CHAPTER - 2

GENETIC PATENT STATISTICS AS INDICATORS OF TECHNOLOGY PROGRESS

As discussed in Chapter 1, the patent regime is believed to promote the progress of Science and Technology by providing incentives to inventors and investors in the form of exclusive rights. Through these incentives, the patent system encourages investment for R and D, expands the limits of a discipline, fosters invention and mandates disclosure. As the incentives form the foundation for operation of the patent system, a granted patent would be an indication of R and D, inventive activity and technology progress. Furthermore, as patents grant exclusive rights to commercially exploit the inventions for a limited period of time, they represent as indicators of business activity.

Patents have long been recognized to be a source of empirical data to understand and analyze inventive activity/innovation, trends and specifics in technology development, R and D processes, technological change and innovation and investment patterns[75]. Patent statistics reflect inventive activity of countries, regions, firms and other aspects of dynamics of innovation process[76]. Patents also indicate diffusion of technology, R and D and productivity. Patents are a good indicator of differences in inventive activity across different firms and the relationship between R & D and patents is close to proportional[77]. As patents are granted to inventions only, patent numbers are invention numbers and can be considered to be positive indicators of inventive activity in the area in which they are available. Because inventive activity in most fields is the result of Research and Development, patents can be effectively used as indicators of R and D activity. If a patent is granted over an invention, it means that the invention is novel, non-obvious and useful because those are three of the basic requirements that an invention should satisfy in order to be eligible for a patent. As one of the basic aspects of

[75] State Of The Art In Patent Statistics - Inventiveness by numbers: towards patent inventor statistics, Robert J.W. Tijssen Center for Science and Technology Studies (CWTS), Leiden University, Leiden, Netherlands.Wipo - Oecd Workshop On Statistics In The Patent Field, Geneva, September 18 and 19, 2003.
[76] Id.
[77] Patent Statistics as Economic Indicators: A Survey, Zvi Griliches, pages 1661-1707, 1702, 1703, Journal of Economic Literature, Vol. XXVIII, (December, 1990).

technology progress is development of new inventions in a field, patent statistics in a particular field can be used to understand progress of technology. By comparing and contrasting patent statistics of different countries, fields and firms good inferences can be drawn on differences and variances in R and D activity, inventive activity and technology progress among them. Furthermore, patents can be used as indicators of business activity or interest because a patent provides exclusive rights to commercially exploit the invention for a limited period of time, which in turn provides a strong business advantage to the patent holder and because acquiring a patent is a costly affair, specially in USA and EU organizations would not be willing to spend on acquiring a patent unless they have business interests. To sum up, patents are the best indicators to measure R and D activity, inventive activity and technological progress because they have close links with invention, cover a broad range of technologies, are well organized and are easily available. Though there are few drawbacks like lack of industrial applicability of certain patents, differences in propensity to patent in different countries, differences and changes in patent laws and regulations, etc., patents are good indicators due to absence of better alternative sources[78].

Patent Filings and Grants as R & D Indicators

While both patent grants and filings can be used to understand inventive activity, R and D activity and technology progress, patent filings reflect R and D activity better than grants because of two reasons. Firstly, patent filings are done during or after an R and D project is completed as opposed to patent grants, which have a time lag of about 2 to 5 years[79] from the completion of R and D and secondly, patent grants are filtered patent applications after they have passed through the patentability filters among which only two filters i.e.

[78] State Of The Art In Patent Statistics - Inventiveness by numbers: towards patent inventor statistics, Robert J.W. Tijssen Center for Science and Technology Studies (CWTS), Leiden University, Leiden, Netherlands.WIPO - Oecd Workshop On Statistics In The Patent Field, Geneva (September 18 and 19, 2003).

[79] Average time taken from patent filing to grant

novelty and non-obviousness test the newness of the invention which is linked with R and D and the other filters such as subject matter, usefulness and specification consider factors that are not directly related to R and D. These two reasons make patent filings a better source for understanding R and D activity when compared to patent grants. Having said that the downside of patent filings is that filing of a patent is very easy and there might be filings over frivolous or non-inventive subject matter, which reduces the value of patent filings as indicators.

Value of patents as R and D indicators can be illustrated by analyzing the table below.

