

APPLIED MICROBIOLOGY

Intellectual Property Rights and TRIPs

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Key words

Intellectual Property Rights, Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPs), Copyright, Trade mark, Brand, Geographical Indications, Patents, Biological Diversity, Biodiversity Act., Biotechnology, Protection of Plant Variety and Farmers' Right Act., Most Favoured Nation, National Treatment, Exclusive Marketing Rights, Appellate Tribunal, Plasmid, Genetically modified organism, *sui generis* system, Budapest Treaty,

Primer to Trade Related Aspects of Intellectual Property Rights (TRIPs)

Historically, the term Industrial Property has been used to ensure legal protection to the author, designer or inventor against imitation and copying of the new ideas, designs, processes, products, devices and apparatus. Scope of the term IPRs as used under TRIPs, is broader as it covers copyrights also (Table 1).

Under the patents rights are available *for any inventions, whether products or processes in all fields or technologies, provided they are new, involve an inventive step and are capable of industrial application* (Article 27, para 1), commonly described as Novelty, Inventiveness and Applicability. While para 3 of the article grants the members the right to exclude from patent ability the diagnostic, therapeutic and surgical methods for treatment of humans and animals as also the biological processes for production thereof, inventions in the field of microbiology are covered under the patent system.

Table 1: Contents of the parts, sections and articles within the area of TRIPs

Part and Particular		Section	Content	Articles
I	General Provisions and Basic Principles			1-8
II	Standards Concerning the Availability , Scope and Use of IPRs	1	Copyrights and related rights	9-14
		2	Trademarks	15-21
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The Agreement also grants the members the right to protect the reproductive material by patent or by *sui generis system or by any combination thereof* (Article 27, para 3b). While most countries have adopted *sui generis system*, US laws grant protection through patents. Although different from the patent, the level of protection provided to the breeders under these rights is comparable to that under patent. The term of protection lasts for a period of 20 years counted from the filing date.

India has also enacted legislation for protection, conservation and sustainable use of its biological resources.

Intellectual Property

Intellectual Property is the product of mind and is created by exercise of intellectual input of an individual. It occurs in the form of new ideas, techniques, products and processes with economic and commercial potential. The movable and immovable property that a person owns can not be used without explicit or implicit permission of the owner. Likewise, the author or the creator of the intellectual property should have a right of possession and its use by others should be with the permission of the author and hence need to be protected from being infringed. In 1967, the World Intellectual Property Organization (WIPO) stipulated that Intellectual Property should include the following:

- i. Literary, artistic and scientific works
- ii. Performance of performing artists, phonograms and broadcasts
- iii. Inventions in all kind of human endeavour
- iv. Scientific discoveries (no property rights to scientific discoveries.)
- v. Industrial designs
- vi. Trademark, service marks and commercial names and designations
- vii. Protection against unfair competition and all others rights resulting from intellectual activity in the industrial, scientific, literary or artistic fields.

The protection to these techniques/ materials by patenting/ *sui-generis* system is most essential. Today all most all countries protect the Intellectual Property of its citizen and even the rights of the citizens of one country will find protection in other countries as well. The Agreement on Trade Related Intellectual Property Rights (TRIPS) including Trade in Counterfeit Goods under Annex 1C is the outcome of such a requirement in WTO framework and has been abridged in the form of the primer.

The grant of Intellectual Property Rights (IPRs) ensures protection to the author, designer or inventor against imitation and copying of the new ideas, designs, processes, products, devices and apparatus. The scope of the term IPRs as used under TRIPs is broader as seven types of IPRs are envisaged under sections 1 to 7 and articles 9 to 39 of part II of GATT 94 negotiations. The corresponding Indian legislations have been enacted and these are now in total compliance of TRIPs provisions (Table 2).

India became signatory to the Patents Cooperation Treaty (PCT) in 1999 and has become part of it. According to PCT one can take patent first for his nation and subsequently patent can be staggered in other countries over 30 months. In latest amendment of Indian Patent Act in 2005, regulations have been introduced to account for the PCT provisions.

Table 2: Different types of Intellectual Property Rights under TRIPS and corresponding Indian legislations

Sec.	TRIPS	Art.	Indian legislation	Amend.
1	Copyright and related rights	9-14	Copy right Act.1957	1999
2	Trade mark	15-21	Trade & Merchandise markAct.1958	1999
3	Geographical indications	22-24	Geographical indication of goods Act. 1999	1999
4	Industrial designs	25-26	The Design Act. 1911	2000
5	Patents	27-34	(I) Patent Act.1970 (II) Protection of Plant Variety & Farmers' Right Act. (III) Seed Act, 1966 (IV) Biodiversity Bill	1999, 2002, 2005 2001 2004 2002
6	Layout designs (Topo-graphics of integrated circuit)	35-38	Layout designs	1999
7	Protection of undisclosed information	39	National Innovation Foundation (NIF)	2000

The grant of Intellectual Property Rights (IPRs) encourages innovation and inventive activity which promotes technical, industrial and economic development. Besides, in corporate sector, Intellectual Capital (IC) is the prime creator of economic value and accounts for 75% of market value of top global corporate. Intellectual Capital consists of intangible factors like human capital (management and employee), internal structured capital (intellectual properties and processes) and relational structural capital (brand, network and customers), that are never captured in the balance sheet. Hence, companies find an IC rating useful during an M&A, an IPO, an organizational development exercise or simply a bench mark.

Implementation and Enforcement

The period within which the Agreement on TRIPs has to be implemented has been mentioned in the section on patents. The implementation will be through laws, regulations and administrative procedure. There will be provisions for judicial review of final administrative decisions. The members have the obligation to ensure that their laws permit effective action against any act of infringement of intellectual property rights covered by the agreement. Detailed requirements have been laid down for the civil and administrative procedures which have to be taken into account in the formulation of laws, regulations and administrative procedures.

Several obligations contained in other multilateral agreements have been repeated or reiterated in this agreement. In this way the enforcement of those provisions through the dispute settlement process of the World Trade Organization (WTO) Agreement has been ensured.

Governments have to formulate laws and amend existing laws in order to implement the TRIPs agreement. At several places, governments have the discretion in respect of the provisions to be incorporated in the legislation. On these matters governments have to determine what will be in the best public interest, keeping their development priorities, and make provisions accordingly.

A developed country member has to apply the Agreement on TRIPs latest before the expiry of one year from the entry into force of the WTO Agreements, i.e. 1 January 1995. A developing country member has, however, the facility to implement it before the end of five years from 1 January 1995, i.e., from 1 January 2000. A least developed country Member has the flexibility to apply it latest by 1, January 2006. Further extension may be allowed by the Council for TRIPs on the request of individual least developed country Members. But the provisions relating to Most Favoured Nation (MFN) and National Treatment have to be made applicable within one year of the coming into force of the WTO Agreements.

In respect of a developing country, Member which is not having at present the system of product patent, the provision is that it can further delay the application of provisions relating to product patent by an additional period of five years. Thus for developing countries the product patent provisions have to be made applicable within 10 years of the entry into force of the WTO Agreements and other provisions within five years, except that the provisions relating to MFN and National treatment have to be applied within one year.

A country in transition from a centrally planned economy to market economy may also delay the application as applicable to developing countries, provided it is facing special problems in the preparation and implementation of IPR laws and regulations. During the transition period, the laws, regulations, etc. of a country will not be modified in a way which makes them less consistent with the TRIPs agreement.

During the interim period of the implementation, certain measures have to be taken in respect of pharmaceutical and agricultural chemical products. Arrangements will have to be made for filing of the applications for patents. When the agreement is made applicable, the criteria of patentability will be applied as if those criteria were being applied on the date of filing of the application. Such patents, if granted on the application of the agreement, will be valid for the remainder of the patent term, commencing from the filing date. Provisions have been made for exclusive marketing rights (EMR) for a period of five years after obtaining marketing approval in Indian patent laws. The condition is that the applicant should have obtained patent for the product in another country after the entry into force of the WTO Agreements and marketing approval has been obtained there.

