

## **Changed patent policy and biopharma innovation in India by foreign investment and technology transfer**

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### **Abstract**

The paper has measured the relationship between the intellectual property rights and Foreign Direct Investment in the context of Indian biopharma Industry in order to know the impact of TRIPs agreement of WTO on the biopharmaceutical industry of developing countries. The central issue in this study is the extent to which patent reform (after the imposition of the TRIPs agreement in 1995) affects India's ability to attract technology transfer for the biopharmaceutical drugs innovation. For the same this study has done an analysis of FDI flow in biopharma industry in Pre TRIPs (before the imposition of product patent protection 1991-1999) and post TRIPs (after the product patent protection, 1999-2005) along with a comparative analysis of the relationship between the amount of foreign investment flown in different Indian states and the investment climate ranking of those states which are the part of Indian biocluster.

**Key words:** TRIPs, Product patent, Investment climate, Foreign Direct Investment

### **Introduction**

Trade Related aspects of Intellectual Property Rights (TRIPs) agreement of the World Trade Organisation (WTO) is considered to be one of the milestones in the international harmonization of patent protection. As product patent protection has been imposed on all its member countries by its Article-27.1(1). Article-27.1 places a strict obligation on member to provide patents for all patentable pharmaceutical and biopharmaceutical

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products. So, after the enforcement of the TRIPs agreement, there is a significant change in the patent regime in the developing countries mainly. Before TRIPs, a vast majority of developing countries such as Argentina, China, India, Korea and Mexico protected process but not product. After the enforcement of TRIPs agreement these countries will not be able to carry out reverse engineering(2). In reverse engineering the new chemical entity or molecule is manufactured with new process, whose development cost is minimal and clinical testing are not required where as it takes several hundred million dollars to discover, develop and gain regulatory approval for a new medicine and without the capacity to spend for the innovation of new molecule(3). After the imposition of product patent protection, generic production of new biopharmaceutical drugs (i.e. those patented post 2005) are not allowed and the firms have to innovate novel biopharma drugs. Indian biopharmaceutical industry is basically a biogeneric (4) industry. India is the supplier of cheap generic drugs to the world, main innovator products on which biogeneric drugs have been produced by the Indian biogeneric industry are Erythropoitin, G-CSF, recombinant Hepatitis B vaccine, Insulin, Interferon alfa, streptokinase etc. On the one hand, there is heavy burden of diseases shares 18% of the worldwide mortality and 20% of the worldwide morbidity (5). On the other hand, there is limited resource to innovate novel drugs as India shares 2% of world GDP and invest just 1% on the healthcare of the world healthcare investment (6). So at the moment monetary resources to innovate novel drugs on its own strength for the generic biopharmaceutical industry of developing nation like India is not possible, therefore foreign direct investment (FDI) and foreign technology transfer is important to enter into the chain of novel drug innovation.

This gives an important situation to study the impact of the TRIPs agreement on the biopharma drug innovation in India by foreign technology transfer. So, the study is concentrated on the Indian biopharmaceutical industry and attempts to analyse the effect of the product patent protection on the foreign technology transfer in biopharmaceutical (7) drugs innovation.

It is also interesting to do such study as it has been argued by the developed countries that strengthening of patent protection will bring innovation through increased foreign direct investment and greater transference of technology in developing countries. At the same time, the objective of the TRIPs agreement which is stated in Article 7 also says; Protection and enforcement of Intellectual Property Rights should contribute to the promotion of

- Technological innovation and transfer and dissemination of technology to the mutual advantage of producer and user of the technological knowledge.

Thus, it can be interpreted that implementation of Art 27.1 will lead to greater foreign technology transfer in Pharma and biopharma sector. In Doha declaration too (Art 37)(5) it was agreed that the WTO would set up a working group to examine the relationship between trade and transfer of technology and to report findings to the fifth session of the Ministerial Conference (Art 38, 41)(6).

In this way the relationship of two very Articles (Article 7 and 27) is interesting to analyse as the same will measure the relationship between the intellectual property rights and FDI in the context of Indian biopharma Industry in order to know the impact of TRIPs agreement on the biopharmaceutical industry of developing countries.

The central issue in this study is the extent to which patent reform (after the imposition of the TRIPs agreement in 1995) affects India's ability to attract technology transfer for the biopharmaceutical drugs innovation. This is in order to see the impact of changed intellectual property protection on FDI and technology transfer.

