CHAPTER – 2
HISTORICAL AND CONCEPTUAL PERSPECTIVES OF PATENT ON LIFE FORMS

The idea of conferring a market monopoly as an incentive to innovate has old roots\(^1\). The birth of patent in the world is based on the concept known as monopoly, it means an exclusive right granted by the state to the traders and later to the inventors and creators as well. Many nations claimed that ‘monopoly’ originated in their country, but history speaks facts differently as seen in the literary works of various historians, antiquarians and scholars. Their contributions indicate to the world the monopoly-based economic structure and its development over many decades. So it is evident that there is a huge difference in respect of monopoly as it existed previously and presently.

2.1 Historical Perspective of Patent in General

The historical origin of our modern patent system dates back to the fourth century B.C. The first recorded reference to patents seems to be in Aristotle’s ‘politics’, through a proposal by a person named Hippodamus of Miletus. According to Aristotle, Hippodamus called for a system of rewards to those who discover things useful to the state\(^2\). But Aristotle condemned the ‘proposal’ as it seemed likely to lead to instability and reduction of social welfare in society. After this historical reference, the history of patents was not found for several centuries. In ancient Greece, during the seventh century B.C., monopoly was granted for cooks for a period of one year by which they could exploit new recipes\(^3\). Later, the middle ages are known to have produced important innovations, however, this era does not appear to have been conducive to the idea of patents, at least in the West\(^4\). Individual credit and gain for inventions was inconsistent with the prevailing social mores\(^5\).

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\(^3\) Dr. Elizabeth Verkey, *Law of Patents*, 1\(^{st}\) Ed, Eastern Book Co., 2005 at p.17  
\(^5\) *Ibid.* at p.118
In Venice, in the early fourteen century patent was granted for “corn mill designs” and in Florence to the celebrated architect Brunelleschi for his 1421 invention of a barge with a hoist for transporting marble. The term patent, derived from the Latin ‘pater’ (to be open) referring to an open letter of privilege from the sovereign, originated in this period. The real administrative system arose only in the late fifteenth century under the Venetian Senate’s Act 1474. Under this Act patent was granted to any ‘new and ingenious’ device; it also laid out all the essential features of a modern patent system. Some patents were issued to inventions originated by inventors as well as for the importation of new technologies to Venice by others. This Venetian system improved trade considerably in Europe and it paved the way for creating and adapting new patent systems, particularly in Europe.

2.2 Position in the United Kingdom

In the United Kingdom, patents were not originally concerned with rewarding an inventor, but rather with rewarding a merchant who introduced a new product into the country. In this way patent monopoly was granted in return for introducing new technology into the country, for instructing and imparting to the English traders knowledge about the use of that technology, rather than as a reward for inventing something ab initio. The history of patents begins with royal grants by Queen Elizabeth for monopoly privileges that developed the country’s economy considerably. The practice of issuing letters patent encouraged the inventors and traders within the country and also induced foreigners to ply their trade in the U.K. The first such instance of a grant was given by King Edward III in 1331 to one John Kempe of Flanders in order to train the traders of his country. The earliest known patent for invention was granted by Henry VI to Flemish born John of Utynam in 1449. The patent had given John a 20 year monopoly for his invention i.e. for a method of making stained glass that had not been previously known in England. In 1552, Edward VI granted such a letters-patent to one Henry Smyth for

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6 Ibid.
his “Normandy glass”; the main purpose of this grant was to train Englishmen in the reproduction of Normandy glass.