Table 2.1 – R&D Expenditure

R&D Expenditure and Patent Distribution								
		USPTO		ESPACE NET				
Company Name	R&D Spending in Croces	Granted patents	Published Patents	World Wide	Japanese	European	WIPO	Indian Patents Applications Published from January 1995 Onwards
Ranbaxy	331	65	0	1190	0	26	263	227
Dr Reddys Labs	283	33	8	1489	0	29	358	55
Sun Pharmaceutical	146	5	8	121	0	0	55	130
Wockhardt	94	10	18	61	0	8	0	22
Lupin	87	14	6	103	0	11	0	65
Cadila Healthcare	71	3	3	78	0	8	33	53
Torrent Pharmaceuticals	51	6	7	293	4	7	0	36
Biocon	27	16	3	249	0	7	0	50
Panacea Biotec	24	11	1	107	10	0	8	115

Data Source: R and D Spending on the rise, Narayan Kulkarni AND Ch Srinivasa Rao, pages 30-34, Biospectrum, Volume 3, Issue 8, August, 2005 and websites of USPTO, ESP@CENET and EKASWA - visited on September 16, 2005.

Table 2.1 shows the top ten companies based on R and D spending for the years 2004/2005 and the number of patents granted or applied for each of them as of September 16th, 2005 at USPTO, EPO, JPO, IPO and PCT. While the first highest R and D spender Ranbaxy has 65 and 26 patent grants to its name in USPTO and EPO, the tenth company on the list Panacea Biotech has 11 and 10 patents granted at USPTO and JPO. The table shows variations in the distribution of patents among USPTO, EPO (World Wide Database), JPO and IPO. With the exception of Ranbaxy all companies in the list have published patent applications pending before the USPTO. Only Torrent Pharmaceuticals and Panacea Biotech have patents at JPO, which is an indication that the top companies do not have markets in Japan. All companies except Sun Pharmaceutical and Panacea Biotech have patents at EPO, which is an indication that Indian Biotech Companies have good business interests in Europe.

Though it would be far fetched to interpret any relationship between R and D spending and patent grants or applications represented on the aforementioned table because of the differences in time lines of R and D spending and patent grants, the statistics give a very broad insight into the patent focus of R and D based companies. A generic inference, which can be drawn from the table, is that all companies that focus on R and D have patents, which means that R and D spenders are interested in patenting and that R and D spending manifests itself as patents at some level. Therefore, patents can be used as indicators of R and D while doing ex post analysis based on number of patents filed or granted.

Genetic Patent Statistics and Analysis

Meaning of 'Biotechnology Patent'

The OECD has derived a definition of biotechnology patent for purposes of statistical analysis. OECD defines a biotechnology patent as any patent falling within the scope of the following International Patent Classes:

A01H1/00,A01H4/00,A61K38/00,A61K39/00,A61K48/00,C02F3/34,C07G(11/00,13/00,15/00),C07K(4/00,14/00,16/00,17/00,19/00),C12M,C12N,C12P,C12Q,C12S,G01N27/327, and G01N33/(53*,54*,55*,57*,68,74,76,78,88,92)[80]. Based on the definitions of the aforementioned classes and subclasses the author has come up with a list of classes and subclasses that would fall within the scope of Medical Biotech Patents. They include, A61K, C07K, C12M, c12 N and c12 Q. Biotechnology and Medical Biotechnology patent data that is analyzed in Chapter III has been isolated based on the aforementioned definitions. Please refer Annexure 1 for detailed definitions of each class and subclass. Genetic patents have been isolated by looking at abstracts of all patents granted to Indian assignees in USA.

Data Collection

The patent and statistical data that is analyzed in this chapter has been generated by collecting empirical data from the USPTO, esp@cenet (World Wide) and IPO patent databases. The data has been selected and isolated based on the aforementioned definitions of biotechnology and medical biotechnology patents using International Patent Classification. The data is current as of 15th September 2005. Information relating to Indian published patent applications has been collected from World Wide database on

[80] Page No.43, Annexure B, Compendium Of Patent Statistics, Organisation For Economic Co-Operation And Development (Oecd) 2004.

esp@cenet and EKASWA-A hosted by TIFAC. Bibliographic data on EKASWA-A was available only from January 1995 onwards.