Further to investigate the actual role of IP in pulling FDI and technology transfer, this study has made a comparative analysis of the relationship between the amount of foreign investment and the investment climate ranking of the different states of India which are the part of Indian bioclusters. By investment climate we mean a menu of policy, regulatory and institutional factors that provide incentives sufficiently robust to induce private sector to invest in socially desirable projects (Weingast 1992)(8). According to Stern Investment climate is policy, institutional and behavioral environment both present and expected that influences the returns and risks associated with investment (Stern 2002 b)(9). Also, as per John Dunning's (10) ownership location and internalisation (OLI) approach ownership specific location, location specific and internalisation specific ownership advantage create monopolistic advantages which can be used to prevail in market abroad. The Ownership, Localisation and Internalization (OLI) paradigm of John Dunning shows that under certain conditions it becomes profitable for the investor to produce in foreign market. Thus this research intends to anatomize the relationship between the FDI and higher patent protection by measuring the strength of factors of investment climate (including higher patent protection for biopharma) in attracting the foreign investment and technology transfer overall on country level as well as state level.

## **Research Questions**

The basic question which has been addressed in this paper is the role of product patent protection in stimulating technology transfer for the biopharma drugs innovation in Indian biopharma sector and to what extent differences in investment climate of different states of India affects inflow of foreign direct investment and technology transfer?

## **Methodology**

The paper has addressed these questions using a industry level FDI and foreign technology transfer data collected from Foreign Investment Promotion Board (FIPB), Ministry of commerce and Industry, Government of India as well as firm-level database derived from the interviews of the biopharma multinational companies (MNC) heads based in India. The survey has covered 10 biopharma MNC firms based in India. The study has selected 5 Indian states: Maharashtra, Gujarat, Andhra Pradesh, Karnataka, and Delhi for the research which forms biocluster of India. Also in these five states out of total 142 biopharma firms in India more than 130 (90%) firms are located in just 5 states, in Andhra Pradesh 38 (27%), Maharashtra 38 (27%), Karnataka 17 (12%), Delhi 16 (11%)(15) and Gujarat which form the Indian biocluster whose Investment climate (IC) grading or ranking has done by the World Bank in its survey of 2000 and 2003. The study has taken support of World Bank FACS IC survey of Indian states 2000 and 2003.

On the basis of collected data from Ministry and IC data of World Bank the relationship between investment climate and FDI have been investigated by comparing both.

## **Study design**

For measuring the impact of product patent protection, data has been collected from 1991 to 2005. 1991-1999 to see post liberalisation effect and pre TRIPs effect and 1999 – 2005 (post TRIPs). TRIPs agreement came into effect on January 1<sup>st</sup> 1995, it set out transitional period of 10 years (until 2005) for the implementation of the TRIPs agreement for the developing countries like India, which had not granted patents for pharmaceutical products. India had however, accepted applications (the mail box provision) (11) and, beginning in 2000, offered “exclusive marketing rights (EMR) by the Patent amendment Act 1999. EMR are very similar to patents in offering monopoly marketing rights to the inventor, so effectively product patent protection was available since 1999. Thus, for analyzing impact of product patent protection on the biopharmaceutical innovation, the time period of year 2000 to March 2005 has been considered.

Two types of data have been collected for the survey, first industry level and second firm level. Industry level data on the flow of foreign technology transfer has been collected majorly from foreign investment promotion board (FIPB), Ministry of Industry and commerce. Firm level data has been collected from the biopharma firms (MNC which are based in India). This has been done by visiting individual biopharma MNCs based in India such as Novo Nordisk, Aventis pharma, Glaxo smithcline, Eli Lilly and Co, LG Chemicals, Astrazeneca etc in order to know their the factors which influenced their decision to invest in India. Survey has been done by interviewing CEOs personally these firms personally which are located in these states mainly in Bangalore, Hyderabad, Mumbai, Pune, Delhi, Gurgaon etc from July 2006 to January 2007.

The study has employed graphical analysis as well as interview analysis to answer the research question.

