CHAPTER - II

BASIC PRINCIPLES OF PATENT LAW
Patent law is primarily concerned with balancing private and public interests involved in the process of economic development. Patent protection is considered to be a necessary precondition for private investment in research and development activities, which is necessary for the growth of pharmaceutical sector. At times excessive patent protection may adversely affect public interest involved in promotion of public health, safety and welfare of the people.

2.1 Nature of patents

A patent may be defined as a grant by the state of exclusive rights for a limited period in respect of a new and useful invention. These rights are in general limited to the territory of the state granting the patent, so that an inventor wishing protection in number of countries must obtain separate patents in all of them. The name patent is a contraction of ‘letter patent’, which means a document issued by or in the name of the sovereign, addressed to all subjects and with the great seal pendant at the bottom of the document so that it can be read without breaking the seal.¹

The Delhi High Court observed that patent is an exclusive right, which the inventor has over his invention as a reward in return of the disclosure of his invention to the public for the benefit of the society. The exclusive right of the

inventor over his invention includes his right to assign his invention or transfer any interest in his invention in favour of any other person in consideration of monetary gain. Thus “a monopoly of the patent is the reward of the inventor”. \(^2\)

It is important to realise that the rights given by a patent do not include the right to practice the invention, but only to exclude others from doing so. The patentee’s freedom to use his own invention may be limited by legislation or regulations having nothing to do with patents, or by the existence of other patents. It is very often heard that patent allows company to do something or other. But it does not, it only allows them to stop someone else from doing it. The right to prevent others from carrying out the invention claimed in a patent may be enforced in the courts. If the patent is valid and infringed the Court can order the infringer to stop his activities as well as providing other remedies such as damages. \(^3\)

It is also important to distinguish between ownership of an invention or a patent and ownership of goods, which incorporate the invention or fall under the patent. The question of who owns the goods is completely different from that of who owns the patent. Unlike the situation with regard to copyright, infringing goods do not become the property of the patentee, and even if the patentee manufactured the goods, once he has sold them, he can retain no control over their subsequent use or resale. The fundamental distinction between the ownership of

\(^2\) Telemecanique and Controls (I) Ltd v. Schneider Electric Industries 2002 (24) PTC 632 (Del.).  
\(^3\) Supra note 1, at p.4.
patents and the ownership of things, which are patented, is often misunderstood or deliberately misrepresented. So that for example patents granted for transgenic animals are described as giving ownership of 'life' and patents for isolated human genes are talked of as if they gave property rights over human beings.  

2.1.1 Property right

A patent is nevertheless a piece of property and may be a very valuable one. Although intangible property, it may be dealt with in the same sort of ways as tangible property such as real estate. Just as the owner of a house may live in it himself, sell or rent it to another, mortgage it, or even have it demolished. So a patentee may keep his patent rights, assign the patent to some one else, grant some one else a licence to do something covered by the patent, mortgage the patent or of course abandon the patent to the public. Abandonment of patent right is very common in the great majority of countries in which renewal fees often rise steeply as the age of the patent increases, and only those patents, which are of real commercial importance, are kept alive for their full term.

2.1.2 Limited duration

In any event no patent can go on indefinitely. It is a point basic to the whole concept of patents that the exclusive rights are granted only for a limited period of time and that once this term has expired the general public is free to use the invention. In Britain patents were granted generally for a term of 14 years. In 1919 the term became 16 years and extensions were possible in exceptional

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4 *Id.* at p.4.
circumstances, for example if the patentee was unable to exploit his invention because of war time conditions or if he had a particularly deserving invention on which, through no fault of his own, he had not made sufficient profit. A combination of these two grounds enabled the British patent for a pioneering invention relating to colour television to be extended to a total term of 32½ years: unfortunately for the patentee, his infringement action against producers of colour television sets was unsuccessful, the patent being finally held invalid.5

In U.S.A. and Canada the term of patent was until fairly recently 17 years from the date of grant, which meant that the longer the patent office took to grant the patent, the later was the expiry date. In most other countries, the term ran from the date of application and so the expiry date was fixed irrespective of how long the process of grant might take. A term of 20 years from the filing date was set for European Patents by the European Patent Convention, which came in to force in 1978, and the Patents Act 1977, which came into force on the same day, set the same term for British National Patents. This has become the international standard set by the GATT-TRIPs agreement and is now adhered to by most countries.6 In India, initially the term of patent was 14 years with respect to all inventions except the inventions relating to food and drugs. For such inventions only process patents were available for a period of 5 years. But after 2002

6 Supra note 1, p.6.
amendment to the Patent Act 1970, the term of patent has become 20 years for all inventions.

The term of available patent protection is more important in some industries than others. In the pharmaceutical industry for example, where it takes many years for a product to reach the market, and where the same product, once introduced, can usually be sold for 20 years or more, it is vital to the patentee to obtain as long a patent term as possible. On the other hand in an industry in which products can be brought to the market quickly but are rapidly replaced by newer products, the patentee is more interested in obtaining rapid grant of an enforceable patent than in prolonging patent term. For products, which require a long approval process before marketing, such as pharmaceuticals and agrochemicals, it is now possible to obtain extensions of the standard patent term in the U.S.A., Europe, and Japan.7

2.1.3 Patents and monopolies

A clear distinction is to be made between a monopoly of an existing commodity and the exclusive rights given by a patent for a new invention. The old definition of monopoly given in Blackstone's commentaries is still a good one.

A licence or privilege allowed by the king for the sole buying and selling, making, working or using of anything whatsoever, where by the subject in general is restrained from that liberty of manufacturing or trading which he had before.

7 Id., at p.7.
According to this definition, exclusive patent rights are not a monopoly because, being for a new invention, they cannot possibly take from the public at large any right, which the public previously had. Even when the term 'monopoly' is given the broader meaning of any exclusive right to make, use or sell, the distinction between a monopoly in an existing commodity and a patent monopoly in respect of a new invention should be kept in mind. The two were clearly distinguished in English law as long ago as 1624, although today it is still being alleged, for example, that patents on new products obtained from the neem tree will stop Indian peasants from using traditional neem remedies.  

2.2 History and evolution of patents

The Intellectual Property Rights as a legal regime has its origin in the Western Europe in Venice, France and British regions. Later it was adopted in the American system and spread to the other regions of the world. The system is said to be originated in the Alps region in the early 1300 AD where the property rights were established for mining, use of timber and water for ore mining. Such special rights to encourage mining is said to have given the birth of Intellectual Property Rights (IPRs). One of the recorded rights was that of the special rights to a German miller to build a grain mill in Venice by the Government to be a forerunner of protecting an innovative idea as an intellectual property rights.  

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8 Ibid.  
Later in 1488, the State of Venice brought the *satuto mineraria* where it prohibited emigration of skilled workers and certain products from being exported from Venice and also rewarded skilled emigrant workers from other parts of the Europe to settle in Venice by providing them with tax holidays for two years. In this period the state of Venice has given more than 100 special privileges to encourage manufacturing and is said to have set the foundation of the later day intellectual property rights. The later day British and French systems were influenced by the development of the intellectual property system of the Venice and its practices.\(^\text{10}\)

### 2.2.1 Evolution of patents in U K

In the British domain, the Crown controlled the trading rights to be given to the various companies. This monopoly irked the Parliament and the Courts where they tried to restrict the same. Queen Elizabeth is said to have given monopoly rights to various manufacturers ranging from salt, knives to playing cards. The monopolies given were more a favouritism of the Crown than on any systematic principles. This led to clash between the Crown and the Parliament. In 1602, the King’s Bench for the first time over turned a monopoly right given to a playing card seller stating that it was already in public domain and hence will not qualify for monopoly right.\(^\text{11}\) This decision set the principle that what is already in public domain will not qualify for a patent, which is also the principle in modern day

\(^{10}\) Ibid.

\(^{11}\) *Dary v. Allein*, (1962) 1 WPC 1 (Court of Queen’s Bench).
intellectual property rights. This was followed by the developments in the later legislations by the British Parliament curbing the powers of the Crown on indiscriminate monopolies of rights. In 1624 Parliament sought to declare these exercises of royal prerogative void. In 1628 it enacted the Statute of Monopolies, which suggested not only the growing significance of trade in the country's economy and the beginnings of the long political campaign to favour competition at the expenses of monopoly; it also shows the readiness of the political force represented in Parliament to challenge policies of convenience to the Crown.