Copyright

Realizing the need of copyright, the Copyright Act, 1911 of UK, passed by the British Parliament with appropriate modifications, was extended to India in 1914 as Indian Copyright Act, 1914. After independence a new Copyright Act, 1957 to cover new and advanced means of communication such as broadcasting, photography etc. was enacted. This

act has been amended from time to time to meet the emerging national and international requirements. The international efforts culminated into two conventions – Berne Convention for the protection of Literary and Artistic works (1948) and Universal Copyright Convention (1952). Both these conventions were revised in 1971. Indian Copyright Act 1957 conforms to the guide lines framed by these conventions.

Copyright laws protect creativity in the choice and arrangement of words, musical notes, colors, shapes and so on. These protect the owner of the rights in literary, scientific and artistic works including productions such as books, pamphlets and other writings, lectures addresses, dramatic or dramatico-musical works, choreographic works, musical compositions with or without words, cinimato-graphic works, works of applied art, the maps, plans, sketches, three dimensional works relating to geography, topography, architecture or science etc. and other forms of expressions like computer software/ program.

Performer will have the right to prevent the following acts when undertaken without their authorization: (i) fixation of their unfixed performance, (ii) reproduction of such fixation, and (iii) broadcasting by wireless means and the communication to the public of their live performance.

Producers of phonograms will have the right to authorise or prohibit the direct or indirect reproduction of their phonograms and commercial rental of the phonograms and their copies.

Broadcasting organizations will have the right to prohibit the following acts when undertaken without their authorization: (i) the fixation of broadcasts, (ii) the reproduction of fixation, (iii) re-broadcasting of the material, and (iv) communication to the public of the television broadcasts of the material.

The rights-holders of computer programs and performance on phonograms will have the right to authorize or prohibit the commercial rental to the public of originals or copies of their copyright works. In respect of cinematographic works, this right may not be insisted upon, if exclusive right of reproduction is not materially impaired by widespread copying.

The copyright holder has exclusive rights to authorize others to use the protected works. (e.g. reproduction, performing, recording, broadcasting, translation). The discovery of new biochemical molecule from medicinal plants or new chemical entity or new formulations is entitled for a copyright.

Ownership of Copyright

There are three factors that are vital for the determination of ownership of the copyright. These factors are: (i) Creation of a work by a person on his own behalf, (ii) Creation of a work by a person at the instance of another person for valuable consideration and (iii) Creation of work by a person employed by another person (Table 3).

The term of protection of a literary work or artistic work is generally the life of the author and fifty years after his death. Similarly, various terms have been fixed for other related rights as given in the Table 4. These are universally accepted tenures/terms.

Table 3: Factors for determination of copyright

Factors	Ownership
Creation of a work by a person on his own behalf	First owner
Creation of a work by a person at the instance of another person for valuable consideration	Person at whose instance the work is created
Creation of work by a person employed by another person.	Employer

Table 4: Terms of copyright

Nature of work	Term of copyright and the conditions
Dramatic, musical or artistic works (other than photographs)	Lifetime of the author plus fifty years from the beginning of the calendar year following the year of death of the author. Where the work is of joint authorship, the fifty years period will commence after the death of the author who dies last. The work should be published during the life time of the author
Anonymous or pseudonymous works.	Fifty years from the year of publication. If the identity of the author is disclosed before the expiry of the fifty years period, the term will extend to fifty years after the death of the author
Posthumous works. Photographs, Cinematograph films and record	Fifty years from the year of publication
Government or a Public Sector Undertaking	Fifty years from the year of publication
International Organizations such as FAO, WHO, UNESCO etc	Fifty years from the year of publication

Moral rights

Moral rights as distinct from economic rights are also there for copyright holders as given below: The right to (i) decide publication of work; (ii) claim authorship of published or exhibited work and (iii) prevent alteration and other actions that may damage the author's honour or reputation.

License for publication

If an author refuses to republish or allow the replication of work or refuses the performance of the work in public, Copyright Board can grant republication or replication rights to other individual subject to payment of compensation to the author.

Registration of copyright

Registration of copyright is not mandatory in the act. Despite this, a ‘register of Copyrights’ is maintained at Copyright office. Author may make an application in a prescribed form along with prescribed fees to the registrar of Copyrights for entering the particulars of the work in the register.

There is a provision for exceptions which says that limitations and exceptions to exclusive rights will be limited to special cases which do not conflict with the normal use of the work or which does not unreasonably prejudice the legitimate interests of the rights-holder. In practice such exceptions are patentable for the purposes of teaching and research and sometimes for obtaining reciprocity

Infringement of copyright

Copyright protects the skill and labour employed by the author in the creation of the work but not the raw materials from which the work is created. If any person does any of the acts/rights that are vested in the copyright owner without authority, he will be committing an infringement of the copyright. Some of the commonly known acts involving infringements of copyrights are as under:

- Making copies for the sale or hire
- Distributing copies for purpose of trade so as to affect prejudicially the interests of the owner of copyright,
- Public exhibition of copies by way of trade,
- Import of copies into India

There are three types of remedies available against infringement of copy right – civil, criminal and administrative. The remedies available are an injunction, damages or account of profits. Infringement of copyright is also an offence punishable with imprisonment, for a period ranging from six months to three years and fine in the range of Rs. 50000/- to Rs. 2.00 lakhs. There is a provision for enhanced penalty for second and subsequent convictions – imprisonment for a period ranging from one to three years and fine in the range of Rs. 1.00 to Rs. 2.00 lakhs.

The Copyright Act provides certain exceptions to infringement. The object of these provisions is to enable the encouragement of private study, research and promotion of education. They provide defenses in some actions for infringement. The following acts do not constitute infringement of copyright:

- (i) A fair dealing with the work for purposes of research, private study, criticism or review.
- (ii) A fair dealing with the work far purposes of reporting current events in newspapers, magazines and periodicals.
- (iii) A fair dealing with the work for purposes of judicial proceedings.
- (iv) A fair dealing with the work for purposes of preparation of any work by Legislature.
- (v) A fair dealing with the work for purposes of reading or recitation of extract of a work in public.
- (vi) A fair dealing with the work for purposes of publication in a collection, mainly composed of noncopyright matter, intended to be used in educational institutions.

- (vii) A fair dealing with the work for the purposes of preparation of notes to be used by a teacher or a pupil in the course of instruction and so on

Copyright Office and Copyright Board

The Copyright Office regulates copyright matters. The registrar of Copyrights heads and superintends this office. There is Copyright Board also. The judge of the Supreme Court or a High Court or a person qualified for the appointment as judge of a High court is the chair person of the Board, with the registrar of the copyright as its secretary. The Board is deemed to be a civil court, and all proceedings before the Board are deemed as judicial proceedings.

Trademarks

A trademark is an identification symbol which is used in the course of trade to enable the purchasing public to distinguish one trader's goods from the similar goods of other traders. The trademark used in connection with services is called '**Service mark**'. These are used by hotels, restaurants, airlines, tourist agencies, car rental agencies, laundries and cleaners. For example KODAK, APPLE, ASHOKA etc.

'Commercial names and designations' are generally names, terms or designations which serve to identify and distinguish an enterprise and its business activities from those of other enterprises. A trade name identifies the entire enterprise and symbolizes the goodwill and reputation of the business.

When a 'Trademark' is registered, the owner will have the exclusive right to prevent a person from using, without the owner's consent, identical or similar signs for an identical or similar trade or service.

The initial registration and each renewal will be for minimum period of seven years. There will be no maximum limit on the renewal. If the use of the trademark is a condition for maintaining registration, the cancellation may take place only after a continuous non-use for at least three years.

Branding

A Brand is a name, term, sign, symbol or design or a combination of them which is intended to identify the goods or services of one seller or group of sellers and to differentiate them from those of competitors. The terms such as marks, brands and logo are some times used interchangeably with Trademark. A good brand name should be legally protectable, easy to pronounce, easy to remember, attract attention, suggest product benefits or suggest usage, suggest the company or product image, distinguish the product's positioning relative to the competition. In medicine branding a product on its molecule name is being replaced by branding a product on its therapeutic usages or efficacy of action (Table 5).

Manufacturers/ distributors use brand names for a variety of reasons from simple identification purposes to having legal protection for unique features of the products from imitations and help consumers recognize certain quality parameters. In some cases, brands are just used to endow the product with unique story and character which itself can be a basis for product differentiation.