During the reign of Queen Elizabeth, a number of letter patents were granted to various traders of her own country and also to foreign traders. Soon after the death of Queen Elizabeth I., the court in Darcy v. Allen⁹, had taken different stand by not appreciating the monopoly system. The court held in Darcy that the royal grant to Darcy for making, selling, and importing playing cards was void at common law. According to Coke’s report of the case, the basis for the outcome was that a monopoly in a commodity that had formerly been available was void as an abrogation of the right of all subjects to engage in a trade and as a harm to the public in the form of reduced employment and higher prices. This is generally taken to be the first patent case recorded in the English Law reports. Later the Crown issued a proclamation known as “The Book of Bounty” in 1610, which excluded new inventions from general prohibitions¹⁰. With the help of this statute all privileges granted by the Crown was reviewed in all common law courts. Despite King James’ verbal commitment to limit the royal power to grant monopolies, the parliament enacted the Statute of Monopolies in 1624. The Statute of Monopolies has been regarded as the first and final authority on the subject of patents. This legal instrument for the first time allowed patent monopolies for 14 years upon “any manner of new manufacture” within the realm to the ‘true and first inventor’ had its own character¹¹. Also it expressed the desire to impose some limitations on the system in the name of higher public interest¹².

After the enactment of the Statute of Monopolies, the development of the law was left to the courts with few interventions. It was soon decided that a patent should do something to make it possible for others to carry out the manner of new manufacture after the monopoly had expired. At first it appears to have been sufficient if the patentee trained two apprentices who would later carry out the method. But by the early 18th century, it was required that he should disclose the

9 77 Eng. Rep. at pp.1262-64
11 Statute of Monopolies 1623, S. 6
12 Ibid.
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full particulars of his inventions. If he failed to do so, persons interested could seek repeal or revocation by the writ of scirefacias\textsuperscript{13}. The Patent Law (Amendments) Act 1852 marks the beginning of the modern practice in patent law, which established a procedure whereby only one patent application was needed to be filed for England, Scotland and Ireland\textsuperscript{14}. Later on the Patents, Designs and Trade Marks Act 1883 required that the specification shall be filed and it should be examined by the patent office before granting patent. Prior to this Act, patents were granted even without any specification regarding how the invention worked. If there was any litigation in respect of the invention, the jury would decide what the patentee claims, and thereby determine the scope of the invention. However, even after the passing of this Act, it was not clear that the claims were to be taken as determining the scope of the inventions. For the first time, this issue was discussed in a famous case\textsuperscript{15}, it was settled that the inventor could not claim anything outside the scope of the claims. Only after this decision did several Acts make minor amendments in this regard. The Patent Act 1902 introduced the requirement of novelty search on previously published specifications in order to find out whether or not the patent has been previously published\textsuperscript{16}. The Patents and Designs Act 1919 introduced a provision - if a patent contains any invalid claims, then the remainder of the claims could still be held to be good. The Patent Act 1949 widened the definition of inventions and also the grounds of opposition to the grant of acts passed in response to individual petitions.

In 1641, the General Court of Massachusetts declined to give monopolies for any new inventions that are useful to the State\textsuperscript{17}. In the colonial period patents were issued by various colonial governments primarily. The constitution of United States grants Congress power to legislate to promote the progress of science and useful arts by securing for a limited time to authors and inventors the exclusive rights to their respective writings and discoveries\textsuperscript{18}. While tracing the history of

\textsuperscript{13} Scirefacieas refers to a writ requiring the person against whom it is issued to appear and showcase why some matter of record should not be annulled or vacated. See Dann’s Patent (1971) RPC 425.
\textsuperscript{14} Ibid.
\textsuperscript{15} Noble Explosive Co. Ltd v. Anderson, II RPC 519
\textsuperscript{17} Ibid. at p.16
\textsuperscript{18} US Constitution, Art. 1 S. 8(8)
patents in the US, it can be seen that earlier patents were granted only to machineries. The first US patent statute was passed in May 1790; it was a general rather than a private Act which authorizes patents for “any useful art, manufacture, engine or device or any improvements therein not before known or used”\textsuperscript{19}. Under this Act fourteen years protection was granted. Shortly after this Act the first patent was issued to Samuel Hopkins, for a process for making potash from wood ashes\textsuperscript{20}.