Section 6 of the Statute of Monopolies, which exceptionally, allowed patent monopolies for 14 years up on "any manner of new manufacture" within the realm to the "true and first inventor" has its own character. Section 6 also expressed the desire to impose some qualification upon the system in the name of higher public interests. The protected manufactures were not to be contrary to the law nor mischievous to the state, by raising prices of commodities at home, or hurt of trade or generally inconvenient.12

A half century later courts were requiring the patentee to make sufficient statement of his conception as "consideration" for the monopoly granted to him. 200 years after the Statute of Monopolies, the patent system developed through the work of lawyers and judges in the courts without Government Regulations. In the reign of Queen Ann, the Law Officers of the Crown established as a condition of

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grant that “for patentee by an instrument in writing describe and ascertain the nature of the invention and the manner in which it is to be performed”. This instrument became known as “specification”. However, by the mid 19th century Britain’s patent system had become extremely inefficient. The great exhibition of 1851 accelerated demands for patent reforms. Up to that time, prospective patentee had to present application to not less than seven offices and at each state to pay certain fees.13

To meet the public concerns over the state of affairs the patent office was established by the Patent Law Amendment Act 1852, which completely overhauled the British Patent System and laid down simplified procedure for obtaining patents for inventions. Legal fees were substantially reduced and the issuing of separate patents for each nation of the union was replaced by the publication of single U.K. Patent. For the first time description of patent had to be filed on applying for a patent. This could be a complete specification giving merely outlines to be completed later, within fixed period after grant. An important step forward was that the patent was dated from its application date, so that a disclosure of the invention during the application procedure would no longer invalidate the patent. As more and more patents were granted, it became necessary to clarify what the patentee thought was crux of his invention, for which he claimed monopoly and the practice grew up of doing this by means of a separate part of the specification referred to as claims. At that time specifications

13 Ibid.
were still heard before a jury, who had to decide on the basis of the specification what was the scope of monopoly, and the claims served only to point the jury in the right direction.\textsuperscript{14} Claims grew in importance with the reorganisations of the courts in 1875, which transferred jurisdiction in patent cases to the chancery division of the High Courts, and with the Patent Act of 1883, which required the specification to contain at least one claim.\textsuperscript{15}

Throughout the nineteenth century, patents were granted in U.K. without anything more than a purely formal examination. Only in 1902 was a novelty examination provided for, and not until five years later could the patent office actually refuse an application on the ground that invention was not new.

The Patent Act 1977 introduced major changes to British Patent Law, primarily to bring the national law into harmony with the European Patent Convention. Among other changes this Act lengthened the term of patents from 16 to 20 years. Subsequent legislations in U.K., has had only minor effects.\textsuperscript{16}

2.2.2 Evolution of patents in USA

The earliest grants of a patent for an invention in the United States seems to have been by the Massachusetts Bay Colony in 1640s. Although pre-independence patent custom in the American Colonies owes much to the English Statute of Monopolies of 1628, which restricted the right of the Crown to grant monopolies so that hence forth they could be granted only for a limited period and

\textsuperscript{14} \textit{Lord Russel in EMI v. Lissen}, (1938) 56 RPC 23 (HL).
\textsuperscript{15} \textit{Supra} note 12.
\textsuperscript{16} \textit{Supra} note 1, pp 19-20.
only for a manner of new manufacture. The Statute of monopolies was never made directly applicable to the American Colonies.

During the period of confederation after independence had been achieved (1783) but before the adoption of Federal Constitution of the United States (1789), most of the states had their own patent laws. However, as noted by James Madison in the federalist "the states cannot separately make effectual provision" for protection of invention and so in drafting the Constitution of the U.S. responsibility for providing such protection was entrusted to the Congress of United States.18

The constitutional basis for federal patent and copyright system is to be found in the Constitution of the United States. Article 1, section 8, clause 8 which states "Congress shall have power... to promote the progress of science and useful arts by securing for limited time to authors and inventors the exclusive right to their respective writings and discoveries".

The first United State’s Patent Act was passed in the year 1790. It was a short Act of 7 sections only entitled “An Act to promote the progress of useful Arts”.19 Under it’s terms any two of the Secretary of State, the Secretary of War and the Attorney General were empowered to grant patents for terms of up to 14

17 This had the effect of limiting the power of Crown to the grant of monopolies only for limited period and most importantly only for manner of new manufacture that were introduced into the realm by the recipient of the monopoly. Such grants were, however, conditioned on their not being mischievous to the state or generally inconvenient
19 A similar title was used for all acts relating to patents before the consolidation of 1870.
years for inventions that were "sufficiently useful and important" provided that an Inventor submitted a specification describing the invention to the Secretary of State at the time of the grant.

In 1793 this Act was repealed and replaced by a slightly longer Act, the drafting of which is largely attributed to Thomas Jefferson, who was at the time Secretary of state and therefore intimately involved in the administration of the 1970 Act. The Act is notable for its definition of what constitutes patentable subject matter in the United States, which definition is almost unchanged upto now and states: "Any useful art, machine, manufacture or composition of matter and any new and useful improvement on any Art, machine, manufacture or composition of matter".20

A short description had to be filed with the application. However, before grant could occur it was necessary to submit a written description of the invention and of the manner of using or process of compounding the same in such full, clear, and exact terms, as to distinguish the same from all other things before known and to enable any person skilled in the art or science of which it is a part, or with which it is most nearly connected, to make a compound and use the same.21

What was meant by the term 'new' in the early statutes varied somewhat but after 1800 the courts considered simply whether the invention was known before the date on which the applicant for a patent claimed to have made his or her

20 A Patent Act 1993 Section 1, the term 'art' was replaced by 'process' in 1952 but this term is itself defined as a "process art or method" 35 USC 101.
21 Section 3 of Patent Act 1793.
invention. In 1829 the Supreme Court in the case of *Pennock v. Dialogue*,\(^{22}\) recognised the potential dangers of such an approach, which enabled the inventor to delay filing a patent application until competition was imminent and construed the statutes so as to create a statutory bar to deny patent protection to one who had previously publicly used his invention.

A major review of the law was undertaken in 1836. Under this revision patent office was set up as a part of the state department and a specification had to be submitted to it and be examined for novelty before a patent would be granted. The 1836 Act finally removed all limitations on the nationality or residence of those who could obtain United State's patents. However, it did not end all discrimination on this score. U.S. citizens or residents intending to become citizens were charged $3000, British subjects were charged $500,0 and all other foreigners $300,00.\(^{23}\)

In 1870 the legislation relating to patents were consolidated into a single Act but without many significant amendments as to substance. Among the changes that were made the following are important. Removal of the requirement that if the patent had been granted abroad a U.S. application had to be filed within six months and replacement by a provision that the U.S. patent must expire at the same time as foreign patent, subject to a maximum term of seventeen years from the grant of U.S. patent, codification of a requirement that the specification

\(^{22}\) 27 U.S. 1 (1980).

\(^{23}\) Section 9 of Patent Act 1836.
described the best method or mode known to the applicant for "applying the principle" of his invention; set up a mechanism for resolving disputes as to who had first invented a particular invention. It was also made clear that any public sale or use of the invention before the start of the two-year grace period was destructive of novelty irrespective of whether that sale or use was by the applicant for the patent.24

In 1930, the Plant Patent Act provided for the possibility of patent protection for asexually reproduced plants. In 1940 the duration of the grace period relating the inventor, which were to be excused as novelty destroying acts, was reduced from two years to one year.25 The two major changes were introduced in the year 1952 to include in the statute for the first time a requirement that to be patentable an invention not only to be novel but also it must satisfy other two conditions, namely, inventive step and industrial application, and to include the definition of infringement which had hitherto been left to the courts.26

Since 1952 law has been amended several times. These amendments were significant in determining the present shape of the world patent system. In 1968 Patent Cooperation Treaty was signed. In 1975 the name “the patent office” changed to the Patent and Trademark Office. In 1987 Supreme Court upholds the patentability of a genetically modified bacterium quoting a congressional Report

24 Lads and Parry, supra note 18.
25 Ibid.
26 The definition specifically stated that the “patentability shall not be negative by the manner in which the invention was made”, apparently to ensure that; issues of obviousness were assessed objectively and that invention did not have to be the result of a “flash of genius”. 
leading up to the 1952 Act that “anything made by man under the sun” should be patentable.27

More important than any of these was the Drug Price Competition and Patent Restoration Act of 1984, commonly known as the Hatch-Waxman Act, which provided for extensions of patent term for human drugs, food additives, and medical devices who’s commercialisation had been delayed by regulatory procedures and at the same time made registration easier for competitors when patent protection expired and provided that testing for regulatory approval involving a patented drug did not amount to patent infringement.28

There have been a number of legislative changes to the U.S. patent law since then, most of them fairly minor, but the most important was certainly the Uruguay Round Amendments Act (URAA) of 1995, which made changes necessary in order to bring U.S. law into line with the TRIPs agreement.

