DESIDOC Bulletin of Information Technology, Vol. 27, No. 6, November 2007, pp. 31-39

Patenting in Biotechnology

Sujit Bhattacharya

National Institute of Science, Technology and Development Studies
Pusa Gate, Dr K.S.Krishnan Marg, New Delhi-110 012
E-mail: Sujit_academic@yahoo.com

ABSTRACT

The paper discusses the patentability of the biotechnological inventions and the international requirements and issues that emerge in addressing patenting of life forms and how they are resolved. It analyses the international patenting trends, patents that have significant impact and countries active in patenting. It also examines Indian patenting activity and its comparison with international trends to assess the Indian efforts.

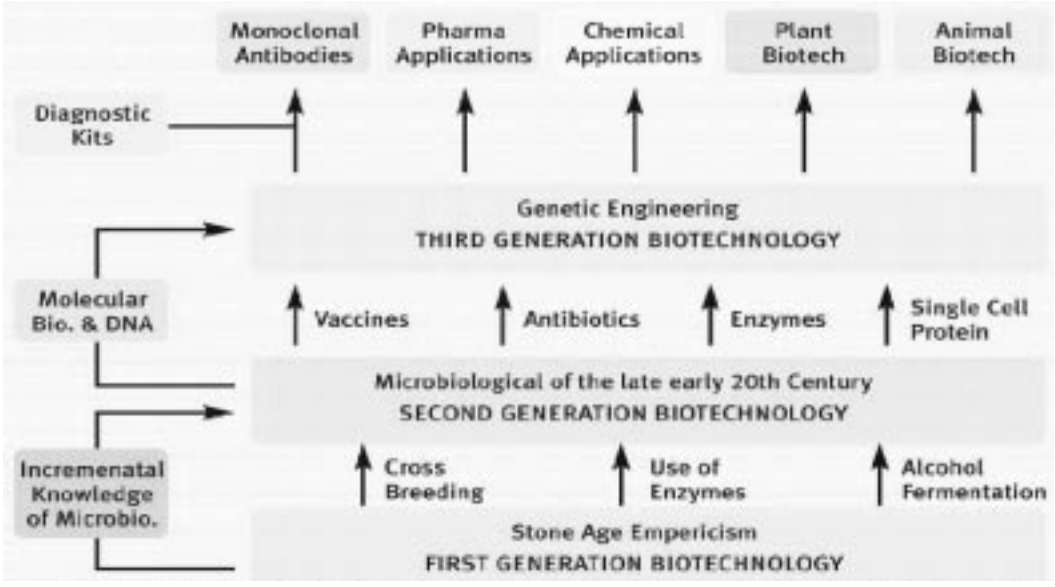
Keywords: Biotechnology, microorganisms, genetic engineering, plant gene, WTO, TRIPs

1. INTRODUCTION

Biotechnology comprises any technology that uses living entities, in particular animals, plants or microorganisms. According to the Organisation for Economic Cooperation and Development (OECD) biotechnology includes any technique that uses living organisms (or parts of organisms) to make or modify products, to improve plants or animals, or to develop microorganisms for specific uses[1].

The biotechnological inventions can be classified broadly into the following categories: (a) inventions relating to an organism or material such as living entities of natural or artificial origin (animals, plants, and microorganisms), biological material (plasmids, viruses and replicas, and parts of organs, tissues, cells, and organelles), and naturally occurring substances from living entities, biological material and parts thereof; (b) inventions relating to the process for the creation of a living organism or production of other biological materials; and (c) inventions relating to the use of such organisms or biological materials. Figure 1 illustrates the domain of biotechnological research and its application areas.

Biotechnology in industry mainly comprises chemical or pharmaceutical substances or processes pertaining to the plant and animal kingdom. Its pharmaceutical applications include production of regulatory protein, blood products, vaccines, antibiotics, monoclonal antibodies, and DNA hybridisation probes. Biotechnology has contributed to the diagnosis, prevention and control of animal diseases, animal nutrition and growth promotion, and genetic improvement of animal breeds. In plant kingdom, it has led to the improvement of specific plant species, and use of microorganisms for crop improvement. Its aquaculture applications include use of marine microorganisms with unusual capabilities, fish culturing, and prevention and control of



Source: Sharpe, M. et al.

