battles against their generic competitors (Rai, 2003). In the U.S. market, there is stiff competition among generic companies to be the first to challenge secondary patents held by originator drug companies and obtain Para IV ANDA, which is market exclusivity for 180 days. Generic companies try to enter the market for value added generics by devising new processes that are non-infringing of secondary patents, and by devising new drug delivery systems. The other option available to generic drug companies is to file a new drug application and directly challenge the patents held by originator drug companies (Chaudhuri, 2005).

A generic company which obtains a para IV ANDA by successfully challenging a patent held by the originator company can make a profit of $2 billion and more during the 180 days for which it is granted market exclusivity. Because of the promise of such huge profits, Indian companies like Ranbaxy spend as high as $13 million on a single patent challenge.[29] However, it may be noted that as regards the risks and returns associated with a patent challenge, there are considerable differences between originator and generic drug companies. For originator drug companies, patent litigation to delay competition from generic drug companies is a high return-zero risk strategy, as they would gain greatly even by delaying the entry of generic competitor by a few months. On the other hand, for generic

[29] See the report 'Where will Indian Drug Companies be in Five Years? Everywhere – If They Innovate', prepared by Knowledge@Wharton in collaboration with Bain & Company, downloaded from <www.bain.com/bainweb/pdfs/cms/marketing/bain%20India%20Pharma%20FINAL%203-21-06.pdf> on 16 September 2006.

drug companies, 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 (with global sales of $12bn in 2004, Lipitor is the highest selling medicine in the world). Ranbaxy fought legal battles against Pfizer in the United States and United Kingdom.[30] However, the rulings by London High Court in October 2005 and by a U.S. Federal Court in December 2005 have gone against Ranbaxy. The financial burden of waging the legal war has been very high for Ranbaxy. Ranbaxy spent US$30million in 2005 as legal expenses (as per reports in January 2006).[31] This must be compared to Ranbaxy's R&D expenditure for the year 2004, which was $75.1 million according to the company website.[32]

Dr. Reddy's Laboratories had a long legal war with Pfizer over the right to market AmVaz, a hypertension drug, in the U.S. market. 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). Dr. Reddy's reportedly spent $12m on legal bills in 2004, which was equivalent to a quarter of the company's R&D budget (Economist, 2005).

2.2.4 Strategies of Pharmaceutical MNCs in the Indian Market

Has the implementation of product patent rules led to increased presence of pharmaceutical MNCs in drug manufacturing in India? India has a large middle class population with a high prevalence of global diseases such as cancer and cardiovascular diseases, and this is an attractive market for pharmaceutical MNCs. According to the Indian Pharmaceutical and

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

31 Mahapatra (2006).

32 Downloaded from <www.ranbaxy.com> on 14-12-05

Healthcare Market Annual Review 2005, India's pharmaceutical market is growing at the rate of 9 per cent per year.[33] Many multinational pharmaceutical companies are moving into India (and China) to take advantage of this market opportunity.

However, trends indicate that pharmaceutical MNCs are not interested in investing in India in the manufacture of bulk drugs; nor are they allocating funds for 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). However, the share of drugs and pharmaceuticals in total FDI inflows into India increased to 3.57 per cent during the period 2000-04. The share had jumped to as high as 9.1 per cent in 2004 but fell to 2.64 per cent in 2005 (Chadha, 2006).[34]

There has been an increase in the outsourcing of clinical research to India. Expenditures on clinical trials account for 40 per cent of the total cost of drug development. After the introduction of product patent legislations, multinational companies are keen to outsource clinical trials to India to take advantage of the cost reduction involved. India's large, ethnically diverse population, majority of them having never been exposed to much medications before, is its other advantage. While outsourcing of clinical trials promises some business opportunities to Indian companies, 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 clinical trials conducted without the informed consent of patients, either through financial inducements or simply by enrolling 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).

---

33 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.

34 Data from Government of India, Department of Industrial Policy and Promotion, Ministry of Commerce and Industry, Secretariat for Industrial Assistance, *SIA Newsletter*, various issues, cited in Chadha (2006).

2.3. PHARMACEUTICAL INDUSTRY IN CHINA

Pharmaceutical industry is expanding fast in China. 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 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).

2.3.1. 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. [35] 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. Only those foreign inventors with whose countries China enjoyed

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

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 the building of domestic invention capability in China (Kong, 2005).

China introduced a stricter patent regime in 1992. This was a period when 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 evolved largely under pressure from the United States, with which it was holding bilateral negotiations. 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 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. China was not given the transition period that was granted to other developing countries (Grace, 2005, pp. 21-25; Kong, 2005). Chinese laws extend patent protection for twenty years and data exclusivity for six years (Grace, 2004).

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.[36] In December 2006, on the occasion of the fifth anniversary of China's entry into the WTO, the U.S. Trade Representative, Susan C. Schwab, slammed China's record in implementation of IPR rules. In a 100-page report submitted to the U.S. Congress, the U.S. Trade Representative accused that piracy of software, videos, pharmaceuticals and other goods was rampant in China, and that the government did very little to curb this (Weisman, 2006). In any case, 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).

[36] 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).

2.3.2 Recent Trends in China's Pharmaceutical Industry

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. One of the means through which China achieves this is by manufacturing intermediates only till the pre-API (active pharmaceutical ingredients) 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, 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 bypass patent restrictions and produce essential medicines (Grace, 2005, pp.23-5). In any case, China has today emerged ass the largest source for India's imports of medicinal and pharmaceutical products. China supplied 34.6 per cent of India's imports of medicinal and pharmaceutical products in 2004-05, up from 18.6 per cent in 1998-99 and 0.2 per cent only in 1991-92 (CMIE, 2006, p. 217; CMIE, 2005, p.217; CMIE, 1997, p.247). [37]

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. Treatment using second-line ARVs 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.[38]

Western multinational companies are eying the market for pharmaceutical products originating from the large middle class population in China as well as India. China's pharmaceutical market is worth US$20 billion and it is expected to grow at double digit rates until 2010. With the introduction of product patent legislations, many multinational

---

[37] 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).

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

pharmaceutical companies are moving into China and India to take advantage of the market opportunity in these countries. In China, pharmaceutical companies are keen on China's eastern region, in particular the Yangtze river area with its increasing purchasing power.[39] In November 2006, Novartis announced plans to set up a research facility in Shanghai, which is expected to become one of three largest research hubs of the company. Novartis expects that with the setting up of the research facility, it can make inroads into the Chinese market for pharmaceuticals.[40]

---

39 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.

40 See the report 'A Novel Prescription' in the *Economist*, November 11, 2006.

Chapter 3
BIOTECHNOLOGY IN INDIA, CHINA AND SINGAPORE

Biotechnology is bringing in revolutionary changes in health and agriculture. It has applications in human and animal health, in agriculture, food processing and fishing, as well as in the fields of industry and environment. Bioinformatics and nanotechnology are two of the newest applications of biotechnology. United States and United Kingdom have been at the forefront of the biotechnology industry from the 1980s. Today, however, Asian countries particularly Singapore, South Korea as well as China and India are making rapid advances in biotechnology and biomedical sciences.

3.1 THE EMERGENCE OF BIOSCIENCES INDUSTRY

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). There are changes in the way pharmaceutical research is conducted. In order to reduce the costs of and time spent in innovation, large pharmaceutical companies are outsourcing research and development (R&D) work to dedicated biotech firms. For instance, Pfizer, the largest pharmaceutical firm in the world, has entered into more than one thousand research agreements with biotechnology firms and research organizations. It appears that the pharmaceutical industry no longer waits for "chance discoveries" of new drugs. On the other hand, "rational drug design" is on the rise in pharmaceutical innovation. That is, supercomputers conduct high throughput screening in search of specific chemical compounds that can act at the molecular level as inhibitors of diseases. Dedicated biotech firms carry out the search for large molecular structures. The therapeutic products they develop are licensed out to pharmaceutical companies (Cooke, 2005).