2.2.3 Evolution of patents in India

India since time immemorial has been the forerunner in the fields of science technology, medicine, dance, arts, literature etc. The ancient books and manuscripts like Vedas and Upanishads not only provide spiritual solace but also serve as sources for the evolution of all science and art. These various sciences have developed over a period of hundreds of years when the other civilisations in the world were in their rudimentary stages. Though India had been the hub of

27 Diamond v. Chakrabarty, 206 USPQ, 193.
28 Supra note 1, p.23.
human wonders in ancient days, today our technology in most of the fields cannot be compared itself with the best in the world. The ancient knowledge at some point of time has not been fully passed to the future generations by our ancestors. Whatever scientific and technical knowledge were possessed was occupied and stolen by the western countries. Our ancestors while being generous in propagating such vital information for the benefit of the mankind did not have the forethought of protecting their inventions and innovations, which in the course of years proved fatal.29

Knowledge is considered to be the product of individual creativity today but earlier knowledge was considered as the most precious gift, which knew no limitations of space or time, was freely given to the aspirants from the guru and this tradition was known as guruparampara. The guru got the knowledge from his guru and after adding his expertise and experience passed it to his students, this was true with all ancient traditional knowledge. “Let noble thoughts come to us from every where let all beings live happily, free from the fear of death and diseases” and many more such ideals were the guidelines for the scientists who worked for the betterment of every living creature. They were so selfless that thinking of petty personal benefits was unknown, unheard and unthinkable too.

Indian society has inherited a rule that each individual owed at least three debts or rinas. One was to his parents, second was to his guru and the third is towards motherland or society for all that has been bestowed upon him. When a

person is repaying his debt by contributing something to the society what can he expect in return except the feeling of intense fulfillment.

So in ancient India the invention of anything and everything useful to the society was offered as a salutation to the god, guru, parents or the ruler and in turn blessed with further progress or the ruler would award him with material benefits or title and engrave the details of such invention either on stone or other inscriptions for the benefit of the whole society.\textsuperscript{30}

But gradually the situation changed and the idea of protecting knowledge emerged in India as a result of influence of British on India. Therefore India’s patent system is drawn from British system. Unlike Great Britain where the concept of patent originated from the exercise of the royal prerogative to grant monopolies, in India a patent for invention has always been the sole creation of statutes of Indian legislature.

The first Act relating to patent rights was passed in 1856, which granted certain exclusive privileges to inventor of new manufacture for a period of 14 years. This Act was found defective and was therefore re-enacted with some modifications in 1859. The provisions of this Act were founded on the English Patent Act 1852. Under the Act of 1859 patent monopolies were called “exclusive privileges”. An inventor of a new manufacture could under the provisions of this Act, by filing a specification of his invention obtain the exclusive privileges of

making, selling and using the invention in India and authorising others to do so for
the term of 14 years.

In 1872 the Patterns and Designs Protection Act was passed, followed by
the Protection of Inventions Act of 1883. These Acts were consolidated by the
Inventions and Designs Act 1988. Subsequently the Patents and Designs Act 1911
was passed repealing all the previous Acts. This Act established for the first time
in India a system of patent administration under the management of the controller
of patents.

After independence, the government of independent India decided to
reform the patent law. In 1948, a Committee headed by Dr.Bhakshi Tekchand, a
retired Judge of the High Court of Lahore was appointed by the Government of
India to review the patent law in India, with a view to ensure that the patent
system is more conducive to national interest. The Committee submitted its
Report in April 1950. Tekchand Committee Report revealed that the Indian
Patent system had failed in its purpose namely to stimulate invention among
Indians and to encourage development and exploitation of new inventions for
industrial purposes in the country, so as to secure benefits thereof to the largest
section of the people. On the basis of this report a bill consisting certain
amendments to the Act of 1911 was introduced in the Parliament in 1953. This

31 Dr.Tekchand Committee's recommendation was incorporated in the amendments that were
introduced to the 1911 Act in the year 1950.
Bill was based on 1949 U.K. Patent Act. The Bill was not however proceeded with and therefore lapsed.\(^{32}\)

Subsequently in 1957, the Government of India requested Justice N. Rajagopal Ayyangar assisted by Dr. Venkateshwaran to advice the Government on the question of revision of the patent law. This Committee submitted its Report in 1959, keeping in mind the factors of economic development and public interest.\(^{33}\) The Report observed, firstly, that with all the handicaps, which the system involves in its application to under developed countries; there are no alternative methods for achieving better results... I consider that the patent system is the most desirable method of encouraging inventors and rewarding them. Secondly, the Committee noted that foreign patentees were acquiring patents not in the interest of the economy of the country granting the patents or with a view to manufacture there but with the object of protecting an export markets from competition from rival manufacturers particularly those in other parts of the world. Thus India is deprived of getting in many cases, goods... at cheaper prices from alternative sources because of the patent protection granted in India. The Report concluded that foreigners held 80 - 90 % of the patents in India and were exploiting the system to achieve monopolistic control of the market. The Committee suggested that a patent system that focussed on access to resources at lower price would be


\(^{33}\) The Report of this Committee is considered to be the backbone of the Indian Patent Law that was enacted in the year 1970.
beneficial to India. On the basis of this Report a Patent Bill was introduced in the Loka Sabha in 1966, which however lapsed.


During the 1970s there was a general weakening of patent protection in developing countries, particularly in the pharmaceutical field, for which protection was totally or effectively abolished in a number of countries. A classic example of this is Indian Patents Act 1970.

This law reduced the term of protection generally from 16 to 14 years, and provided for government use without compensation, and even government expropriation of patents. Furthermore all patents for chemical inventions were automatically endorsed with ‘Licence of Right’ three years after grant. Patents granted for processes for the manufacture of any food or medicine had a maximum term of only 5 years from the grant, and the royalty payable on a licence of right

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34 Supra note 32.
35 A Joint Parliamentary Committee was formed to study the Bill, the Committee made various changes to the Bill and it was tabled again as the Patent (Amendment) Bill 1965.
36 Supra note 32.
37 Supra note 1, p.38.
granted on such a patent was limited to 4 percent of the bulk sales price of the product. For this class of inventions not only was the patent life reduced to a point at which the patent would normally have expired well before the product came on the market, but if there was any patent term left, a competitor could operate under the patent on payment of a nominal royalty. Erosion of patent rights was also very marked in Latin America, for example in Brazil, where patent term was reduced and all patent protection for pharmaceutical inventions was abolished.\textsuperscript{38}

Amendments were carried on by India to survive the onslaught of global competition earlier, in order to re-enforce her inventiveness as well as strengthen and efficiently use the patent system. But in order to fulfil TRIPs obligations India introduced the first patent amendment to the Indian Patent Act 1970 in April 1999. Two key aspects of this amendments were the "provision for a mailbox" to file applications for product patents in India and the "provision for exclusive marketing rights", for products related to drugs, pharmaceuticals and agrochemicals.

The Patent (Second Amendment) Bill 2002 carried changes in the scope of patentable inventions, grant of new rights, extension of the term of protection, provisions for reversal of burden of proof in case of process patent infringement and conditions for compulsory licences.

The third amendment to the Indian Patent Act 1970 was introduced on March 23, 2005 to comply with WTO agreement. Its main feature are: the product

\textsuperscript{38} Ibid.
patent regime for all inventions, and the deletion of section 5 of the Principal Act. As a result an Indian company has lost the opportunity to develop processes for patent protected drugs in the country, preventing domestic drug manufacturers from making low cost generic copies of patented drugs. There are over 8000 product patent applications (mail box) pending in India, which could now be granted. Indian firms may have to wait for three years before they can apply for compulsory licences of newly patented drugs to meet an emergency need and Indian firms currently making generic versions of these drugs would have to pay royalties.\textsuperscript{39}

It has introduced the provision of granting compulsory licences to supply drugs to countries which have no manufacturing capacities to meet their acute public health problems as per the Doha Declaration on TRIPs agreement and Public Health and to strengthen issues related to national security. It has replaced pre-grant opposition by post grant opposition but introduced third party intervention or representation on patentability before the grant of patent. Further introduced direct grant of patent without a sealing request, to expedite the grant of patent and has introduced a provision for early publication on request of applicant. The compulsory licensing provisions of the Patent (Amendment) Act 2003 is of fundamental importance to ensuring competition on competitive prices not only for domestic supply but also to supply drugs to countries, which have no manufacturing capacities to meet their acute health problems.\textsuperscript{40}

\textsuperscript{39} Vandana Vaidya, “Legal Menaces”, \textit{Vijaya Times}, Sunday, 19\textsuperscript{th} Feb. 2006, p.4.