### **Case Study**

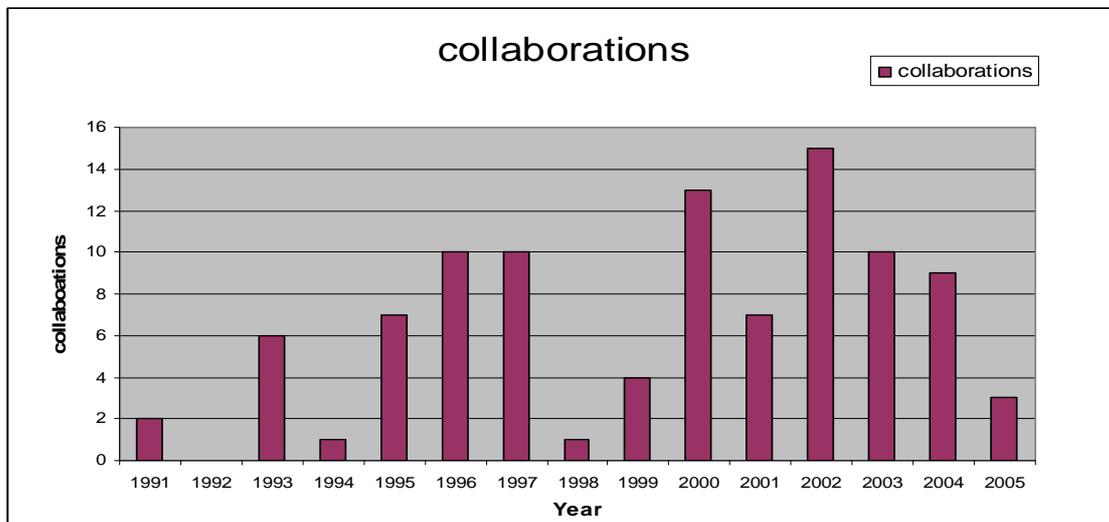
If we see the number of foreign collaborations in Indian biopharma industry in the initial years of liberalisation then we find that the change in the liberalization policy did not yield dramatic results immediately. By liberalisation we mean the economic reforms in India which started in the early 1990s, or to be more precise, in July 1991. These reform processes and the liberalisation of the economy continued throughout the decade and into the 21st century. In brief, the reforms include flexible exchange rates regime, full convertibility of current account transactions and removal of many international trade restrictions, transfer in India by the announcement of the new industrial policy in July 1991.

After 1991, with the liberalisation (12) of the Indian economy, foreign investment started flowing into various sectors of the India ranging from the manufacture of cereals to the IT industry. However, by analysing the technology transfer data ranging from 1991 to March 2005, it can be inferred that the Indian biopharmaceutical industry did not attract much foreign investment in the initial years of liberalisation (See chart 1).

As per chart 1 there is increase in the technology transfer trend though the increase is not sharp and continuous. The chart 1 also shows that the number of technology transfer cases has increased in post TRIPs era although not sharply as there are ups and downs in the flow. So, it cannot be said for sure that the strong IPR leads to an increase in foreign investment alone because if it is product patent protection only then the trend would have

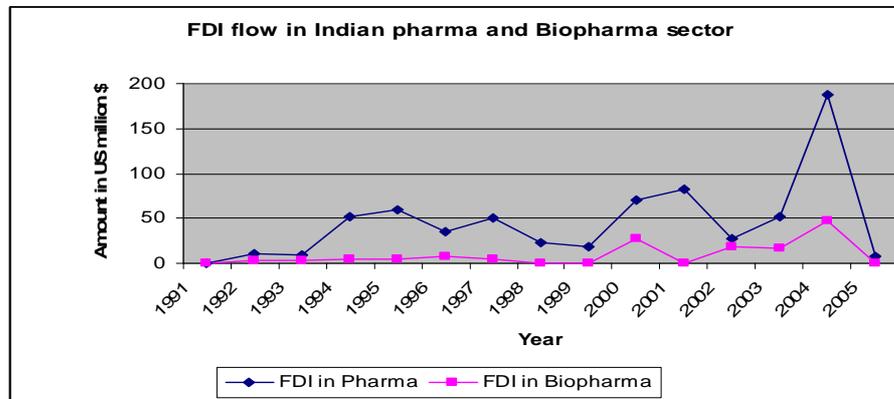
been sharp and continuous. Therefore it can be inferred that there are other factors as well which affect the foreign technology transfer. At the same time it can also be said for sure that product patent is one factor which influence technology transfer in the Indian biopharmaceutical sector.