Biotech firms are located in clusters – no longer near centres of business or banking but close to universities and public research laboratories. Old centres of pharmaceutical industry such as New York and London are giving way to "science driven megacentres" like Cambridge (UK), Cambridge (MA), San Diego (CA) and San Francisco (CA). Montreal,

Toronto, Munich, south Paris, and Stockholm-Uppsala are the upcoming 'megacentres' in biotechnology (Cooke, 2005) (see Table 3.1).

Clustering in the biomedical sciences industry is taking on important dimensions. One of the recent developments is the emergence of meta-clusters. These are networks of biomedical clusters in geographically connected countries. A good example is EuroBioCluster South, a project initiated in 2005 to combine bioclusters situated over the geographical area from Heidelberg, Germany to Barcelona, Spain. Another example of a meta-cluster is ScanBalt, which connects biotech and life sciences clusters located over 11 countries in Northern Europe; this meta-cluster encompasses 60 universities and 870 biotech-related companies (Rinaldi, 2006).

Singapore is trying to develop its 'Biopolis' as a major biosciences cluster. There are certain activities such as biomanufacturing and clinical research that do not have to be located near biosciences clusters. China and India are increasingly emerging as destinations for biomanufacturing (Cooke, 2005).

Table 3.1: *Important Biomedical Sciences Clusters in the World*

North America	**Central/South America**	**Continental Europe**	**Asia**
United States	West Havana, Cuba	Brussels, Belgium	*China*
Seattle	*Brazil*	Medicon Valley, Denmark/Sweden	Beijing
San Francisco	Belo Horizonte/Rio de Janeiro	Brussels	Shanghai
Los Angeles	Sao Paulo	Stockholm/Uppsala, Sweden	Shenzhen
San Diego	**United Kingdom/Ireland**	Helsinki, Finland	Hong Kong
Minneapolis/St. Paul/Rochester	Glasgow-Edinburgh	Paris, France	*Japan*
Austin	Manchester-Liverpool	Biovalley, France/ Germany/Switzerland	Tokyo-Kanto
Boston	London	BioAlps, France/Switzerland	Kansai
New York/New Jersey	Cambridge-SE	Sophia-Antipolis, France	Hokkaido
Philadelphia	Dublin	BioRhine, Germany	*Taiwan*
Baltimore/Washington DC	**Oceania**	BioTech Munich, Germany	Taipei
Research Triangle NC	*Australia*	BioCon Valley, Germany	Hsinchu
Canada	Brisbane	Middle East	*Singapore*
Saskatoon	Sydney	Israel	Biopolis
Toronto	Melbourne	Africa	*Malaysia*
Montreal	*New Zealand*	Capetown, South Africa	Dengkil
	Dunedin		*India*
			New Delhi
			Hyderabad
			Bangalore

Source: The Global Biotechnology Clusters Map built by William Hoffman, University of Minnesota, available at the website of MBBNet, University of Minnesota, Minneapolis, MN, USA, downloaded from <http://mbbnet.umn.edu/scmap/biotechmap.html> on 17 October 2006

3.2. NATIONAL PROGRAMMES IN BIOTECHNOLOGY IN INDIA AND CHINA

3.2.1 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).[41] The DBT has recently unveiled plans to expand the country's biotech industry to $5 billion in revenues per year by 2010.[42]

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.

DBT has a programme called the National Jai Vigyan Science and Technology Mission. Its major objective is the development of new generation vaccines for cholera, rabies, Japanese encephalitis, tuberculosis, malaria and HIV infections. The Indian Council of Medical Research (ICMR) promotes research to meet national health requirements. ICMR has a network of 22 permanent research institutes or centres in different Indian cities. They

---

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

42 See Jayaraman (2005).

include Tuberculosis Research Centre in Chennai, National Institute of Malaria Research in New Delhi, National Institute of Cholera and Enteric Diseases in Kolkata, Genetic Research Centre in Mumbai and National AIDS Research Institute in Pune. ICMR also has six regional medical research centres in Bhubaneswar, Dibrugarh, Port Blair, Jabalpur, Jodhpur and Belgaum.[43] CSIR too carries out projects in health biotechnology. Many Indian universities conduct research in biotechnology. The Department of Biochemistry of the Indian Institute of Science (coming under the division of biological sciences at the Institute) carries out work on immunology, reproductive biology, plant development, as well as on diseases such as malaria, rabies and tuberculosis (Kumar *et al*, 2004).

India is today giving great emphasis on the development of bioinformatics. A network of 57 research centres linked by a high speed computer network called the Biotechnology Information System Network (BTISnet) has been set up in India (Chaturvedi, 2005).

3.2.2 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 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 established 17 national biotechnology laboratories that were open to both domestic and foreign scientists. In 1995, there were approximately

[43] <www.icmr.nic.in/institute.htm>

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 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 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).

Some of China's earliest biotechnology firms began operations in the special economic zone of Shenzhen. Today, the major centres of China's biotechnology industry are Shenzhen, Shanghai and Beijing. Growth of biotech companies received a boost in the 1990s. Between 1997 and 2002, the number of biotech companies shot up in China. 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). China's participation in the Human Genome Project, China's sequencing of the rice genome, influx of Chinese scientists working abroad, and greater availability of capital have all been factors that aided the growth the of the biotech sector in China (Chervenak, 2005).

The government encouraged Chinese firms to establish links with western biotechnology companies. Chinese firms were allowed to enter into licensing agreements with foreign firms since the early 1970s. The Patent Act enacted in 1985 covered aspects of biotechnology and offered some form of intellectual property protection to foreign companies investing in China. China granted product patents for medicines in 1993 (Gross, 1995). In addition, the reorganization of science and technology ministries and a movement toward peer-review system in research have contributed to the growth of China's biotechnology industry with greater foreign participation (Chervenak, 2005).

However, China's biotechnology industry suffers from the problem of environmental pollution, especially pollution due to coal combustion. Biotechnology

research and biomanufacturing demands a highly sterile environment, which is not easily available in China (Gross, 1995).

3.3. SIZE AND STRUCTURE OF BIOTECHNOLOGY INDUSTRY

3.3.1 The Size of Biotechnology Industry in India and China: A Comparative View

Indian biotech industry generated revenues worth US $0.7 billion (Rupees 32.65 billion) in 2003-04. Indian biotechnology industry had a share of 1.5 per cent of the US $46 billion global biotechnology industry in 2003-04[44]. According to an Ernst & Young (E&Y) report on biotechnology, the Indian biotechnology industry could earn as much as $5 billion in revenues over the next five years (Raja, 2004).[45] The cumulative investment in India's biotechnology sector till the year 2002 was US $10.6 billion (purchasing power parity adjusted). Of the total investment, 47 per cent was directed to health biotechnology and 32 per cent was directed to agriculture biotechnology (Chaturvedi, 2005, pp.21).

In China, the government enhanced allocation of funds for the biotechnology sector after 2000. According to estimates made in 2005, the Chinese government spends more than $600 million per year on biotech research and development (R&D) through its various funding programmes (Chervenak, 2005). This, however, is small compared to the investment in biotechnology industry in the United States. It is reported that the United States spent US$15.7 billion in 2001 for research and development in biotechnology (Economist, 2002).