Later, in 1793, another patent Act was passed, it brought within its privy, “any useful art, machine, manufacture or composition of matter any new or useful improvement thereof”\textsuperscript{21}. This Act was substituted by the 1836 Act, which reinstated the examination system and also fixed the patent term for 14 years with seven years as the renewal period\textsuperscript{22}. In 1842, a patent statute was passed to provide for the grant of patents for “any new and original designs” for a manufacture for printing on a fabric. However, the right to obtain a patent for such a design was confined to US citizens or residents who were intending to become citizens; In 1870, the legislation relating to patents was consolidated into a single Act. Thereafter the Congress re-codified the patent laws in the year 1952 and substituted the word ‘art’ with ‘process’. The Congress made this substitution with the intention to give wider protection to inventions and to expand the ambit of the subject matter.

### 2.3 Position in India

The patent system in India emerged during the British colonial period. The first Act for protection of inventions in India, Act VI of 1856, which gave protection to inventions, was based on the British Patent Law 1852. Under this Act, fourteen years of exclusive privileges were granted to the inventors of new manufactures. This Act was modified in the year 1859. The Patents and Designs Protection Act was passed in 1872. Later, the Protection of Inventions Act was passed in the year 1883. Both the 1872 Act and 1883 Act were consolidated as the Inventions and Designs Act 1888. The first major patent legislation in India, the Patent and Design Act 1911 was introduced to protect the interest of inventors.

\textsuperscript{19} Patent Act of April 10, 1790. Ch.7, I stat, co 9-11-2
\textsuperscript{20} \textit{Ibid.}
\textsuperscript{21} Patent Act of February, 21, 1793 ch.11, I stat-318
\textsuperscript{22} Act of July 4, 1836, Ch.357, 5 Stat-117
much more effectively. Since the introduction of this Act, the legal system has undergone many changes. The main aim of this Act was to ensure that patents were not worked in a manner detrimental to the consumers or prejudicial to the industrial development in India.

In 1948, the Government appointed a Patents Enquiry Committee under the Chairmanship of Dr. Bakshi Tek Chand, a retired judge of the Lahore High Court to review the working of the Indian patent system and also to find out whether the patent system was in line with national interests. The Committee submitted its final report in 1950. Based on the report, a Patent Bill was introduced but it lapsed with the dissolution of the first Lok Sabha. In 1957 a fresh attempt was made by the Government by appointing another committee under the chairmanship of Justice N. Rajagopal Ayyangar to study and recommend changes to the patent law in India. The Ayyangar Committee recommended the retention of the patent system subject to the modifications suggested therein. The recommendations on patents for food, medicines or drug along with a few other changes were introduced as the Patent Bill on 21st September 1965. In 1967, after making some amendments this bill was again introduced in the Parliament and it was passed in 1970.

2.4 Patent Act 1970

The present law with regard to patents is stated in the Patent Act 1970, as amended and the rules made there under. The Patent Act 1970 had many unique provisions that were acclaimed by many as appropriate for a country like India.\textsuperscript{23} The Act brought about the abolition of product patents for food, medicines or drug, which was earlier granted under the 1911 Act. It also brought about the distinction between process and product patents for pharmaceutical substances and also it contains a more elaborate definition for inventions. Due to the impact of the TRIPS Agreement, the Patent Act 1970 was amended in 1999, 2002 and 2005 respectively. Particularly in the year 2005, the Parliament made a drastic amendment in order to comply with the TRIPS Agreement.

\textsuperscript{23} \textit{Ibid.}
2.5 Justifications for Patent Protection

Many jurists and economists argued in favour of a patent system as a primary requirement in society and emphasized the positive impact of such a patent system on society and particularly, on Industry. Thus, patent jurisprudence has grown dynamically to possess various legal and economic dimensions.

Theories of Patent:

In dealing with a patent case, a court anywhere in the world will want to examine the policy reasons for protecting patents. These policy reasons can be grouped under some broad theories.

