Lecture 42
Scientific Knowledge in India: From Public Resource to Intellectual Property

Patent Law and Changes in Scientific Research in India

This lecture introduces patents given their relevance in the context of research in plant molecular biology in India today. Other relevant types of IPR such as plant breeders' rights and geographical indications are discussed briefly.

India has been in the peculiar position of having had a much longer experience with the patents system than some European countries because colonial rulers introduced a patent regime in the nineteenth century. The last colonial piece of legislation in this field was the Patents and Designs Act 1911, which was still in force at Independence (Cullet 2005: 72). The Government of India after Independence decided that the Act that was closely modeled on laws applicable in England had to be comprehensively reworked because it was deemed inappropriate to realise the economic development goals of India. This was due to the fact that the Colonial Act had failed to stimulate invention by Indian citizens and to encourage the development and exploitation of new inventions for industrial purposes in the country so as to secure benefits to the larger section of the people (Dhavan, *et al.* 1991). This was, for instance, reflected in the fact that the 1911 Act had led to a situation where 90 per cent of Indian patents were held by foreigners and about 90 per cent were not worked in India (cited in Cullet 2005: 72).

The first committee, the Tek Chand Committee, was set up to inquire into the usefulness of the 1911 Act for India and delivered an interim report in 1949. Further work was carried out in this area by Justice Ayyangar who delivered a comprehensive report in 1959. His basic finding, which followed the views of the Tek Chand Committee, was:

> The Indian patent system has failed in its main purpose, namely to stimulate invention among Indians and to encourage the development and exploitation of new inventions for industrial purposes in the country so as to secure the benefits thereof to the largest section of the public (Justice N. Rajagopala Ayyangar, Report on the Revision of the Patents Law 11 (September 1959).

Justice Ayyangar did not propose the abolition of the patent system because despite the handicaps which the system involved for developing countries, he could not see an alternative method for achieving better results. As a result, he recommended the maintenance of the existing basic system but was aware of the introduction of stringent limitations on the scope of patentability and stated, for instance, that patentability should not be accepted where this would be detrimental to national health or well-being. One of the questions, which he addressed in detail, was the issue of patentability in food and medicine related areas of technology and proposed to prohibit patentability for products in these two areas. This was based partly on a

comparative analysis of other countries, which showed even most developed countries had restrictions in place in this field. Further, from a domestic point of view, he argued that the denial of product claims was necessary so that important articles of daily use such as medicine or food

> which are vital to the health of the community should be made available to, everyone at reasonable prices and that no monopoly should be granted in respect of such articles. It is considered that the refusal of product patents would enlarge the area of competition and this result in the production of these articles in sufficient quantity and at the lowest possible cost to the public (*Ibid*.).

As a result of the Ayyangar report and other consultations, the patents regime was eventually modified in an attempt to make it fit the developmental priorities of the country.

The Indian Patents Act 1970

The Patents Act 1970 introduced a system that was largely modeled after the erstwhile existing laws and treaties. However, at the level of the scope of protection, the 1970 Act introduced a number of significant exceptions. First, it generally excluded the patentability of life forms and specifically precluded the patentability of methods of agriculture and horticulture (Section 3, Patents Act 1970). Secondly, the Act rejected the possibility of granting patents in respect of substances intended for use as food, medicine or drug (Section 5, Patents Act 1970). Drugs were deemed to include insecticides, germicides, fungicides and herbicides and all other substances intended to be used for the protection or preservation of plants (Section 2, Patents Act 1970). Thirdly, the Act introduced a distinction between product and process patents in the fields of nutrition and health. While product patents were excluded, process patents were allowed.

The Act also discriminated between different types of inventions with regard to the rights conferred. While the normal duration of patent rights was fourteen years, it was of a reduced period of seven years with respect to processes of manufacture for substances intended for use of food, medicine or drug (Section 53, Patents Act 1970). Further, the Act included a series of measures restricting the rights of patent holders, in particular to encourage use of the invention in India (Chapter XVI, Patents Act 1970 concerning compulsory licences and licences of right). Thus, the Act specifically indicated that the general principles governing the use of patents were that:

(a) patents are granted to encourage inventions and to secure that the inventions are worked in India on a commercial scale; and
(b) they are not granted merely to enable patentees to enjoy a monopoly for the importation of the patented article (Section 83, Patents Act 1970).

