Chapter No 2

Intellectual Property Rights in India
2.0 Introduction

**Property and intellectual property**

Property is corporal property and incorporeal property or tangible property and intangible property. Corporeal property indicates the material, tangible things owned by the human being, organizations, associations etc. they are the physical objects and hence they are perceptible by touch. While incorporeal property is intangible which, can be a subject matter of right. Such property does not have a physical existence and hence cannot be perceived by touch. From this point of view, actionable claims, goodwill, easementary rights, intellectual property rights are considered as intangible or incorporeal property.

Intellectual property is a right pervading some material object. The intangible products of a man’s brain are as valuable as his land, building, goods, money, belongings etc. it is quite different from real property or a formal property. In fiction, it is a property. Hence it is called as intellectual property. The rights relating to the intellectual property are recognized by law as the subject matter of rights of various intangible or immaterial products is human intelligence, skills and labor. In short intellectual property is basically a creation of intellect or relates to intellect. Intellectual property rights are legal rights which govern the use of creations of the human mind and work.

The nature of intellectual property is as,

- a) Intellectual property is only a property in fiction or a fictional property and not a real property though it is pervading some real property.
- b) Intellectual property includes the right relating to scientific discoveries, industrial designs, trademarks, service marks, literary, artistic and scientific works and all other rights resulting from intellectual activity in the industrial, scientific, literacy or artistic field.
- c) Intellectual property rights are legal rights governing the use of creations of the human mind. Legal protection is granted to the owner or creator of the Intellectual property under different acts such as Patents act, Trademarks act etc.
- d) Intellectual property can be divided mainly into four kinds or types i.e.
1. Patent rights
2. Copy rights
3. Trademarks right
4. Design rights

e) Intellectual property rights are protected under related acts.
f) The owner of an intellectual property can earn income by selling the rights of using the same. Such rights can be confined or extended to some prescribed period according to the provisions of the related acts.

**Patent**

Section 2(m) of the Patent Acts, 1970 defines patent as a Patent for any invention granted under this act. A grant from the Government to the inventors for a limited period of time, the exclusive right to make use, exercise and vend his invention. After the expiry of the duration of patents, anybody could use the invention.

**Invention**

Section 2(i) defines invention as a new product or process involving an inventive step and capable of industrial application. Invention means any new and useful,

1. Art, process, method or manner of manufacture machine, apparatus or other article.
2. Substance produced by manufacture and includes any new and useful improvement of any of them, and alleged invention.

Under Patent act, the invention to be patentable should meet the following criteria as,

I. Novel: the invention disclosed in the specification is not published in India or elsewhere before the date of filing of the patent application in India.

II. Invention: the invention is not obvious to a person skilled in the art in the light of the prior publication/ knowledge/ document but as a new product or process involving an inventive step

III. Industrial applicable: invention should possess utility, so that it can be made or used in the industry.

**Inventions not patentable**

Section 3 provides for inventions that are not patentable, they being,
I. Invention which is against natural law.

II. Causes injury to human, animal or plant life or health or to the environment.

III. Mere discovery of a scientific principle.

IV. Mere discovery of thing occurring in nature.

V. Mere discovery of a new form of a known substance.

Section 5 provides where only methods or processes of manufacture patentable, they being,

1. Claiming substances intended for use, or capable of being used as food or as medicine or drug, or

2. Relating to substances prepared or produced by chemical processes, no patent shall be granted in respect of claims for the substances themselves, but claims for the methods or processes of manufacture shall be patentable.

The world Intellectual property organization that is WIPO is very important international organization which is engaged in the field of promote and protection of Intellectual property and right therein.

According to the article 2 (VII) of the convention established the WIPO, Intellectual property includes certain rights. There are some of such important rights relating to the following matters,

I. Invention in all fields of human Endeavour

II. Scientific discoveries,

III. Literary, artistic and scientific works,

IV. Industrial designs,

V. Trademarks and service marks for marketing the products,

VI. Protection against unfair competition,

VII. Various other rights resulting from intellectual activities in the industrial, scientific or artistic fields.

Advantages of Patents

1. The patentee gets the exclusive right under this act to use his invention. His rights relating to this patent registered under this act are well protected.
2. The patentee gets the right to bring a suit for any infringement of his patent and to pray for an injunction, damages or an account of profits against a person who infringes his patent.

3. If the patentee has no means or if he is not himself in a position to work the invention patented commercially, he can sell it and grant licenses to some other capable person or persons to exploit the same and thereby earn income.

4. The holder of an exclusive license gets the rights of a patentee and he can enforce such rights by taking proceedings against the infringement of the patent. “Exclusive licensee” means a license from a patentee which confers on exclusion of all other persons (including the patentee) any right in respect of the patented invention and exclusive license shall be construed accordingly section 2 (f).

5. A patentee gets the right to make improvements in or modifications of an invention described or disclosed in the complete specification of the main invention and obtain the grant of a patent for the improvement or modification as a patent of Addition.

2.1 Intellectual property legislations in India

India is a member of almost all international conventions. The obligation of the member state arising out of the conventions can be enforced on the basis of reciprocity only. No right or obligation is enforceable unilaterally. Therefore to pass own laws on Intellectual property is in the interest of every country. In 1999, a considerate passage of major legislations with regard to protection of Intellectual property rights in harmony with international practices and in compliance with India’s obligations under TRIPS. These include,

1. The Patents (Amendment) Act, 1999 to amend the patents act of 1970 that provides for establishment of a mailbox system to file patents and accords exclusive marketing rights for five years.

2. The Trade marks Act, 1999 which repealed the Trade and Merchandise Act, 1958


5. The Industrial Designs Act, 2000 which replaced the Designs act, 1911.
6. The patents (Second Amendment), 1999 further to amend the Patents Act, 1970.

This was a beginning of a new era in the field of Intellectual property. To streamline and strengthen the Intellectual property administration system in the country the government has taken several measures. Projects relating to the modernization of patent information services and trademarks registry have been implemented with the help from WIPO/UNDP. The government has implemented projects for upgrading of patent office’s incorporating several components such as human resource development, recruiting additional examiners, infrastructure support and strengthening by the way of computerization and re-engineering work practices and eliminating backlog of patent applications, an amendment to the patent rules also was notified to simplify the procedural aspects. The first Indian patent laws were first promulgated in 1856. From time to time these were modified. New patent laws Indian Patent Act 1970 were made after the independence. The Act has now been radically amended to become fully compliant with the provisions of TRIPS. The most recent amendment was made in 2005 which were preceded by the amendments in 2000 and 2003.