**Chart 1: Total number of technology transfer cases in Indian Biopharmaceutical sector during 1991-2005**



**Source:** Foreign Investment Promotion Board, Ministry of Commerce and Industry, Government of India, 2005

**Chart: 2: FDI in Indian biopharmaceutical and pharma sector**



**Source:** Foreign Investment Promotion Board, Ministry of Commerce and Industry, Government of India, 2005

By examining the trend of technology transfer in Indian biopharma sector carefully, it can be seen that the flow has increased more sharply in the post TRIPs era (1999- 2005 March ) than in pre TRIPs period (between 1991 to 1999) (see Chart 2).

Similar trend has been found in FDI flow in Indian pharma industry (see Chart 2). The trend of FDI flow is more or less the same in both the sectors and the same has increased more in post TRIPs period (1999- 2004). The foreign investment flow in Indian biopharmaceutical sector is sharper in 2000- 2004 period (total FDI during this period is 40.12 US \$ million) than 1995 - 2000 period (total FDI during this period is 83.12 US \$ million). The total amount of investment undertaken by foreign firms during 2000–March 2005 stood at \$83.12 million, more than double the investment they had undertaken over 1995–2000 \$40.12 million) (Table1). The total flow of FDI into biopharma sector was \$16.22 million between 1991 and 1994 which increased five times during 2000 and March 2005. Such trend can be seen as a result of increasing interest in the Indian

biopharmaceutical industry through direct investment. As a consequence, the share of biopharmaceuticals in the total FDI inflows has increased from 2.4 per cent from 1995 to 1999 which further increased to 4.9 per cent from 2000 to March 2005. The result shows that India's shifting from a weak patent regime to a stronger patent regime has taken place during this period and this final shift in the patent regime might have promoted hesitating foreign enterprises to enter into Indian market. The actual FDI inflow into Indian biopharmaceutical industry is estimated to be only \$ 47.57 million in 2005 which is just 2.4% of the total amount \$2171 million received by the economy although it has increased from 1991 which was around 1% of the total FDI (Table 1).

**Table 1:**

**Comparison of the statement of yearwise breakup for Foreign Direct Investment (FDI) & Foreign Technology Cases approved by Government during August 1991 to December 2005 in Drugs & pharma and biopharma sector**

Year	Amount of FDI approved in all sectors (in US \$ million)	Amount of FDI approved in Drugs and pharma sector (in US \$ million)	Amount of FDI approved in Biopharmaceutical sector (in US \$ million)
1991	165	0.32	nil
1992	383	11.13	3.76
1993	654	9.76	3.76
1994	1374	51.91	4.35
1995	2141	59.54	4.35
1996	2770	34.37	8.36
1997	3682	50.99	4.77
1998	3083	23.07	Nil
1999	2908	18.55	0.14

2000	4222	70.85	26.85
2001	3134	82.82	0.33
2002	2634	28.03	18.35
2003	3754	51.92	16.87
2004	2171	188.01	47.57
2005		7.23	.71
TOTAL		688.51	131.57