The first and simplest theory of patent is the ‘reward theory’. The reward theory begins with the assumption that some inventions once known are easily copied and imitated. Presumably no one would want to invent such an invention and put in the years of research and the expenses that would be required. Thus the inventor owns a ‘propriety right’ in his invention. So the proprietor may demand a high price for his invention as a reward. More so, the patent system exists to prevent free riding i.e. the subsequent copying by others. By granting the inventor a limited-time monopoly, the patent system makes it possible for the inventor to recapture his investment in inventing and developing his invention. This obviously makes possible an effective competitive environment in the market and creates lot of new and useful products for society. Thus it is apparent that inventors render a useful service to society and that society must reward them for it. An inventor has a right to receive and therefore society is morally obligated to give a reward for the inventor’s services in proportion to their usefulness to society.

Secondly, the natural law theory also supports patent protection based on property rights involved in an invention. The inventor is entitled to an inherent right over the product to that the invented. This theory focused on two new concepts: that a patent grant constituted ‘private property’ and that an inventor has

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24 Ibid.
26 Gustaro Ghidini, IP and competition Law, 1st Ed, Edward Elgar Pub, Ltd., Massachusetts, 207 at p.1
an inherent right to claim patent protection\textsuperscript{28}. So the rights created by a fair property system i.e. patent system serves as the appropriate method of giving the inventor freedom to expand his own creativity, inventiveness and undefeated care. According to this theory, “Property should be in a certain sense common, but as general rule private\textsuperscript{29}”. Fritz Mechlup opined that providing adequate patent protection to the inventor will ensure his rights which he naturally derives from his own mental ideas. Otherwise people would start imitating the invention without the consent of the inventor. Hence natural law theory says that such kind of imitation of others’ invention, which is the result of his mental idea, amounts to stealing or theft. So it is obvious that natural law theory also influenced the development of the modern patent system.

Thirdly, the labour theory also emphatically justified patent protection. This theory was propounded by the famous jurist John Locke. So much so that theory is called Lockean labour theory. Locke also followed natural law theory and said that man has property in his ‘own person’ and he can produce a property in a tangible form with the help of his mental as well as physical labor. So invention is a product of the labourer. The labor theory of property holds that a person’s productive work is the basis for a property claim. Inventors are entitled to claim what they make or create as their own.

Fourthly, Bentham’s utilitarian approach focuses mainly on social interest and it inspires policy makers to make laws, which will maximize the interest of the society. So the exclusive rights granted to the inventor as patent stimulates the creation of further inventions and innovations, so that society continues to benefit from more and more new and useful products and processes. Hence it is understood in accordance with utilitarian theory, that providing adequate legal protection to the owner of a patent will satisfy the long-felt wants of consumers, for example lifesaving medicines etc.

Fifthly, the Hegalian ‘individual will’ theory argues that private property rights are crucial to the satisfaction of some fundamental human needs. Patents

\textsuperscript{28} \textit{International Patent Legislation and Developing Countries}, 1\textsuperscript{st} Ed., Martinos pub., The Hague, 1971

\textsuperscript{29} Gary Chartier, \textit{Economic Justice and Natural Law}, 1\textsuperscript{st} Ed, Cambridge University Press, London, 2009 at p.32
may be justified on the ground that they create social and economic conditions conducive to create intellectual activity, which in turn are important for human prosperity and development.

The sixth theory of patent protection, associated primarily with professor Edmund Kitch, is called the “prospect theory”. This theory holds that patent rights enable inventors to efficiently coordinate investment by others to engender second generation improvements\(^{30}\). According to Kitch, the patent system promotes efficiency in the allocation of resources to the development of existing inventions by awarding ownership to new technological prospects. Thus, making improvements upon existing inventions obviously leads to further invention and utility.

The next and the last theory of patent is the “incentive to invent” theory. In analyzing how patent promotes scientific progress, Courts have emphasized two mechanisms: first, the prospect of obtaining a patent monopoly provides an incentive to invest in research to make new inventions and second, the patent system promotes disclosure of new inventions to society. Also this theory holds that the patent system achieves its objectives by offering monopoly profits as a lure to promote innovation. The incentive to invent and incentive to disclose theories are concerned with incentive that operates before a patent is issued. This may also inspire the inventor to make the invention more familiar and comfortable for consumers so that the invention will get social recognition and economic benefits.