2.1 India’s journey to intellectual property right protection:

<table>
<thead>
<tr>
<th>Year</th>
<th>Event</th>
</tr>
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<tbody>
<tr>
<td>1967</td>
<td>The patent bill is introduced in parliament.</td>
</tr>
<tr>
<td>1972</td>
<td>The patents act 1970 comes into force.</td>
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<tr>
<td>1994</td>
<td>The Uruguay round negotiations are ratified.</td>
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<td>1994</td>
<td>India accepts WTO membership.</td>
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<td>1994</td>
<td>Ordnance to amend patent laws is promulgated.</td>
</tr>
<tr>
<td>1995</td>
<td>The Uruguay round agreement come into force.</td>
</tr>
<tr>
<td>1995</td>
<td>The patents (amendment) ordinance lapses.</td>
</tr>
<tr>
<td>1995</td>
<td>The patent (amendment) bill is introduced in the Lok Sabha.</td>
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<tr>
<td>1996</td>
<td>A patent Bill, 1995 Lapses after the Rajha Sabha fails to clear it.</td>
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<tr>
<td>1997</td>
<td>The US complains to the WTO that India is violating the TRIPS agreement.</td>
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<td>1997</td>
<td>EU files complaint with the WTO on the failure to setup mailbox facilities.</td>
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<td>1997</td>
<td>The WTO's dispute settlement body rules (DS 13) against India.</td>
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<td>1997</td>
<td>India appeals against the DS 13 ruling.</td>
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<td>1997</td>
<td>The WTO's appellate body rejects India appeal.</td>
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<td>Year</td>
<td>Event</td>
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<tr>
<td>1998</td>
<td>The WTO formally asks India to amend her patent laws.</td>
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<td>1998</td>
<td>India agrees to 15 month implementation period.</td>
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<td>1998</td>
<td>The introduction of the amended patent act is deferred.</td>
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<td>1998</td>
<td>India decides to accede to Paris convention.</td>
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<tr>
<td>1998</td>
<td>The DSB rules against India in EU complain.</td>
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<td>1999</td>
<td>Deadline for complying with the recommendations of the DSB.</td>
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<td>1999</td>
<td>&quot;I&quot; amendment in patents act 1970.</td>
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<td>2001</td>
<td>Protection of plant varieties and farmers rights act 2001 passed.</td>
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<tr>
<td>2002</td>
<td>Doha declaration on TRIPS agreement and public health.</td>
</tr>
<tr>
<td>Jun-02</td>
<td>&quot;II&quot; patent (amendment) bill 2002 passed. New drug policy 2002 and drugs (price control) order 2002 published. (presently under litigation in supreme court)</td>
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<tr>
<td>Oct-02</td>
<td>Central government appeals in supreme court against stay on pharmaceutical policy 2002 by Karnataka high court.</td>
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<tr>
<td>2003</td>
<td>&quot;I&quot; patent ordnance.</td>
</tr>
<tr>
<td>2004</td>
<td>&quot;II&quot; patent ordnance</td>
</tr>
<tr>
<td>4th April 2005</td>
<td>Act published in gazette.</td>
</tr>
</tbody>
</table>

(Source- Unpublished Data by Monika Khanna thesis, University Of Pune)

2.2 Introduction to Origin of Patent System

In 1300s, the first person who found resources in the Alps dictated property rights for mining, timber and water. As competition progressed special privileges were granted for useful creation. In 1409, first patent was granted to a German for the construction of a model mill. A monopoly by the British was not granted to sell playing cards due to obviousness. The first English patent was granted for a period of 20 year to John of Utynam on making stained glass. Meanwhile, the French advanced the system by registration and examination. In the United States, a patent was granted for a grain elevator 'hopper boy' to Oliver Evans.
In the Indian context, in 1856, the Act VI [1] on protection of inventions based on the British Patent Law of 1852 was established. During this period certain privileges were granted to inventors of new manufacturers for a period of 14 year. In 1859, the act was modified as Act XV in which making, selling, using of inventions in India and authorizing others to do so for 14 year from the date of filing the specification. In 1872, the act was renamed as The Patents and Design Protection Act, in 1883 as The Protection of Inventions Act, in 1888 consolidated as The Inventions and Designs Act and in 1911 as the Indian Patent and design act.

Reasons for the Origin of Paris Convention, BIRPI

Primarily, inventions were kept covert so that it is well protected. As technology developed periodically, as a matter of national prestige the inventions were exhibited. At the Paris exhibition in 1867, Germany received the first genuine recognition as an industrial nation. During the 1873 Vienna exhibition, it was the Americans who refused to participate. The reason was that the Americans need intellectual protection of their creations from German nations so that the ideas are well protected. This led to the origin of Paris convention in 1883. This international treaty helped people of one country to protect their creations in another country, provided the other country is also a member of the convention. The main advantage is that the inventor has the right of priority of his invention. This in turn was the origin of the protection of industrial property in different countries. In 1893, in order to carry out the administrative tasks, an international organization called United International Bureaux for the Protection of Intellectual Property (BIRPI) was established in Berne, Switzerland.

Reasons for Formation of GATT and WIPO

After World War II, economy in many European and Asian countries was shattered. After the UNO was born, three bodies were born in 1947, i.e., World Bank, International Monetary Fund (IMF) and International Trade Organization (ITO). It was the US senate, which blocked the ITO. The objective of these organizations was to revive the economy especially in developing countries. It was in the same year India signed General Agreement on Tariffs and Trade (GATT). The agreement was designed to provide international free trade within member states by regulating and reducing tariffs on traded goods. The main objective was to encourage trade. On January 1, 1948, 23 contracting states including India ratified GATT. Mean while, with the increasing awareness of the intellectual property, in 1960, in order to bring closer to United Nations and other international organizations, BIRPI was shifted from Berne to Geneva.
in order to modernize and for better administration of the unions with respect to protection of the intellectual property and artistic works, while fully respecting the independence of each of the union, World Intellectual Property Organization (WIPO) replaced the BIRPI.