**Source:** Foreign Investment Promotion Board, Ministry of Commerce and Industry, Government of India

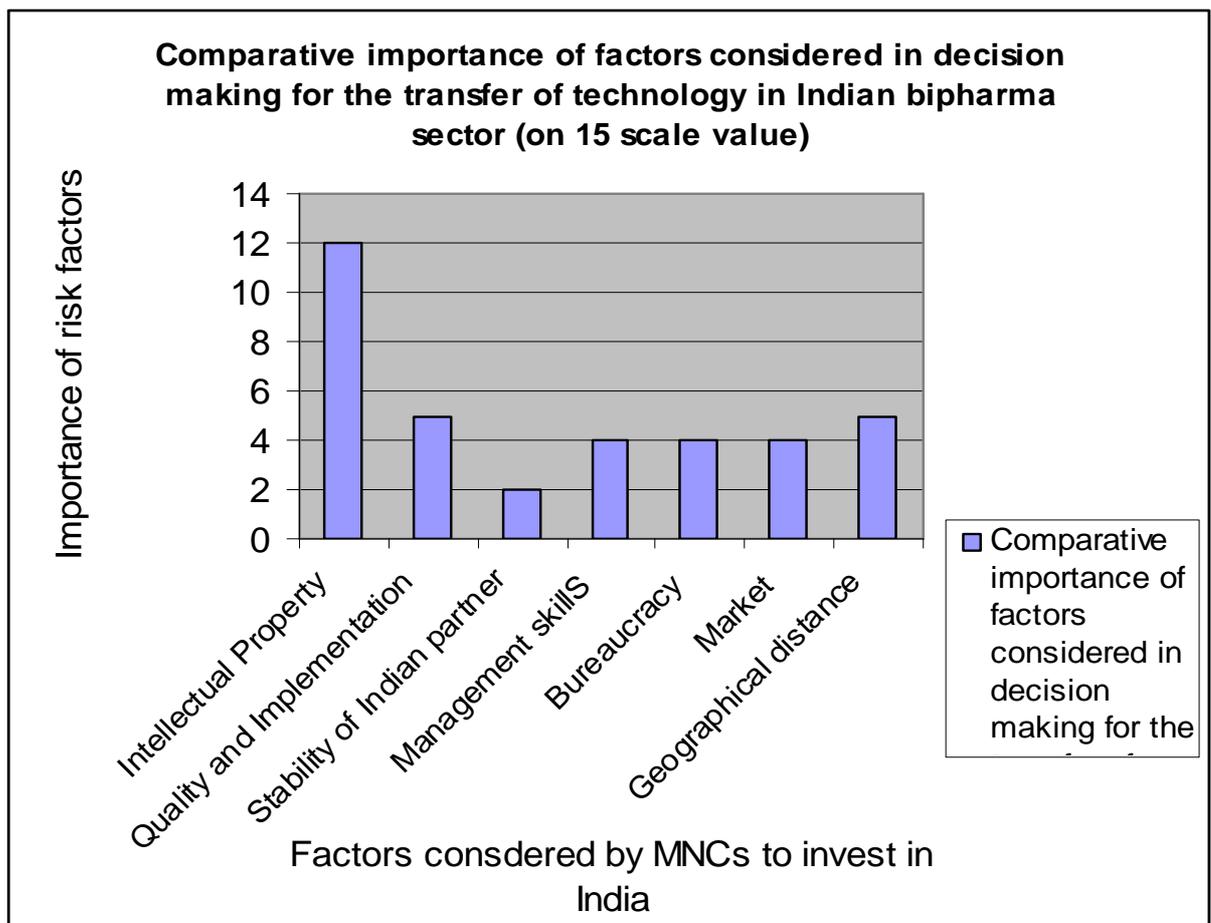
This also shows that the foreign technology flow is increasing but not very smooth and sharp

and the reason can be given that as the product patent protection has been imposed in India in 2005 and this is the effect of the transition period from EMR (13) protection to product patent protection. So, the actual effect of product patent protection may not be visible as yet. On such trend, it can be interpreted that though, the advent of product patent did not bring dramatic increase in FDI flow in IP driven industry such as drugs and pharma but trend may be sharper with the years to come as product patent protection has just imposed in the biopharma sector.

Along with the above analysis and discussions to be more accurate in finding the actual relation between the product patent protection and foreign technology flow in biopharma sector, the same relationship has been further examined by interview data to validate the outcome stated above. For the same, field research has been done and in the same field research, 10 CEOs and director level officials of Biopharma MNCs were interviewed and asked about the most influencing factor in making decision to invest in India. These

MNCs are also located in different bioclusters of the country- Bangalore, Hyderabad, Mumbai – Pune, Delhi and Gurgaon. They were given 7 factors to grade them according to their preference. Factors were Intellectual property Rights, quality and implementation, stability of Indian partner, management skills, bureaucracy, market, geographical distance. On 15 scale value 12 scale values was given to stronger patent protection or higher intellectual property rights. (See Chart 3).

**Chart: 3 Comparative Importance of Factors in Decision of Technology Transfer**



**Source:** based on own Research

So, by looking at this trend, it can be said that certainly stronger patent protection is one of the strongest factor which has influenced the foreign MNCs to transfer their technology to India which seem to increase with time. At the same time other factors also influence the decision of making the foreign investment such as regulatory policies, fiscal policy, infrastructure, bureaucracy etc along with patent policy.