According to Biotech Consortium India Limited (BCIL), jointly promoted by Government of India's Department of Biotechnology and Industrial Development Bank of India, there were 176 biotech firms in India in 2001. The number of biotech firms in the country increased to 401 by 2003 (Chaturvedi, 2005). In China, in 2002, there were 300 publicly funded biotech laboratories and around 50 start-up biotech companies, mainly in Beijing, Shanghai and Shenzhen (Economist, 2002).

---

44 Data from *Cygnus Research* cited in *Biotech India 2005*, Background Paper for 2nd International Conference on Biotechnology, Organised by Confederation of Indian industry and supported by Department of Biotechnology, Government of India, New Delhi, 9-10 February 2005.

45 See the Ernst &Young report titled 'On The Threshold: The Asia-Pacific Perspective' (Raja, 2004).

United States and European Union have built very large research capabilities in the field of biotechnology. Organisation for Economic Cooperation and Development (OECD) has published statistics on various aspects of the biotechnology industry in 26 countries including 23 OECD countries, 2 OECD observer countries and Shanghai in China. These statistics refer to the years 2003 or 2004. As per the OECD database, there were 2196 biotechnology firms the United States in 2003. In the 15 countries of the European Union for which data were collected, there operated 3154 biotech firms in total. There were 804 biotech firms in Japan and 755 biotech firms in France in 2003; and 640 biotech firms in South Korea and 607 biotech firms in Germany in 2004. According to the same database, there were 158 biotechnology firms in Shanghai in 2003 (Table 3.2; see also OECD, 2006, pp.14-5).

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 (Economist, 2002). Wang Hongguang, Director of China's National Centre for Biotechnology Development, points out that approximately 20,000 Chinese biotechnology researchers are working abroad, and their return to the country will give a further boost to biotechnology industry in China (Economist, 2002).

Table 3.2: Biotechnology Industry in Selected OECD Countries and Shanghai (China), 2003

Country	Number of firms	R&D Employment	R&D expenditure in million US dollars
European Union	3154		--
United States	2196	73520	14232
United Kingdom	455	9644	--
Japan	804		--
South Korea	640	6554	699
Shanghai (China)	158	1447	205

Notes: Data for South Korea relate to 2004.
Data for number of firms in United Kingdom refer to core biotechnology firms only, not all biotechnology active firms.
Employment data for United States and United Kingdom refer to all R&D employees in biotechnology firms, and for others biotechnology R&D employees only.
Source: van Beuzekon and Arundel (2006).

3.3.2 The Structure of Biotechnology Industry

Globally, the largest chunk of investments in biotechnology R&D is directed towards health. The OECD database on biotechnology relating to 26 countries gives statistics on distribution of biotechnology R&D expenditures by sectors. As per the OECD database, 87 per cent of all biotechnology R&D expenditures in the 12 countries (for which data was available) was spent on health, 4 per cent on agriculture and food, and the remaining 9 per cent on applications in industry and environment as well as in the field of bioinformatics (OECD, 2006, p.30). United States spends 89 per cent of its biotech R&D expenditure on health applications and 4 per cent on agriculture and food. In China (Shanghai), the corresponding proportions spent on health and on agriculture and food were, respectively, 72 per cent and 13 per cent (figures for 2003; OECD, 2006, pp.31-2).

The Structure of Biotechnology Industry in India

In India, the number of biotech firms in the health sector increased from 43 only in 2001 to 142 in 2003 (see Table 3.3). Much of this increase was in the segment of small firms employing less than 50 employees (see Table 3.4). Between 2001 and 2003, the number of small firms in the health biotechnology sector increased from 10 to 74. Chaturvedi (2005, pp.18-20) writes that the small firms that emerged in India after 2001 are largely contract research organizations. The number of large firms employing more than 150 employees in the health biotechnology sector increased from 25 to 47 between 2001 and 2003 (see Table 3.4). According to Chaturvedi (2005), this is an indication of the growing presence of multinational companies in this sector in India. Indian biotech firms in the health sector that have alliances with foreign biotech firms increased from 17 in 2001 to 70 in 2003 (Chaturvedi, 2005, pp.21).

There are five major segments in Indian biotechnology industry. They are biopharmaceuticals, bioagriculture, bioinformatics, bioservices and bioindustry. Biopharmaceutical companies in India manufacture vaccines, recombinant therapeutic products and diagnostic products. Indian companies such as Shantha Biotechnics, Bharat Biotech and Wockhardt are involved in the production of Hepatitis B vaccine. Indian companies also focus on diagnostic products, reproductive health, and contraceptives. India manufactures industrial biotechnology products such as enzymes, which have applications in

starch processing, breweries and distilleries, industrial alcohol, detergent and cleaning aids. Indian firms are engaged in the production of biofertilizers, biopesticides, and in tissue culture. With the growth of genomics research and expansion of life sciences data, there is potential for the growth of bioinformatics industry in India. India has opportunities in data mining, data handling, finger printing and DNA sequencing. Institute of Bioinformatics located in Bangalore is carrying out research in genomics and proteomics.

In India, bioservices and bioinformatics derive more than 80 per cent of their revenues through exports. Given the less-developed state of India's biotechnology industry, domestic demand for bioservices and bioinformatics is relatively low. More than 70 per cent of India's exports of bioservices and bioinformatics are targeted to the United States. Within India's biotechnology sector, the major source of export revenues is biopharmaceuticals. In 2003-04, of India's total biotechnology exports worth Rs.18.7 billion, biopharmaceutical exports accounted for 76 per cent (or Rs.13.9 billion).[46] Fears have been expressed that as Indian biotech firms increasingly engage in contract research, clinical trials and validation studies for MNCs, they are not giving adequate emphasis on the development of innovation skills (see Jayaraman, 2005).

Table 3.3: Biotechnology Firms in India by Sector, Number and Shares in Total, 2001 and 2003

	2001		2003	
	Number	Share in total (%)	Number	Share in total (%)
Agriculture	85	48.3	132	32.9
Health	43	24.4	142	35.4
Environment	4	2.3	16	4.0
Industrial biotechnology	--	--	42	10.5
Others	44	25.0	69	17.2
Total	176	100	401	100

Source: Chaturvedi (2005), p.19 based on BCIL (2001, 2003).

[46] Data from *Cygnus Research* cited in *Biotech India 2005*, Background Paper for 2nd International Conference on Biotechnology, Organised by Confederation of Indian industry and supported by Department of Biotechnology, Government of India, New Delhi, 9-10 February 2005.

Table 3.4: Number of Biotechnology Firms in India, by Size and Sector, 2001 and 2003

	Total		Agriculture		Health		Others	
	2001	2003	2001	2003	2001	2003	2001	2003
Small firms (<51 employees)	107	243	63	87	10	74	34	87
Medium firms (51-150 employees)	24	78	10	26	8	21	6	31
Large firms (>150 employees)	45	102	12	19	25	47	8	36
Total firms	176	401	85	132	43	142	48	127

Source: Chaturvedi (2005), p.20 based on BCIL (2001, 2003).

BIOCON'S BUSINESS STRATEGIES

Biocon, the leading Indian biotech firm in the private sector, began as an enzyme manufacturer. Today it manufactures generic drugs, importantly statins (which are cholesterol-lowering drugs), mainly for the U.S. and European markets. Biocon sells two statins -- Simvastatin and Pravastatin -- in Europe. The company is trying to enter the U.S. generics market for these two drugs; the U.S. patents on these two drugs are due to expire soon. In export markets, Biocon is facing tough competition from Chinese companies. Chinese statin makers, who use synthetic molecules, is a big threat to Biocon's plans to enter the US market. Iin certain statin categories, Biocon was forced to cut down its prices by as much as 50 per cent. Biocon is actively engaged in contract and clinical research. Syngene, Biocon's contract research arm, and Clinigene, the company's clinical research business, are making large profits. According to the company's Chairperson, Kiran Mazumdar-Shaw, Biocon will make use of the profits generated in its contract and clinical research for innovation of new drugs based on monoclonal antibodies and oral insulin

Source: Sachitanand (2006).