\textsuperscript{40} \textit{Ibid.}
2.3 Evolution of pharmaceutical patents

The patent system was apparently devised to encourage inventions and enable the public to enjoy the benefits of the new inventions. It is legally enforceable right which grants an inventor by the government of a country, exclusive privileges and rights for working and selling the patented product for a limited period of time, provided it fulfils the triple criteria of novelty, non-obviousness and industrial applicability. Ostensibly, the philosophy of patent is not to grant monopoly but to enable the full utilization of a product or process in a country, which has granted the patent rights. As far back as the middle ages patents were granted by the crown to entice foreign workers to come and settle in England and in 1551, Venetian Thesco muto was granted a patent for a ten-year monopoly for the manufacture of type of Venetian glass ware but it was in the drug industry, the patents realised it’s fullest potential. As the Kefaver Committee, investigating the patent system in the U.S.A. in 1959 stated, pharmaceutical patents lead to high profits. Ironically, the founder of Seimens and Hoechst, who were members of a Special Committee appointed by Bismarck in 1876 to study the possible impact of the patent system on industries, had warned against the tendency to monopolise production/invention as well as the possibility of abuse of patent rights.41

In the 1870s Britain had come close to abandoning the patent system altogether because it was considered to be protectionist in nature and was opposed

by free trade advocates including the economists.\textsuperscript{42} Having passed that crisis, the patent system in the U.K. increased gradually in strength until it took its first backward step in 1919, up to then patents had been granted as a matter of course for new chemical substance. However, British Chemical industry felt itself technologically inferior to that of Germany, which before First World War had dominated the dyestuffs market. British industry pressed for abolition of patent protection for chemical as such, and limitation of patent protection to that for specific processes for the preparation of chemicals. In this way British firms hoped to be free to imitate a German dyestuff appearing on the British market so long as they could find an alternative process for its preparation, a task of good deal easier than that of inventing a new and better dyestuff themselves. This change in the law was duly made in 1919, together with the further weakening of patent protection for pharmaceuticals by allowing compulsory licences to be granted virtually on demand for patents relating to medicines. The first of these retrograde steps was abolished after the Second World War in 1949, the second only in 1977.\textsuperscript{43}

Worldwide, national governments in the past used their sovereign prerogative to evolve their own approach towards their patent systems, particularly for drugs and pharmaceuticals. They gradually modified the patent laws related to their stage of development. Intellectual property rights laws in these countries


\textsuperscript{43} \textit{Supra} note 1. p.19.
therefore, compatible with their developmental objectives. The right to sub serve the public interest in these countries prevailed over the intellectual property right whereas in the developed countries the welfare objectives are no longer their concern – profiteering is the sole objective of the transnational corporation through patent monopolies. In this background the patent systems of countries as such differed widely from one another. National laws have been gradually upgraded in the developed countries to provide for greater protection to their scientific and technological achievements. For example Italy, U.K., Germany Switzerland and Japan changed over to the product patent from process patent system in the Pharmaceutical field only recently. The evolution of intellectual property rights standards has been particularly tangible following changes in the relative technological strength in different industries in these countries.\textsuperscript{44}

Historically, intellectual monopoly in pharmaceuticals has varied enormously over time and space. The patent lobbyists have lobbied long and successfully, to increase patent protection for pharmaceutical products. Here are some of their accomplishments.

In the U.S. drugs have been patentable since the beginning for the very simple reason that chemical products have always been patentable. The U.S. recognises two distinct forms of patents. The process by which a drug is produced may be patented independently of the chemical formula for the drug. Until 1984 U.S. patent law treated medical discoveries in the same way as other innovations, \textsuperscript{44} \textit{Ibid.}
and special treatment was reserved for drugs. In more recent years, the USPO and the Federal Court of Appeal have began to allow longer and more frequent extensions for drug patent than they do for the rest of patented innovations. For example, the Drug Price Competition and Patent Term Restoration Act of September 24, 1984 (the Hatch-Waxman Act) was designed to compensate for regulatory requirements that delay the introduction of new drugs. It is estimated that it increased effective length of patent protection for pharmaceuticals by about five years.45

In most of continental Europe, until recent years, only the process of producing a drug could be patented, so once a drug was discovered, a second producer could also produce it provided they found a different ways of doing so. The rationale behind process versus product patents was given by the German Association of Chemical Industry. They point out that the same chemical product can be obtained by different processes and methods and even starting from initially different materials and components. Hence, there is social value in patenting a specific product, as this excludes all others from producing it, even through different processes. It should be noted that though this did not prevent German chemical companies from patenting their products where possible, i.e., in United Kingdom and the United States.46

In France, under the law of July 5, 1844 pharmaceutical inventions could not be patented. Legislation then evolved, keeping the prohibition for patenting products but allowing patents for process. The executive order of February 4, 1959, and then the law of January 2, 1966 finally introduced limited protection for pharmaceutical products in France; the ban on patenting drugs was completely lifted only in 1978. In Germany the law of May 25, 1877 introduced patents for both chemical and pharmaceutical process, while products were explicitly excluded. The law of April 4, 1891 extended patent protection to products obtained via a patented process. Finally, the law of September 4, 1967 introduced general patentability of chemical and pharmaceutical products in Germany.47

In Italy, pharmaceutical patents were prohibited until 1978, when the Supreme Court ruled in favour of eighteen pharmaceutical companies, all requesting the enforcement of foreign patents on medical products in Italy. Despite this complete lack of any patents protection, Italy had developed a strong pharmaceutical industry; by the end of the 1970s it was the fifth world producer of pharmaceuticals and the seventh exporter.48

Pharmaceuticals are also covered by variety of international agreements. The contemporary era of patenting began with the Convention of the Union of Paris in 1883 following the Vienna Conference of 1873. More recently, the Patent Cooperation Treaty was signed in Washington on June 19, 1970, which started a

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48 Ibid.
process of international extension of stronger patent protection for medical products. The Munich Convention of October 3, 1973 implemented since October 7, 1978 defines the notion of an “European Patents”. Further revisions and modifications of the original basic agreements led, eventually, to the definition of a European Community Patent, based on a Convention signed in Luxembourg on December 15, 1975, while the latter was not ratified by Denmark, Ireland, Greece, Portugal and Spain it has been fully implemented and accepted by E.U. member states since 1992. 49

In India patent rights were introduced in 1856 and later modified in 1859, along with lines of the English Patent Act of 1852. In 1872, the Patent and Designs Protection Act was introduced and was replaced with the Patents and Designs Act in 1888. The Indian Patents and Designs Act, was passed in 1911 and several amendments were made to this Act between 1911 and 1970. Subsequently, the Patents Act 1970 was passed repealing all of the previous legislations. India is also a signatory to the Paris Convention for the protection of Industrial Property 1883 and the Patent Cooperation Treaty 1970.

India had a product patent regime for all inventions under the Patents and Designs Act 1911. Under this Act product patents were granted for all inventions including pharmaceuticals. However in 1970, the Indian Government introduced the new Patents Act, which excluded pharmaceuticals and agrochemical products from patenting. This exclusion was introduced to overcome India’s dependence

49 Ibid.
on imports for bulk drugs and formulations and to establish a self-reliant indigenous pharmaceutical industry.\textsuperscript{50}

In the absence of product patents for pharmaceuticals, the pharmaceutical industry grew rapidly by developing cheaper versions of a number of patented drugs for the domestic market and eventually moved aggressively into the international market with generic drugs produced at low cost.\textsuperscript{51}

The establishment of the World Trade Organisation (WTO) has led to a tremendous paradigm shift in world trade. The Agreement on Trade Related aspects of Intellectual Property Rights (TRIPs) was negotiated during the Uruguay round of negotiations of the General Agreement on Tariffs and Trade (GATT) and one of the reasons for incorporating intellectual property issues into the GATT framework was the pharmaceutical industry. India became signatory to the GATT on 15 April 1994, thereby making it mandatory for it to comply with the requirements of GATT, including TRIPs Agreement.

The so-called developing countries were given a transition period of 10 years to bring their national laws in accordance with TRIPs. Indian government passed two amendments, one in 1999 and the other in 2002 to the Patent Act 1970 to prepare the groundwork for full implementation of TRIPs Rules.

In December 2004 the Indian Government issued a Presidential Ordinance to bring the country into mandatory compliance with TRIPs by January 1, 2005.