Table 5: Branding of Pharmaceutical drugs

Brand name	Therapeutic uses
Rejoint	Skeleto-muscular
Xtra	General Pain killers
Urotei X	Urinary problems
Fluzet	Flu
Enuff	Diarrhoea
Alcoliv	Liver problems
Manforce; Jaun; Kamagra; Joygra; Forzest; 11 PM	Erectile Dysfunction

- Originally branding helped trace the source of the guild producer
- In modern era, makes it easier to identify all the products from a particular company
- Makes shopping easier
- Helps the companies launching new products

No investment in any organized business can be as gainful as an investment in trade mark, which over a period of time, if blended properly, culminates into brand. If you are in business and you are not branding you are many steps behind everyone else, as it is impossible to survive without brand in today's business.

The brands are not built overnight; it needs years and warrants blending of resources in a unique way. The famous brands of today have not erupted as a coincidence or a magic, rather they all have had well planned strategy and speak volumes of clear perception, which started right from their inception on registering trademarks. These brands have now turned out to be the largest asset in the asset portfolio of a Corporation.

Brand owners must invest in maintaining brands by Innovating, Gain mind share and market share Distribution network, Expanding consumer base and finally, by keeping margins intact and maintaining capital efficiency.

It should be appreciated that Trademark is a legal concept and remain valid over time so long it is renewed and /or used. Brand is a marketing concept and brand profile or positioning may vary over time. In several cases a brand is also registered as Trademark as it value and protects its other assets.

Those involved in business of selling products/services must, therefore, seek Trademark and or Copyright protection of their distinctive signs, logos, advertisements etc. so that the consumer easily identifies them with the products as origination from a particular source. The distinctive shapes or ornamentation if any should be protected by design registrations

Role of Collective Marks and Certification Marks in Brand Building

In the field of trademark "Collective Marks" and "Certification Marks" are important. Collective marks are those, which distinguish goods/services of members of an association of persons, which is the proprietor of the trademark from the goods or services of others. This

becomes important especially for industry associations, cooperatives etc. The Small and Medium Enterprises (SME) sector especially those governed by some associations of their own can own collective marks and specify the conditions of membership and conditions for use of these collective marks.

Certification Marks are given to those who do not themselves trade but who certify that goods or services satisfy prescribed standards concerning origin, material, mode of manufacture, quality, accuracy and other characteristics. For example in India "Ag mark" is a certification mark used for food Items Including spices, milk products etc.

The competitive potential in the use of "collective marks" and "certification marks" by the SME sector and their role in brand building exercise have not been exploited in most countries and is only waiting to be unleashed.

The SME sector should be able to cost effectively utilize Industrial Designs Registration in a large number of sectors to retain their competitiveness, as this IPR tool is relatively cheaper and simpler to obtain as compared to patents.

Design

The 'Design' means only the features of the shape, configuration, pattern or ornament applied to any article by any industrial process or means where manual, mechanical, or chemical, separate or combined, which in the finished article appeal end are judged solely by the eye. Design means the feature of the shape etc. applied to an article and not the article itself. The features are conceived in the author's intellect. For example Shape of a Coca Cola bottle, etc.

To qualify for the design it

- (i) must be a new or original design, and
- (ii) must not have been published in India prior to the date of registration.

In respect of textiles designs, it is mentioned in the agreement that the requirement for seeking protection (for example, cost examination or publication) should not unreasonably impair the opportunity to obtain protection. The owner of the protected design will have the right to prevent a person from making, selling or importing products bearing a design which is a copy of the protected design, if the owner's consent has not been obtained for entering into such activity. The duration of protection will not be less than 10 years.

Patents

Concept of patents can be traced to ancient Greece. In English common law, patent has been defined as a grant-by the sovereign to a subject under some authority, title, franchise or property. In US, the concept of intellectual property right can be traced to Art 1, Sec 8 of the constitution which gave the congress the power to promote the Progress of Science and Useful Art, by securing for limited time to the Authors und Inventors the exclusive right to their writings and discoveries. Based on this, the US congress enacted nation's first Patent and Copyright law in 1790 providing protection to any new and useful art, machine, manufacture or composition of matter, or any new useful improvement (thereof).

The UK Patent Act of 1949 has been accepted as model for commonwealth countries. Under this, the inventor was granted the right to record his specification first in a provisional manner

and thus lay foundation for his claim and then present a more complete version within one year. The Patent Act of 1952 replaced the word Art with Process as patentable subject matter. The Committee Report accompanying the 1952 Act intended to include any thing under the sun that is made by man under patentable subject matter even though the Supreme Court held that nature, physical phenomenon and abstract ideas were not patentable.

German laws can be considered as prototype of laws of European countries. European Patent Convention signed in 1973 came in to operation in June 1978. Japanese law and the Indian Patent Act, 1970 may also be added to the list. In the march to develop such provisions as could be imposed globally, several international agreements have been signed. They have provided basis for drafting section 5 on patents, as given in TRIPs head of the agreement.

Patents are related to scientific and technological innovations in various industrial and service sectors. The government, while registering the patent, confers certain exclusive rights on the patent holder. Patents are crucial for the pharmaceutical industry. These are a monopolistic rights granted by a government to inventor for a fixed period, to exclude other persons from imitating, manufacturing, using or selling a patented product or utilizing a patented matter or process to improve upon. It can be assigned or transferred by succession (Art.28 a, b, c). The 'Patent right' is not intrinsic in any product or creation. It is invisible like beauty or soul. It appears only vicariously, embodied in capital goods. The objective is to promote technical innovation and transfer and dissemination of technology (Art.7).

Patent shall be available for any invention, whether products or processes, in all field of technology, provided they are new (novelty), involved an inventive step and has industrial application (Art.27 Para 1). Thus a request for patent registration cannot be automatically granted. The application has to be examined to see if the subject of the patent application satisfies these basic criteria

Members may exclude from patentability the following:

- (i) an invention on ordure public or morality including to protect human, animal or plant life or health or to avoid serious prejudice to the environment (Art. 27, Para 2),
- (ii) diagnostic, therapeutic and surgical methods for treatment of humans or animals.
- (iii) plants and animals and essentially biological processes for the production of plant and animals.

However, the following cannot be excluded from patentability:

- (i) micro-organisms, e.g., bacteria, viruses, fungi, algae, protozoa, etc., and
- (ii) non-biological and microbiological processes of production of plants and animals and member will provide protection to plant varieties either by patents or by an effective sui generis system or any combination thereof (Art.27, Para 3).

The Rights of a Patent Owner

In the case of a patent on a product, the owner will have exclusive rights to prevent anybody from making, using, selling, offering for sale, or importing the product without the consent of the owner.

In the case of a patent on a process, the owner will have exclusive rights to prevent anybody from using the process without the owner's consent and also from making, selling, offering for sale, or importing the product produced directly by that process. Also if somebody makes the product and claim that it has been made by another process, the burden of proof is on the other person to show that another process has in fact been used.

The period of patent will be at least twenty years from the date of filing of the application for the patent.

Constraints on the Rights of Patent Owner

A Member may authorise the use of patents without the consent of the owner in the following circumstances:

- (i) in national emergency or some other extreme urgency or for public non-commercial use;
- (ii) in other cases, if the proposed user has made efforts to get authorisation from the owner on reasonable commercial terms and conditions and has not been able to get the authorisation within a reasonable period of time.

The situation mentioned in item (ii) above may normally emerge when the rights-holder is not willing to use the patent or let others use it, with the result that there is scarcity of the product in the country, thus adversely affecting public interest. However, there is a provision in the TRIPS agreement that patent rights will be enjoyable without discrimination as to whether products are imported or locally produced. It might mean that the situation of scarcity would not be presumed if the owner is prepared to import the product produced in another country. But import needs, foreign exchange; and a country with scarcity of foreign exchange may find it difficult to get the supply exclusively through imports. Further, the scarcity of the product may raise the price of the product, which may harm public interest. All these points will have to be considered in the granting license to an applicant without the consent of the patent-holder.

The important conditions permitting the use of patent without the consent of the owner are as follows:

- (i) the owner shall be paid adequate remuneration,
- (ii) the authorisation of such use will be mainly for the supply to the domestic market,
- (iii) the scope and duration of such use will be limited to the purpose for which it is used.

There is also a provision for limited exceptions to the exclusive rights of the owner, provided such exceptions do not unreasonably conflict with the normal utilisation of the patent and do not prejudice the legitimate interest of the owner.