Statistical Analysis of Genetic Patents

Patent Filings at USPTO

Table 2.2 - Patent Filings at USPTO - Grant Database (Indian Assignees)

Year	All Patents	Biotech	Medical Biotech	Genetic
1995	29	2	2	0
1996	53	4	3	0
1997	82	9	7	2
1998	98	13	10	3
1999	109	13	8	2
2000	178	32	27	4
2001	272	39	28	6

Graph 2.2

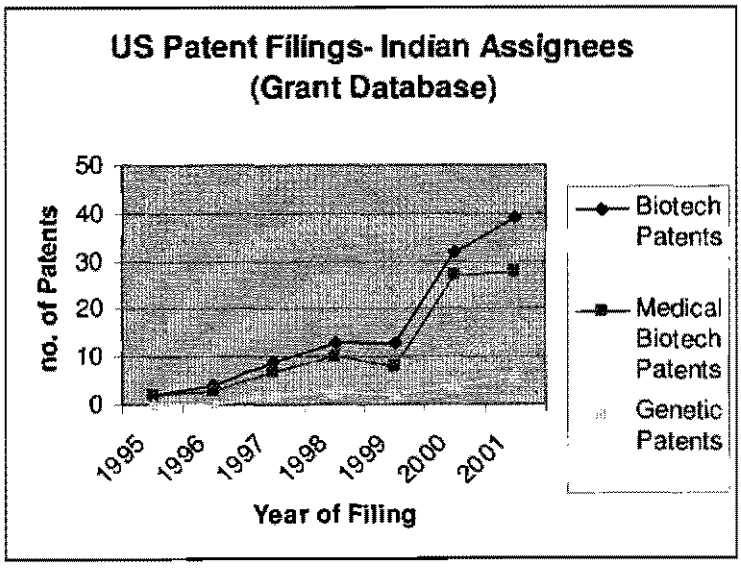


Table 2.2 and Graph 2.2 show the increase in patent filings among patents granted in USA. The graph shows that there has been a steady rise in patent filings from 1995 to 2001. The number of general patent filings increased from 29 in 1995 to 272 in 2001 and patent filings in biotech and medical biotech patents increased from 2 and 2 in 1995 to 39 and 28 in 2001. The number of genetic patents increased from 0 in 1999 to 6 in 2001. This indicates a steady increase in R and D activity and inventive activity generally and in medical biotechnology and genetics specifically. The increase in the rate of filings by Indian Organizations at USPTO is a strong indication that Indian Organizations have business interests in USA and the rise in patent filings every year indicates that their business activity in USA has been on the rise.

Table 2.3

US Patent Filings - Indian Assignees				
Year	Total	Biotech Patents	Medical Biotech Patent	Genetic
2001	23	3	3	0
2002	58	13	10	0
2003	106	17	11	1

Graph 2.3

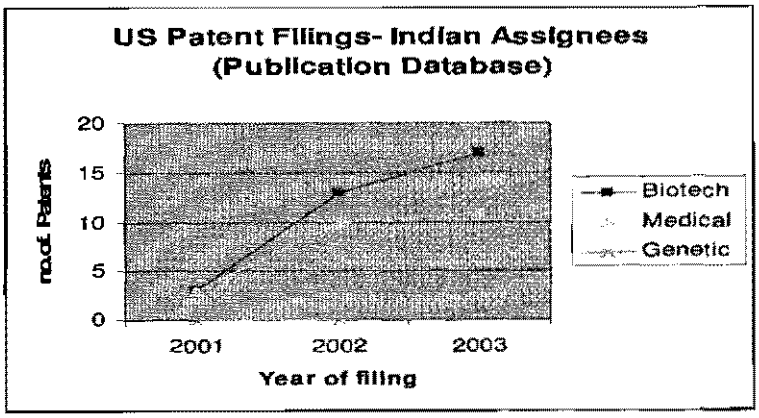


Table 2.3 and Graph 2.3 show US Patent filings by Indian Assignees in general and biotechnology/medical biotechnology and genetics in particular. The data comes from US Patent Office's published applications database and shows patent filings, which have been published by USPTO. The number of patent filings as shown in the graph/table has increased from 23 in 2001 to 106 in 2003 for all patents, which is an increase of more than 469 percent. In biotechnology and medical biotechnology, the number of filings has increased from 3 in 2001 to 13 in 2003 for biotech and 3 in 2001 to 11 in 2003 for medical biotech, which is an increase of 433 percent for biotechnology and 333 percent for medical biotechnology. Only one genetic patent was filed in 2003. Though the percentage of growth is very good, it has not been consistent. The rise in number of patents filed in biotechnology and medical biotechnology indicates an increase in R and D activity and inventive activity in those fields. The share of medical biotechnology in biotechnology patents is 72.7 percent, which is an indication that most biotechnology R and D in India is happening in the field of Medical Biotechnology.