3.4. AGRICULTURAL BIOTECHNOLOGY

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).[47] Research in biotechnology offers the hope for dramatic increases in agricultural productivity.

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).

[47] Cited in Bernauer (2003), Table 2.1.

3.4.1 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 3.5).[48] Globally, area under cultivation of GM crops increased from 2.8 million hectares in 1995 to 90 million hectares in 2005 (see Table 3.5). So far, GM techniques have been employed only in the case 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.[49] 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 U.S. 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

---

48 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).

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

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 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.[50]

3.4.2 Agricultural Biotechnology in India

The early proposals for cultivation of genetically modified (GM) crops were met with considerable resistance in India. The U.S. 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

[50] See McFadden (2005).

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).[51] GEAC held a 'public dialogue' in 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 Nuzhiveedu 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 3.5).

Debates on Biotechnology in India

The use of genetically modified crops has been the subject of much debate in India. Critics such as Vandana Shiva argued that GM crop cultivation would lead to MNC dominance in Indian agriculture. They also expressed concerns about the problems of biopiracy and bioethics associated with the introduction of GM crops. At the same time, an alternate view emerged that highlighted the benefits that biotechnology could bring to Indian farmers. Some of the scientists who took this position including Suman Sahai were of the opinion that Europe's opposition to biotechnology should not be a reason for India to turn its back to the new technology. Europe is surplus in food. It produces agricultural products far in excess of demand, and even incurs large expenditures on disposal of its surplus food

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

production. Europe's opposition to and ethical concerns on biotechnology should be seen in the above context. On the other hand, India has to ensure food security for its large population. It is important therefore that India takes the lead in developing biotechnology (Visvanathan and Parmar, 2002).

Monsanto made an early attempt to enter the Indian market with its GM cotton technology in 1990. However, this turned out unsuccessful as Indian government denied permission to Monsanto and its GM technology. Ramanna (2006) writes that changes in India's policy stance towards biotechnology and Monsanto in the years after 1990 were precipitated by several factors. First, Monsanto built alliances with Indian firms and organizations such as Mahyco and Tata Energy Research Institute (the latter for development of 'golden mustard'). Monsanto also established links with industry associations such as Federation of Indian Chambers of Commerce and Industry (FICCI) and Confederation of Indian Industry (CII) (Ramanna, 2006). Secondly, many respected scientists including M.S. Swaminathan and C.S. Prakash expressed the view that biotechnology will contribute to national development. This helped to enhance the acceptance of biotechnology in India. According to M.S. Swaminathan, biotechnology will promote sustainable agriculture and sustainable livelihoods, and enhance agricultural productivity without adverse ecological or social consequences.[52] Thirdly, in October 2001, it was reported that *Bt* cotton hybrid Navabharat 151 (NB 151) sold by Navabharat Seeds Company Limited was illegally grown in 10,000 acres in Gujarat. This incident led to a change in the way GM crops was portrayed in the public discourse. Farmers were seen to be adopting the GM technology voluntarily, and this motivated government's decision to approve commercial cultivation (Ramanna, 2006).

The area under cotton cultivation in India – 9 million hectares -- is the largest in the world. However, productivity of cotton cultivation in India is very low, much lower than in China and the United States. It is reported that Indian farmers spend Rupees 12 billion (or

[52] See the report on 'Inter-disciplinary Dialogue on Biotechnology and Organic Farming', M.S. Swaminathan Research Foundation, Chennai, 7-10 March 2005. (<http://mssrf.org/events_conferences/content_events/organic_farming/of.htm>)

US$250 million) annually on control of bull worms.[53] With the use of GM crops, it is argued, India can enhance productivity in GM crop cultivation.

At the same time, there are strong arguments against the use of GM crops. First, GM cotton varieties are four to five times more expensive than the usual cotton seeds available. It is questionable whether the use of costlier GM seeds will lead to proportionately large benefits in yield. Secondly, in cultivation using *Bt* crops, farmers have to leave 20 percent of cultivated land area for insect refuge in order to prevent or delay pests developing resistance against *Bt* toxin. Given that 65-70 per cent of India's farmers cultivate cotton in small plots of 1 to 1.5 hectares, leaving 20 per cent of land for insect refuge is not a desirable strategy.[54] Thirdly, concerns have been expressed that *Bt* cotton seeds are less likely to produce good results in the hot, tropical climatic conditions of India. Suman Sahai, a leading Indian academic on agricultural biotechnology, points out that *Bt* cotton is developed for cold countries where bollworm is the predominant pest. In India's tropical weather conditions, pests will quickly develop resistance to *Bt* toxin, leading to crop failure, according to Suman Sahai (Jayaraman, 2002).[55]

Fourthly, there are problems associated with the excessive use of the same gene. According to Suman Sahai, more than 40 per cent of the research on GM crops carried out in India in the public and private sectors uses the same gene, *cry 1 Ac,* developed by Monsanto.[56] 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.[57] It could also lead to monoculture with alarming consequences on biodiversity.

It may be noted that the two leading government agencies on biotechnology in India -- GEAC and the Department of Biotechnology (DBT) -- have taken considerably different

---

53 According to T.M. Manjunath, Director of the Monsanto Research Centre in Bangalore, cited in Jayaraman (2002).

54 According to Devinder Sharma, President of the Forum for Biotechnology and Food Security, New Delhi. See Jayaraman (2002).

55 Suman Sahai also pointed to the experience of South Sulawesi, Indonesia where pests developed resistance against Bt toxin. See Jayaraman (2002).

56 See Krishnakumar (2002).

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

positions on GM crop cultivation. While the DBT has been upbeat about the prospects of using biotechnology for agricultural growth in India, GEAC has adopted a more cautious approach (Jayaraman, 2003).[58]

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.[59] 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

---

[58] According to Devinder Sharma, President of the New Delhi-based Forum for Biotechnology and Food Security, National Centre for Integrated Pest Management (NCIPM), New Delhi had developed and field tested technologies that would enhance cotton crop yields without the use of pesticides or GM crops. However, the Indian government did not promote the use of this technology; instead, it opted for the technology from Monsanto. See Jayaraman (2002).

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

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. [60]

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.[61] It may be noted here that almost 70 per cent of royalties from seeds sales of Indian subsidiaries of Monsanto are ploughed back into the parent U.S. 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.[62] 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.

---

60 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.

61 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).

62 See Shiva (2001).

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 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.[63]

3.4.3 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 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

[63] See Subramaniam (2005).

China.[64] In fact, in the late 1990s, Chinese firms were competing with U.S. multinationals such as Monsanto to be the leading supplier of transgenic crops in the various Chinese provinces (Chen, 1999).[65] 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 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*

---

64 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.

65 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).

cotton cultivation in China increased from 1.5 million hectares in 2001 to 3.3 million hectares in 2005 (see Table 3.5). 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 3.5: *Area under Cultivation of Genetically Modified (GM) Crops, 1996 to 2005, in million hectares*

	1996	1997	1998	1999	2000	2001	2002	2003	2004	2005
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.