\textsuperscript{50} Supra note 29.
The Government had six months to codify this Ordinance by obtaining the approval of the Parliament. This was done on March 23, when after virtually no public debate India’s Parliament passed the third amendment to India’s 35-year-old Patent Act. Under the new amended Act product patents are also available for inventions relating to food and drugs.52

2.4 Need for patent system

In the course of time both “individual” and “public” justifications have played prominent roles in the arguments in favour of patents for invention and for other kinds of intellectual property rights. At various periods the idea of a patent as an instrument of justice to the inventor has proved attractive, and the power of this sort of argument is by no means exhausted. Yet rewarding inventive ingenuity may seem little more than an incidental consequence of modern patent systems. They do not protect each inventor who conceives an invention. Only the first comer is entitled in most systems, indeed, it is the first to apply for a patent, rather than the first to invent, who is given priority. The protection is then good not only against those who derive their information from that patentee but also against those who work it out independently. The period of protection, moreover, is very short compared to other forms of “intellectual property”. If a major object were to give the inventor his just reward, a system more closely akin to copyright with its “property” like duration and it’s protection of all original creations, but only against copying – would seem more appropriate.53

53 Supra note 12, p.108.
Today the debate over patent systems tends to concentrate upon their role as a “public” instrument of economic policy. Patents are looked upon to provide two kind of aid towards the technical efficiency, and hence the growing wealth, of the community as a whole. They are intended to encourage the making of inventions and the subsequent innovative work that will put those inventions to practical use; and they are expected to procure information about the invention for the rest of the industry and the public generally, which otherwise might be withheld, at least for a period that could be crucial.\textsuperscript{54}

2.4.1 Patents as incentive to invent and innovate

Patents have also been justified by the fact that they provide an incentive for the production of new inventions. As Lord Oliver said in Asahi, the 'underlying purpose of the patent system is the encouragement of improvements and innovation'. In return for making known his improvement to the public the inventor receives the benefit of a period of monopoly during which he becomes entitled to prevent others from performing his invention except by his licence.\textsuperscript{55} More specially, it is said that as patents provide the possibility for inventions to be exploited for a twenty-year period, this means that inventors will be more willing to fund research and development. In this sense, patents act as a vector that links scientific and technical research with commercial spheres. Arguments of this nature have proved to be particularly important in situations where an invention


can be readily ascertained (or reverse-engineered) from the product, which is put on the market.\textsuperscript{56}

One persistent argument against patents in the nineteenth-century controversy was this: since inventions are there to be discovered, industries that have progressed to a certain point will inevitably make them, and so artificial aids are unnecessary. It was line of argument that carried some conviction when the bulk of inventions concerned relatively simple mechanical contrivances that were often worked out as a by-product of ordinary manufacturing. In the face of increasingly systematic organisation of research and development, and the extensive process of education, which precedes it, this point of view is harder to maintain.\textsuperscript{57}

\subsection*{2.4.2 Patents as an information system}

In Britain the policy of making the patent system a source of technical information has been deliberately pursued since the early industrial revolution. For many years the results have justified treating this aspect of the system as more than a useful by-product. Patents do make available a large quantity of information about the latest technical advances, and they are regularly consulted by those concerned with development in many industries. Nevertheless, exaggerated expectations need to be avoided. If the inventive concept is one that has to be embodied in a marketed product, the patent may give earlier access to the

\begin{footnotesize}\begin{enumerate}
\item \textsuperscript{57} \textit{Id.}, at p.132.
\end{enumerate}\end{footnotesize}
information and perhaps a more explicit statement of what the invention is. Only if the invention is one that need never be revealed to the rest of the industry in the course of exploiting it does the patent provide a clear long-term gain in terms of publicity? But this, of course, is the case where secrecy offers a real alternative— a route that despite the danger of leak, may seem simpler and cheaper to pursue.\(^5\)

The information aspect of patents is not a policy that is altogether easy to implement. There is an obvious temptation to any patentee to omit from his specification information that may seem incidental but is in fact useful or important to commercial success. When this effect can be achieved the patent system is reduced to an index of sources from which further information may be had on application and payment. This leaves the policy maker, whether legislator, patent office administrator or judge, with a choice: either to recognise that the system cannot hope to provide more information, or to insist that it should be declaring such patents invalid. Countries with examining offices have arrived at rather varied results in their approach to this dilemma. The typical American specification is noteworthy for its dogged attention to pedestrian detail; a German specification may be hazy about practical steps but is more likely to reveal basic concepts. One decision of the English court of Appeal leans in the former direction; it holds that a specification about basic ideas in a new technology should teach it's principles to second rank technicians rather than to leading researchers in

\(^{58}\) \textit{Supra} note 12, p.113.
the field.59 This sort of insistence carries with it the danger that really significant
developments may be the subject of invalid patents. Yet to give up a real effort to
police the disclosure requirement may be to surrender the one public advantage of
the patent system that remains relatively uncontroversial.60

2.4.3 Adapting the patent system: new technology

The emergence of each major technology requires adjustments in the patent
system, and is, therefore, likely to stir up arguments about underlying rationale
and specific policy objectives. The coming of computers first activated symptoms
of denial, with a series of moves to place computer programs beyond the reach of
the system; latterly, there has been growing industrial pressure to take the opposite
position. Over a much longer period resistance to the idea of monopoly over
something as fundamental as chemical substance (particularly where it is
pharmaceutical) has gradually given way. A set of rules on the disclosure
requirement have enabled claims of commercially significant breadth to be made;
but at the same time, where necessary, biological material has to be made
available to others through culture collection.61

A half-century after Crick and Watson's uncoiling of living structures,
genetic knowledge and techniques of genetic manipulation have undergone a
series of remarkable advances. Once revealed, each procedure has been rapidly
taken over by laboratories everywhere, spurning quantities of competitive

60 Supra note 12, p.l 14.
61 Id., at pp. 114-115.
research. In particular medical applications of biotechnology have attracted a rash of new business, often spinning out of academic research. There have been rushes to patent, accompanied by demands for very wide claims modelled on those of the initial master patents by now familiar in organic chemistry. Courts in the United Kingdom have shown a tendency to react slowly and cautiously to this. Patent officers, by contrast, have been ready to embrace the new technologies. In Europe that attitude must be sharpened by the fact that there are competing routes to patent protection. However, over the last fifteen years, they have faced a growing barrage of objection, which has made the issue far more prominent and is leading to a some what more critical attitude towards what should fall within the patent system under what conditions.\footnote{Ibid.}

Each invention has a multiplier effect. A single invention, when patented is not the end of technological development. It is the basis for further research and increasing technical development.

2.4.4 Economic justification

If there were no patent system, it would be possible for any one to copy a new invention and profit from it without having to bear the costs of developing the invention. Since the cost of copying many inventions will be substantially less than the development costs, this would allow the copier to sell the invention at lower price than the original inventor, which may make it impossible for the inventor to profit from the invention.
This could mean that business or individuals would have little incentive to invest in research and development or would invest only in those inventions, which could be kept secret. If businesses are not provided with adequate incentive to invest in research and development, economic growth may be inhibited.

Patent is a form of industrial property conferring monopoly right on a person, who invents a product or a process to exclusively produce it or to use the said process for a pre-determined period of time. It is a reward given by state to the inventor for input of his intellectual labour with something useful to the public. By granting patent, the promise of the state is that there will be an exclusive right to use the invention and recover the costs and make reasonable profits.

To get patent right, the inventor has to disclose his invention while applying for patent registration. The disclosure of the invention can be helpful to the public to work upon the invention once the patent term expires. This can also be of great help in enhancing the industrial and in turn, the economic growth of the society.  

2.5 Patentability of inventions

Patents do not protect each and every inventor who conceives an invention. Every legal system insists upon certain conditions for an invention to get patent right. Although the requirements vary in different legal systems, certain basic common features do exist. They are novelty, inventive step/non obviousness and

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63 Basic Principles of Patent Law, Paer-1 Basic Principles & Acquisition of Intellectual Property Rights, Bangalore: CIPRA National Law School of Indian University, p.18.
industrial application. These standard requirements that existed from earlier times of patent regime were given a new dimension by the legislative and judicial interventions.\textsuperscript{64} An analysis of these basic requirements of patentability will be of great help in understanding the patent regime.

2.5.1 Novelty

No patent system grants valid patents for inventions that are already known; that would be to encumber industry with constraint upon the use of information without any sufficient return. Accordingly, the present law requires a patented invention to be new in the sense of forming no part of the state of the art, that is it must not be found at the priority date\textsuperscript{65} in any "matter which has at any time been made available to the public by oral or written description, by use, or in any other way".\textsuperscript{66} This concept draws no distinction between information published by the inventor and by some one unconnected with; if the inventor were protected from prejudicing himself, he might delay his patent until it was commercially most advantageous to apply.\textsuperscript{67} Prior publication involves publication in earlier patent specifications or any other material available to the public prior

\textsuperscript{64} Id, at p.19.

\textsuperscript{65} There shall be a priority date for each claim of a complete specification. The priority date of a patent is the date on which it is tested against "the state of the art". Where a complete specification is filed in pursuance of single application accompanied by a provisional specification and the claim is based on the matter disclosed in such specification the priority date of that claim shall be the date of filing of relevant specification.

\textsuperscript{66} Supra note 12, p.148.

\textsuperscript{67} Supra note 53, pp 174 -175.
publication bar is grounded on the principle that once an invention is in the public domain, it is no longer patentable.

In India, as in U.K., there is no direct statutory definition of novelty. Section 2(1)(i) as amended by the Patents (Amendment) Act 2002 defines invention as including any new product or process involving an inventive step and capable of industrial application. The word “new” found even before the amendment emphasizes the requirement of novelty in inventions to be patented.