Role of GATT

It was under GATT, the biggest advancement in international trade liberalization have come in to existence through multilateral trade negotiations. The role of GATT is to provide a stable and predictable international trade system. Secondly, it acts as a mediator in settling the disputes between countries regarding trade. Thirdly, it holds frequent negotiations, encourages reductions in tariffs so that expansion in world trade becomes possible. The objective of India signing the GATT agreement is to export indigenous products and in turn purchase oil, industrial raw materials, machines, new technology and other things that are domestically needed. During 1950s and 1960s, continuous reductions of tariffs led to high rate of world trade growth. Thus in the GATT era, trade liberalization helped in trade growth consistently instead production growth.

Role of WIPO

The role of WIPO is to promote international cooperation with respect to creation, dissemination, use and protection of works of the human mind for economic, social, cultural progress of all mankind. It enhances a worldwide balance of the creation i.e., by protecting moral, material interests of the creators and providing access to the socio-economic and cultural benefits to others. WIPO promotes protection of intellectual property and bring out cooperation among the union. In addition to these, WIPO sets norms, standards and execute legal technical assistance, registration activities for intellectual property protection to member countries. It is the WIPO; which is responsible for the formation of Patent Co-operation Treaty (PCT).

Reasons for Formation of PCT (Patent Cooperation Treaty)

Basically, under the traditional patent system, the inventor has to file applications in each and every country where he wishes to possess a patent. The Paris Convention provided a great opportunity in claiming the priority date of an earlier application for the subsequent filings in foreign countries if the parent and foreign countries are members of the convention. The
advantage with the Paris Convention is that, the inventor after filing a patent in his/her owns
country can decide within a period of 12 months whether to file patent applications among Paris
Convention countries. This in turn means that the inventor if wishes to file patent application in
foreign countries; within a period of 12 months he/she has to make all the necessary
arrangements of language translations, filing of patent applications in all the countries, bare fees
of patent offices, attorney's. To overcome the problem of duplication, BIRPI/WIPO came out
with a new treaty called Patent Cooperation Treaty in 1970. PCT became an international
cooperation treaty with respect to filing, searching, and examination of patent applications and
dissemination of the technical information contained in it.

**Role and Objective of PCT**

Patent Cooperation Treaty brings out several benefits for the users of patent system i.e., brings
one application filing with one single language which in turn is valid in PCT member countries,
provides single time examination of the patent instead each member country, provides
international search rather than each country search so that prior art can be easily judged in order
to get a patent, provides international publication of international publications with related
international search reports, bring down one single communication to all designated offices,
provides any person from the member country to file single opposition regarding the
patentability of the invention, provides uniform procedure and economical benefit to the
inventor in all mentioned aspects. In addition to these the main objective of PCT is to facilitate
and accelerate access by industries and other sectors to technical information relating to
inventions and to assist developing countries in gaining access to technology.

**Reasons for the Patents Act, 1970**

The major sources of the medicine for India were from foreign countries. Medicines required for
human cure were not easily obtained to the common human being in India. The lack of
indigenous medicines and their huge demand led to very high prices. It was the external law that
influenced the local law. Drug prices in India were amongst the highest in the world. In 1957,
the Indian Government appointed Justice Rajagopala Ayyangar committee to revise the patent
law to comply with the industrial needs. The report suggested for a process patenting so that the
medicines reach even the poor sections of the society. The government vested the Patents Act in
1970. This revolutionized the economic system in India by providing the medicine at a low
price.
Look on the Patents Act, 1970

One should evaluate the Patents Act, 1970 and understand how different aspects of intellectual property were considered at that moment. Section 3, 5 of the Patents Act, 1970 mentions that inventions that are frivolous, obvious, exploiting commercially to public, immoral, prejudice to human, animal, plant life or health or to the environment, scientific principles, abstract theories, identified to possess new use for a known substance, known process, known machine or known apparatus, aggregation of the properties by admixture and process for production of such substances, arrangement or re-arrangement or duplication of known devices, methods of agriculture, horticulture, processes for the medicinal, surgical, curative, prophylactic or other treatment of human beings, animals to render them free of disease or to increase their economic value or that of their products, a mathematical or business method or a computer programme perse or algorithms, literary, dramatic, musical, artistic work, cinematographic works, television productions, rule or method of performing mental act, method of playing game, presentation of information, topography of integrated circuits, aggregation or duplication of known properties of a traditional knowledge, atomic energy, claiming substance intended for use, or capable of being used, as food or as medicine or drug, or substances prepared or produced by chemical processes are not patentable.

Opportunities from the Patents Act, 1970

With the provisions made in the Patents Act, 1970 the citizens of India got an opportunity to develop processes. This led to a huge benefit in economic growth of India. Bulk drug manufacturers made use of this opportunity in manufacturing drugs in bulk and selling at a cheaper price.

GATT Tuning to WTO

In 1970s despite, GATT's success in trade growth through tariff reductions, global competition led a series of economic recessions leading to high rate unemployment, factory closures. To overcome this, governments were driven to devise other forms of protection i.e., bi-lateral market sharing agreements within competitors and embark subsidies to maintain holds on agricultural trade. In addition to this, advancements in science, individual needs, world trade became complex. Trade services were found promising globalization of world economy, but rules not covered in GATT. These changes undermined the credibility and effectiveness of
GATT. Together, these and other factors influenced among GATT members and concluded to vest multilateral system. This led to Uruguay round of negotiations; the last and largest round of GATT.

**Uruguay Round**

Having found some setbacks in the rules of GATT, the members came together to negotiate issues regarding international trade liberalization, improve the rules. Starting in 1986, the negotiations ended in 1993. Not only the inclusion of the traditional areas of trade in goods, the rules relating, trade in services, trade related intellectual property rights (TRIPS) in the negotiations, but also the approval of farm trade by services, market access, anti-dumping rules and the proposed creation of new institution by all member countries dragged attention on Uruguay round. It was on April 15, 1994 at Marrakesh, Morocco, the ministries of 125 governments signed the agreement.