This constitutes the basis for the compulsory licence regime. Under the Patents Act 1970, a compulsory licence could be granted upon application, if after three years it was shown that the reasonable requirements of the public with respect to the patented

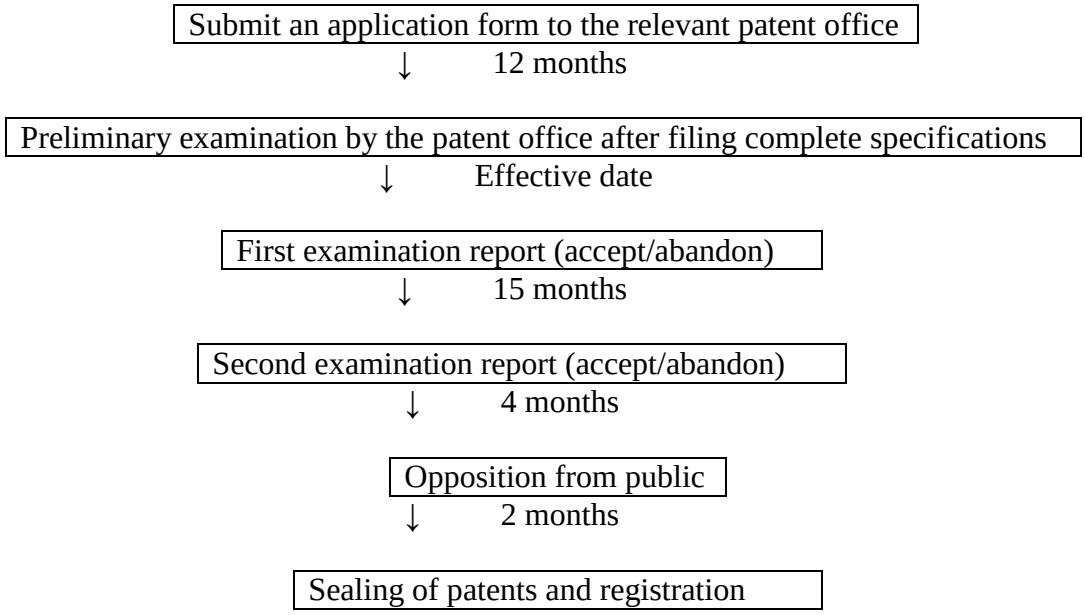
invention were not satisfied or that patented invention was not available to the public at a reasonable price (Section 90, Patents Act 1970).

In this context, the specificity of the Act was the introduction of "licences of right". This constituted a stronger form of compulsory licensing where the government could directly request after three years from the Controller General of Patents that s/he should endorse the patent with the mention "licence of right", if the reasonable requirements of the public were not met or if the patented invention was not available to the public at a reasonable price (Section 86, Patents Act 1970). This endorsement then gave anyone interested in working the patent the right to ask the patent holder for a licence on terms that had to be mutually agreed (Section 88(1), Patents Act 1970). An even stricter regime was put in place for patents relating to food, medicine or drugs. In this case, all patents were automatically deemed to be endorsed with the mention "licence of right" at the expiration of period of three years (Section 87, Patents Act 1970). Further, the Act provided the ultimate penalty of patent revocation where compulsory licences and licences of right failed to achieve the goal of meeting the reasonable requirements of the public. An application for revocation could be made after the expiration of a period of two years from the date of the grant of a compulsory licence or licence of right (Section 89, Patents Act 1970).

Procedures to File a Patent

The inventor has to file a patent in the concerned regional office in the country in case of national patents. With regard to international patents, the guidelines and requirements of the country in which patenting is proposed must be thoroughly understood and then proceeded. The procedures, fee and the duration required, etc. vary from country to country. Publication in the gazette and inviting opposition to the patent from public also differ between countries. A flow chart of patent application and its sealing (approval) in India is given below with approximate time taken for each step.