Table 2.4 US Patent Grants - Indian Assignees

Year	All Patents	Biotech Patents	Medical Biotech Patents	Genetic Patents	% Growth in All Patents	% Growth in All Biotech Patents	% Growth in Al Medical Biotec Patents
1995	16	1	0	0			
1996	18	1	1	0	12.5	0	
1997	31	2	2	0	72.22222	100	100
1998	54	6	4	0	74.19355	200	100
1999	73	7	7	2	35.18519	16.66667	75
2000	83	6	3	2	13.69863	-14.2857	-57.1429
2001	121	13	9	3	45.78313	116.6667	200
2002	200	28	25	2	65.28926	115.3846	177.7778
2003	237	32	24	6	18.5	14.28571	-4
2004	227	22	14	3	-4.21941	-31.25	-41.6667

Graph 2.4

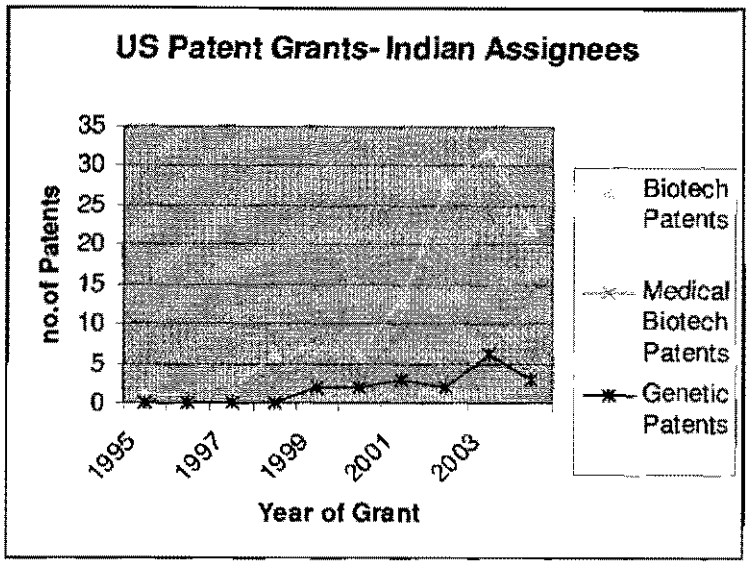


Table 2.4 and Graph 2.4 show patent grants at USPTO from 1995 to 2004. As seen in the table, the number of patent grants to Indian Assignees has picked up dramatically from the year 1995. The number of patents increased from 16 in 1995 to 227 in 2004, which is an increase of 151.2 percent. The number of biotech and medical biotech patents started picking up in the year 1996. They rose from 1 in 1996 to 22 in 2004 for biotech and 1 in 1996 to 14 in 2004 for medical biotech. That is an increase of 1100 percent in biotech and 700 percent in medical biotech. The increase in patent grants indicates increase in R and D and inventive activity in biotechnology generally and in the field of medical biotechnology specifically. It also indicates increase in business interest and activities of Indian organizations in USA. Table 2.4 and Graph 2.4 show patent grants at USPTO from 1995 to 2004. As seen in the table, the number of patent grants to Indian Assignees has picked up dramatically from the year 1995. The number of patents increased from 16 in 1995 to 227 in 2004, which is an increase of 151.2 percent. The number of biotech and medical biotech patents started picking up in the year 1996. They rose from 1 in 1996 to 22 in 2004 for biotech and 1 in 1996 to 14 in 2004 for medical biotech. That

is an increase of 1100 percent in biotech and 700 percent in medical biotech. The number of gene patent grants increased from 2 in 1999 to 6 in 2003, which is an increase of 150 percent. The increase in patent grants indicates increase in R and D and inventive activity in biotechnology generally and in the field of genetics specifically. It also indicates increase in business interest and activities of Indian organizations in USA. As the number of patent grants in genetics has increased multifold after 1999, it can be said that genetics as a field and industry has been progressing rapidly in India.