### 2.6. Economic Impact of Patents:

A patent confers on the inventor monopoly rights to commercially exploit the invention by preventing others from doing so. Patent law provides that a patent is granted to encourage invention and to ensure that the inventions are worked in a country on a commercial scale and to the fullest extent that is reasonably practicable without undue delay\(^{31}\), and that they are not granted merely to enable patentees to enjoy a monopoly for importation of the patented articles\(^{32}\). This poses

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\(^{31}\) Indian Patents Act 1970, S. 83(a)

\(^{32}\) *Ibid.* S. 83(b)
an obligation on the patentee to ensure that the patent is worked to the fullest extent for the benefit of the general public. Assuredly, the presence of a strong and effective patent system will bring numerous benefits such as the dissemination of information and providing an incentive to invest in the development of new products and processes.

1. **Patent Stimulates Inventions and Innovations:**

   The fundamental premise of the patent system is that society benefits when people conceive new inventions and develop and commercialize new products, incorporating those inventions, so that others may learn from and improve upon these inventions\(^{33}\). The justification proffered that the grant of a patent will stimulate innovation by securing investment in both seeking and exploiting new ideas needs careful consideration\(^{34}\). This justification can be examined in two stages, first by asking whether a patent does stimulate invention and secondly whether it also helps to stimulate innovation by securing the positive explanation of that invention. By endowing inventors with property rights over the fruits of their efforts, patents affect the incentive to innovate and are likely to increase the flow of innovations. This increase is evidently desirable, given that otherwise the market system may provide too little new knowledge. But by giving the patentee exclusive rights on the exploitation of a unique economic good, one can obviously stimulate the inventor and the industry to invest more capital. It is understood that the exploitation of patent stimulates the owner to innovate or develop his product. Hence, the benefit of the innovation would have to be weighed against the very obvious monopoly costs associated with patents\(^{35}\). Finally, the existence and the extent of innovation may be correlated with investment and the size of research facilities\(^{36}\). Innovation and technological progress will require large amounts of production and will result in goods entering the market place. Furthermore they

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\(^{33}\) *Ibid.*


\(^{36}\) Graham Dulfield (ed.,), *Innovation Without Patents*, 1\(^{st}\) Ed, Edward Elgar Pub., Massachusetts, 2007 at p.9
provide businesses an opportunity to mitigate the cost of an investment\textsuperscript{37}. Finally it will lead to technological activities and economic development in a country.

2. Patent Disseminates Knowledge:

One of the important benefits of patent is related to the disclosure requirement. In most countries, patents are disclosed 18 months after the filing date or earlier\textsuperscript{38}. The importance of this feature is predicated on the fact that absent patents, inventors can rely on trade secret to protect their inventions. By providing an incentive for disclosure, patents are held to contribute to a desirable dissemination of scientific and technical information, allowing other inventors to avoid duplicating existing inventions and making it easier to develop further innovations that build on the known state of the art.

Also 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. If the inventive concept is one that has to be embodied in a marketed product, the patent may give earlier access to the information and perhaps a more explicit statement of what the invention is\textsuperscript{39}. The disclosure side of patent bargain is not a policy that is easy to implement. There is an obvious temptation for any patentee to omit from his specification information that many seem incidental but is in fact useful or important to commercial success. Moreover the inventor has an obligation under the Statute to disclose his invention sufficiently without hiding the best method of its operation or structural formation and functional application\textsuperscript{40}. This is so that the consumers or the purchasing public, academicians and other researchers may do their research and experimentation. Finally, it is obvious that patents disseminate knowledge to the society for the betterment or well-being of the people thus leading to considerable utility.