Amendments in the Indian Law have been introduced for granting Product Patents for fulfilling India's commitments under TRIPS Agreement through the removal of Section 5(1) of the Patents Act, 1970, which provides for process patents in this field, and also by removing the definition of food (Section 2(1) (g) of the earlier act). This means that from

January 1, 2005 product patent applications shall be accepted and examined in India. Included in these product patent applications would be those applications that were made since 1995 using the “mailbox” provisions introduced in the Patents Act through the first amendment undertaken in 1999 in order to fulfill the condition imposed in Article 70 of the TRIPS Agreement (the so-called “Transitional Arrangements”). The “Transitional Arrangements” were in the nature of a trade-off for the longer period that India could enjoy for introducing product patents in areas that were hitherto covered by process patents.

The “Transitional Arrangements” required India to introduce two provisions in its Patents Act. Article 70.8 of the TRIPS Agreement required India to provide “a means” by which product patent applications can be filed from January 1, 1995. If the products figuring in these applications were granted a patent in any of the WTO member countries and the products were granted marketing approval in any of the WTO Member countries, then, according to Article 70.9, five years exclusive marketing rights (EMRs) had to be granted by India before the patent on the product was either granted or rejected in India. The first amendment of the Patents Act, 1970 introduced the requirements under the “transitional arrangements through Section 5(2), which allowed product patent applications to be filed, while Chapter IVA provided for the grant of EMRs. With the end of the transitional period for India, after the ordinance became effective on January 1, 2005, both these provisions had to be repealed, which has been provided for in the ordinance. However, an additional provision has been included in Section 11B of the Act to take into consideration the rights of the applicants whose request for the grant of EMRs was made before the enforcement of the ordinance. This provision also ensures that the applications in respect of which EMRs have been granted before the ordinance took effect would be examined for the grant of patents in keeping with the provisions of the new Act.

Pre- versus Post grant opposition

The Section 25 of the Patents Act provided for the initiation of proceedings for opposing the grant of a patent, which could be launched within four months from the date of advertisement of the acceptance of complete specification. In other words, India followed a system of pre-grant opposition. The grant of patents could be opposed on the grounds that included (i) the invention for which the patent has been claimed was publicly known or publicly used in India, (ii) the invention is obvious and does not involve an inventive step, (iii) the invention is not patentable under the Patents Act, 1970, (iv) the complete specification wrongly mentions the source or geographical origin of biological material used in the invention, and (v) the invention on which the patent is claimed forms part of the traditional knowledge whether in India or elsewhere.

The ordinance introduces two sets of changes to the conditions relating to opposition to the grant of patents. First, the post-grant opposition has been introduced and secondly, provisions relating to pre-grant opposition have been whittled down quite significantly.

Post-grant opposition, which has been provided in Section 25(3) of the Patents Act, 1970, allows any interested person to oppose the grant of a patent before the expiry of one year from the date of grant of patent. But while a change in the system of opposition has been included, the ground for opposition has been left unchanged. The grounds for pre-grant opposition in the 1970 act have been retained in the post-grant opposition of ordinance.

Pre-grant opposition included in Section 25(1) can be made after the publication of the patent application on the ground of patentability, including novelty, inventive step and industrial application. Two other grounds for this representation have been provided, viz. non-disclosure or wrongful mentioning of the source and geographical origin of biological material used in the invention and anticipation of the invention by the knowledge, oral or otherwise available within any local or indigenous community in India or elsewhere. Two issues need to be pointed out in the context of the changes effected in the provisions relating to opposition to patents. The first is that with the exception of the above mentioned ground, all other grounds on which pre-grant opposition could have been made before the introduction of the amendment have been removed. This implies that the pre-grant opposition has been rendered specious. Secondly, Section 25(2), as amended through the ordinance, provides that the person making the pre-grant representation cannot be a party to the proceedings, which would weaken case of those opposing the grant of patents.

Provisions relating to compulsory licences

The provisions relating to the grant of compulsory licences, the instrument that allows exploitation of a patent granted in India on commercial terms (better known as working of patents) have undergone several changes in course of the amendment that was brought about to make Indian Patent Act compatible to the TRIPS Agreement. Chapter XVI of Patents Act, 1970 contains these provisions, which were aimed at ensuring that manufacture of the patented products took place in India to meet the requirements of "working".

In case a patent is not worked in India for three years after its grant, the Controller General of Patents can issue a compulsory licence to any one interested in exploiting the patent. Three other conditions are to be satisfied in this regard: (i) "reasonable requirements of the public" are not satisfied, (ii) the patented invention is not worked in the country and (iii) the patented invention is not available to the public at a reasonably affordable price. The last mentioned provision is critical in case of pharmaceutical patents. Among the issues that have been included for making an assessment of whether or not "reasonable requirements of the public" have been satisfied are: (i) development of the new trade or industry in the country, and (ii) development of a market for export of the patented article manufactured in India. The last mentioned provision is aimed at ensuring that India has the option to export the products that have been produced using the licenses from the patent holders. The major impact of this provision could be felt in the pharmaceutical sector, where India could well emerge as a major supplier of pharmaceuticals to the developing countries that do not have sufficient domestic manufacturing facilities.

The use of compulsory licenses for "working" the patents in the country of grant may be constrained by the terms of the licenses that the patent holder may demand. Article 31(h) of the TRIPS Agreement, which provides the guideposts in this regard, states that "the right holder shall be paid adequate remuneration taking into account the economic value of the authorisation" (emphasis added). The problem with this Article is that it has the potential of making the cost of the license prohibitive for the firms in developing countries given that the drug majors have in the past claimed that the average cost of bringing one new medicine to market is at least \$800 million. What needs to be pointed out in this context is that transfer of technologies to developing countries have mostly been hampered because of the inability of the recipients to meet the stiff financial terms set by the owners of technology.

The Doha Declaration on TRIPS Agreement and Public Health required WTO Members to take measures for ensuring that countries having insufficient or no manufacturing capacities in the pharmaceutical sector could be provided medicines at affordable prices. Section 92A of ordinance incorporates this requirement. Paragraph 1 of this section provides that compulsory license would be “available for manufacture and export of patented pharmaceutical products” It may be mentioned that compulsory licenses are not required for exporting the products manufactured under license and hence this provision goes beyond the contours of the rights to the patentee provided under the TRIPS Agreement. The paragraph 2 of Section 92A also provides that Controller shall grant a compulsory license solely for manufacture of the concerned pharmaceutical product intended for export to such country”.

Steps to obtain a Patent

- Establish essentiality of protection through Patents
- Decision to file a Patent
- Drafting of original Patent Application
- Basic elements of Patent application:
 - (i) Title of the invention
 - (ii) Abstract containing a concise summary of disclosure in the description
 - (ii) Description
 - (iii) Claims
 - (iv) Any drawings etc.
 - (v) Technical field to which the invention belongs
- Seeking assistance of the legal experts
- Filing the Patent Application with the Patent Office
- Examination of the Patent Application in the patent office
- Grant of Patent\Publication of Patent documents

Drafting of the patent application is an important art. The draft should neither be too general nor to be too narrowly defined.

The cost of filling a patent application is Rs. 300/-. The booklet entitled “General Information for Applications for Patents in India” is available free of cost from Patent office.

Patent Offices

The head office of the patent office is at Kolkata and branch offices are in Mumbai, Delhi and Chennai. The territorial jurisdiction of the head office and branch offices is indicated below:

1. **Mumbai** – Maharastra, Gujarat, M.P., Goa, Daman and Diu, Dadar and Nagar Haveli

Patent Office Branch, Todi Estates, 3rd floor, Sun Mill Compound, Lower Parel (West) Mumbai -400 013

2. **Chennai** – Kerala, A.P., Tamil Nadu, Karnataka, UTs of Pondicherry, Laccadive, Minicoy and Aminidevi Islands

The Patent Office Branch, 61, Wallajah Road, Madras – 600 002

3. **Delhi** – Punjab, Haryana, H.P., J&K, Rajasthan, U.P. Delhi, UT of Chandigarh.

(i) Patent Office Branch, United 401- 405, 3rd. Floor, Municipal Market Building

- Saraswati Marg, Karol Bagh, New Delhi – 110005
- (ii) IPMD Unit (CSIR), 14, Satsang Vihar Marg, New Delhi – 110067
 - (iii) NRDC, 20-22, Zamrudpur Community Centre, Kailash Colony Extension, New Delhi

4. **Kolkata – Rest of India.**

The Patent Office Branch, 2nd, MS Office Building, 5th & 7th Floor, Nizam Place, 234/ 4, AJ Bose Road, Calcutta -700020.