Figure 1. The development of biotechnology.

fish diseases. Environmental applications of biotechnology include pollution control and toxic waste treatment, microbial mining and microbial enhanced oil recovery. In electronics, biotechnology has led to bioelectronics, e.g., biosensors and biochips.

Genetic engineering has emerged as the most important areas of research. Essentially, it is only one possible method, for artificial modification of the hereditary material of animals, plants, and microorganisms. It makes the practical use of the fact that genetic make up of all living things, from the most primitive viruses through the entire plant and animal kingdom to mankind, is determined by the sequence in which just four nucleic acids are arranged in their DNA. Today, molecular biologists can not only identify these sequences and decipher (determine) their biological function, but also intervene to modify or clone one genotype, isolate individual genes and also transfer them to bioreactors. Many biotech patents are directed to specific proteins and the DNA that codes for the protein. Important breakthroughs have happened in genetic engineering with some of them being granted patents also[2,3]. A few of these have been elicited below:

- Genetically engineered bacterium capable of breaking down multiple components of crude oil. This bacterium was granted patent by the United State Patent and Trademark Office (USPTO) in 1980. This invention had 36 claims.
- Cloned sheep (Dolly).
- Genetic modification of mouse to make it susceptible to breast cancer and, therefore, particularly suitable for testing cancer drugs. The invention was granted US patent (4,736,866) in 1988 to Leder and Stewart of Harvard College. This patent had 12 claims and was licensed to DuPont.
- Tracy, a sheep whose germ line contains a genetic construction comprising a human gene plus 'promoter'. Tracy's milk glands produce proteins identical to human ones, which can then be removed from the milk by using known processes. Proteins that can be extracted are human insulin, tissue plasminogen activator and alpha antitrypsin—a very important drug for treating mucoviscidosis (severe lung function impairment).
- Control of plant gene expression. A broad patent (55 claims) covering genetically modified plant was granted US patent (5,723,765) in 1988 to the US inventors. Essentially, this is a method of creating transgenic plants wherein expression of

certain plant traits could be externally controlled.

- Corn, alfa-alfa, radicchio, cotton seed, soyabean, tomato are some of the common food items that have been genetically modified.

2. PATENTING OF BIOTECHNOLOGICAL INVENTIONS

Strong intellectual property rights (IPRS) in biotechnology are of critical importance for the continuous growth of the biotechnology industry. Significant investment in the biotechnology has been attributable to the patenting system which first officially started to allow patents for living matter such as microorganisms in 1980 [Diamond vs Chakrabarty (1980) 26 USPQ 193 changed the direction of patent laws in the US by holding claim to a bacterium valid. In essence, Chakrabarty developed a genetically engineered bacterium capable of breaking down multiple components of crude oil]. Biotechnology has emerged as one of the most important domain of patenting. It is also one of the most important area of conflict between developing and developed economies.

Some of the biotechnological domains being patented today are: genetic engineering process; method of producing organisms; method of isolation of microorganisms from culture medium; method of mutation; biologically pure cultures; mixed cultures; Eukaryotic cells; tissue or organ cultures; mutants; transformants; plasmids; process for making monoclonal antibodies; and cell lines for making monoclonal antibodies. However, patenting has also raised important issues. For example:

- A number of very basic inventions, fundamental methods, research techniques and tools significant for product development, have been made and granted patents[4].
- In many cases, there were initial doubt about patentability, but the doubts have regularly been resolved in favour of patentability [at least by the US Patent and Trademark Office (USPTO)].
- The transgenic research mouse designed as a laboratory model for cancer studies at Harvard under NIH funding was patented, and licensed to DuPont, which further sought strong controls over it and other forms of modified mice.
- Concentrated stem cells, which are undifferentiated or partially differentiated cells, which can be developed into a number of other cell types, have been patented in the US.
- Partial gene sequences including 'expressed sequence tags' (EST's), which are components of genes being expressed at a particular time, can now be sequenced by machine.