Size of Patent/Public Domain

As discussed in the earlier chapter, public domain is as important as the patent regime for promoting progress of science and technology and the size of public domain varies with changes in size of patent domain. As soon as a patent is granted an invention enters into the patent domain of countries in which a patent is granted. In countries where a patent is not granted, the invention enters into the public domain as soon as the application or the patent is published in the other country. So, if patent is granted in one country and not in another, the size of public domain is larger in the country in which a patent is not granted. This entry of invention into the public pool of knowledge in a country enables the people to use the patent and develop over it without any liability. However, in the first country where a patent is granted the technology relating to the invention cannot be developed because the invention is blocked from public use. When it comes to individual organizations, they generally apply for patents only in countries in which they have business interests. By doing so, they create patent domains in countries in which they get a patent grant and they add to the public domain in others. So, each organization plays a role in defining the progress of science and technology by determining the size of public and patent domains in different countries. This analysis is based on the assumption that the factors under

patent law that influence the size of public domain like, patentability requirements, research exemptions, compulsory licenses, etc are constant in all countries.

The table below shows the comparison between patents granted to different organizations in biotechnology and medical biotechnology at USPTO, EPO and IPO. The organizations consisting of companies and research institutes have been isolated from the top patent holders at USPTO. The search for Indian patents was done on Esp@cenet's worldwide database based on the OECD biotech patent classification. As only the publication date was available, the statistics have been generated using patent publication date as the reference point.

Table 2.5

Patents to Indian Companies/Research Institutes

ame of the company /Institute	US Biotech Patents	EPO Biotech	IPO Biotech	Total Biotech Patents	US Medical Biotech Patents	EPO Medical Biotech	IPO Medical Biotech	Total Medical Biotech Patents
ovt. Research Institutes								
ouncil of Scientific and Industrial esearch	114	32	109	255	81	22	85	188
ational Institute of Immunology	8	2	9	19	6	1	6	13
niversity of Delhi	2	3	2	7	1	1	2	4
l India Institute of Medical ciences	1	2	1	4	1	2	1	4
epartment of Biotechnology	1	0	1	2	1	0	1	2
ational Institute of Cholera and nteric Diseases	1	1	0	2	1	1	0	2
ndian Council of Medical Research lew Delhi, IN)	1	0	0	1	1	0	0	0
aharashtra Association for the ultivation of Science	1	0	0	1	1	0	0	1
ational Diary Development Board	1	0	0	1	1	0	0	1
OTAL	130	40	122	292	94	27	95	216

Companies								
Biocon India Limited	3	5	5	13	1	1	1	3
Dabur Research Foundation	4	0	0	4	4	0	0	4
Vittal Mallya Scientific Research Foundation	2	0	1	3	2	0	0	2
Bharat Biotech International Limited	2	1	0	3	2	1	0	3
Panacea Biotec Limited	2	0	0	2	2	0	0	2
Cadila Pharmaceuticals, Ltd	1	1	0	2	1	1	0	2
Proalgen Biotech Limited	1	0	1	2	1	0	1	2
Orchid Chemicals & Pharmaceuticals Ltd.	1	0	0	1	0	0	0	0
TOTAL	16	7	7	30	13	3	2	18

The table shows that government sponsored research institutes hold 292 biotech patents out of 322 patents held by a select sample of top patent holders at all USPTO, EPO and IPO put together. This reflects the fact that most biotech research activity in India is carried out by government organizations and that the government is providing strong initiatives for research at public institutes. Among the research institutes, CSIR holds 255 patents, which forms 79.2 percent of total biotech patents. This is an indication that research among government institutes is lead by CSIR. Biotech companies as can be seen from the table hold just 30 out of 322 biotech patents, which is a very minimal amount. This indicates that companies carry out not much biotech research.