Figure 1 Filing a Patent in India – The Flow Chart



The Indian Patents Act 1970 was quite different from the Western patent model of the time. In retrospect, it was a model that took effective notice of the interests of developing countries. It is even more interesting because most of the exclusions in the field of health and food were significant, as these fields are directly connected to the fulfilment of basic needs. The system put in place specifically sought to discipline the prices of essential commodities such as food and medicine to ensure their availability to the greatest number (Sahai 1993). The rationale of the Patents Act 1970 was to promote the growth of the domestic industry at the expense of foreign companies but especially in fields related to basic needs, it specifically sought to control the monopoly rights conferred on domestic producers.

There is a consensus that this strategy was of the Indian Patents Act 1970, for instance, largely successful in the pharmaceutical sector. The associated measures such as price control have had a number of positive impacts on access to drugs. First, relative drug prices have decreased significantly since the 1960s compared to other countries (Cullet 2005: 76). While drug prices in India were among the highest in the world after Independence, they are now among the lowest (Chaudhri 1997). Secondly, the Patents Act also constituted the bedrock of the growth of the domestic pharmaceutical industry that had remained relatively small even after two decades after Independence, and by 1970 only accounted for about 25 per cent of the domestic market. The restrictions on product patents, prices and foreign investment contributed to the rapid development of the industry, which now accounts for 70 per cent of bulk drugs and meets nearly all the demand for formulations (Department of Chemicals and Petrochemicals, Annual Report 1999-2000). Thirdly, some of the local companies have developed sufficient expertise to produce their own new medicines. This does not mean that the patent system introduced in the 1970s managed to solve the problem of access to drugs for all, which is related to socio-economic conditions. Some recent estimates indicate that only 20 per cent of the population has access to all the essential drugs they need (*Ibid.*: 2004-2005).

The Patents Act 1970 in the TRIPS Era

After the adoption of the Patents Act 1970, there was no further major policy debate concerning the patents system partly because the system was seen to provide a suitable compromise and partly because civil society also made the link between patents and sustainable development concerns. In any case, national policy developments in the field of patents were undermined by international policy developments in the form of the negotiations and subsequent adoptions of the TRIPS Agreement. By signing the TRIPS Agreement, the government committed itself to a complete change of patent policy that amounts in part to a return to the pre-1970 regime. This is significant because the changes envisaged by the TRIPS were not meant to initiate full policy debates at the national level.

In fact, there was not only a lack of policy debate but also a lack of congruence between the commitments taken by the government and Parliament's position on attending the patents regime. The divergence came out clearly as soon as Parliament got its first opportunity to debate the TRIPS Agreement. Though this was after the government had ratified it, Parliament refused to endorse the set of changes that were required as of January 1, 1995 for TRIPS compliance. Interestingly, the changes were linked to India's special treatment under the clause allowing a longer implementation period for introducing product patents where there were specific restrictions in place before the adoption of the TRIPS Agreement. In exchange for this special exemption, India had to introduce from 1 January 1995 a system for the filing of applications for product patents in the field of health and genetic engineering. The government tried to submit a proposal for amending the Patents Act. However, the Bill failed to pass in the Rajya Sabha. This led to the promulgation of the Patents (Amendment) Ordinance 1994 on 31 December 2004 to amend the Patents Act to provide filing and handling of patent application for pharmaceutical or agricultural chemical products. The Ordinance lapsed in March 1995.

The lapse on the part of the Parliament to adopt an amendment to the Patents Act resulted in India being the first country to be targeted in the WTO dispute settlement system in the context of the implementation of the TRIPS Agreement. Having lost patience, the US Government filed a complaint with the WTO Dispute Settlement Body alleging that India did not have in place a mailbox system corresponding to the requirements of Article 70(8) of the TRIPS Agreement. India argued that despite the lack of appropriate legislation, it was offering in practice a mailbox. However, the WTO Panel and the Appellate Body concluded that India had failed to comply with its obligations under Articles 65 and 70(9) of the TRIPS Agreement. This was followed by another complaint by the European Union that led to a similar report. One of the direct outcomes of the dispute settlement procedures was that India and the US agreed that India should be given until April 1999 to implement the conclusions of the Appellate Body's report of December 1997.