Private firms are filing patent applications for newly identified DNA sequences including gene fragments before identifying a corresponding gene, protein, biological function or potential commercial product. The patents on isolated gene fragments can block foreseeable commercial products such as therapeutic proteins or genetic diagnostic tests that will be more likely to be required for the use of multiple fragments. Receptors are useful for screening potential pharmaceutical products. As receptors are being granted patents, it makes it difficult to understand the therapeutic and side effects of potential products at the preclinical stages. Similarly, promoters are inserted into plants along with the new substantive genes and that encourage the plant to express these substantive genes.

There is also the issue of overlapping patents. For example, claims covering the use of transgenic *Bacillus thuringiensis* (Bt) maize—maize that contains a gene from a bacterium that kills insects—have been awarded to the (a) first firm to clone the Bt gene, (b) to the first firm to put it in any plant, and (c) to the first firm to put it in a crop plant.

Microbiological inventions include new products, processes, uses and compositions involving biological materials. These inventions cover methods to isolate and obtain new organisms, improve their character, modify them and find their new and improved uses.

Patenting of new microorganisms is based on their differences with the characters and uses. Known microorganisms are restricted to new uses wherever patent laws permit such protection. The same is the case with genetically modified microorganisms. Genes and gene products are treated similarly to chemical compositions. Patenting of animal and human genes quite often attracts issues regarding public order and morality.

2.1 Conditions of Patentability for Biotechnological Inventions

Usually, to be patentable, patent laws require a new invention to comprise an inventive step and industrial applicability. Also, inventions must be repeatable. Disclosure under the patent system must enable others to repeat the technical solution described in the patent. Determination of what has been specified (claimed) in the invention and whether specifications and claims disclose a credible utility for the claimed invention is a guiding principle. If no credibility has been asserted (disclosed) and any utility is readily apparent to one of normal skill, the application should normally be rejected.

The examiner determines whether asserted utility (by the applicant) is specific and substantial, and if so, determines whether such asserted utility is credible. In determining credibility, the examiner should consider whether or not there are similar or equivalent materials and/or procedures available for achieving that utility. However, distinction between 'discovery' and 'invention' is difficult to make in the field of biotechnology. It is also not clear how 'microbiological' processes differ from 'essentially biological' ones. Article 28.2 of TRIPS extends the rights of process patentees to the product directly obtained from the patented process. It is not clear however, if patented microbiological processes would give their owners product-patent-like rights over the products produced directly with the use of these processes. New microorganisms isolated for the first time from the natural surrounding can only be patented if they differ in character from the known microorganisms and have a new or improved use or function. Claims to microorganisms have been allowed on the grounds that they are the products of microbiological processes.

Standards of novelty and non-obviousness are difficult to set for living organisms. Most developed countries now recognise that novelty is met if the claimed biotechnological product or process does not exist in the prior art. Sufficiency of disclosure is met for microorganisms by depositing microorganisms in any of the internationally rcognised depository under the Budapest Treaty.

Article 27(2) of the TRIPS Agreement has excluded certain inventions from the patentability on the ground of morality. These include protection to human, animal or plant life or health or to avoid serious prejudice to the environment provided that such exclusion is not made merely because exploitation is prohibited by domestic laws. Provisions of Article 27(3) of the TRIPS Agreement further allows members to exclude from patentability diagnostic, therapeutic, and surgical methods for the treatment of human or animals, plants, and essential biological processes for the production of plants and animals. However, members must provide opportunity for patenting of microorganism and non-biological and microbiological processes. Therefore, microorganisms are patentable with regard to process of their production and use.