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.[66]

3.5 BIOTECHNOLOGY IN SINGAPORE

3.5.1 Government Initiatives in Biotechnology in Singapore

The government leads the biotechnology sector in Singapore. In 2000, Singapore launched plans to build a biomedical hub. The government spent nearly US$4 billion on biomedical sciences between 2000 and 2005, and has announced a further investment of US$7.5 billion for the years between 2005 and 2010 (or an investment of US$1.5 billion per year). On a per capita basis, government spending on biomedical sciences in Singapore is three and a half times the amount the government in the United States spends on the National Institutes of Health and the Food and Drug Administration combined.[67] 'Biopolis', a science city designed for biotech firms, was inaugurated in Singapore in 2003. In the 'Biopolis', the government has invested US$300 million; and this has triggered investments worth US$400 million by biotech firms that have started operations there.[68] In August 2006, Singapore's Prime Minister Lee Hsien Loong identified biomedical sciences, water technology and interactive and digital media as the three priority areas for research and development (R&D) spending by Singapore in the coming years.[69]

With wage costs rising, Singapore has been losing its competitive edge in low value adding, labour-intensive industries to its neighbouring Southeast Asian countries and now to China and India. In response to this, Singapore's strategy has been to move up the value chain and to focus on high value adding, knowledge-intensive industries. In the hard disc drive industry, for example, Singapore upgraded itself from assembly of low-end drives to

---

66 See the report 'India, China Sign Agriculture Cooperation Pact', *Financial Times*, March 30, 2006.
67 See Benesh (2006).
68 See Elias (2006).
69 See Prime Minister Lee Hsien Loong's National Day Rally Speech on 20 August, 2006. See <www.gov.sg/NDR06Engspeechtranscript.pdf >

assembly of high-end drives and fabrication of media and semiconductor wafer (Gourevitch *et al*, 2000). The drive to a knowledge-based economy in Singapore received a major push in the wake of the East Asian financial crisis of 1997.[70]The government's Economic Review Committee (ERC) recommended in its report submitted in February 2003 that Singapore should strive to become an "entrepreneurial and creative nation."[71]

In the biotechnology industry, Singapore enjoys certain advantages of being a relatively low cost location. According to a report by the consultancy firm KPMG, research and development (R&D) costs in Singapore are 31 per cent lower than in the United States. Opportunities for clinical trials are also considerable given the racial diversity of the country's population (Benesh, 2006). For all these, however, Singapore can not establish lasting advantages in the biotechnology industry unless it emerges as a centre for innovation. Parayil (2005) explains that in Singapore's attempt to emerge as an innovation leader in the biomedical sciences, it is helped by a close knit relation between the state, industry and universities. National Science and Technology Board that has been renamed in 2002 as Agency for Science, Technology and Research (A*STAR) has been highly instrumental in building links between the government, universities and industry. National University of Singapore (NUS) has been establishing linkages with foreign universities to a give a boost to its programme in biosciences. Singapore's Economic Development Board (EDB) has identified biotechnology, medical devises, health care services, pharmaceuticals and bioinformatics as areas for potentially fast growth (Parayil, 2005).

3.5.2 Biopolis and Stem Cell Research in Singapore

There have been many ambiguities in United States' policy stance towards stem cell research, and this has given a fillip to biotechnology research in Singapore as well as South Korea and China. A section of the public opinion in the United States – that originating particularly from Christian fundamentalists -- is opposed to embryonic stem cell research on the ground that it involves destruction of human embryos (Armstrong, 2006). In 2001, the U.S.

[70] In the words of Beh Swan Gin, Director of Biomedical Sciences, Economic Development Board, Singapore, reported in Simons (2006).

[71] See Economic Review Committee (2003) cited in Parayil (2005).

President George Bush announced restrictions on federal finances allocated to stem cell research. The governments of Kentucky, Mississippi, Florida, Missouri, Michigan and Nebraska have either banned or imposed some or other forms of restriction on stem cell research in their States. At the same time, some other States such as California, Connecticut, New Jersey, Pennsylvania and Delaware continue to support stem cell research (Herrera, 2005). Restrictions on stem cell research have come on top of major cuts in scientific research and education announced by the U.S. government in recent years (Simons, 2006). In July 2006, President George Bush vetoed a bill passed by the U.S. Senate to remove restrictions on federal funding for stem cell research.[72] This is a major setback to stem cell research in the United States.

ABOUT STEM CELLS

Stem cells are cells that possess the ability to divide and renew themselves for long periods. They are unspecialized cells. That is, stem cells can not perform specialized functions such as pumping blood through the body (a function performed by red blood cells). But stem cells can give rise to specialized cell types, red blood cells, for example. This process in which unspecialised cells give rise to specialized cells is called differentiation. By controlling stem cell differentiation in the laboratory, scientists can grow cells or tissues for specific purposes including cell-based therapies. These therapies can be used in the treatment of diseases such as diabetes, Parkinson's disease, and Alzheimer's.

There are two varieties of stem cells: embryonic stem cells and adult stem cells. Embryonic stem cells are derived from discarded human embryos; and adult stem cells from blood, bone marrow, fat and other tissues. Embryonic stem cells are capable of generating any cell in the body. Adult stem cells are less potent and they typically generate cell types of the tissues in which they reside. For example, a blood-forming cell in the bone marrow can give rise to many new types of blood cells but not nerve cell. However, recent research has raised the possibility that adult stem cells of one tissue may be able to generate cell types of a different tissue.

Source: Stem Cell Information, National Institutes of Health Resource for Stem Cell Research. See <http://stemcells.nih.gov/info/basics/basics5.asp>

[72] See the report 'Bush Vetoes Embryonic Stem Cell Bill', *Cable News Network*, July 20 2006, <http://www.cnn.com/2006/POLITICS/07/19/stemcells.veto/index.html>

To take advantage of United States' ambiguous policy stance towards stem cell research, countries such as United Kingdom, Sweden, Singapore, South Korea, Japan and Australia have created legal, regulatory and funding mechanisms that are conducive for biomedical research (Herrera, 2005). Many top researchers in the field of biomedical sciences have been migrating out of the United States, partly because of the difficulties of doing stem cell research there. South Korea, China and Singapore have greatly benefited from this talent flow.

Singapore has already roped in 50 senior scientists in the field of biomedical sciences drawn from different parts of the world. Another 1800 young scientists recruited internationally work at Biopolis. Researchers working at Biopolis point out that research facilities available to them are better than facilities in places such as the Massachusetts Institute of Technology (MIT) in the U.S. (Simons, 2006).[73] Researchers who have recently moved to Singapore include Dr. Judith Swain, previously a molecular cardiologist with the University of California, San Diego, who joined the Singapore Institute for Clinical Sciences; Dr. Philippe Kourilsky, an expert in molecular immunology and tumour immunity who left a senior position in France to become the Chairman of the Singapore Immunology Network (SIgN); and Dr. Edward Holmes, previously with University of California, San Diego, who took up the job of Executive Deputy Chairman of Clinical Translational Sciences at A*STAR's Biomedical Research Council.[74] Neal G. Copeland and Nancy A. Jenkins, researchers at the National Cancer Institute in Maryland for 20 years, have accepted positions at Singapore's Institute of Molecular and Cell Biology.[75]

Singapore's Biopolis -- along with Wisconsin, California, Maryland's I-270 Tech Corridor and New Jersey -- has been identified as a centre with very high potential for biotech growth, according to a study conducted by FierceBiotech, a biotechnology industry

---

[73] For example, Taiwan-born researcher, Jackie Ying, says that facilities for research available at the Biopolis are better than those available at Massachusetts Institute of Technology (MIT). She was a full Professor at MIT before becoming the first executive director of the Institute of Bioengineering and Nanotechnology, Singapore in 2003. See Simons (2006).