**WTO, Trips Origin**

The agreement signed at Marrakesh, Morocco led to replacement of GATT by the World Trade Organization (WTO), on January 1, 1995. Upon signing the agreement all the countries became WTO members. Under the annex 1C of WTO agreement an agreement regarding Trade Related Aspects of Intellectual property has been included.

**Role of WTO**

The World Trade Organization mainly deals with agriculture, textiles, clothing, banking, telecommunications, government purchases, industrial standards and products safety, food sanitation regulations and intellectual property. The principle [2], [4] is foundation of multilateral trade system by treating foreigners and locals equally, bringing free through negotiations, predicting through binding and transparency, promoting fair competition, encouraging development and economic reforms.

To improve welfare of the people of the member countries WTO bring benefits like peace, solving disputes among countries, free trade that in turn reduce cost of living, choice of products, quality, economic growth and good government. Thus in turn WTO improves welfare of people of the member countries.
**How WTO Different from GATT**

Despite GATT's commitments are being provisional; the WTO is being complete and permanent. GATT rules were applied to trade in merchandise goods where as the WTO rules were applied to trade in services, trade-related aspects in intellectual property additionally. In case of dispute settlements, the WTO system of dispute settlement is faster, automatic and less susceptible to blockage when compared with GATT. In addition to these, the 'GATT 1947' will continue to exist until the end 1995, meanwhile ascending the members to WTO. One should keep in mind that the amended version of GATT 1947 i.e., "GATT 1994" exits as an integral part of the WTO agreement. In 1974, WIPO became a specialized agency of the United Nations system of organizations to administer the intellectual property matters recognized by the member states of the UN.

**Reason behind Origin, Role of Trips**

The wide variation in the standards and protection of intellectual property, lack of multilateral frame of principles, rules and disciplines dealing with international trade led to tensions in international economic relations. In order to solve these tensions, an agreement i.e., Trade Related Aspects of Intellectual Property Rights was framed addressing basic GATT principles and those of international intellectual property agreements was brought under WTO. Thus a provision of adequate intellectual property rights, effective enforcement measures of those rights, multilateral dispute settlements and transitional arrangements were framed.

**Drawbacks in Patents Act, 1970**

Indians have the attitude of sharing the knowledge to others without protecting it, which is in turn, a major drawback. Thus there was no mention in the Patents Act, 1970 for the protection of products such as Darjeeling tea and Basmati rice, which are famous for their superior quality from that geographical location. In addition to these, since ancient times some plant parts of turmeric, neem were well used as medicine, but there is no mention in the Patents Act, 1970 for the protection of the ancient knowledge which is being used since generations.

**Aspects India Must Comply with Reference to Trips**

The dispute in case of turmeric, neem and basmati brought awareness and the debate made to realize the need for strong intellectual property laws. The conclusion of the Uruguay round in
1994 paved the way for more change in this area of law and India joined the World Trade Organization and became obligated to comply with the Trade Related Aspects of Intellectual Property Rights (TRIPS). TRIPS provided a three-stage time frame by introduction of mailbox facility, exclusive marketing rights and product patent for India to comply with the obligation.

**Patents (First Amendment) Act, 1999, DT. 26-3-1999 W.E.F 1-1-1995**

Under the amendment of this act from January 1, 1995, a product patent application can be filled provided the product is used as medicine or drug, except intermediate. Since, India is having a ten-year transition period. The application for the product patent cannot be processed until end of 2004. A major provision is made under section 24 A, B of chapter IV A of the Patents Act, 1970 for a grant of Exclusive Marketing Right provided certain conditions are fulfilled for a period of 5 year.

**Mailbox Facility**

India has to amend its Patent Act, 1970 for availing patent protection for products. From January 1, 1995 till January 1, 2005, an application can be filed for a product patent under the provision of mailbox and after January 1, 2005 the applications will get examined and those that comply are granted product patents.

**Doha Declaration**

The Doha ministerial conference in November 2001 was considered as a success. The new round is a challenge, opportunity for developing countries to get more favorable concessions under the emerging regime. One of the important aspects was the implementation of obligations under TRIPS by member countries. The Doha declaration also solved the issue of non-affordability of patented products especially to half of the world's population. The members agreed that each member has the right to grant compulsory licenses, with the freedom to determine the grounds upon which such licenses are granted and can determine what constitutes a "National Emergency" or other circumstances of "Extreme Urgency". The provision made speedy issue of compulsory license where needed. Another point of concern among
pharmaceutical companies is the interpretation in some countries that the diseases indicated in the declaration, namely HIV/AIDS, Malaria and TB are only illustrative and the country concerned would be free to consider any disease of grave public health concern to be added. However, several countries raise concern regarding the abuse of the provisions.


The patents act 1970 (third amendment), w.e.f. 1st Jan 2005:

Third amendment required amendment in following section of act to make it compliant with TRIPS obligation.

TRIPS articles

27, 29(b), 31(b), 73

27: patentable sublet matter.

29: condition of patent applications.

31: other use without authorization of right holder.

73: security exceptions.

Section amended

2(1) (a), 3(d), 7, 8,9,10, 119a) (b), 12, 13, 16, 17, 18, 19, 87, 90, 100, 107 (a), 113, 116, 117(a) (d) (g), 120, 123, 126, 135, 138, 142, 143, 159

New section inserted

14,15,21,25,26,39,43,58,65,68,92(a), 133.

Omission of section

4,22,23,24,151,152,163.

2.2 Issues not sorted

Definition of patentability of new chemical entity (NCE) and micro-organisms

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<tr>
<td>2 (1) (j)</td>
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<td>Consideration of report of examiners by controller, power of controller to</td>
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</table>

**Ground for opposition of patent:**

1) Obtaining invention wrongfully.
2) Prior publication of complete specification before priority date of claim.
3) Filling application patent in India, being claim of which the primary date is earlier than of application claim.
4) Claim is publicly known of used before priority data of claim.
5) Claim is obvious within means of this act or is not attestable under this act.
6) Claim is not inventive which in means of this act or is not attestable under this act.
7) Claim does not describe the invention or method by which it is to be performed.
8) Applicant fails to disclose to the controller the information require by section 8.
9) Convention application not made within 10 months.
10) Wrong mention of source or geographical origin of biological material use for invention.
11) Claim or specification is anticipated having regard to the knowledge, oral or otherwise available within any local or indigenous community in India or elsewhere.
Section 163 (omitted)

Transitional provisions:

1) EMRs will demand to be treated as request for specification for grand of patent under subsection (3) of section 11(b) of principle act.
2) Exclusive rights granted before 1st Jan 2005 shall continue to be effective with same terms and conditions on which it was granted.
3) EMRs granted before 1st Jan 2005, shall be examined for grant of patent immediately on the commencement of this act.
4) All suits related with EMRs before 1st Jan 2002 shall be dealt with same manner as if they were suits concerning infringement of patent under chapter XVIII of principle act.
5) No liability of EMRs by central government for grant of EMRs after 1st Jan 2005.