2.2 Patenting of Biotechnological Inventions in the Indian Patents Act

The Indian Patents (Amendment) Act 2005 has specified [under Section 3(a) to 3(j)] inventions that will not be considered as a patentable subject matter in India[5]. Two of the Clauses 3(c) and 3(j) are important in the context of patentability of biotechnological inventions. Clause 3(c) states that "The mere discovery of a scientific principle or the formulation of an abstract theory or discovery of any living thing or nonliving substances occurring in nature" will not be considered as patentable invention. This provision of non-patentability is common to patent laws of other countries. The Clause 3(j) states "plants and animals

in whole or any part thereof other than microorganisms but including seeds, varieties and species and essentially biological processes for production or propagation of plants and animals as non-patentable invention". This provision differs from the patent laws of countries like the US, the European Union, and Japan who follow liberal patent standards and where patents are also granted to genetically modified animals and plant varieties. This exception of non-patentability is allowed as per TRIPS Agreement provided member countries provide alternate effective system for protection of plant varieties patentable subject matter in India[5]. Two of the Clauses 3(c) and 3(j) are important in the context of patentability of biotechnological inventions. Clause 3 (c) states that "The mere discovery of a scientific principle or the formulation of an abstract theory or discovery of any living thing or nonliving substances occurring in nature will not be considered as patentable invention". This provision of non-patentability is common to patent laws of other countries. The Clause 3(j) states that "Plants and animals in whole or any part thereof other than microorganisms including seeds, varieties and species and essential biological processes for production or propagation of plants and animals as non-patentable invention". This provision differs from the patent laws of countries like the US, the European Union, and Japan, who follow liberal patent standards and where patents are also granted to genetically modified animals and plant varieties. This exception of non-patentability is allowed as per TRIPS Agreement provided member countries provide alternate effective system for protection of plant varieties (*sui generis* system). The above provisions clearly identify microorganisms as patentable subject matter and are in compliance with the TRIPS requirement.

3. METHODS OF CONFERRING IPRS TO PLANT MATERIALS

Some of the methods for conferring IPRS to plant materials are:

- The US model of plant patents, which is distinct from the normal (utility) patents.
- Through allowing normal patents on plants or parts thereof, such as cells.
- Through applying a *sui generis* form of plant variety protection (PVP).
- International Union for the Protection of Plant Variety style legislation based on the 1978 or 1991 Convention.
- Through allowing patents on DNA sequences and gene constructs (including the gene), plants transformed with these constructs, the seeds and progeny of these plants.

Apart from the use of patents and PVP, the intellectual property (IP) in plants can be appropriated by technological means. For instance, crops such as commercial hybrid maize cannot be reused if hybrid yield and vigour have to be maintained. Genetic Use Restriction Technologies (GURTs) is a term used to describe different forms of controlling the action of genes in plants. The so called 'terminator technology', which renders the seed sterile so that it is physically not possible to grow a second crop, is well known but other characteristics can also be controlled, either for agronomic or commercial reasons.

Patents are the strongest form of IP protection as they normally allow the rights holder to exert the greatest control over the use of patented material by limiting the rights of farmers to sell or reuse seed they have grown or other breeders to use the seed (or patented intermediate technologies) for further research and breeding purposes. For example, the patent on plant gene expression has wide control of controlling gene expressions in plants. However, patent laws can provide exceptions such as farmer's exception on genetic material or compulsory licensing.

Under PVP a lower standard is used[6]. The variety has to be (i) 'new', i.e., never sold prior to the date of application or priority date, (ii) 'distinct', i.e., clearly distinguishable from previously known varieties, (iii) 'uniform' where the variations in the variety can be described and predicted and are commercially acceptable, and finally (iv) 'stable', i.e., the

variety must be capable of being reproduced with the same essential and distinctive characteristics with a reasonable degree of certainty. Mere discoveries of plants growing in the wild is protectable provided other criteria are met. Thus, PVP laws allow breeders to protect varieties with similar characteristics.