[74] See 'Singapore Continues to Attract Scientific Luminaries', *PR Newswire Association LLC*, 11 April 2006.

[75] According to the husband-and-wife team, research financing is a major problem in the United States. See Arnold (2006).

email publication.[76] The Institute of Bioengineering and Nanotechnology in Singapore is using stem cells in its research to produce artificial kidneys that would help to avoid frequent kidney dialysis sessions (Simons, 2006). A Singapore company ES Cell International is claimed to be the first to start commercial production of human embryonic stem cell lines for use in clinical trials (Arnold, 2006). CyGenics, a Singapore-based biotech start-up, is focusing research on adult stem cell therapy. [77]

3.5.3 Prospects for Biomedical Sciences Industry in Singapore

Singapore faces several challenges in the biotechnology industry. A steady supply of highly talented researchers is required to sustain the current momentum. Secondly, small and medium enterprises (SMEs) in Singapore will face stiff hurdles from drug regulatory regimes in the U.S. and Europe as they try to enter these markets. The intellectual property rights regime too will erect challenges. Lastly, civil society movements against biotechnology at the international level will have implications for the future of biomedical industry in Singapore, as the small city state depends on the world market for its products (Parayil, 2005). Given the many risks involved in biotechnology investments, Parayil (2005) argues that as a strategy, Singapore should first focus on development of biomaterials, where problems imposed by regulatory regimes will be the least.

Should Singapore be concerned about the growing presence of India and China in biomedical sciences? Industry analysts observe that biomedical sciences industry in Singapore, India and China need not be engaged in a zero sum game. India, China and Southeast Asia can have many centres of biotech industry -- just as there are several centres of biomedical sciences in the United States and Europe. In fact, biomedical centres in Singapore, China and India can be networked with each other to form metaclusters. Singapore's proximity to China and India can be turned into its advantage: the two emerging giants will be sources of highly skilled labour and raw material to Singapore's biomedical

[76] These are findings from a study conducted by FierceBiotech, a biotechnology industry email publication. See Gallagher and Rust (2006).

[77] See Chen (2006).

industry.[78] Singapore can take the lead in biomedical innovations directed at the huge markets in Southeast Asia, South Asia and China.

[78] Interview with Marc Kozin, President of international consulting firm LEK consulting. See Huifen (2006).

Chapter 4

SUMMARY AND CONCLUSIONS

Some Asian countries, particularly China and India, are emerging as major centres for research and development (R&D). 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 and India were identified by the respondents as, respectively, the first and the third most attractive locations for future investments in R&D (United States being the second most attractive location). Foreign direct investment (FDI), especially in technology-intensive industries, used to be largely circulated within the developed countries. Therefore, this new wave of MNC investments in R&D in China, India, and other developing countries is a significant development.

There are several reasons behind Asia's growing prominence as an R&D location. First, the large supply of highly skilled professionals at relatively low costs in Asian countries, particularly in India and China, is a major attraction. Both China and India are today ahead of the United States with respect to tertiary technical enrolment. Secondly, public investments in science and technology over the past decades have built 'national innovation systems' in these countries. In turn, this has created a favourable environment for new investments in R&D. Lastly, India and China have, in recent years, introduced product patent laws, in compliance with the provisions of the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS). This has further encouraged MNCs to invest in R&D in India and China.

There are, however, very many important concerns. As a consequence of the above-mentioned trends, there is the possibility of a shift in the nature of innovation originating from India and China. That is, domestic firms in these countries may reorient themselves to become contract research organizations for big MNCs. More over, R&D firms in India and China may compete with one another on costs to corner a larger slice of the market for outsourcing of R&D. This will have undesirable consequences. A vast market for innovative products – including affordable medicines, high yielding crops and cheap telecommunication – exist in developing countries. China and India possess the capabilities to produce innovations targeted at the poor in the third world. However, as firms in India and China partner with MNCs and target their innovations at the market of rich consumers in

developed and developing countries, their capabilities to innovate for the poor in the third world will be diminished.

Recent trends in India's pharmaceutical industry appear to confirm the concerns discussed above. India's pharmaceutical industry has had an excellent record as suppliers of generic drugs at affordable prices within the country and outside. Strong state intervention has been a crucial feature of the development and growth of India's pharmaceutical industry. The most vital component of state intervention was in the implementation of the Indian Patent Act of 1970. The Act of 1970 disallowed product patenting for pharmaceuticals and food products, and thereby aided the learning of process technologies by Indian pharmaceutical firms. However, with India joining the World Trade Organization (WTO) in 1995, the intellectual property rights (IPR) regime in the country underwent changes. Between 1999 and 2005, India brought in a series of legislations that eventually introduced TRIPS-compliant product patenting in India.

The gradual shift to a product patenting regime has brought forth important changes in the nature of innovation in India's pharmaceutical industry. Leading Indian pharmaceutical companies such as Ranbaxy and Dr. Reddy's have increased their allocation for research and development (R&D) expenditures; at the same time, they are orienting their sales increasingly to the regulated markets of North America and Europe. Encouraged by the stronger intellectual property rights regime that has come to be built in India, MNCs are outsourcing clinical trials and stages of pharmaceutical and biotechnology innovations to Indian firms. With respect to financial resources and R&D capabilities, even the top Indian pharmaceutical companies are much smaller than western pharmaceutical MNCs. Indian firms do not possess the resources to go through the lengthy and financially risky process of new drug innovation. The strategies adopted by Indian firms in response to this business scenario involve competition and collaboration with MNCs. Indian pharmaceutical companies conduct research, develop new molecules, and license them out to MNCs, which take these molecules through the stages of clinical trials and regulatory approval. As they seek to enter the regulated markets of North America and Europe, Indian companies have also challenged patent rights held by originator drug companies. Originator companies have retaliated by drawing the Indian generic drug makers into long and costly patent battles.

To summarise the recent changes in India's pharmaceutical industry: first, as a consequence of product patenting legislations in India, the ability of Indian firms to

manufacture cheap generic drugs for developing country markets has been considerably reduced. Secondly, while Indian firms have been increasing their R&D expenditures and exporting to the markets in North America and Europe, there are fears that they may end up becoming junior partners of western pharmaceutical MNCs. At the same time, many smaller Indian pharmaceutical companies are even facing the threat of closures. The reasons include the rise in mergers and acquisitions (M&A) activity in Indian pharmaceutical industry in the post-TRIPS phase, toughening competition and increase in regulatory standards in Indian and export markets.

The evolution of intellectual property rights regime in China has been shaped by two factors: a commitment to development of domestic capabilities in science and technology, and international pressure, particularly from the United States, as China was negotiating its entry into the global trading system. China introduced product patenting in 1993, and fully complied with the TRIPS provisions as it entered the WTO in 2001. Evidence indicates that China, like India, is becoming a destination for outsourcing of research in pharmaceuticals and biotechnology. Pharmaceutical research conducted by MNCs in India and China is oriented to the cure of global diseases that are prevalent among affluent sections of the world's population-- not of the many neglected diseases whose incidence is primarily among the poor in these two and other third world countries. At the same time, pharmaceutical MNCs are targeting the market of global diseases among rich patients in China and India.

In the context of the challenges discussed in earlier paragraphs, it is crucial that technology-intensive firms in India and China cooperate to develop products of innovation aimed at the market for poor consumers in the third world. In fact, the potential for India and China to cooperate in pharmaceuticals and biotechnology is very high. China is today an important player in the supply of pharmaceutical chemicals and active pharmaceutical ingredients, while 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, 2006). Governments in China and, to a lesser extent, India are investing greatly in health biotechnology. China's biotechnology industry has had many successes including participation in the Human Genome Project.