The patents (amendment) act 2005;

Salient features

Important sections of amended act which are significant as far as pharmaceutical industry are.

1. Scope of patentability

1. Defines what is patentable, thus limiting protection to new entities and preventing pharmaceutical companies from filling patent application for drugs that are not substantially difficult from the original patent.
2. Software patents excluded.
3. Substituted new use for mean new use thus strengthening the provision that can be used to deny patents on the new use of known substances.
4. Refers the question of whether a pharmaceutical substance should be defined as new entity involving, or more inventive steps or a new chemical entity to expert committee.
5. To prevent frivolous claims, it clarifies that the “mere discovery of new form of known substance, which does not result in enhancement of known substances” is not patentable.
6. Salts, esters, ethers, polymorphs, metabolites, particle size, isomers, mixtures of isomers, complexes, combination of other derivations of known substances cannot be patented unless they “differ significantly” in properties with regard to “efficiency”.
7. The applicant has to comply with inventive step, which means that the invention has to involve technical advances as compared to existing knowledge or having economic significance or both.

2. Immunity for generic production:-

   A. Drugs that being were produced, marketed by Indian companies before 1st Jan. 2005 can continue reasonable royalty (1).

3. Export of patented pharmaceutical product:

   A. The requirement the country to which drugs were being exported needs to issue compulsory license has been removed.

4. Opposition to the grant of patent:

   A. Pre-grant opposition restored.
   B. The number of grounds on which patent can be opposed restored.
   C. Provision related to mandatory provision not restored. One has to pay fees to access this information.
   D. Invention either filed or claiming priority as of July 2003 are “deemed to be published” without making physical publications available.

5. Terms of patent:

   A. 20 years from date of filling for all patents. The date patent comes into force is calculated from the date of publication of the mailbox application.

6. Compulsory license:

   Reasonable period for grant of compulsory license has changed to six months.

   A. Company can apply for compulsory license only after three years after license is granted.

**Ambiguity in certain issues:**

1) Qualification regarding “enhancement of known efficiency”.
2) Interpretation of term “differ specifically in properties with regard to efficiency”.
3) Reasonable royalty to be paid to inventors for drugs invented prior to 1st Jan 2005 term “reasonable royalty” has not been defined. (In most of the countries it is fixed at 4%).
4) Mechanism of issuing compulsory license to export drugs.
5) Access to information for claims filled or claimed as of July 2005.

The patents (amendment) rules, 2005

The ministry of commerce and industry by notification in official gazette on 25th Dec. 2003 updated patent rules, 2003 on lines contained in amendment to the patent act 1970 under provisions section 159(3) of the patent act 1970; central government dispenses these rules named, the patent rules 2005, w.e.f. Jan 1, 2005. Rules which are particularly significant to pharmaceutical industry are given below (2)

1 – Business world.

2 – The patent (amended) rules 2005, ministry of commerce and industry 28/12/2004
### 2.3 Section substituted in the patents rule 2005

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<th>Principle rule( the patent rule 2003)</th>
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To cross the barriers of TRIPS other than EMR, India introduced second amendment bill and several changes were made in the Act. The following are the key changes made.

**Patentable inventions:**

Invention as a new product or process involving an inventive step and capable of industrial application define section 2 of the Patents Act, 1970. With the proposal of introduction of product patents, the definition is broadened by introduction of the words 'non-obvious' and 'useful' synonymous to inventive step and capable of industrial application, respectively.

**Not inventions:**

A provision is made in Section 3 of the Patents Act indicating that plants and animals in whole or any part thereof other than micro-organisms but including seeds, varieties and species and essentially biological processes for production or propagation of plants and animals as not inventions.

**Exclusions from patentability:**

Section 3 of the Patents Act, 1970 clears that are not inventions. The new definition excludes, in sub-section 3, inventions whose 'primary or intended use or commercial exploitation' is contrary to law and morality. In addition to this, the bill also excludes medical, surgical, curative, prophylactic, diagnostic, therapeutic treatments for humans, plant and animals. India also excludes the patenting of computer software, business method patents specifically and biotech patents.
**Term of date of patent:**

Earlier the patent protection term was 14 years from the date of filing the complete specification of the patent. However, the proposed bill extended the term to 20 years.

**Application requirements:**

Section 10 of the Patents Act, 1970 mainly clears about the contents of the specifications in a patent. The section mainly tells that a patent must include with title, description of the invention, drawings, model or sample of anything illustrating the invention, description of the operation, use, method of performance of the invention, the best method of performance, ending with a claim defining the scope of the invention. The amendment includes additionally an abstract of the invention, which must be included in to the patent.

**Compulsory licensing:**

The chapter XVI of the Patents Act, 1970 provides compulsory licensing as a necessary safeguard for protecting public interest. After 3 year of a sealed patent, any interested party can request for a compulsory licensing provided the invention is not reasonably available to the public. Central government has the right to make an application requesting the controller to endorse a patent with the 'license of right'. The amendment removed the provision of the central government. In addition to this necessary amendments were done with reference to requirement of the public are not satisfied, if the invention is not manufactured in India or the patentee refuses to grant a license by removing a presumption that requirements of the public are not satisfied based on local manufacture. The amendment also made a provision to the controller for granting compulsory license under conditions of national emergency. A provision has also been made enabling the third party to seek for compulsory license even the invention is not manufactured in India. The amendment also provides the revocation of the compulsory license by the controller himself if the circumstances that gave raise to it cease to exist.