The question of novelty includes an inquiry as to whether there was ‘prior publication or prior use’. But in 1888, the question arose as to whether the secret use of a process of manufacture before the patent application would amount to a use. The court held that selling of product produced by a secret method amounted to public use. But, this rigid approach laid down by the Calcutta High Court was diluted by the Bombay High Court. The Court accepted the principle that sale of products made in secret amounted to public use, but the court also added that if the process applied was not traceable by the examination of the product in the market, the secret use could not be held as public use.68

Further, the Bombay High Court held that availability of an invention for public reference is sufficient to constitute prior publication. It is not necessary that the public or the persons connected with the trade must have an actual knowledge of the invention.69

Further the question was whether an invention, which "was not itself new" would be entitled for a patent, it was held that the particular use of the invention for the purpose described in combination with other element of the system for producing advantageous results would be a sufficient element of novelty to support the patent.\textsuperscript{70} A new invention may consist of a new combination of all integers so as to produce a new or important result or may consist of altogether new integers. The claim for anticipation has to be either by prior use or by prior publication. This was the principle laid down in 1978.\textsuperscript{71} Indian courts have insisted on the requirement of novelty based on the investigation into prior publication and prior use.

\textbf{2.5.2 Inventive step/non obviousness}

Non-obviousness /inventive step measures the technical accomplishment reflected in an invention. It attempts to measure an even more abstract quality than novelty and utility. Non-obviousness asks whether an invention is an adequate technical advancement to merit the award of a patent. Even if an invention is new and useful, it does not deserve a patent if it represents merely a trivial step forward in the art. The objective of the patent system is the advancement of science. It aims to protect those, which would not be obvious to anyone skilled in the art if they had put their mind to it. It is regarded as the final gatekeeper of the patent system.

The philosophy underlying the concept of inventive step is similar to that in novelty. By granting monopoly over an obvious thing, the public should not be prevented from doing anything that is merely an obvious extension or workshop variation of what was already known.\footnote{Supra note 63, p.27.}

In 1985, in the classic case,\footnote{Windsurfing International v. Taburmarine (1985) R.P.C. 159, CA.} the Court propounded four-step test to determine the inventive step in an invention. They are as follows:

(i) the Court must identify the inventive concept embodied in the patent;

(ii) it must assume the mantle of the normally skilled but unimaginative addressee in the art at the priority date and impute to him what was, at that date, common general knowledge in the art in question;

(iii) it must identify what, if any, differences exist between the matters cited as being “known or used” and the alleged invention;

(iv) it must ask itself whether, viewed without any knowledge of the alleged invention, those differences constituted steps which would have been obvious to the skilled man or whether they required any degree of invention.

This test laid down in *Windsurfing case*, stands as the guidepost in determining whether an invention involves inventive step or not.

The Patents Act, 1970 as amended in 2002 defines invention as a new product or process involving an inventive step and capable of industrial
application.\textsuperscript{74} Further, inventive step is defined as a feature that makes the invention not obvious to a person skilled in the art.\textsuperscript{75}

The Bombay High Court formulated the rule regarding the inquiry as to the existence of the inventive step. The test was "was it for practical purposes obvious to a skilled worker, in the field concerned in the state of knowledge existing at the date of the patent to be found in the literature then available to him, that he would or should make their invention the subject of the claim concerned?".\textsuperscript{76}

It was held that for improvement or a combination of something known before to be patentable, it must involve an inventive step and should be something more than a mere workshop improvement. The ingenuity, independent thought and skill of the inventor must be assessed to judge the degree of inventive step. There must be the exercise of some inventive faculty over the collection of more than one integer for it to qualify the grant of patent. Thus the test is formulated in the following terms, "the material question to be considered is whether the alleged discovery lies so much out of track of what was known before as not naturally to suggest itself to a person thinking on the subject, it must not be obvious or material suggestion of what was previously known".\textsuperscript{77}

\textsuperscript{74} Section 2 (1) (j) of Patent Act 1970.

\textsuperscript{75} Section 1(1) (ja) of Patent Act 1970.

\textsuperscript{76} Hoechst v. Unichem (1969) R.P.C. 55

\textsuperscript{77} M/s Bishwanath Prasad Radhey Shyam v. Hindustan Metal Industries (1979) 2 S.C.C. 511.
Thus the existence of inventive step is a question of fact, while assessing the existence of the inventive step at that particular point of time, it must be enquired whether the invention would be obvious to the notional skilled worker aware of the existing knowledge about the subject matter of invention. Any assessment must be done based on the content of information and the state of technology that the notional worker could have used.

### 2.5.3 Industrial application

One of the prerequisites that the purported invention must possess before it can be patented is that it must be capable of industrial application, i.e. it must perform some function of positive benefit to society. To comply with the utility requirement, an invention need not be superior to existing products or process. But it must operate to perform the functions and secure the result intended. It is not necessary to establish the commercial success of the product or process, even a small degree of utility is sufficient. An invention does not lack utility merely because the particular embodiment disclosed in the patent lack perfection or performs crudely. The purpose of the utility requirement is to assure that society obtains a “quid pro quo” in the form of substantial utility and specific benefit in currently available form before granting monopoly to the invention.

The Phrase “capable of industrial application” clearly indicates that for an invention to be patentable in India, it should satisfy the criterion of utility. The

78 Supra note 63, p.24.
79 Id., at p.27.
test has been now statutorily expressed in the definition of the expression ‘capable of industrial application’ in Sec.2(1) (a) as meaning the invention must be capable of being made or used in an industry. This means that an invention must take the practical form. Industry should be taken in its broad sense as including any useful practical activity as distinct from purely intellectual or aesthetic activity and does not necessarily imply the use of a machine or the manufacture of an article. It includes agriculture.  

2.6 Inventions not patentable

The limitations of patent system have forced it to keep laws of nature, Physical phenomena, and abstract ideas outside the purview of patent system. The legal system has always kept the welfare of the society in the forefront. It was always against anything that would go against the public order and morality. On that ground, certain types of inventions were excluded from patent regime. These were mainly policy decisions by the states as to what should be excluded from the patent system and for what reasons.

The TRIPs agreement mandates the member countries to grant patents for all inventions, whether be product or processes irrespective of the field of technology, provided they are new, involve an inventive step and capable of industrial application. But the member countries are free to exclude from patentability, inventions whose commercial exploitation would be dangerous to

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80 Ibid.
81 Supra note 62, p.31.
82 Article27 of the TRIPs Agreement.
public order and morality, including human animal or plant life or health or which causes serious prejudice to the environment. Also every member country may exclude from patentability, diagnostic, therapeutic and surgical methods for the treatment of humans and animals, plant and animals other than microorganisms and essentially biological processes for the production of plants or animals other than non-biological and microbiological process. The member countries were to provide protection for plant varieties either by patents or by effective *sue generis* systems or by combination of both.83

The UK Patents Act 1977 excluded certain subject matters from the patent system. The Act gives an exhaustive list of what does not constitute an invention in UK and therefore not entitled to patent protection.84 They are: a discovery, scientific theory or mathematical method; a literary, dramatic musical or artistic work or any other aesthetic creation; a scheme, rule or method for performing a mental act, playing a game or doing business, or a program for a computer; the presentation of information; an invention the publication or exploitation of which is offensive, immoral or anti-social and; any plant or animal variety or any biological process for the production of plants and animals.85

In USA, the basic requirement for patentability is that the invention should fall within the scope of patentable subject matter as defined under section 101 of US code. As per this section, any new and useful invention or discovery, which is

84 Sections 1 (2) to 1 (5) of UK Patents Act 1977.
85 *Supra* note 62, p.32.
a process, machine, manufacture or composition of matter is patentable. It also includes any new and useful improvements made to an existing invention. The Courts have construed the terms process, machine, manufacture and compositions of matter very broadly. In *Diamond v. Chakrabarty*, the US Supreme Court stated that every thing under the sun made by man is patentable.

The statute does not expressly bar any subject matter from patentability, the courts have held physical phenomenon, abstract ideas and products of nature to be outside the scope of patentability. The Atomic Energy Act of 1954 excludes the patenting of inventions useful solely in the utilization of special nuclear material or atomic energy in an atomic weapon.

In India, Patents Act 1970 as amended in 2005 prescribes what all are not inventions. They are as follows:

(i) An invention which is frivolous or which claims anything obviously contrary to well established natural laws.

The patent regime needs to exclude all that which is contradictory to natural laws. No intellectual property system can afford promotion of anything, which goes against the interest of the public. Any invention which is not sufficient on its face or which is of little importance is considered frivolous.