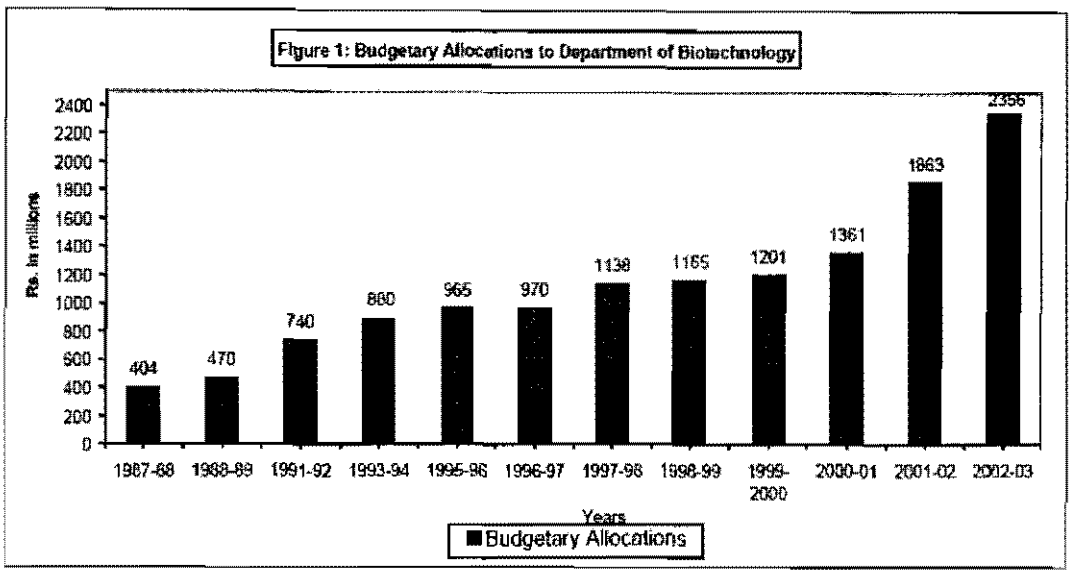
The table shows great variability in number of patents granted to organizations at different patent offices, which is an indication of variability of patent and public domains generated by each of them. It also reflects variability of business activities of different organizations in different countries. While CSIR holds 114 and 109 patents at USPTO and IPO, the number of patents held at EPO is just 32. The numbers indicate that the size of patent domain created by CSIR is big in USA and India when compared to EU, which means that EU has a bigger public domain than the other two countries.

Another organization Panacea Biotech holds 2 patents in USA and no patents in India and EU, which means that the company creates a patent domain and has business activities only in USA and those patents are in the public domain in other countries. There are other organizations in the table such as Biocon, which holds 5 biotech patents in USA and EU and only 3 in India. This indicates that the size of patent domain created by Biocon in India is smaller than in other countries. Assuming that the costs of patenting can be borne by all companies, the number of patents granted to each company reflects the business interests of different organizations in different countries and their role in creating patent or public domains.

To summarize, the statistics analyzed in this chapter indicate that:

a. R and D activity and inventive activity in genetics is on the rise in India.
b. Indian Organizations have biotech business activities in US and EU apart from India, which is variable,
c. The biotech research in general and genetic research in particular, initiative in India is led by government research institutes headed by CSIR,
d. Government is providing strong initiatives for biotech and specifically genetic research and
e. The size of patent domain and public domain is variable in different countries based on patent grants at different patent offices.

Biotech R and D and inventive activity has been on the rise in India due to initiatives provided by the Indian Government. The initiatives taken by the government is reflected in the graph below, which shows the allocation of funds to department of biotechnology.



Source: RIS Discussion paper, Status and Development of Biotechnology: An Analytical Overview, Sachin Chaturvedi, RIS-DP No. 28/2002.

The Department of Biotechnology, which is a part of the Ministry of Science and Technology, has been given the responsibility of carrying out R and D activities in Biotechnology. The Government of India increased the budgetary allocation to Department of Biotechnology from 404 million rupees in 1987-88 to 2,356 million rupees in 2002-03. The graph shows that the government has been consistently increasing the funds for biotechnology from 1987 to 2003. This indicates that the Government of India has been providing good financial incentives for the development of the field.

As a result of the financial and other initiatives of the government there is an increase in patent grants, which indicate progress of biotechnology as a field. In order to enable the already growing biotech industry to play a major role in the global market, the Indian government should take all necessary steps to promote progress from the patent perspective. As the size of public domain is as important as the patent domain to promote the progress of any field, the government has to ensure that the size of Indian patent or public domain in genetics are in synchrony with the domains of other countries. It has to ensure that the sizes of patent and public domains are in such balance that they would ensure optimal progress of genetics in India.