**Right to import and parallel imports:**

The Patents Act, 1970 that did not vest on the patentee or a license holder the right to importation a patented product is dissolved. This made an accessibility of products in all ranges of cost in India. However, importing a patented product from the patentee, valid license holder will amount to infringement under TRIPS. The doctrine of exhaustion specifies that the patent
holder does not have any control over a buyer or a licensee once the product has been placed in the market. The implied license suggests that a buyer can remanufacture the goods and import them into the same market for a lesser cost thus restricting spurious parallel imports into the country and balance the effect of taking away the need for local production and will also be in line with TRIPS.

**Bolar provisions:**

For the submission of data relating to bio-equivalence of drugs before the expiration of the patents a provision has been made under the Patents Act, 1970. The stock piling before the expiry of the term of the patent is prohibited.

**Burden of proof:**

In case of suits concerning infringement of a patent in which the subject matter is a process for obtaining a new product. Under such conditions the court may ask the defendant to prove that the process used by him to obtain the product, is identical to the product of the patented process is different from the patented process.

**The Patents (Amendment) Ordinance, 2004**

As part of the three-stage frame to comply with TRIPS, India passed the Patents (Amendment) Ordinance, 2004. In section 2 of the Patents Act, 1970 definition and interpretation of Budapest Treaty was included. It means the Budapest Treaty on International recognition of the deposition of microorganisms for the purposes of patent procedure done at Budapest on April 28, 1977, as amended and modified from time to time. Section 3 of the Patents Act, 1970 relating to inventions where only methods or processes of manufacture patentable are omitted. The Act gave provisions for patenting a process as well as a product.

In section 7 of the Patents Act, 1970 the filing date of an application referred to in sub-section (1A) shall be considered as the international filing date accorded under the "Patent Cooperation Treaty". The sections 22, 23 and 24 dealing with acceptance, advertisement and effect of acceptance of complete specification are omitted. The sections 24A, 24B, 24C, 24D, 24E and 24F of the Patents Act, 1970 dealing with mainly Exclusive Marketing Rights are omitted indicating that a provision being made during the transition period. A new section 92 A, was introduced for grant of compulsory license for manufacture or export to any country, which has
insufficient, or no manufacturing facility provided an application is made by the convention country.

2.3 Impact on business

TRIPs will transform the legal and business framework in India. It is going to fundamentally alter competitive equation for starters; better intellectual property protection will facilitate the transfer of technology. Better intellectual property protection will facilitate transfer of better technology. Foreign firms are often accused of transferring outdated technologies to their Indian partners, but it is often forgotten that a lax intellectual property rights regime does not offer much incentive to do otherwise.

Quality of intellectual property protection improves expenditure on research and development by industry as a whole will climb. The Switch from process patent to product patent will transforms the pharmaceutical industry and will the TRIPs agreement expanding the scope of patent protection to include all fields of technology.

Pharmaceuticals:

Due to TRIPS new drugs under development for treatment of various diseases will be under patent and hence will be priced beyond the reach of all, meanwhile indigenous industry will be negatively affected. In the 30 years since the patent act, 1970, came into being, the industry moved from trading in transnational brands to producing and exporting pharmaceutical substances and formulations. Since the patents were lined out. Indian firms could freely reverse engineer, the polite term for organized piracy that made drugs available in India at a fraction of their price abroad for a fraction of investment. Naturally numbers mushroomed. India pharmaceutical manufacturers spend on an average, 1.80% of its total turnover on research and development. In the US, the comparable figure is 16 %.( 3)

The number of manufacturers is bound to affect adversely due to the introduction of product patent. To survive, expenditure on research and development must grow exponentially. The basis for sustained competitive advantage in this industry will be research and development. Prices too are bound to rise, but the scope and extent of price rise is exaggerated (4). Patents worldwide cover less than 10% of India’s list of essential drugs. Moreover prices of essential drugs are low cost not because of process patents, but because of drug price control order (DPCO). Sure a patent by definition confers a limited monopoly. But most new drugs are
substitutes for existing drugs. Their therapeutic properties and side effects may differ slightly. Thus, it’s making difficult for the monopolist to extract full monopoly prices. Even a monopolist can charge only what the market can bear. The assumption that drugs will retail here at international prices is a mistake. (5). The Indian consumer is used to cheap drugs, and will not prefer 10-12 times more for a basic drug.


4 – Making drugs available and affordable: a practical approach industry highlights, Dec 2004 (1-8).

5 – Practica M. Danzon, Jonathan D. Ketchem; reference pricing of pharmaceutical for Medicare, evidence from Germany, the Netherlands and NEW Zealand, working paper 10007, national bureau of economics research, Cambridge, Sep. 2003.
The strategic impact

The scope of patent protection is constantly widening. Companies have to spend enormous amount on researching innovations which will circumvent of patents.

Add the considerable costs of litigation and the possible compensation to be paid in case patent violation is proved, and the costs can be prohibitive.

Effect of change in patent regime

Effect on transnational’s:-

1. Investment will granted better intellectual property rights protection,
2. Their research and development center can be set up in India.
3. Technology transfer to Indian joint ventures will be safer.
4. Patents held by global patents will be recognized in India.

Effects on consumers:

1. Global product will become more easily available in India.
2. Better product will be available to the consumer.
3. More products will meet higher quality standards.
4. Prices of some patented product will increase.

Effects on research and development

1. Research results must be patented before publication.
2. Technologies development will be licensed out.
3. Corporate and lab will collaborate on research and development.
4. Commercialization of research will earn royalties to fund research and development.

Effects on government

Policies are conforming to the new regime must be created.

1. The process of granting patents must be speeded up.
2. Patent application fees will become a source of revenue.
3. Penalties for violation of patent laws will have to be hiked.

Reforms taken by Indian patent offices

1. Modernization and computerization of patent offices.
2. Initiatives for integrated intellectual property offices in the metro cities.
3. Logo for intellectual property administration has been designed and put in use.
4. A website of intellectual property office has been launched. (http://www.ipindia.nic.in)
5. 227 additional posts of patent examiners have been created.
6. An intellectual property training institute has been established at Nagpur, for training of examiners.
7. Online search facilities have been established.
8. Work manual for intellectual property office have been prepared.
9. The patent (amended) act, 2002 introduces examination on request system in place of examination of all application to reduce backlog of pending patent applications.
10. Digital database of over 1,00,000 patents record and 48,000 design records are prepared.