India has rightly opted for PVP through PVP legislation 2002. It has further specified a Clause [39(1) (iv)] that states: "A farmer shall be deemed to be entitled to save, use, sow, re-sow, exchange, share or sell his farm produce including seed of variety protected under this Act in the same manner as he was entitled to before the coming into force of this Act and provided that farmer shall not be entitled to sell branded seed of a variety protected under this Act".

4. PATENTING TRENDS IN BIOTECHNOLOGY

4.1 Indian Patenting Trend

Patents granted to Indian organisations during 1990-2002 in different sectors are given in Table 1. It can be observed from Table 1 that chemicals and pharmaceuticals were the major areas in which Indian organisations had obtained patents. However, it can also be observed that Indian organisations also got patents in biotechnology. Majority of these were overlapping patents addressing other sectors (mainly pharmaceuticals). The main technological domains of patenting activity in biotechnology were in microorganism compositions; macromolecular compounds; and biocide and plant reproduction techniques. Table 2 highlights patenting activity in biotechnology in three sub-periods (1990-94; 1995-98; 1999-2002). Steady increase in patenting activities in biotechnology can be observed from the Table 2.

Table 1. Patents granted to Indian organisations by the USPTO and IPO during 1990-2002

Sectors	USPTO (% share)	IPO (% share)	Total patents
Chemical	278 (43%)	1073 (22%)	1798 (33%)
Pharmaceuticals	219 (34%)	1579 (32%)	1351 (25%)
Machinery	28 (4%)	691 (14%)	719 (13%)
Instruments	17 (3%)	200 (4%)	217 (4%)
Biotechnology	*53 (8%)*	*130 (3%)*	*183 (3%)*
Transport	6 (1%)	122 (2%)	128 (2%)
Electrical equipment	1 (0.15%)	99 (2%)	100 (2%)
Electronics	9 (1%)	74 (2%)	83 (2%)

Analyses of Indian patenting activity during 2003-04 again shows that in this period also, pharmaceutical and chemical sectors were the dominant areas of patenting activity. Pharmaceuticals had 213 patents (46 per cent of total patents) during these two years while chemical sector had 125 patents (27 per cent of total patents). Biotechnology sector was also well addressed with 48 patents granted during this period. Other major sectors contributed insignificant number of patents.

4.2 International Patenting Trend

The US, Japan and the European Patent Office are the three major patent offices where international firms file patents. However, in the context of biotechnological inventions, the USPTO has a long tradition of firms filing their patents therein because of a number of factors such as emergence of firms from the universities, venture capital investments, and landmark rulings. Thus, by observing patents granted by the USPTO, a good estimate of patenting activity in biotechnology can be obtained. Figure 2 shows patenting activity in the USPTO by some developed and developing countries during 1972 to 2006. Differential scale has been used to properly distinguish countries that are intensively patenting from the other with lower patenting intensity. Left scale depicts the patents granted to India, China, Brazil, Korea, Russia and Italy. Right scale depicts the patents granted to the US, Canada, Great Britain, Japan, Germany, and France.

Table 2. Patenting activity in USPTO and IPO in biotechnology during 1990-2002

Patent Office	1990-94 (Pre-WTO)	1995-98 (Post-WTO)	1999-2002 (Current Period)	Cumulative from 1990-2002
USPTO	0	7	46	53
IPO	32	38	60	130