This led to two significant developments. First, the government decided in 1998 to accede to the Paris Convention. This largely constituted a political move to reaffirm India's commitment to the international IPR regime and to enhance India's image towards foreign investors. This is due to the fact that by joining the Paris Union after having ratified the TRIPS Agreement, India did not take on added international

commitments. Secondly, in view of the April 1999 deadline, the government tried again in December 1998 to submit an amendment to the Patents Act 1970 modeled after the failed 1994 amendment. Following its failure to see the amendment through by the end of the winter session of Parliament, the government promulgated in January 1999 another temporary Ordinance. Finally, hardly less than a month before the 19 April 1999 deadline for compliance with the WTO decision, both houses of Parliament adopted the amendments necessary to put India in compliance with its TRIPS obligations.

The Patents (Amendment) Act 1999 introduced two main changes to the Act. First, it introduced a new sub-section to section 5 prohibiting product patents on medicines or drugs. The new clause left the prohibition untouched but permitted the filing of a patent claim. Secondly, patent applications for food or health related products had to be dealt with according to a new Chapter IV A, which set out the specific conditions under which this was to take place and provided for the grant of exclusive marketing rights as called for the TRIPS Agreement [see Patents (Amendment) Act 1999].

While the adoption of the 1999 amendments proved to be a lengthy process, it constituted only a tiny part of the overall changes that had to be put in place for TRIPS compliance. Since India had to comply with most of its other obligations by 1 January 2000, this led to the introduction of another proposed set of amendments in December 1999 (Ibid.). These amendments were referred to a Parliamentary committee that studied the proposed changes for the period, 1999-2002. Eventually, the amendments proposed by the government in 1999 were adopted without major changes in 2002.

The Patents (Amendment) Act 2002 and the Patents (Amendment) Ordinance 2004

The amendments adopted in 2002 have removed most of the elements that gave the Patents Act 1970 its specificity. The most important impact of these changes is to have clearly shifted the balance between the interests of patent holders and the interests of the society, at large in favour of the patent holders. Some of the changes include the increase of the duration of protection to uniform 20-years, thereby increasing significantly the average duration of protection and removing the discrimination put in place in the case of process patents in the fields of health and nutrition where the term was of only seven years. The amendments have removed altogether licences of right from the Act at the level of the sections governing the working of patents.

Amidst changes, which significantly reinforce the position of patents holders, the amendments also seek in some respect to limit the rights of patent holders. The specific flexibility offered by the TRIPS Agreement has, for instance, been used in several cases. The environmental and health exceptions authorised by Article 27(2) of the TRIPS Agreement are, for instance, drafted into section 3(b). Similarly, a new section 3(j) uses all the exceptions allowed under Article 27(3) of the TRIPS Agreement. Further, the amendments seek to provide as extensive as possible a scope for section 5 that restricts patentability to process patents by specifying that the

chemical processes referred to also include biochemical, biotechnological and microbiological processes.

In this context, the question of the protection of plant varieties requires to be addressed. The revised section 3(j) specifically rejects the patentability of seeds and plant varieties. However, Article 27(3) b requires protection for plant varieties. This is one of the few areas where governments can choose the protection system that they want to introduce through the sui generis option. In this case, the government decided to use this option and choose to draft a separate Act for this purpose. The Plant Variety Protection Act that introduces plant breeders' rights and farmers' rights in the legal system is analysed separately in Chapter 8 of the Patents (Amendment) Ordinance 2004.