Recommendations

1. Training of patent examiners and attorneys.
2. Formation of tribunal/appellate board as soon as possible.
3. Electronic filling of patent application.
5. Appointment of permanent controller general.
6. Digital bank for traditional bank.
7. Development of database on lines of PCT gazette and USPTO.
8. Single set of serially allocated numbers, allotted both PCT and Non PCT application.

2.4 Indian Patent System

Ministry of Commerce & Industry

The Department of Industrial Policy and Promotion under the Ministry of Commerce & Industry is responsible for Intellectual Property Rights relating to Patents, Designs, Trade Marks and Geographical Indication of Goods and oversees the initiative relating to their promotion and protection. These include the outlining of policy and its implementation through the Office of
the Controller General of Patents, Designs and Trade Marks. Promoting awareness regarding protection of the Intellectual Property Rights is inherent in industrial property in conjunction with the World Intellectual Property Organization (WIPO) and apex industry organizations apart from similar initiatives involving regional industry associations. It also provides inputs on various issues relating to the Agreement on Trade Related Aspects of Intellectual Properties (TRIPS) related to World Trade Organization (WTO) in these fields. The Department undertakes technical cooperation programs with the World Intellectual Property Organization (WIPO), Geneva for the modernization and upgradation of Intellectual Property (IP) administration.

Office of the Patent Information System (PIS)

Ministry of Commerce and Industry, Department of Industrial Policy and Promotion established Patent Information System (PIS), in the year 1980 with the following objectives.

1. To obtain and maintain a comprehensive collection of patent specification and patent related literature on a worldwide basis to meet the needs for technological information of various users in R&D establishments, Government Organizations, Private Industries, Business, Investors and other users.

2. To provide technological information contained in patents or patent related literature through publication services, search services and patent copy supply service; and to meet statutory obligation regarding novelty search under the patent Act, 1970 (Amended).

3. The major initiatives by the Department include modernization of IP infrastructure and establishment of new integrated offices in Delhi, Kolkata, Chennai and Mumbai which was completed during July 2007. A program costing Rs.153 crores implemented in the 10th Five Year Plan of Indian Government.

4. The program focused on the following: Infrastructure development; Computerization; Human resource development; Training and awareness. Further modernization of IP Offices to provide additional human resources, higher level of computerization to support on-line processing, strengthening of data-base and novelty search facilities, awareness generation activities, accession to international treaties/ conventios is being taken up in 11th Five Year Plan.

5. The Department has introduced e-filing facility for patent and trademark applications. Along with the legislation, rules have also been amended to install a user-friendly system
for processing of IP applications. As a result of modernization, the filing of patent applications has increased.

**Technology Information, Forecasting & Assessment Council (TIFAC):**

An autonomous organization under Department of Science and Technology (DST) aims to keep a technology watch on global trends and formulating preferred technology options for India. The Patent Facilitation Centre (PFC) of TIFAC has conducted 305 awareness workshops sensitizing about 3200 scientists, technologists and policy makers from 85 Universities, 100 R&D institutions and 150 industries. Besides providing assistance for filing patent applications, the centre provides patent search services through two databases viz. Ekaswa-A: Patent applications filed in India as published in the issues of the Gazette of India (Part III, Section 2) from January 1995 onwards and Ekaswa-B: Patent applications notified for opposition in the Gazette of India (Part III, Section 2) published from January 1995 onwards.

**Patent Facilitating Centre (PCT) by TIFAC under DST**

A Patent Facilitating Centre was set up by Department of Science and Technology under Technology Information Forecasting and Assessment Council (TIFAC) in the year 1995. The major objectives of PFC are introduction of patent information as a vital input in the process of promotion of R&D programs. Aim is to provide patent facilities to scientists and technologists in the country for Indian and Foreign patents on a sustained basis, keep a watch on developments in the area of IPR and to make important issues known to policy makers, scientists, industry etc. To create awareness and understanding relating to patents and the challenges, opportunities in this area including arranging workshops, seminars, conferences, etc. This Single Window facility to serve with a smile and "May we help you" approach. PFC has been undertaking specialized studies based on patents granted and also on other patent related subjects.

**National Research Development Council (NRDC) under DST**

The NRDC team has a singular purpose which is to identify and satisfy the potential investor in the use of innovative, reliable and competitive technologies co-developed or marketed by the corporation.

1. To this purpose, NRDC harnesses its human resources to promote, through flexible funding schemes, the development of marketable technologies in close association with industry and national R&D institutions.
2. To evaluate the technological merits and commercial potential of incipient or mature technologies by conducting techno-economic surveys; technology and business forecasts and investment appraisals, preemptively protect intellectual property rights worldwide.

3. To design and engineer manufacturing plants of commercial scale.

4. To shape and manage technology contracts those are fair and equitable.

5. To test -market products and assist in obtaining certifications for products and their quality, where these are prerequisites for entering commerce.

This Institute's Research Department undertakes to research in Intellectual Property Rights (IPRs) issues and aims at establishing, maintaining and managing center(s) of research to promote the knowledge of intellectual property laws of India as well as intellectual property systems of other countries. The Institute aims at establishing rapport with research bodies, Chambers of Commerce, businessmen and other professional institutes to ensure promotion of Intellectual Property research. The Institute provides training in the field of Intellectual Property research and management to lawyers, scientists of R&D labs, students and other professionals.

**Confederation of Indian Industry (CII) Initiatives in IPR**

Confederation of Indian Industry (CII) has a National Committee of Intellectual Property (IP) Owners, Chaired by Mr. Shanker Annaswamy, MD, IBM India Ltd. and having members from IP Owners' Industry. Andhra Pradesh Technology Development & Promotion Centre (APTDC--jointly promoted by CII, TIFAC and Government of AP) Governing body, Chaired by Secretary, Department of Science & Technology, Government of India and having members from Industry, Government of India & Andhra Pradesh. APTDC established in the year 2000 as an autonomous organization in Hyderabad to help SMEs in technology and IPR areas. APTDC's IPR Facilitation Cell is the pioneer institution in the country in providing various IPR services towards Training, Information & Advisory services and IP protection facilitation. The overall objective of CII's initiatives in IPR is to enhance competitiveness of Industry through wealth creation through IPR. The primary focus of the initiative is to take policy initiatives, awareness creation, capacity development, IPR services, international networking and also combating the menace of counterfeiting & piracy.