Plant / Animal Variety Protection / Breeders Right

The US laws grant protection to improved biological materials through patents while most countries have adopted *sui generis* system because provisions of patent laws of novelty, innovative step, distinctiveness and reproducibility becomes very acute when a new species (e.g. *Triticale*) is made by Biotechnological technique or by natural selection process. In many cases it may not be possible to repeat the process (e.g. mutants). Biological materials may also not qualify for sufficiency of disclosure, characterization /description of biological material and commercial utility. Hence, a different type of protection needs to be provided to living entities. Hence, there is confusion about PVP and Patent.

On the subject of protection of plant varieties, there is a multilateral agreement at present, popularly called UPOV 1978 (UPOV stands for Union Internationale pour la Protection des Obtentions Vegetales, i.e. International Convention for the protection of New Varieties of Plants). A revised version, UPOV 1991, has been negotiated; but it has not come into force, as an adequate number of countries have not formally communicated their decision to join it (as of November 1997). UPOV 1991 is more heavily weighted, than the current 1978 version, in favour of the plant breeders, i.e., those having exclusive rights on plant varieties.

India has enacted 'Protection of Plant Varieties and Farmers' Right' (PPV& FR) legislation in 2001, based on *sui generis* system. For the grant of Plant Variety Protection (PVP) a variety has to be (i) **new** and **distinct** from other existing known varieties, (ii) **uniform** and **homogeneous** and, (iii) **stable** in terms of its identifying traits. Traditional rights of farmers including the use, exchange, sale or disposal in any manner the seed produced on their farm or material harvested from the use of such seed are protected along with rights of researchers and breeders. The necessary amendments have been made in Seed Act also.

The enforcement of PPV&FR will increase the healthy competition among the breeders and plant breeding institutes to develop varieties with high yield potential, greater stability, better diseases and pest resistance and good quality attributes. The private sector is likely to make considerable investment in agriculture, basic and strategic researches in seed production and distribution.

Protection to microbiological inventions

In 1873, LOUIS PASTEUR was granted patent by US (US 141072) for claim on yeast free from organisms or germs of disease as an article of manufacture and recognizing microorganisms as handy work of nature. Thus biological systems can have effective written description, principle of operability and reproducibility of written instructions. Indian patent Act, 1970 do not patent animals and plants. However, industrial processes using

microorganisms such as in fermentation, antibiotics, waste matter degradation etc. can be patented. Also patentable are the processes for producing new microorganisms through genetic engineering and the products that result out of this process, such as microorganisms including plasmids and viruses, if they are non-living.

In 1971, Anand Chakrabarty was granted patent on modified bacteria that digests hydrocarbon. The patent was claimed on bacteria itself, its method of production and introduced vector. The bacteria eat away oil spills. Under TRIPS Article 27, sub-section 2, patents are granted on the utility function of the gene i.e. the sequence or expressed sequence tag (EST) can be patented if is useful. The US patent office has now included a new section in its Manual of Patent examining procedures, where by microorganisms qualify for patenting if it is shown that the hand of man has been involved in their procurement.

Microbiologists have accepted scheme of classification such as Bergey's Manual for protection of microorganisms. In 1949, Patent and Trademark Organization (PTO) of USD recommended deposit of microorganism with a culture collection, which is given an accession number of the deposit of a culture. World Intellectual Property Organization (WIPO) in 1973 worked on procedure of deposition which leads to signing of the Budapest Treaty on the International Recognition of the deposit of Microorganisms for the purpose of Patent Procedure. Amendment of 2005 in Indian patent act also recognized Budapest Treaty and procedure of culture deposition for the purpose of Patent on microorganisms.

In 1977, the recognized depositories have been, ATCC and NRRL of USA, FRI of Japan, CBS of Netherlands, DSM of Germany and NCYC and NCIB of U.K. Since the public to which any patent is addressed is primarily the public in the territory covered by the patent, it is reasonable for every patent examining body to require an internationally approved deposit in its own territory. This is even more essential for huge country like India.

In India, national depositories for fungi, algae, bacteria, cells, tissue culture organism etc. have been established at Delhi, Chandigarh and Pune. Agriculture will be affected if our efforts to develop bio-fertilizers and bio-pesticides, both based on microorganisms are hindered by foreign patents.

Patents in Genetic Engineering

The process of producing a known product using conventional method by isolating or synthesizing gene and transforming the cell (Genetic manipulation), may possess novelty but lacks required degree of inventiveness. But the claim for patents based on application of these techniques, are still not dismissed because particular tricks are required to be applied to make the system (cell) effective. These tricks provide the missing elements of ingenuity and form the basis for grant of patents as may be revealed by investigating the scheme for genetic manipulation using plasmid vector. The Biotechnological innovations have their multifarious applications (Table 6). The various categories of inventions worthy of patentable significance have been listed in Table 7. There is a market for these agents in research work and this may justify the cost of patent protection.

GMO testing

EU norms for GM traceability in imports, requires that all foods more than 0.9% GMOs should be labeled. Thus non-GMO certified products will have the competitive advantage,

perceived value addition and greater acceptance. Testing would cover a range of exports including: Bakery and Confectionary products (coffee); Cattle feed supplement (tobacco); Dry fruits and nuts (tea); dyes and colour additives (Spices and derivatives); Edible oils and allied products (seeds); Flavours and aromatics (rice wheat, pulses and other food grains); Food processing plants (processed foods and snacks); fresh dried, preserved and dehydrated fruits and vegetables (pickles, chutney, ketchup and sauces); liquors, mineral water and beverages (natural dried live and grafted plants); meat and poultry food (milk and dairy products).

Table 6: Applications of Biotechnology

Technology	Applications
Meristem and bud culture	Micro-propagation, genetic conservation and exchange of materials.
Zygotic/ embryo culture	Wide hybridization
Anther & microspore culture	Haploid production
Cell & Tissue culture	In vitro selection, somaclonal variation, somatic embryogenesis, plant propagules & artificial seeds; specialty chemicals
Chromosome engineering	2n gametes for interspecific crosses
Protoplast culture	Protoplast fusion
Genetic engineering	Gene transfer, Molecular farming, Transgenic plants & animals.
Molecular Marker (RFLP & RAPD)	Aid to breeding programs, Genetic diversity, Genetic linkage maps and marker aided selection, Pathogen variability
Monoclonal antibodies	Disease diagnostics
Modified microbes	Mycoinsecticides, Nematode bacteria complexes, Bacteria based insecticides, Myco- herbicides, insect viruses.

Avesthagen Quality Agricultural Services (AQUAS)- a Bangalore based firm with its traceability testing laboratory for foods in the International Centre for Research in Semi Arid Tropics (ICRISAT) campus, Hyderabad has first mover advantage with its cutting edge Polymerase Chain Reaction (PCR) technology. AQUAS has clinching alliance for lab testing with world traceability major Genetic ID which has accreditation on all of its analytical methods through United Kingdom Accreditation Service (UKAS), recognized throughout Europe and widely on five continents. AQUAS are now the exclusive license holder of Genetic ID for Bangladesh and India. AQUAS also provide services for Total Plant Certification ID, seed purity testing, genetic purity through DNA finger printing.

Table 7: Various microbial/ Biotechnological inventions worthy of patent

Category of invention	Significance of patentability
Choice of host/vector relationship	Bringing together a particular plasmid and a particular host cell/ earticular host cell
Isolation of plasmid	None, Methods are well known
Enzymes for cleaving & sealing	New sources of enzymes*
Hybrid plasmid/ constructs/cells/tissues	Product <i>per se</i> claim
Transformation conditions	New methods of inducing cells to take up hybrid or increase in efficiency
Cloning (selection)	Ingenious marker system and new and more effective method of separating our transformed cells '
New strains	Live product per se**
Genomics	Sequenced data for knowledge and functional & structural genomics
Proteomics	Protein profiling and protein – protein interactions
Metabolomics	

** Novelty will be centred on the Hybrid plasmid component.

Impact of Biotechnological patents on Technology development, biodiversity etc. The Biotechnological innovations will increase productivity of farms and industry, enhance quality of products, provide easy and cost effective processes for industrial applications, protects environment and health. However there are apprehensions about their adverse effects on biodiversity, development of monopoly and ethenic and social issues involved in their use (Table 8).