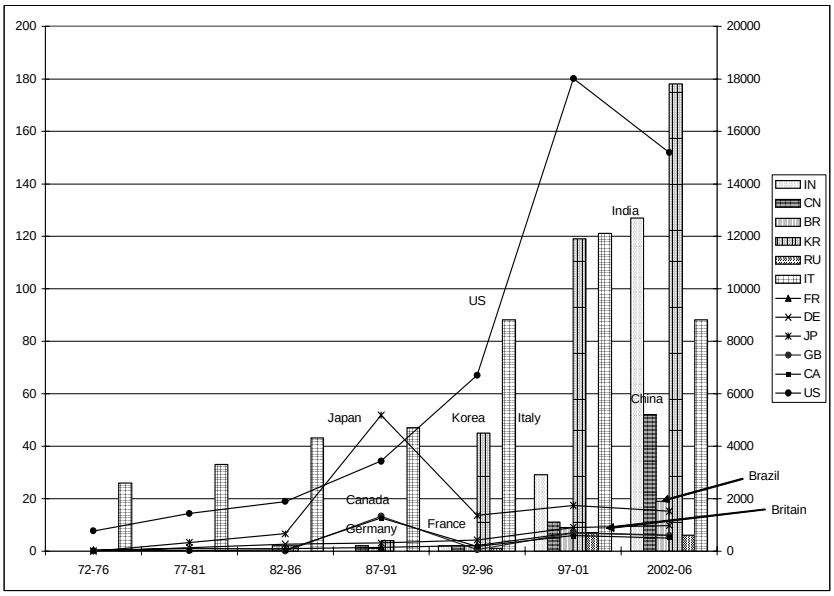


Figure 2. Patenting trends in biotechnology by different countries in the USPTO during 1972-2006.

Figure 2 clearly depicts the US dominance in patenting in biotechnology. Japan is the second most prolific country being granted patent in this area by the USPTO (however, a steady decline has been observed from 1992 onwards). Among emerging economies, India shows significant patenting in 2002-06. Patents granted by the USPTO in biotechnology in comparison to other sectors to some developed and developing economies have been illustrated in Table 3.

Table 3 shows that patents granted to biotechnology inventions are relatively less than other sectors. However, they do contribute to substantial patents in the overall profile of developed economies. Firms in developing countries have dominated innovation in biotechnology with extensive patenting, but the US has clearly dominated patenting covering different application areas of biotechnology. These innovations have high degree of science linkages and joint partnership between industry and university.

The patenting activity exhibited by India in this sector is a positive sign of innovation activities taking place. It can be observed that India has shown higher degree of patenting in biotechnology than China and Brazil. Figure 3 shows that microorganisms or enzymes-compositions, thereof, and measuring and testing processes involving enzymes or microorganisms were the major technological areas where patenting activities were intensively undertaken within the biotechnology. These areas show significant increase in activity over the years. Another domain of patenting attention was in fermentation.

5. CONCLUSION

The study examined the field of biotechnology and identified some of the important areas in the context of patentability in this field. The article underscores the fact that patenting in biotechnology gives rise to complex issues as it involves patenting of living organisms, and how Indian patent provisions address the issue of patentability in this subject domain without violating the TRIPS Agreement.

The study shows that Indian firms have been able to obtain a number of patents in biotechnology during 1990-2004 by the US and Indian patent offices, particularly in the later period. International comparison of patenting trends in the USPTO in this area highlights Indian organisations having higher share then other emerging economies. However, relative to technologically developed economies Indian activity is still insignificant.

Table 3: Patenting activity in different sectors by developed and developing countries during 1998-2002

Sector	USA	Japan	South Korea	China	Brazil	India
Electronic equipment	83499	40208	7441	49	2	7
Office machinery & computers	63049	37568	3876	16	8	6
Machinery	62212	23426	2453	66	91	17
Miscellaneous	59171	18175	932	71	57	48
Instruments	56359	21047	1401	24	40	16
Pharmaceuticals	39772	5959	437	43	15	245
Chemical	35624	13128	802	76	17	179
Biotechnology	*16470*	*1802*	*134*	*11*	*9*	*57*
Electrical	17863	10083	672	18	18	1
Transport	16020	10452	436	13	19	5

Source: Bhattacharya, *et al.*[7]