The amendments also seek to provide answers to some of the new issues facing the patent system. The amendments provide at least a partial answer to biopiracy concerns by requiring the disclosure of the source and geographical origin of the biological material used in a claimed invention [see Section 10, Patents Act 1970 (as amended up to 2002)]. This is supplemented by a provision that makes the failure to disclosure the source and geographical origin of the biological material used a ground for opposing the grant of a patent [see Section 25(j), Patents Act 1970 (as amended up to 2002)]. The Act also indirectly addresses questions related to traditional knowledge protection by denying the patentability of traditional knowledge [see Section 30(p), Patents Act 1970 (as amended up to 2002)]. In other areas, the Act seeks to use some of the restrictions that have been put in place in other countries. Thus, the Act now allows generic producers to get ready for marketing their products immediately after the patent expires, thereby reducing the time lag between patent expiration and availability of generics [see Section 107A, Patents Act 1970 (as amended up to 2002)].

With regard to compulsory licences, the amendments seek to strengthen the overall framework for compulsory licensing. Section 83 specifically mentions that patents granted should not "impede public health", should not prohibit the Central Government from taking up measures to protect public health and that patents should be granted to make the benefits of the patented invention available at reasonably affordable prices to the public[1]. In this context, the compulsory licensing regime requires to be discussed at length and in detail. First, this is the only place in the Act where a specific attempt has been made to make TRIPS responsive to domestic needs and priorities. Secondly, compulsory licensing enables the government to enhance the access to processes and/or products. In this context, it is important to note that the amendments in TRIPS Agreement stop short of proposing clauses like compulsory licensing in relation to TRIPS flexibility as guiding principles for the whole Patents Act. If a real attempt would be made concerning TRIPS flexibility, this would allow the Patents Office to use similar criteria in examining patent applications. The revised act – amendments made in 2002 in TRIPS Agreement – only proposes to apply flexibility at the level of the implementation of already granted patents and thereby restricts the potential effectiveness of the proposed clauses. Thirdly, it is doubtful whether focusing on compulsory licensing as the main tool to redress the perceived inequities of the international patent system constitutes an appropriate strategy. As

Abbott (2002) puts it, 'Experience does not seem to show that compulsory licensing is a tool, which can be used effectively by developing countries'.

The 2002 amendments were followed by a set of amendments, which were required to put India in compliance with its obligation to introduce product patents in the health and food sectors as of 1 January 2005. A Patents (Amendments) Bill 2003 was introduced at the end of 2003, which was not passed by Parliament and has been dealt with by the Government of India. In December 2004, while the Bill was not reintroduced in Parliament, the government promulgated a temporary Ordinance after the end of the parliamentary session that had the effect of putting India in compliance with its TRIPS obligations by the imposed deadline, though this is only on a temporary basis[2]. For this reason, a bill was introduced on 1 January 2005 for effective compliance with the TRIPS Agreement.

The Patents (Amendment) Act 2002 and the subsequent changes are significant because they are likely to have completely reoriented the patent regime. To a large extent, it deviates on a number of important provisions adopted in the Patents Act 1970 as a result of the policy debates that took place after India's Independence. The significance is not so much linked to the fact that changes have been adopted, a prerogative to any sovereign government but to the fact that these changes have been adopted largely on the basis of international commitments taken under the TRIPS Agreement whose policy implications were not debated in Parliament before its adoption in 1994. While socio-economic conditions have significantly changed since the 1959 Ayyangar report, as mentioned earlier, some of the basic challenges such as access to food for all and access to medicines for all are far from solved. Futher, there has been no change in domestic or international provisions regarding the fundamental rights to health or to food, which could provide a policy basis for changing the patents regime. The rationale for doing away with the restrictions on the rights of patent holders in fields linked to basic food and health needs is, therefore, far from obvious.

Table 1 Indian Patents Sealed by Indian and Foreign Inventors

Patents Sealed			
Year	**Indian**	**Foreign**	**Total**
1975-76	426	1894	2320
1976-77	928	1964	2892
1977-78	657	1857	2514
1978-79	281	499	780
1979-80	516	1657	2173
1980-81	349	670	1019
1981-82	421	936	1357
1982-83	405	822	1227
1983-84	340	980	1320
1984-85	263	1206	1469
1985-86	451	1500	1951
1986-87	532	1594	2126
1987-88	588	1516	2104
1988-89	795	2585	3380