Table 8: Issues involved in patenting of Biotechnological Innovations

Technical problems	Germplasm resource	Research, Academics & Society
- Discovery v/s Inventions, - Equivalents v/s Novelty, - Homogeneity and reproducibility of products, - - Grace period and scope of patent	- Erosion of biodiversity, - Sale of gene bank to MNCs, - Germplasm and indigenous knowledge heritage of mankind - Relevance of Biodiversity Convention	- Brain drain – Institutional and National - Relation between Research and Industry - Social and Industrial relations - International relations between countries - Employment

Bio-diversity Protection

In the **International Convention on biodiversity (CBD)** signed at **Rio in 1992**, nations agreed to recognize the sovereign rights of nations with respect to their genetic resources. The transfers of genetic resources will be made under material transfer agreements designed to protect source nations' interests in any resulting profits. If a country wants biological resources from another country, it can get them only with 'prior informed consent'. Likewise others, only with the consent and involvement of the concerned community, and after entering into a benefit-sharing arrangement, can use community knowledge. Under the compromises of the CBD, this sovereign right applies only to genetic resources possessed in *in-situ* conditions. Resources already outside of the nations, as in international repositories, are not subject to such rights. The task of registration and conservation of plants and animal genetic diversity has been entrusted to National Bureau of Plant Genetic Resources (NBPGR), New Delhi and National Bureau of Animal Genetic Resources (NBAGR), Karnal, respectively

The National Bio-diversity Bill, 2002, seeks to safeguard the country's biological resources from being destroyed and stolen, and empower the tribal, farmers and the like who protect our genetic wealth. If a country wants biological resources from another country, it can get them only with 'prior informed consent'. Likewise others only with the consent and involvement of the concerned community, and after entering into a benefit-sharing arrangement can use community knowledge. The legislation prohibits transfer of Indian genetic material out side the country without the specific approval of the government. It provides for establishment of Bio-diversity Heritage Sites and funds at national, state and local levels to support conservation and benefit sharing. A National Bio-diversity Authority (NBA) shall be set up which will scrutinize proposals for transfer of genetic resources and guide the Center on conservation, sustainable use and benefit sharing.

The 30 nation trading block of which India is a leading country, has evolve a strategy in which an applicant for the patent relating to biological materials or traditional knowledge would have to provide certain information as a precondition to acquiring patents rights. This would include international disclosure of biological origin or evidence to show that traditional knowledge holder is aware and equitable benefit sharing under the natural regime of country of origin has been settled. Thus various governments would turn down patent applications if knowledge about the 'innovation' is already in public domain and shall be treated as 'prior art'. India is pursuing similar deals of international disclosure of biological origin with 11 international patent search agencies. It is a low cost strategy for patent opposition and benefit sharing is only a distant possibility.

Geographical Indications

Geographical indications refer to such indications which identify goods originating in a particular geographical region to which distinct quality or characteristics is attributed (Article 22, Para 1), like Basmati rice, herbal medicinal plants etc. in India. For this, the agreement binds member to article 10 of Paris Convention of 1967. Article 22, 23 and 24 of TRIPs, deal with the protection of goods that are geographically indicated.

This provision offers propriety rights to a specific area over the products associated with it. It is not an individual property for use by owner alone but it suggests the geographical indication of that region, which any producer may use. Geographical indication is in relation to goods originated or manufactured in the territory or a region or a locality (name of a town,

a region or country) where a given quality/ reputation or other characteristics of goods is attributed to its geographic origin. In case of manufactured goods one of the activities either the production or of processing or of preparation of goods concerned takes place in such a place, region or locality (Appellation of origin). Appellation of origin is a specific type of geographical indication, which may be due exclusively or essentially to its place of origin or may be because of peculiar conditions, e.g. soil in that area. Geographical Indications reinforce the regional and national identity of select products and system can help developing countries empower underprivileged workers and small entrepreneurs.

The members will prevent the use of designation or presentation of a product which indicates that the product originates in a place different from where it actually originates misleading the public as to the true geographical origin. In respect of wines and spirits, in particular, it is provided that such geographical indication will be prevented even if the true origin of the product is indicated. For example, Scotch whisky made in country ABC will not be permitted.

The Geographical Indication of Goods – Registration and Protection Act (1999) has come into force w.e.f. 15th September, 2003 and central Government has established the “Geographical Indication (GI) Registry” at Chennai. After GI is registered, any person claiming to be the producer of goods designated by the registered GI can file an application for registration as an authorized user. The GI Act is to be administered by the Controller General of Patents, Designs and Trade Marks – who is the Registrar of Geographical Indications.

The register of Geographical Indications is divided in two parts. Part ‘A’ consists of particulars relating to registered Geographical Indications and Part ‘B’ consists of particulars of the registered authorized users. Registration of Geographical Indications is for a period of ten years and further renewal is possible for further period of ten years each. At domestic front, prized GI of the country should ensure absolute level of protection to avoid further IPR- theft in the international arena.

This provision can be utilized for providing protection to fermented medicinal preparations given in Ayurvedic text, such as Asavas and Aristas. Ayurvedic Vaid Sala Kottayam has tried to protect its products through geographical indications. The other products associated with our region could be Darjeeling tea, Alfonso and Dasherri mangoes or Shahi Leechi. It is the same kind of association that France has with Champagne and Scotland with Scotch Whisky.

The Institute of Developmental Studies (IDS) has sought protection of names of certain food stuff like Bikaneri Bhujia, Sojat Ki Mehendi, Mathania Chillies, Ajmer Ka Hakwa and Jaipur Gazak, with strong geographical linkage with Rajasthan.

Layout Designs of Integrated Circuits

The essential provisions for protection of layout-designs of integrated circuits as contained in the relevant multilateral agreement, viz., the Treaty on Intellectual Property in Respect of Integrated Circuits (commonly known as the Washington Treaty) have been included in this agreement.

The following acts, if undertaken without the authorisation of the rights-holder, must be considered unlawful reproduction of a protected layout-design, importing, selling or

otherwise distributing for commercial purposes a layout-design or an integrated circuit incorporating a protected layout-design or an article incorporating such an integrated circuit.

Those persons who might have purchased such a product without knowledge of illegality are free from legal consequences, but they must pay to the rights-holder a reasonable royalty.

There are some exceptions to the right of protection for example, the acts of reproduction for private purposes or for evaluation, analysis, research or teaching, etc.

The term of protection is for ten years from the date of filling application for registration or from the first commercial exploitation in the world. A Member may provide that the protection will lapse 15 years after the creation of the layout - design.

Protection of undisclosed information/Traditional Wisdom

Members will provide protection to undisclosed information. Person having such information will have the right to prevent such information being used by others without their consent. Similarly, they will also have the right to prevent such information being disclosed to or acquired by others without their permission. The condition is that such information should be secret, it should have commercial value because of secrecy and the person having the information has taken reasonable steps to keep it secret.

There is a special provision for data in respect of pharmaceutical or agricultural chemical products which utilise new chemical entities. It is laid down that such data when presented to members for obtaining marketing approval will be protected against unfair commercial use.

The know how at grass root level in respect of medicinal herbs, various traditional practices, customs, cultures, secret ideas on bio-fungicide and foods etc has been handed down for generations orally and has barely been documented. It may lead to new innovations and hence be protected. “Traditional wisdom would have to be part of research now” said Dr Paroda, Director General of ICAR.

Dr. V. Prakash of CFTRI suggested that several educated but unemployed youths in rural India can go to the interiors and tribal areas to find the people who protect such information as family secrets. These young men and women can help the family make a patent on the product or remedy. In return they can ask for a percentage of royalties that accrue from the patent. In this way family get I.P.R benefit monetarily from the process while young volunteers who acted as intermediary also make some money.

National Innovation Foundation (NIF), an autonomous body set up by DST shall provide institutional support in scouting and scaling up grass root innovations; convert them to into expertise and help to link excellence of formal science with informal innovations and protect their IPR; promote social awareness and possible commercial and non-commercial applications. Holding of Bal Vigian Congress for school students has helped to gather information for grass root level knowledge.