From the above finding it is clear that changed IP protection is one of the components of the investment climate. The change in patent protection imposed equally all over the India and if IP is the only factor which influence the FDI flow in sector like biopharma then the flow of FDI should be more or less the same in all the biocluster states. To be surer about the role of IP in pulling FDI into Indian biopharmaceutical sector the foreign technology transfer data collected from FIPB has been further divided state wise and then relationship of the same had been measured by the investment climate of the state. For the data on the investment climate of different states of India the paper has taken the data provided by the World Bank in its joint survey with Confederation of Indian Industries (CII) in 2000 and 2003.

The World Bank has conducted surveys FACS in 2000 (14) and in 2003 (15) by jointly with Confederation of Indian Industries in which 12 states and large number of industries were covered which include: (i) Food processing, (ii) Textiles, (iii) Garments, (iv) Leather goods, (v) Pharmaceuticals, (vi) Electronic consumer goods, (vii) Electrical white goods, (viii) Auto components, (ix) Metal and metal products, (x) Plastics, and (xi) Machine Tools. Since the pharmaceutical industry is covered so the survey is relevant base our findings on the same. In this survey the business managers were asked to

identify the states that they thought had a better or worse IC than the state in which they were currently based. They were also asked to say which of the states in their opinion had the best IC and which had the worst. The subjective ranking of the states according to IC, as expressed by the business managers, is presented in Table 2.

**Table 2: Subjective Ranking of Best to Worst IC (FACS 2000)**

Category	States	
Best investment Climate	1. Maharashtra 2. Gujarat	<u>Sectors Covered in this Survey</u> 1. <i>Auto components</i> 2. <i>Drugs and pharmaceuticals</i> 3. <i>Electrical white goods</i> 4. <i>Electronic consumer goods</i> 5. <i>Garments</i> 6. <i>Textiles</i> 7. <i>Machine tools</i> 8. <i>Software</i>
Good Investment climate	3. Andhra Pradesh 4. Karnataka 5. Tamil Nadu	
Medium Investment Climate	6. Delhi 7. Punjab	
Poor Investment Climate	8. Kerala 9. West Bengal 10. Uttar pradesh	

**Source:** Estimates provided by the World Bank 2000

**Table 3: Subjective Ranking of Best to Worst IC (FACS 2003)**

Category	States	% say best minus % say worst
Best Investment climate	1. Maharashtra	29.1
	2. Delhi	16.7
Good Investment Climate	3. Gujarat	9.6
	4. Andhra Pradesh	
	5. Karnataka	8.6
	6. Punjab	
	7. Tamil nadu	6.8
	8. Harayana	4.9
Poor Investment Climate		3.7
		1.1
	9. Madhya Pradesh	-6.8
	10. Kerala	-15.0
	11. West Bengal	-30.6
	12. Uttar Pradesh	-30.6

**Source:** Estimates provided by the World Bank 2003

The paper has tried to find the match or relationship between the FDI data collected from FIPB and the World Bank data of IC of the Indian states and then tries to find the results. For the same the complete FDI data of 1991 to 2005 has been rearranged state wise (see Table: 4). Table 4 shows that maximum number of foreign collaboration took place in western cluster which is formed by Maharashtra and Gujarat. Now if we see the investment climate of these states then we will find that these two states have the best IC in country as in the 2000 survey Maharashtra stood at the first place whereas Gujarat stood second. Although in 2003 survey Gujarat lost its position from best IC state to Good IC state but remained at the top among the good IC states. In 2003 too Maharashtra

maintained its position as the best IC state therefore it can be interpreted that the FDI investment happened the most in this region because of the best investment climate.

**Table :4**

**FDI in Indian states between 1991 and 2005**

Biopharmaceutical Cluster	Foreign Technology transfer cases	Percentage
Southern	26	26.532
Western	38	38.775
Northern	14	14.285
States not indicated	20	20.408
Total	98	100

**Source:** Foreign Investment Promotion Board, Ministry of Commerce and Industry, Government of India, 2005

As per the FIPB FDI data the second highest foreign collaborations happened in Southern cluster which is formed by Andhra Pradesh and Karnataka, if we see the investment climate of these states the we will find that these two states are in Good IC states and are just behind Maharashtra and Gujarat in 2000 survey whereas in 2003 survey these states are at 4<sup>th</sup> and 5<sup>th</sup> position so overall from 1991 to 2005 this cluster maintained the second best IC states position which is directly correlated with the second highest FDI flow which flowed around 26.532 % of the total FDI flow in the country after the western cluster of 38.775%.