1989-90	519	1371	1890
1990-91	379	1112	1491
1991-92	551	1125	1676
1992-93	251	1021	1272
1993-94	442	1304	1746
1994-95	476	1283	1759
1995-96	415	1118	1533
1996-97	293	614	907
1997-98	619	1225	1844
1998-99	645	1155	1800
1999-2000	557	1324	1881
2000-01	399	919	1318
2001-02	654	937	1591

Source: 1. Controller General of Patents, Designs and Trade Marks (2002)

2. Science & Technology, Data Book, Government of India, Ministry of Science and Technology, Department of Science and Technology, New Delhi (March 2004)

Table 1 indicates that the number of patents filed by foreign inventors is much higher than that by Indian inventors, which implies that more and more foreign direct investment is coming into play in the fields of R&D in India. This may ultimately not only result in declining public investment in R&D in India but also weakening the domestic economy, as a whole. Though the TRIPS Agreement provides a set of minimum standards for patentability below which the member states of the WTO cannot go, this limits, for instance, the opportunities that countries previously had to restrict patentability in certain specific fields such as health and food.

There were 669 patents that were granted to the organisations in India during 1990-2002. Table 2 depicts the Indian patenting activity during the pre-WTO (1990-94), post-WTO (1995-98) and the current period (1999-2002).

Table 2 India Owned Patents (IOP) during the Pre/Post-WTO and the Current Period

Different Phases	Number of Patents Filed
1990-94	50
1995-98	127
1999-2002	492
Total	**669**

Table 2 indicates significant patenting activity in the current period (1999-2002). Out of 669 patents, 492 (74 per cent) patents were granted in the current period. Further, it would be pertinent to note that patenting activity in India is on rise since the Government of India became signatory to the WTO on the IPR on January 1, 1995.

Only a few organisations are involved in patenting activity in the United States Patent and Trademark Office (USPTO). The Indian Patenting Activity in International and Domestic Patent System: Contemporary Scenario (2005), a report by the National Institute of Science, Technology and Development Studies (NISTADS), New Delhi mentions that 93 entities are granted patents during the period, 1990-2002. In comparison to other entities, industry is most predominant. Overall, 73 firms are involved in patenting activity. Among other organisational types involved in patenting activity, 10 are research institutes, seven universities and two are from ministries/departments (non-scientific ministries) and one specialised research institute. Table 3.4 illustrates the number of distinct organisations entering in each period. The increase in the number of new organisations that are involved in patenting activity in the current period (1999-2002) is highlighted in Table 3.

Table 3 Organisations in India involved in Patenting Activity during the Pre/Post-WTO and the Current Period

Period	Research	Industry	University	Special Institute	Other Ministries/ Departments
1990-94	2	11	1	--	--
1995-98	3	21	1	--	1
1999-2002	8	52	5	1	1

Out of 73 industrial firms, there are 59 Indian private industries, nine MNCs and five public-sector undertakings (PSUs). Pharmaceutical and biotechnology firms are predominantly involved in patenting activity. Among 73 industrial firms, there are 23 firms in the "pharmaceutical" and/or "biotechnology" sector. Only seven universities in India are involved in patenting activity during the period, 1990-2002. Even institutions of excellence like IITs were not granted any patenting activity. Further, major scientific agencies such as the ICAR and the DAE had no patents granted during this period.

Further, patenting activity across organisations in India exhibits a skewed pattern. Fifty organisations possess only one patent, and fifteen organisations possess only two patents for the overall period, 1990-2002. This indicates that for a considerably large number of organisations in India, patenting in the US is only a one-time activity. Only eight organisations in India have more than ten patents during the entire period. These eight organisations account for 522 patents (80 per cent) of the total number of patents granted. These organisations classified as prolific organisations comprise four from industry, two research institutes and one public-sector undertaking. Even within these eight organisations, the patenting activity is skewed that can be judged by the fact that the Council of Scientific and Industrial Research (CSIR) accounts for 378 patents.