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87 42 U.S.C.2181 (a).
89 Section 3 (a) of Patent Act 1970.
(ii) An invention the primary or intended use or commercial exploitation of which could be contrary to public order or morality or which causes serious prejudice to human, animals or plant life or wealth or to the environment.\footnote{Sec.3 (b) of Patent Act 1970.}

For an invention to be patentable it must be useful. Only an invention which is beneficial to the society and which is not injurious can be treated as useful.

(iii) The mere discovery of a scientific principle or the formulation of an abstract theory or discovery of any living thing or non-living substances occurring in nature.\footnote{Sec.3 (c) of Patent Act 1970.}

Mere ideas are not patentable, some physical manifestation is necessary to obtain patent protection. Both discovery and invention adds to the human knowledge. But discovery merely discloses something whereas invention involves a concrete manifestation, whether be a product or process. Patent system is intended to promote industrial innovations thereby encouraging commercial exploitation. Also patents cannot be granted over something, which already exists in the nature, whether living or non-living since it is already known to the public.

(iv) The mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such
known process results in a new product or employs at least one new reactant.\textsuperscript{92}

For an invention to be patentable there must be the use of knowledge and ingenuity for the purpose of producing a new and useful product and process. There should be some novelty in the adaptation of the old process to the new use or there must be a new method of producing an old thing or result to get patented.

(v) A substance obtained by a mere admixture resulting in the aggregation of the properties of the components thereof or a process for producing such substance. \textsuperscript{93}

(vi) The mere arrangement or rearrangement or duplication of known devices each functioning independently of one another in a known way. \textsuperscript{94}

A mere alteration in the arrangement or duplication of known devices each performing functions independently of one another in a known way or admixture thereby resulting in an aggregation of the properties of the components and the process involved for producing such substance is not an invention. Since no new product is evolved in mixing these integers, no patent can be obtained. But in cases where, by way of rearrangement or duplication of known integers something new or better is

\textsuperscript{92} Sec.3 (d) of Patent Act 1970.

\textsuperscript{93} Sec.3 (e) of Patent Act 1970, Example: A detergent composition consisting of an active ingredient and a carrier where in the carrier does not possess any activity and does not play any part in the activity of the composition.

\textsuperscript{94} Sec.3 (f) of Patent Act 1970.
obtained; it is entitled to patent protection. Mere collection of known integers without the exercise of the inventive faculty does not qualify an invention for the patent monopoly.

(vii) A method of agriculture or horticulture.

A method of agriculture or horticulture is not a manner of manufacture, it is only a function of natural phenomenon, therefore it cannot be patented.

(viii) Any process for the medicinal, surgical, curative, prophylactic, diagnostic, therapeutic or other treatment, of human beings or any process for a similar treatment of animals to render them free of disease or increase their economic value or that of their products.

Patents are meant to promote industrial innovations and are concerned with the production of goods, which may be sold or used for industrial purposes. A process for the treatment of human beings or a process for a similar treatment of animals is of no industrial application nor is a process of manufacture.

(ix) 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.

95 Section 3 (h) of Patent Act 1970.
Plants and animals including seeds, varieties and species and essentially biological process for production and propagation of plants and animals are not patentable. Non-biological and microbiological processes are patentable. Thus a distinction is drawn between products of nature, whether living or not, and man made inventions.

(x) A mathematical or business method or a computer program *per se* or algorithms.98

Computer program is a set of instructions or commands or data given to a computer to obtain specific result. It is input in a machine-readable medium in order to cause the computer to perform a particular task. Algorithm is described as a formula, a series of formulae and is a mathematical function. Thus computer program is essentially a mathematical algorithm. Computer program is considered as a literary work under copyright law and is copyrightable. It cannot be protected under patent law.

(xi) A literary, dramatic, musical or artistic work or any other aesthetic creation what so ever including cinematographic works and television productions.99

These are excluded since they are not a new manufacture as the invention. They consisted solely of matter having literary or artistic connotation, which can be protected under copyright.

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(xii) A mere scheme or rule or method of performing mental act or method of playing game.\textsuperscript{100}

No patents are granted for ideas or phenomena of nature. It is not the idea that is patentable, but it should have industrial applicability.

(xiii) Presentation of information.\textsuperscript{101}

A presentation of information is not an invention to be patentable because they are not manufacture.

(xiv) Topography of integrated circuits.\textsuperscript{102}

Layout designs of the integrated circuits are not patentable. Article 36 of the TRIPs agreement provides for a separate law to offer special protection to integrated circuits.

(xv) An invention which in effect, is traditional knowledge or which is an aggregation or duplication of known properties of traditionally known component or components.\textsuperscript{103}

Patents cannot be granted for something, which is already known, to the public. It should have the element of novelty within it. Something known from ancient times cannot be conferred patent protection.

\textsuperscript{100} Section 3 (m) of Patent Act 1970.
\textsuperscript{101} Section 3 (n) of Patent Act 1970.
\textsuperscript{102} Section 3 (o) of Patent Act 1970.
\textsuperscript{103} Section 3 (p) of Patent Act 1970.
Further section 4 absolutely prohibits the grant of patent in respect of an invention relating to atomic energy. This is in consideration of national security of India.

2.7 Procedure for the grant of patents

Every patent system establishes a definite procedure for the grant of patents. The procedure for obtaining patent protection is highly relevant from the perspective of an inventor. The patent Act provides a full-fledged procedure to ensure that patent is granted to a person who applies for a patent and to make it sure that the patent rights are not misused. The patent procedure comprises four main steps, namely: application for the patent; examination of the application; opposition to the grant of patent and finally grant of patent.\(^\text{104}\)

2.7.1 Application for the patent

An applicant wishing to file an international patent application has to go through the procedural formalities laid down in the patent co-operation treaty. According to patent law in India, an application for a patent can be made by any person claiming to be the true and first inventor of the invention, any person being the assignee of the person claiming to be the true and first inventor or by the legal representative of any deceased person who immediately before his death was entitled to make such an application. Thus it is not mandatory that only an inventor can apply for and get a patent over an invention.\(^\text{105}\)

\(^{104}\) Supra note 63, p.37.

\(^{105}\) Section 6 of the Patents Act 1970.
An assignee has to furnish evidence of assignment of right to apply for a patent in his favour before making such application. An application must contain the fact that the applicant is in possession of the invention and shall name the owner claiming to be the true and first inventor, and where the person so claiming is not the applicant or one of the applicants, the application must contain a declaration that the applicant believes the person so named to be the true and first inventor.\textsuperscript{106}

An application for a patent can be made for only one invention and should be in the prescribed form. The application must be accompanied by a provisional or complete specification.\textsuperscript{107}

The first to file system is employed, in which among persons having filed for the same inventions, first one is granted a patent, therefore a patent application should be filed properly after conceiving the invention. Therefore it is advisable to apply for a patent as soon as the inventor’s idea of the nature of the invention has taken a definite shape, they need not wait until their inventions are fully developed for commercial working before applying for patents.

It is permissible to file an application for a patent accompanied by a “provisional specification” describing the invention. The application may therefore be made even before the full details of working of the invention are developed. The filing of an application for a patent disclosing the invention would

\textsuperscript{106} Section 7 of the Patents Act 1970.
\textsuperscript{107} Ibid.
secure priority date of the invention, and thereby, enable the inventor to work out the practical details of the invention and to file “complete specification” within 12 months from the date of filing of provisional specification.\textsuperscript{108}

2.7.2 Appropriate office for filing an application and for other proceedings

Application is required to be filed according to the territorial limits where the applicant or the first mentioned applicant in case of joint applicant for a patent normally resides or has domiciled or has a place of business or the place from where the invention actually originated. If the applicant for the patent or party in a proceeding having no business place or domicile in India, the appropriable office will be according to the address for service in India given by the applicant or party in a proceeding. The appropriate office once decided in respect of any proceedings under the Act shall not ordinarily be changed. The four patent offices are located in India at Kolkota, Mumbai, Delhi and Chennai.

2.7.3 Publication and Examination of Patent Applications

All the applications for patent, except the application prejudicial to the defence of India or abandoned due to non filing of complete specification within 12 months after filing the provisional specification or withdrawn within 15 months of filing the application, are published in the patent office journal just after 18 months from the date of filing of the application or the date of priority whichever is earlier. The publication includes the particulars of the date of the application, application number, name and address of the applicant along with the abstract.

\textsuperscript{108} Section 9, Patents Act 1970.
The applications for patent are not open for public inspection before publication. After the date of publication of the application, the complete specification along with provisional and drawing, if any, abstract, application on any form or plain paper and any correspondence between the office and applicant may be inspected at the appropriate office by making a written request to the controller in the prescribed manner and on the payment of prescribed fees.  

2.7.4 Early request for publication

The applicant may also file a request for early publication in form-9 with a prescribed fee of Rs.2500/- or Rs.10,000/- for natural person and other than natural person respectively. The above application is published ordinarily within one month from the date of the request the applicant shall have provisional right from the date of publication.