To protect our genetic wealth from bio-piracy, there is an urgent need to document the data on biodiversity, geographical indications on origin/agro eco-practices, undisclosed information on production and management techniques on animal rearing/crop production, agro-processing, use of bio-forms for human and animal health care. This would have an obvious impact not only on diversification in agriculture, but also on the on-going crops and

animals improvement programmes. It would also provide safeguard to the agri-based industries.

Traditional knowledge Digital Library

The CD - ROM database of Traditional knowledge Digital Library project on Ayurveda is available in a patent application format and retrievable through Key Words. Search is also possible on International Patent Classification (IPC) and Traditional Knowledge Resource Classification (TKRC), which is a unique classification scheme developed by India for classification of Traditional Knowledge for the purpose of the ease of abstraction and retrieval. TKRC also establishes the linkage between Sanskrit / common / local names to modern names such as Masoorika to Smallpox, Guduchi to *Tinospora cordifolia*.

The TKDL database holds promise of being a handy tool to prevent grant of patents on traditional knowledge at the international level. International Patent Examiners until now had no source to fall back on when considering the patentability of any claimed subject matter dealing with traditional knowledge since literature pertaining to this aspect was buried in diverse sources. The dimension of misappropriation of Traditional Knowledge could be further appreciated in light of the fact that on a study of 762 randomly selected US patents, a TKDL Task Force found that 374 (49%) were based on traditional knowledge. This raises the possibility of grant of wrong patents. The TKDL database is of immense value, designed as it has been as a potential bridge between modern science and Traditional Knowledge. It can be used to prevent grants of untenable patents at international levels.

Trade Secrets /Anti-Competitive Practices

The agreement permits members to adopt appropriate measures to prevent or control practices constituting an abuse of intellectual property rights from having an adverse effect on competition in the market. Specific licensing practices and conditions can be specified by members for this purpose.

Employees especially in the field of bioinformatics would be privy to a lot of information during the time of providing service. The service providers should be made to sign a statutory or contractual instrument or a mix of both. For an entrepreneur, IPR is a question of the fastest finger first.

Material Transfer Agreement

In addition to the formal statutory schemes of intellectual property protection, there is the trade secret approach based on the investor's ability to keep information secret. To assist in the process, law often provides for enforcement of a trade secret and also offers remedies against improper acquisition of a trade secret. Reverse engineering of a product is, for example, a permissible way to acquire such secrets; theft of documents or materials from a business is not.

At the same time, it is quite clear that some form of trade secret protection is essential for negotiation and in structuring cooperative research arrangement and licenses. Moreover, it is required by the Uruguay Round Agreement also.

Technical Barriers to Trade

Technical Barriers to Trade (TBT) are expected to directly hit small and medium exporters due to lack of awareness on TBT agreement. Under TBT, India has only nine notifications. At present, over 60% barriers are TBTs. Till 2000, there have been 6098 notifications in all. The TBT Agreement suffers from (i) Lack of transparency particularly in the statement of objectives; (ii) Arbitrariness of stated objective; (iii) Definition of what constitute 'urgent problem' is not clear; (iv) Competitiveness arbitrariness issues; (v) Review the heads of environment and security and prevent double counting of objectives and overlapping in case of human health/security v/s consumer protection, protection of environment v/s consumer protection, new technology v/s quality etc. and (vii) Coordination between WTO bodies such as TBT committee and CTE, TRIPs council, Committee on market access etc.

To deal with above mentioned issues (i) an Export Alert System similar to the ones prevailing in Thailand, Brazil (Alert Exportador), Canada (Export Alert), Mexico (Notification Alert) and other countries is being established; (ii) Setting up an effective mechanism to promptly assess the impact of different notifications issued under TBT on Indian trade.

Dispute Settlement

The Agreement on TRIPs prescribes a dispute settlement process under Section 4 Article 63 and Articles CCII and XXIII of GATT 1994 and the Dispute Settlement Understanding (DSU). The action can, however, be initiated only if a benefit under the agreement is being nullified or impaired; or if the attainment of any objective of the agreement is being impeded as a result of failure of any Member to carry out its obligations. The other two provisions of Article CCIII of GATT 1994, viz., application of a measure whether or not in conflict with the agreement and existence of any other situation is excluded for a period of five years from the entry into force of the WTO Agreements.

Intellectual Property Services

'Intellectual property service' means; (a) transferring temporarily; or (b) permitting the use or enjoyment of, any intellectual property right as per Section 65 (55b). Thus it is clear that only temporary transfer of any IPR will be subject to service tax.

Any service provided to any person, by the holder of IPR, in relation to Intellectual Property is a 'Taxable service'

A permanent transfer of intellectual property right does not amount to rendering of service. On such transfer, the person selling these rights no longer remains a holder of intellectual property right' so as to come under the purview of taxable service. Thus, there would not be any service tax on permanent transfer of IPRs - MF (DR) circular No. B2/8/2004 - TRU dated 10-09-2004.

The Protection of Plant Varieties and Farmers' Rights Act, 2001

The Government of India has enacted a legislation based on a *sui generis* / UPOV system known as '**The Protection of Plant Varieties and Farmers' Rights Act**'. The objectives of the Act are:

- To establish an effective system for protection of plant varieties, the rights of farmers and plant breeders for the development of new plant varieties;
- To protect the right of farmers in respect of conserving, improving and making available plant genetic resources for the development of new plant varieties;
- To make provisions for giving effect to sub-paragraph (b) of paragraph 3 of article 27 in Part II of TRIPs agreement and
- To facilitate growth of the seed industry in the country.

The provisions of the bill have been covered in 11 chapters under 97 sections. Some sections have sub-sections and explanatory notes also.

Establishment of the Protection of Plant Varieties and Farmers' Right Authority

An Authority known as 'The Plant Varieties and Farmers' Rights Protection Authority' will be established by the Central Government. It shall be a corporate body and consists of a Chairperson and 15 members. The members to be appointed by the Central Government shall be as follows :

- i) The Agriculture Commissioner,
- ii) Joint Secretary (Seed),
- iii) Horticulture Commissioner (All from Govt. of India Department of Agri. & Cooperation),
- iv) Deputy Director General (Crop Science), I.C.A.R.,
- v) Director, N.B.P.G.R.,
- vi) Representative of Deptt. of Biotechnology, GOI. (Not below the rank of Joint Secretary),
- vii) Representative of Deptt. of Environment and Forest, GOI. (Not below the rank of Joint Secretary),
- viii) Representative of Ministry of Law, GOI,
- ix) Two representatives, one each of National or State level farmers'/ women organisations,
- x) Representative, Tribal Organisations,
- xi) Representative , Seed Industry,
- xii) Representative , Agricultural University ,
- xiii) Two Representatives, State Governments (on rotation basis).

The Chairperson shall be appointed by the Central Government. Authority shall appoint Registrar General of Plant Varieties and such number of Registrars as it thinks necessary. They shall be under the control and management of Authority.

The authority will have its head office at **Delhi**. Its zonal offices will be at:

- (i) **Calcutta** (Bihar, Orissa, West Bengal, Sikkim),
- (ii) **Bombay** (Gujrat, Maharastra, Goa, Dadar Nagar Harveli, Lakshvadeep),
- (iii) **Guwahati** (All North Eastren States),
- (iv) **Chandigarh** (Haryana, Punjab, Himachal Pradesh, J & K, Chandigarh),

- (v) **Lucknow** (U.P. and M.P.),
- (vi) **Hyderabad** (A.P., Tamil Nadu, Pondicherry & Islands)
- (vii) **Bangalore** (Kerala, Karnataka),
- (viii) **Delhi** (Delhi & Rajasthan)

Functions of Authority

The Authority shall promote/encourage development of new varieties of plants and protect the rights of farmers and breeders. Accordingly, it will frame rules and guidelines as per Sec. 8.2 for:

- (i) The registration of extant and new plant varieties,
- (ii) Administration of its headquarters and zonal offices,
- (iii) Characterization, documentation and publication of plant varieties,
- (iv) Fixing the fees for registration of variety,
- (v) Maintenance of National Register of Plant Varieties,
- (vi) Assessment mechanisms for Novelty, Non-obviousness and potential economic benefits as prerequisites of a PVP system,
- (vii) World wide PVP search prior to initiation of R & D of varieties,
- (viii) Compulsory licensing
- (ix) Management of Gene Fund and schemes out of gene fund to promote conservation of biodiversity,
- (x) Systems for management and marketing of PVP portfolios,
- (xi) Incentive / reward system for S & T,
- (xii) Building cost of PVP into R & D costs,
- (xiii) Funds for IPR. and PVP based information services.
- (xiv) Amendments in National Seed Act. and
- (xv) Development of legal procedures.