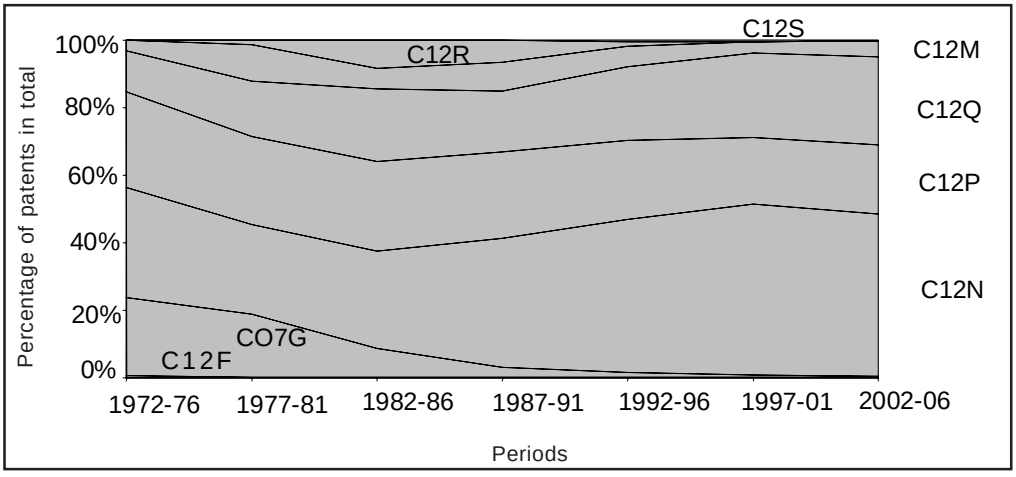


Figure 3. Number of patents in different fields of biotechnology in USPTO during 1972-76 to 2002-06.

Legends: C12f: Recovery of byproducts of fermented solutions; Denaturing; or denatured alcohol; C07G: Compounds of unknown constitution; C12N: Microorganisms or enzymes; compositions thereof; C12P: Fermentation on enzyme using processes to synthesise a desired chemical compound; C12Q: Measuring or testing processes involving enzymes or microorganisms; C12M: Apparatus for enzymology or microbiology; C12S: Processes using enzymes or microorganism to liberate, separate or purify a pre-existing compound or composition; C12R: Microorganisms

ACKNOWLEDGMENT

The author thanks Indian Law Institute (ILI) for providing him the opportunity to deliver lectures at the institute to the students. The paper is primarily constructed from the lectures delivered by him at ILI. The author also takes the opportunity to thank Prof. Lisa P. Lukose who coordinated the lecture series and Shri Ajit Gautam and Shri Anirban Chatterjee for their help in data capturing.

REFERENCES

1. Patents and Innovation: Trends and policy challenges. OECD, Paris, 2004.

2. Rudolph, R. John; Gowling, Strathy & Henderson. A study of issues relating to the patentability of biotechnological subject matter. Intellectual Property Policy Directorate, Canada, 1996.

3. http://www.uspto.gov

4. Hellar, A. Michael & Eisenberg, S. Rebecca. Can patents deter innovation? The anticommons in biomedical research. *Science*, 1998, **280**(5364), 698-701.

5. The Patents (Amendment) Act, 2005. The Gazette of India. No. 15, 2005.

6. Watal, Jayshree. Intellectual Property Rights in the WTO and Developing Countries. Oxford University Press, New Delhi, 2001.

7. Bhattacharya, S; Garg, K.C.; Sharma, S.C. & Bharvi, D. Indian patenting activity in international and domestic patent system: Contemporary scenario. *Current Science*, 2007, **92**(10), 1366-69.

Contributor

Dr Sujit Bhattacharya obtained his PhD from the Indian Institute of Technology Delhi, New Delhi for his work on Infometrics. He has a number of publications in international journals, has coauthored two books, and coedited one book. He is a member of the International Programme Committee for the biannual International Conference of Scientometrics, World Patent Information and Research Policy. His areas of interest include scientometrics and informatrics (patent-related studies) and technology, trade and IPR. Presently, he is working as Senior Scientist at NISTADS, and has recently joined Centre for Science Policy Studies, Jawaharlal Nehru University, as Visiting Professor.