2.7.5 Request for Examination

No application for patent will be examined if no request is made by the applicant or by any other interested person in form-18 with prescribed fees of Rs.2500/- or 10,000/- for natural person and other than natural person respectively, within period of 48 months from the date of priority of the application or from the date of filing of the application, whichever is earlier. Where no request for examination of the application for patent has been filed within the prescribed

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109 Section 11 A Patents Act 1970.
period, the application will be treated as withdrawn and, thereafter, an application cannot be revived.\textsuperscript{110}

\textbf{2.7.6 Examination}

Where the request has been made by the applicant or by any other interested person, the application for patent will be taken up for examination according to the serial number of the requests received on form-18. A First Examination Report (FER) stating objections / requirements is communicated to the applicant or his agent according to the address for service ordinarily within six months from the date of request for examination or date of publication whichever is later. Application or complete specification should be amended in order to meet the objections or requirements within a period of 12 months from the date of First Examination Report. No further extension of time is available in this regard. If all the objections are not complied with within the period of 12 months, the applications shall be deemed to have been abandoned. When all the requirements are met the patent is granted after 6 months from the date of publication, entry is made in the register of patents and it is notified in the patent office journal.\textsuperscript{111}

\textbf{2.7.7 Withdrawal of patent application}

The application for patent can be withdrawn at least 3 months before the first publication which will be 18 months from the date of filing or date of priority whichever is earlier. The application can also be withdrawn at any time before the

\textsuperscript{110} Section 11 E Patents Act 1970.
\textsuperscript{111} Section 2 Patents Act 1970.
grant of the patent. The application withdrawn after the date of publication cannot be refiled as it is already laid open for public inspection. However, application withdrawn before the publication can be refiled provided if it is not opened to public otherwise.

2.7.8 Opposition proceedings to grant of patents

The main purpose of the provisions, which provides for opposition, is to ensure that patents are granted only for inventions and not for discoveries and patents are granted only for those inventions, which fulfil the legal criteria of patentability.

For this purpose, Indian Patents Act has provided for opposition proceedings. Any one can give notice of opposition to the grant of patent to the controller on any of the grounds stipulated in section 25 of the Act. Generic Companies have already filed number of pre-grant oppositions. Besides companies, patient groups and public interest organisation are also working to oppose patent applications for essential drugs.

This provision also gives an opportunity to the true and first inventor to raise objection to the grant of patent if the applicant for the patent has wrongfully obtained the invention or any part thereof from the inventor. Even after the grant of patent he can attack the validity of patent through post grant opposition.

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112 Section 25 of the Patent (Amendment) Act 2005 provides for both pre-grant and post-grant opposition. This section sets out the grounds on which the notice of opposition can be given to the controller. The grounds for pre-grant as well as post-grant opposition are the same.
2.7.9 Pre-grant opposition

Where an application for patent has been published but patent has not been granted, any person may, in writing represent by way of opposition to the controller against the grant of any patent. The representation shall be filed at the appropriate office and shall include a statement and evidence, if any, in support of the representation and a request for hearing if so desired.

The above representation may be made on the following grounds.

a) that the applicant for the patent or the person under or through whom he claims, wrongfully obtained the invention or any part thereof from him or from a person under or through whom he claims;\textsuperscript{113}

b) that the invention so far as claimed in any claim of the complete specification has been published before the priority date of the claims;\textsuperscript{114}

c) that the invention so far as claimed in any claim of the complete specification is claimed in a claim of complete specification published on or after the priority date of the applicants claim and filed in pursuance of an application for a patent in India, being a claim of which the priority date is earlier than that of the applicant’s claims;\textsuperscript{115}

d) that the invention so far as claimed in any claim of the complete specification was publicly known or publicly used in India before the priority date of that claims;\textsuperscript{116}

\textsuperscript{113} Section 25 (i) (a) of Patent Act 1970.
\textsuperscript{114} Section 25 (i) (b) of Patent Act 1970.
\textsuperscript{115} Section 25 (i) (c) of Patent Act 1970.
\textsuperscript{116} Section 25 (i) (d) of Patent Act 1970.
c) that the invention so far as claimed in any claim of the complete specification is obvious and clearly does not involve any inventive step, having regard to the matter published as mentioned in clause (b) or having regard to what was used in India before the priority date of the applicant's claim.\textsuperscript{117}

f) that the subject of any claim of the complete specification is not an invention within the meaning of this Act, or is not patentable under this Act;\textsuperscript{118}

g) that the complete specification does not sufficiently and clearly describe the invention or the method by which it is to be performed;\textsuperscript{119}

h) that the applicant has failed to disclose to the controller the information required by section 8 or has furnished the information which in any material particular was false to his knowledge;\textsuperscript{120}

i) that in the case of convention application, the application was not made within 12 months from the date of the first application for protection of the invention made in a convention country by the applicant or a person from whom he derives a title;\textsuperscript{121}

j) that the complete specification does not disclose or wrongly mentions the source or geographical origin of biological material used for the invention.\textsuperscript{122}

\textsuperscript{117} Section 25 (i) (e) of Patent Act 1970.

\textsuperscript{118} Section 25 (i) (f) of Patent Act 1970.

\textsuperscript{119} Section 25 (i) (g) of Patent Act 1970.

\textsuperscript{120} Section 25 (i) (h) of Patent Act 1970.

\textsuperscript{121} Section 25 (i) (i) of Patent Act 1970.

\textsuperscript{122} Section 25 (i) (j) of Patent Act 1970.
k) that the invention so far as claimed in any claim of the complete specification is anticipated having regard to the knowledge, oral or otherwise, available within any local or indigenous community in India or elsewhere, but on no other ground.  

The controller shall, if requested by such persons for being heard, hear him and dispose of such representation. If the opposition is decided in favour of the applicant, the patent is granted, the grant of patent is published in the patent office journal there by opening the application, specification and other related documents for public inspection on payment of prescribed fee.

2.7.10 Grant of patent

When all requirements of the First Examination Report are met or in case of opposition under section 25(1), if the opposition is decided in favour of the applicant, the patent is granted, after 6 months from the date of publication under section 11 A, the letter of patent is issued, entry is made in the register of patents and it is notified in the patent office journal.  

2.7.11 Term and date of patent

Term of every patent will be 20 years from the date of filing of patent applications, irrespective of whether it is filed with provisional or complete specification. Date of patent is the date on which the application for patent is filed.  

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124 Section 43 Patents Act 1970.
2.7.12 Post grant opposition

Any interested person can file notice of opposition (along with written statement and evidence, if any) anytime after the grant of patent in the patent office journal. The above notice under section 25 (2) shall be filed on Form 7 along with a fee of Rs.1500 or 6000/- for natural person and other than natural person respectively, in duplicate at the appropriate office. The grounds of opposition under section 25 (2) are the same as given before in case of pregrant opposition. The post grant opposition is decided by an opposition Board followed by, a hearing and the reasoned decision by the controller.

2.8 Conclusion

A patent is a limited monopoly given to individuals/ corporations for limited number of years for technological inventions/innovations by preventing others from using the patent technology. It is granted at the request of the applicant by the patent office in respective countries. Hence the patent right is available within the territory of the granting countries. Patents are tools of public policy that are supposed to guarantee that society as a whole benefits from any innovation. Patents have been developed in order to achieve two aims:

Firstly, to promote the publication of ideas, inventions and creations in order to make them available to others.

Secondly, to provide economic incentive for people to invent or to engage in creative efforts. The patent system was apparently devised to encourage inventions and enable the public to enjoy the benefits of the new inventions.
Therefore patents should be worked to meet the full demands of the domestic market.

Much of the Indian patent law is derived from English. In U.K. the concept of patent originated from the exercise of royal prerogatives to the grant of monopoly. In India, patent for an invention has always been the sole creation of the statutes. The idea of conferring market monopoly as an incentive to innovate has old roots. In the course of time both individual and public justifications have played a prominent role in the arguments in favour of patent protection for inventions.

The conferment of intellectual property right in the form of patent is justified both from the perspectives of the inventor and the general public. From the perspective of the person who invented it, these rights act as an incentive for him to invent and will encourage him to invest in working on new inventions. The requirements of patentability ensure the general public that the invention is not kept out of their reach. Thus the patent system attempts to harmonise the interests of inventor and public at large.

Patents do not protect each and every inventor who conceives an invention. Every legal system insists upon certain conditions for an invention to get patent right. Although the requirements vary in different legal systems, certain basic common features do exist. They are novelty, utility or industrial applicability and inventive step.
Every patent system has excluded law of nature, physical phenomena and abstract ideas from patentability and kept certain other inventions outside patent system on the ground that they are against public order and morality.