Registration of Plant Varieties

Central Government shall establish Plant Variety Registry at Head Quarter and Branch Offices. Authority shall appoint Registrar General Plant Varieties and Registrars as it thinks necessary. They shall be under the control and management of Authority.

- (I) Any plant variety of any (a) Genera and species notified by the Central Govt., (b) Extant variety, and (c) Farmers' variety will be registered which conforms the criteria of: Novelty, Distinctiveness, Uniformity and Stability (Sec.15.1). An extant variety shall be registered if it conforms the criteria of Distinctiveness, Uniformity and Stability (sec.15.2);
- (II) Registrar may register a variety whose denomination comprises solely or partly of a Geographic locality (sec.15.4);
- (III) Every variety should have a single and distinct denomination which shall not be registered as trade mark (sec.17.4);
- (IV) The variety should not contain any gene or gene sequence involving Terminator technology (sec.18.1 c);
- (V) The contributions of Farmer, Village Community, Institution or Organization and geographic location of germplasm in developing the variety should be acknowledged (sec.18.1 e);
- (VI) Sufficient quantities of seed of the registered variety shall be made available to the Registrar for conducting evaluation tests /reproduction purposes at breeder's expense

- (sec.19.1-19.2); (vii)The application for Farmers' Variety will be in special form (sec.18.1h-I);
- (VII) Farmers shall not be liable to pay any fees in any proceedings before Authority or Registrar or Tribunal or High Court (sec.44)

Compulsory License

At any time after the expiry of three years of registration of a variety, if sufficient quantities of seeds or other propagating material is not available at a reasonable price Authority may order the breeder to grant a compulsory license to under take production, distribution, and sale of the seed. The duration of the license may vary from case to case but in any case shall not exceed to the total remaining period of the protection of that variety (sec. 47.1-47.3).

Infringement

This act is infringed by a person - (a) who, not being the breeder of variety sells, exports, imports or produces that variety without the permission of the breeder, (b) who uses, sells, exports, imports or produces any other variety having identical or deceptively similar denomination. (sec. 64 a, b) and one is punishable (i) for a term not less than three / six months which may be extended to two years or (ii) fine not less than fifty thousand rupees extendable up to five lakhs rupees , or (iii) both (sec. 70.1 & 71 c)

Breeder's Right

The certificate of registration confer an exclusive right on the breeder or his successor, his agent or licensee , to produce, sell market, distribute , import or export the variety . However, for an extant variety unless breeder establishes his right, State Govt. shall be deemed to be the owner of such variety (sec 28.1).

The breeder may authorize any person to avail exclusive rights (sec.28.2). Such right cannot be transferred further thereof by a agent or registered licensee (sec. 28.8).

The certificate shall be valid for nine years for trees & vines and six years for other crops and may be reviewed and renewed for remaining period to the condition that the total aggregate period of validity shall not exceed: (i) 18 years for trees & vines, (ii) 15 years for extant variety and others from the date of notification (sec. 24.6(i)-(iii)).

The Authority shall explicitly indicate the amount of benefit sharing as per section 26.5. The amount of benefit sharing shall be deposited in National Gene Fund vide section 26.6 and it will be recoverable as an arrear of land revenue by the District Magistrate within whose jurisdiction breeder shares such benefit.

Researchers' Right

The use of any registered variety for conducting Experiments or Research shall not be prevented (sec 30 a). Use of variety as an initial source of variety for creating another variety shall not be prevented. However, authorization of breeder of a registered variety is required where repeated use of such variety as a parental is necessary for commercial production of other variety (sec. 30 b).

Farmers' Rights

(i) Registration of Farmer's Variety

- Farmers variety will be registered which conforms the criteria of novelty, distinctiveness, uniformity and stability (sec. 15.1c)
- Registration and other protection to farmer's variety in like manner as that of a breeder (sec.39.1).
- The application for Farmer's Variety will be in special form (sec. 18.1h-I)

(ii) Farmer's Right for his own produce

- Farmer can save, use, sow, exchange, share or sell his farm produce including seed of a registered variety but shall not be entitled to sell branded seed i.e. seed put in a package (sec 39.1 I-iv).
- Claim of **Compensation** from the breeder in the event of poor yields (sec 39.2).

(iii) Recognition of farmer / community rights for PGR

- The contributions of Farmer, Village Community, Institution or Organization and geographic location of germplasm in developing the variety should be acknowledged (sec. 18.1 e). If breeder fails to disclose, registrar may reject the application (sec.40.1 -40.2).
- Any person on behalf of **village or local communities** can stake claim attributable to **communities** (sec.41.1).
- Conservation of **Genetic resources**, improvement and preservation shall be recognized and rewarded from the **National Gene Fund (sec.45)**.

(iv) Benefit Sharing

- After verification and hearing the breeder, The Authority shall explicitly indicate the amount of benefit sharing as per section 26.5. The amount of benefit sharing shall be deposited in National Gene Fund vide section 26.6 and it will be recoverable as an arrear of land revenue by the District Magistrate within whose jurisdiction breeder share such benefit.
- Registrar may grant **compensation (sec 41.2 - 41.3) which** is to be deposited by the breeder in the **Gene Fund** (sec 41.4). The compensation recoverable like an arrear of land revenue (sec 41.5).
- When **Essentially Derived Variety** is derived from a farmers' variety, the breeder shall not be given **marketing rights** without the consent of the farmers (sec.43).
- **Gene Fund** will be established to which shall be credited the benefits from breeders, annual royalty, compensation and contributions from National and International organizations or other sources (**sec.45.1 a-d**)

(v) Scheme for benefit sharing, conservation of PCR

- **Gene Fund** will be utilized for payment of (a) benefit sharing , (b) compensation , (c) expenditure on **in-situ and ex-situ** conservation of genetic resources and, (d) Schemes of benefit sharing (sec.45.2 a-d) for all matters related to registration under section 42 , enforcement, maintenance of records of claims , utilization of benefit sharing and maintenance of audit of accounts and formation of special schemes(sec. 45.1, 46.2)

(vi) Infringement

- A farmer who at the time of infringement was not aware shall not be infringed (sec.42)
- Farmers shall not be liable to pay any fees in any proceedings before Authority or Registrar or Tribunal or High Court (sec. 44)

(vii) Use of registered variety of research

- The use of any registered variety for conducting Experiments or Research shall not be prevented (sec 30a). Use of variety as an initial source of variety for creating another variety shall not be prevented. However, authorization of breeder of a registered variety is required where repeated use of such variety as a parental line is necessary for commercial production of another variety as in the case in production of hybrid seed (sec. 30b).

Suggested Readings

1. Agreement on Trade Related Aspects of Intellectual Property Rights, including Trade in Counterfeit Goods. In GATT: Final Text of Uruguay Round, 1994 MVRIDC, World Trade Centre, Bombay. Pp. 178-96.
2. Kumar S Anand (1993) The need for protection of intellectual property rights for Indian inventions in biotechnology. JSIR 52: 304-307.
3. National Biodiversity Strategy and Action Plan- India. Guidelines and Concept Papers. Ministry of Environment and Forests, Government of India and Kalpavriksh, New Delhi. October, 2000.
4. Note on Central Sector Scheme 'Implementation of the legislation on Plant Varieties and Farmers' Right Protection 29th Nov.1999, Seed Division of DAC Govt. of India, N. Delhi.
5. The Protection of Plant Varieties and Farmers' Rights Bill, 2000 (redrafted Bill No. 123 Of 1999). Ministry of Agriculture and Cooperation, Govt. of India, passed by the Lok Sabha on August, 2001.
6. Rai Mangla (1996) Dunkels' Draft and Issue of Intellectual Property Rights on Living Forms. In Book: Plant Breeding & Crop Improvement, edited by Kapoor & Saini.
7. The Patents (Amendment) Act, 2005: The Gazette of India, Extraordinary, Part II- Section 1, Ministry of Law and Justice (Legislative Department); 5th April, 2005.