Another area which offers high potential for collaboration between the two countries is agricultural biotechnology. 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 new varieties of GM crops (141 in 2002), including genetically modified cotton, tomato, tobacco and rice.

Singapore can play an important role as a facilitator for India-China cooperation in the fields of pharmaceuticals and biotechnology. In Singapore, government spending and policy attention on the biotechnology industry is very high. Singapore's Biopolis is a leading global centre in biomedical sciences research. Today the world is witnessing the emergence of meta clusters, that is, networks of biomedical centres in geographically connected countries. Singapore can act as a centre where the talents from India and China interact. Singapore can also take the lead in biomedical innovations directed at the large markets of Southeastasia, South Asia and China.

References:

Armstrong, Karen (2006), 'Bush's Fondness for Fundamentalism is Courting Disaster at Home and Abroad', *The Guardian*, July 31.

Arnold, Wayne (2006), 'Singapore Acts as Haven for Stem Cell Research', *New York Times*, August 17.

Balasubramaniam, Kumariah (1983), 'The Main Lines of Cooperation among Developing Countries in Pharmaceuticals', *World Development*, Vol.11, No.3, pp. 281-87.

Benesh, Peter (2006), 'Where to Start Up Your Biotech? Consider Looking East', *Investor's Business Daily*, May 22.

Bernauer, Thomas (2003), *Genes, Trade, and Regulation: The Seeds of Conflict in Food Biotechnology*, Princeton University Press, Princeton and Oxford.

Centre for Monitoring Indian Economy (CMIE) (2006), *Foreign Trade and Balance of Payments*, CMIE, July.

Centre for Monitoring Indian Economy (CMIE) (2005), *Foreign Trade and Balance of Payments*, CMIE, July.

Centre for Monitoring Indian Economy (CMIE) (1997), *Foreign Trade*, CMIE, July.

Chadha, Alka (2006), 'Destination India for the Pharmaceutical Industry', *Delhi Business Review*, Vol.7, No.1, pp.1-8.

Chanda, Rupa and Niranjana Sreenivasan (2006) 'India's Experience with Skilled Migration' in Kuptsch and Pang (eds.) (2006).

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, downloaded from <www.oecd.org/dataoecd/43/35/34947073.pdf> (on December 17, 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*, Oxford University Press, New Delhi.

Chen, Huifen (2006), 'On the Cusp of the Stem Cell Revolution', *Business Times*, March 9.

Chen, Zhangliang (1999), 'Unlimited Prospects for Biotechnology', Interview with Chen Zhangliang by *Knowledge Economy*[*Zhishi Jingji*], December, pp.22-28, downloaded from <www.usembassy-china.org.cn/sandt/biotechch.html> (on March 15, 2006).

Chervenak, Mathew (2005), 'An Emerging Biotech Giant?', *China Business Review*, May-June, downloaded from <www.chinabusinessreview.com/public/0505/chervenak.html> (on March 15, 2006).

Chudnovsky, Daniel (1983), 'Patents and Trademarks in Pharmaceuticals', *World Development*, Vol.11, No.3, pp. 187-193.

Cookson, Clive (2005a), 'Innovative Asia: How spending on research and development is opening the way to a new sphere of influence?', *Financial Times*, June 9.

Cookson, Clive (2005b), 'Research and Development in Asia: Eastern Rebirth of the Life Sciences', *Financial Times*, June 10.

Cookson, Clive (2005c), 'Research and Development in Asia: The Invention House in the East', *Financial Times*, June 17.

Cookson, Clive (2005d), 'Research and Development in Asia: India and China Reach for the Moon', *Financial Times*, July1.
Cookson, Clive (2006), 'China Treads a Careful Path towards Biotech Greatness', *Financial Times*, February1.
Drahos, Peter with Braithwaite, John (2002), *Information Feudalism: Who Owns the Knowledge Economy?* The New Press, New York.
Economic Review Committee (2003), *Report of the Economic Review Committee: New Challenges, Fresh Goals – Towards a Dynamic Global City*, Ministry of Trade and Industry, Singapore.
Economist (2002), 'Biotech's yin and yang', *Economist*, December 12, downloaded from <www.economist.com/science/displayStory.cfm?story_id=1491569>
Economist (2005), 'Prescription for Change: A Survey of Pharmaceuticals', *Economist*, June 18 – 24.
Elias, Paul (2006), 'Singapore Woos Top Scientists with New Labs, Research Money', The Associated Press State and Local Wire, April 12.
Ernst, Dieter (2005), 'Complexity and Internationalisation of Innovation – Why is Chip Design Moving to Asia?', *International Journal of Innovation Management,* Vol.9, No.1, pp. 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).
Freeman, Chris (1995), 'The 'National System of Innovation' in Historical Perspective', *Cambridge Journal of Economics*, Vol.19, No.1, pp.5-24.
Gallagher, Kathleen and Rust, Susanne (2006), 'State's Biotech Industry: A Spot on World Stage?', The Milwaukee Journal Sentinel (Wisconsin), January 27.
Government of India (2006), *Research and Development Statistics 2004-05*, Ministry of Science and Technology, Department of Science and Technology, New Delhi.
Grace, Cheri (2004), 'The Effect of Changing Intellectual Property on Pharmaceutical Industry Prospects in India and China: Consideration for Access to Medicines', DFID Health Systems Resource Centre, London, June, downloaded from <http://www.dfidhealthrc.org/shared/publications/Issues_papers/ATM/Grace2.pdf> (on December 28, 2005).
Grace, Cheri (2005), 'Update on China and India and Access to Medicines', DFID Health Resource Centre, London, November, downloaded from <www.dfidhealthrc.org/what_new/ Final%20India%20China%20Report.pdf> (on December 28, 2005).
Gross, Ames (1995), 'Opportunities in the China Biotechnology Market', *Pacific Bridge Medical*, January-February, downloaded from <www.pacificbridgemedical.com/publications/html/ChinaJanFeb1995.html> (on December 28, 2005)
Hepeng Jia (2004), 'IP Litigation in China could Drive Innovation', *Nature Biotechnology*, Vol.22, No.4, p. 368.
Herrera, Stephan (2005), 'Leaders and Laggards in the Stem Cell Enterprise', *Nature Biotechnology*, Vol.23, pp.775-77.
Huifen, Chen (2006), 'Room for More Biomedical Hubs in Asia', *Business Times*, March 16.
Jack, Andrew (2005), 'Patently Unfair? Makers of Branded Drugs Struggle to Counter the Generic Onslaught', *Financial Times*, November 22.
James, Clive (1997), 'Global Review of Transgenic Crops', The International Service for the Acquisition of Agri-biotech Applications (ISAAA), Ithaca, New York.