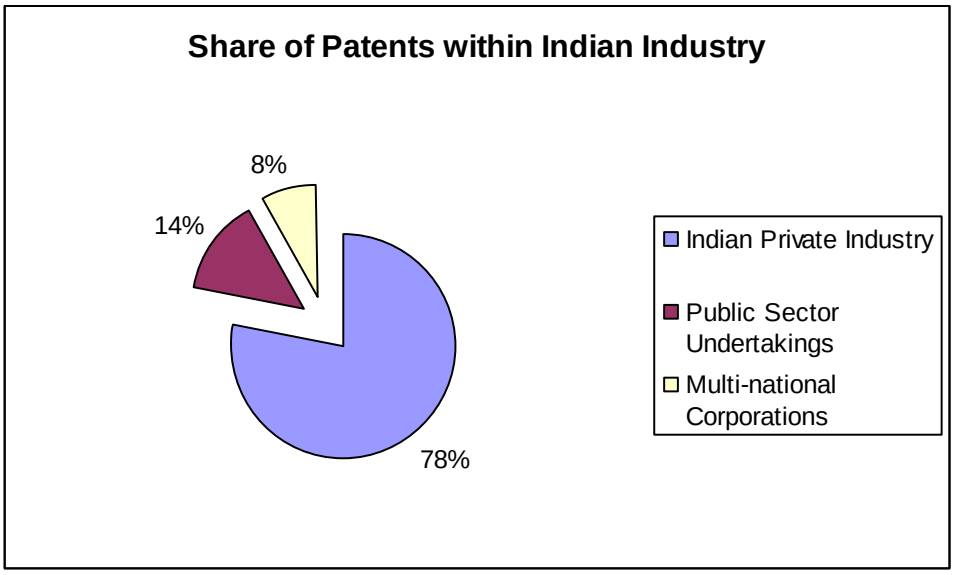
The broader classification of research institutions under scientific agencies highlights the stark contrasts. Among scientific agencies, except for the CSIR with 378 patents, the other scientific agencies have a limited role in the patenting activity in the USPTO. Table 4 presents the patenting activity by different scientific agencies. Patents shown by the DBT and the DST are also likely to have originated from research organisations that are affiliated to them.

Table 4 Patents by different Scientific Agencies in India

Scientific Agencies	Number of Patents
Council of Scientific and Industrial Research (CSIR)	378
Department of Biotechnology (DBT)	18
Department of Science and Technology (DST)	10
Defence Research and Development Organisation (DRDO)	6
Indian Council of Medical Research (ICMR)	2
Department of Space (DoS)	1

The other scientific agencies namely the Department of Electronics (DoE), the Department of Atomic Energy (DAE) and the Indian Council of Agricultural Research (ICAR) had no patents granted during the entire period, 1990-2002. Further, only a few firms account for majority of the patents within the industry. Indian private industries have the major share, as they account for 201 (78 per cent) of total (258) patents are granted to industries. The PSUs and MNCs account for 36 (14 per cent) and 21 (8 per cent) patents respectively. The share within the Indian industry is highlighted in Figure 2.

Figure 2 Share of Patents within Indian Industry



We observe that patenting activity is moderate to insignificant in the other sectors, apart from pharmaceuticals and chemicals. Firms in developing countries including India have dominated innovations in biotechnology with extensive patenting. These innovations possess a high degree of science linkages and joint partnership between

industry and university. Table 3.6 indicates the details of the patenting activity in the three defined time periods: pre-WTO (1990-94), post-WTO (1995-98) and the current period (1999-2002).

Table 5 Indian Patenting Activity in Major Sectors during Pre/Post-WTO and the Current Period

Sectors	1990-94	1995-98	1999-2002	Total (1990-2002)
Pharmaceuticals	9	48	227	284
Chemical	24	42	166	232
Miscellaneous	8	15	42	65
Biotechnology*	--	7	46	53
Machinery	7	6	15	28
Instruments	--	5	13	18
Electronics	--	2	7	9
Transport	--	--	6	6
Electrical Equipment	--	--	1	1

* Patents in biotechnology are culled out from other sectors (primarily they were in the pharmaceutical sector).

Notes and References

[1] See Section 83(d), (e) and (g), Patents Act 1970 (as amended up to 2002).
[2] The Patents (Amendment) Ordinance 2004, Ord. No. 7 of 2004.