**Biotechnology Patent Facilitating Cell (BPFC) under Department of Biotechnology**

The BPFC has organized a series of national seminars on "Patenting in Biotechnology" and "IPR
in Biotechnology" at various Institutions and Universities around the country, in collaboration with World Intellectual Property Organization (WIPO), Geneva, to enhance the awareness of the scientists about the inventions, process of patenting, issues in IPR in biotechnology and the strategic importance of the IPR in post-GATT era, the procedures and nuances of writing patent documents with description, claims and issues associated with the protection of live forms, international patenting, product patents etc. TKDL access agreement with International Patent office’s has been permitted by the Government. Access to TKDL would be secured and shall be utilized by the examiners of Patent Offices for patent search and examination purpose only. Negotiations with leading International Patent Offices are in an advanced stage. Two journals published by the institute namely National Institute of Science Communications and Information Resources (NISCAIR) Indian Journal of Traditional Knowledge (IJTK) and Medicinal and Aromatic Plants Abstracts (MAPA) have been included in the PCT minimum list.

Ministry of Health and Family Welfare (MoH&FW)

The WTO Cell in the Ministry of Health and Family Welfare works on ascertaining impacts on public health due to globalization and suggests ways to formulate effective legislation and policy initiatives to deal with it. In particular, the function of the WTO Cell includes providing technical assistance to the MoH&FW in the area of international trade related agreements, such as TRIPS, GATS, SPS and TBT.

2.5 Patenting Process in India

When the inventor finds value in his/her invention and starts thinking to protect invention Patenting starts. Process of obtaining patent begins when the inventor discloses the full details of invention in written format to the patent office details such as the nature of the invention, details process steps involved in the development of the invention, the various merits and demerits of the invention over other existing methodologies, usefulness of the invention etc. If the inventor discloses the invention by means of illustrations, drawings and it is important that whatever has been described in written format should be similar to when has been explained through drawings the possibility of obtaining patent is more. At last, the inventor should sign at the end of disclosure and clearly specify the date on which the disclosure was made which ensures there was somebody who had witnessed the invention disclosure.

Every application shall be accompanied by a provisional or complete specification. Filing of a provisional specification allows the applicant to get an early application date. Provisional
Specification contains Title, Written Description, Drawings, if necessary and Sample or model if required. The complete specification shall contain Title, Abstract, Written Description, Drawings (where necessary), Sample or Model (if required by the examiner), Enablement and Best Mode, Claims and Deposit (Microorganisms).

The following documents have to be submitted at the time of filing patent applications are:

Form 1--Application for the grant of patent,

Form 2--Provisional or Complete Specification,

Form 3--Statement and undertaking by the applicant,

Form 5--Declaration as to inventor ship,

Form 26--Authorization of patent agent or any other person.

Priority document details have to be filed for a Convention application. To get a U.S. patent, it should be filled in U.S. Patent and Trademark Office. There are two types of patent applications namely provisional and non-provisional patent application. Patent Application can be filed at any of the four patent offices in India. Patent Offices are located at Kolkata, New Delhi, Chennai and Mumbai. A patent provides protection for the invention to the owner of the patent. A patent is granted by a national patent office or by a Regional Office. The protection is granted for a limited period, generally 20 years. Priority date is the date of first filing allotted by the patent office to an application. There are three different types of patents utility patent, design patent and plant patent on a new variety of living plant.

By filing of a patent application patentee is securing a patent. Before filing the application, Patent search should be conducted. After submission with the Patent Office, the officer then starts publication and examining the authenticity of invention. If everything is in order, the patent would be granted to the inventor. If the application gets rejected, the inventor has to make the necessary amendments and resubmit the application. It is advisable to use help from the Patent professionals or IPR firms so that the entire process is smooth and painless. Usually there are specialized firms that take care of patent applications and it is advisable to use help from these professionals so that the entire process is painless and smooth.
Patent Application Examination

Any application is filed for a patent in a Patent Office, the application is examined for patentability by a Patent Examiner. Examining the value of a particular invention is an aspect that is very much important while issuing a patent. A Patent examiner looks for in inventions which include novelty, usefulness and non-obviousness. An invention should not be an elaboration of a fact that was already explained nor should it be an extension of something that already exists. Every application must meet all these three conditions otherwise patent application would be rejected. Non-obviousness is the most difficult criterion that is to be explained in a patent application. Obviousness of an invention refers to previous arts, printed publications and several other patent applications that were successfully filed earlier.

Electronic (e)-Filings of patent Applications

During July 2007, Indian Intellectual Property Office (IPO) has commenced e-filings of patent and trade mark applications. With this facility, India joined elite group of dozen countries including U.S., Japan, South Korea, China and the EPO having e-filing of patent applications, with this first phase of modernization of Indian Patent Office’s came to an end.

Indian patent trends ISA & IPEA

By the World Intellectual Property the Indian Patent Office recognized as the International Searching Authority (ISA) and International Preliminary Examining Authority (IPEA) Organization (WIPO) which consists of more than 170 member nations. As an ISA and IPEA, major functions of the Indian Patent Office will be to approve or establish the title and conduct international searches. The recognition of India as an ISA and IPEA places India among 15 nationals currently recognized at a global level. This status would also generate an income through fees. India is the only country in the Asian region recognized as an ISA and IPEA. (Source- Patenting: an Indian scenario by R. Balamurugan, R. Radhakrishnan)

2.6 Summary

By referring all above points, it seems that Indian government has positively tackled issues related with intellectual property by making necessary amendment in patents act in following areas of intellectual property rights:-

1. Exclusion from patentability.
2. Protection of traditional knowledge.
3. Redrafting of compulsory license provisions.
4. Reintroduction of national security provisions.
5. Provisions to check process and ensure prompt availability of patented product after expiry of the term of patent by incorporating “Bolar provision” and similar import provisions.
6. Introduction of pregnant publication and deferred examination system.
7. Protection of bioavailability.