James, Clive (1999), 'Global Review of Transgenic Crops', The International Service for the Acquisition of Agri-biotech Applications (ISAAA), Ithaca, New York.
James, Clive (2004), 'Global Review of Transgenic Crops', The International Service for the Acquisition of Agri-biotech Applications (ISAAA), Ithaca, New York.
James, Clive (2005), 'Global Review of Transgenic Crops', The International Service for the Acquisition of Agri-biotech Applications (ISAAA), Ithaca, New York.
Jayaraman, K.S. (2002), 'India Approves GM Cotton', *Nature Biotechnology*, Vol.20, p.415.
Jayaraman, K.S. (2003), 'India Dawdles over *Bt* Cotton', *Nature Biotechnology*, Vol.21, pp.590-91.
Jayaraman, K.S. (2004), 'India Produces Homegrown GM Cotton', *Nature Biotechnology*, Vol.22, pp.255-6.
Jayaraman, K.S. (2005), 'Biotech Boom', *Nature Biotechnology*, Vol.23, No.9, pp. 1183-1184.
Jayaraman, K.S., Jeffrey L. Fox, Hepeng Jia, and Claudia Orellana (2005), 'Indian *Bt* gene monoculture, potential time bomb', *Nature Biotechnology*, Vol.23, No.2, p.158.
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, http://yaleglobal.yale.edu/display.article?id=2526
Keayla, B.K. (2005), 'Patents (Amendment) Ordinance 2004: A Critique', National Working Group on Patent Laws, New Delhi.
Kleinknecht, Alfred and Jan ter Wengel (1998) 'The Myth of Economic Globalization', *Cambridge Journal of Economics*, Vol. 22, No.4, pp. 637-647.
Kong, Qingjiang (2005), *WTO, Internationalization and the Intellectual Property Rights Regime in China*, Marshall Cavendish Academics, Singapore.
Krishna, Gina, S (2004), 'NORVASC: Who will Pop the Bitter Pill?', Business World, March 4, downloaded from <www.businessworldindia.com/mar0104/indepth04.asp> (on October 4, 2005).
Krishnakumar, Asha (2002), '"India needs a Biotechnology Policy": Interview with Dr. Suman Sahai ' *Frontline*, Vol.21, No.10.
Kumar, Nandini. K, Uyen Quach, Halla Thorsteinsdóttir, Hemalatha Somsekhar, Abdallah S Daar and Peter A Singer (2004), 'Indian Biotechnology – Rapidly Evolving and Industry Led', *Nature Biotechnology*, Vol.22, 31-36.
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 Margaret MacLeod (2005), 'Pharmaceutical R&D for Low Income Countries: Global Trends and Participation by Indian Firms', *Economic and Political Weekly*, September 24, pp. 4232-42.
Lawrence, Stacy (2005), 'Trends in the Biotech Literature', *Nature Biotechnology*, Vol.23, No.4, p. 408.
Mahapatra, Rajesh (2006), 'India's Ranbaxy Labs Blames Pricing Pressure in US market for Sharp Drop in 2005 profit', Associated Press Financial Wire, January 18.
McFadden, Johnjoe (2005), 'Top of the Crops', *Guardian*, August 23, downloaded from <www.guardian.co.uk/gmdebate/Story/0,2763,1554374,00.html> (on December 28, 2005).
Menon, Parvathi (2001), 'The Transgenosis Debate', *Frontline*, Vol.18, No.14, July 7-20.

Menon, Parvathi (2005), 'Business as Bridge', *Frontline*, Vol. 22, No.9, April 23-May 6.
Ministry of Petroleum and Chemicals (1971), 'Drugs Prices Control: Aims & Achievements', Government of India, New Delhi.
Mukerjea, D.N. (2003), 'Brar's Ranbaxy', *Business World*, September 29 (downloaded from <http://www.businessworldindia.com/sep2903/coverstory01.asp>)
National Bureau of Statistics of China (2005), *China Statistical Year Book 2005*, China Statistics Press.
Nundy, Samiran and Chandra M Gulhati (2004), 'A New Colonialism: Conducting Clinical Trials in India', *New England Journal of Medicine*, Vol.352 No. 16, pp, 1633-36.
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*, International Food Policy Research Institute, Johns Hopkins University Press, Baltimore and London.
Pharmaceutical Enquiry Committee (1954), *Report of the Pharmaceutical Enquiry Committee*, Ministry of Commerce and Industry, Government of India, New Delhi.
Rai, Saritha (2003), 'Generic Drugs From India Prompting Turf Battles', *New York Times*, December 26, 2003.
Raja, M (2004), 'Boost for India's Battling Biotech Business', Asia Times Online Limited, June 24, downloaded from <www.atimes.com/atimes/South_Asia/FF24Df03.html> (on October 7, 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*, Oxford University Press, New Delhi.
Ramanna, Anitha (2006), 'India's Policy on Genetically Modified Crops', Working Paper 15, Asia Research Centre, London School of Economics and Political Science.
Rao, Ijaz Ahmad (2006), 'Effectiveness of Bt Cotton', *Business Recorder*, April 24.
Rinaldi, Andrea (2006), 'More than the sum of their parts?', *European Molecular Biotechnology Organization* Reports, Vol.7, No.2.
Sachitanand, Rahul (2006), 'Transition Pangs', *Business Today*, June 18.
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, downloaded from <www.who.int/entity/intellectualproperty/_studies/PadmashreeSampathFinal.pdf> (on December 17, 2005)
Shiva, Vandana (2001), *Protect or Plunder? Understanding Intellectual Property Rights*, Zed Books, London.
Shiva, Vandana (2005), 'WTO, Patents on Life Forms and Amendments in India's Patent Law', Z magazine, April 7, downloaded from <www.zmag.org/sustainers/content/2005-04/07shiva.cfm> (on 12 February 2005).
Simons, Craig (2006), 'Singapore's Botech Gain is America's Loss', *Cox News Service*, May 31.
Spence, Jonathan D. (1999), *The Search for Modern China*, Second Edition, W. W. Norton & Company, New York and London.
Subramaniam, G Ganapathy (2006), 'India, US have a tiff over TRIPS', *Economic Times*, December 16.
Taverne, Dick (2005), 'The New Fundamentalism', *Nature Biotechnology*, Vol.23, 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*, Oxford University Press, New Delhi, pp.126-40.

Tomlinson, Heather (2005), '$12bn Battle that Pits an Indian Upstart against the Mighty Pfizer', *The Guardian*, August 29, downloaded from <www.guardian.co.uk/business/story/0,3604,1558296,00.html>

UNCTAD (2005), *World Investment Report 2005: Transnational Corporations and the Internationalization of R&D*, United Nations Conference of Trade and Development, New York (downloadable from <www.unctad.org>)

UNDP (2005), *Human Development Report 2005: International cooperation at a crossroads: Aid, trade and security in an unequal world*, United Nations Development Programme (downloadable from http://hdr.undp.org/)

van Beuzekon, Brigitte and Anthony Arundel (2006), *OECD Biotechnology Statistcs-2006*, Organization for Economic Cooperation and Development, accessed from <www.oecd.org/dataoecd/51/59/36760212.pdf>

van Beuzekon, Brigitte and Anthony Arundel (2006), *OECD Biotechnology Statistcs-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*, Vol. 23, No.1, Jan. 14 – 27.

Visvanathan, Shiv and Parmar, Chandrika (2002), 'A Biotechnology Story: Notes from India', *Economic and Political Weekly*, July 6, pp.2714-24.

Wartensleben, Aurelie Von (1983), 'Major Issues Concerning Pharmaceutical Policies in the Third World', *World Development*, Vol.11, No.3, pp. 169-175.

Weisman, Steven R. (2006), 'Before Visit to China, A Rebuke', *New York Times*, December 12.

World Health Organization (2004), *The World Medicines Situation*, World Health Organization, downloaded from <http://w3.whosea.org/LinkFiles/Reports_World_Medicines_Situation.pdf> (on January 7, 2005).

Xun Zi (2005), 'GM Rice Forges Ahead in China amid Concerns over Illegal Planting', *Nature Biotechnology*, Vol.23, No.6, p. 637.

Xun, Zi (2005), 'GM Rice Forges ahead in China amid Concerns over Illegal Planting', *Nature Biotechnology*, Vol.23, p. 637.

Zaidi, Annie (2006), 'Failure in Nimar', *Frontline*, Vol.23, No.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).