Now if we see the IC state of the northern cluster which comprise of Delhi and Utter Pradesh then we will find that in 2000 survey Delhi was in the category of medium IC states whereas UP was placed in the poor IC state. Although Delhi's IC improved and it occupied second position in 2003 after Maharashtra among the best IC states but still the

FDI flow in this region flowed less than western and southern cluster may be because the calculation of FDI is from 1991 to 2005 and till 2000 the IC of Delhi was at 6<sup>th</sup> position and still Maharashtra occupies the best states position and Gujarat also remained at the 3<sup>rd</sup> position. Among the southern cluster states also these states maintained their position in the good IC states throughout therefore it can be said that it remained second choice for the foreign investors to invest.

Thus this research finds that the factors of location advantage is important for the foreign investment destination in the local market, which includes factors like resource endowment and also economic and social factors such as market size and structure, prospect for market growth and degree of development, the cultural, legal, political and institutional environment and Government legislation and policies of the different states of India. In terms of the demand side factors, the host's overall attractiveness to FDI is determined by location advantages it possesses or the investment climate of the country. As resource endowments are not evenly distributed among countries and social and economic factors as well as Government policies are different among countries, even it is different among the states of the same country, the attractiveness different states in India for FDI is different. In biopharma sector attractiveness of the location in country like India depends on the cost advantage in clinical trials and labour as these are largely the factors which affect the drug development cost significantly (10). Biotechnology is a knowledge-driven sector because it consists of knowledge working on knowledge to create value, decoding in genomics and proteomics being paradigmatic knowledge-based economic activity. In the case of biotechnology, foreign investments are key magnets for the Indian biopharma industry to shift to novel innovation in change patent regime. Since

transfer science from the laboratory bench to the market involves complex, interactive chains of transactions among scientists, entrepreneurs, and various intermediaries therefore proximity to services such as investors and lawyers and, in biotechnology, research hospitals for clinical trials are important which also create an innovation system. These factors form the factors of investment climate. Since patent policy has changed and applied uniformly to whole of the India but other factors of the investment climate differs state to state therefore foreign investment has been also flowed according to the investment climate of the states.

Thus, form the above analysis it is clear that the factors of investment climate play their role in influencing the decision of the investment and Intellectual property is the one factor among the different factors of investment climate which influence the decision of foreign investment. Therefore the paper concludes that product patent protection is certainly worked as stimulant to pull foreign investment in Indian biopharma industry but it is not the only factor as there are other factors of investment climate which affect the foreign technology transfer and investment.

## References

<sup>1</sup> Patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application. patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.

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11. EMR can be applied in the case the product 'waiting for a patent in the mail box' obtained marketing approval before the mailbox is opened and a decision is made on whether or not to grant the patent. In such a case the manufacturer could request exclusive marketing rights for up to five years or until a decision is rendered on the patentability of the product, whichever is shorter. The grant of EMR stifles with the generic competition. In theory, EMR could reduce the benefit of transition period

12. Following independence, India pursued a development policy based on centralized planning, regulation and control of private enterprise, state ownership, trade protection and limits on the penetration of foreign capital and technology. This regime determined India's economic development until the mid-1980s when there began some movement towards economic liberalization and market orientation. India experienced a crisis in its balance of payments in early 1991, which threatened to destabilize the economy. In response to this crisis, the Government implemented a program of structural reforms, aimed at stabilizing the economy and promoting reliance on market mechanisms, broadly referred to as 'liberalization'. The main components of the structural reforms program were exchange and trade liberalization; financial sector reforms and control of the budget deficit; inflation and money supply. A great deal of significance was placed on promotion of foreign technology transfers and foreign investment in key areas, as well as, the further development of the private sector.

13. India provided for a mailbox provision with effect from January 1, 1995, in Section 5(2) of IPA (1970), after its first amendment. India also provided for the option of EMR in Sections 24 a-e. All applications in the mailbox have been examined after India moved to the product patent regime.

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