3. Patent Avoid Wasteful Innovation Efforts:

It is obvious that the disclosure requirement of patents has an important and beneficial effect on new knowledge and that it will make possible further

\textsuperscript{37} Adrian Sterling, \textit{Perspectives on IP and Market Freedom}, 1\textsuperscript{st} Ed, Sweet & Maxwell, London, 1997 at p.70
\textsuperscript{38} Indian Patents Act 1970, S. 11A(1); \textit{See also} Patent Rules 2003, Rule 24
\textsuperscript{39} Supra note 37 at p.139
\textsuperscript{40} Indian Patents Act 1970, S. 10
inventions and innovations. Inventions from basic research are often of this sort, at times opening up entire new fields of research. It can be considered that patenting of such seminal inventions can have useful social pay offs. This rationale is articulated in the so-called prospect theory of patents. It relies upon the notion that broad, early property rights on key inventions allow an orderly pursuit of follow-up innovation and reduce wasteful innovation races. An analogy can be made to the practice of granting mineral claims on land where no discovery has yet been made to avoid a wasteful mining of the prospect. Whereas patents in such cases can clearly have positive efficiency effects, it is also easy to see that broad, early patents can adversely affect further research especially when the original invention has applicability in many uses\textsuperscript{41}. Thus, such kinds of innovation will considerably reduce wasteful innovation efforts including all the amount which may have been spent by the inventor or the industry.

4. Patent Helps Transfer of Technology:

Technical knowledge is an essential factor for the growth of the economy. It leads to competition in production and efficient use of products. Every invention has its own technical knowledge or information. It is obvious that the patent document discloses such technical knowledge to the person skilled in the art or to the industry in general. On the other hand, when the invention enters the market, the technology is automatically transferred by certain modes i.e. by sale, assignment or license. So it is apparent that the inventor has a right and an obligation to transfer the technology.

One of the basic concepts of technology derives from economic theory i.e. the relation between innovative methods and productivity. Technology in this sense can be associated with the idea of innovation and invention, generally defined as any creative human activity performed in order to produce new and improved products or processes\textsuperscript{42}. Technology comprises a set of indivisible technology modules that are transmissible by means of technical document blueprints or training and can be indispensable for the creation of a new product or


\textsuperscript{42} Yi Shin Tang, \textit{The International Trade Policy for Technology Transfer}, 1\textsuperscript{st} Ed, Wolters Kluwar, NewYork, 2009 at p.23
process\textsuperscript{43}. Labour skills are a central element in attracting technology in terms of both the nature of goods traded and of capital and technology imparted\textsuperscript{44}.

Strong patent protection provides incentives to codify and organize new knowledge in ways that are meaningful and useful to others. The potential contribution of patents to encouraging technology transfer is also indirect. Patents can help specialized technology suppliers earn returns for their services and thus facilitate a market for technology. Patent documents disclose technological information by describing the inventions in accordance with the requirements of the applicable patent law and by indicating the claimed novelty and inventiveness by reference to the existing state of the art. They are, thus, sources of information not only on what is new but also on what is already known; and in many cases furnish a summarized history of the technological progress in the field to which they relate\textsuperscript{45}. It is in fact considered that technological innovation, science and creative activity are recognized as important sources of material progress and welfare to the society. So the technology involved in every invention should be transferred without any legal or technical hurdles. Also, continuous technological flows in the market may enrich the industrial growth and economic development of a country.

5. Patent Enriches Market Activities:

The conventional justification for a patent system is that inventors and investors are rewarded for their time, work and risk of capital by the grant of a limited, though strong, monopoly. This benefits society by stimulating investment and employment and ensures that details of the invention are added to the store of available knowledge. The economic rationale for the anticipated benefits was that preventing competitors from imitating an invention alone can ensure that the inventor generates sufficient returns on investment to cover costs associated with the inventive process. Patent enriches market activities with hands of industry in association with the inventions and high level technological efficiency and new standard of consumer choice. Free trade will always be making new efforts to

\textsuperscript{43} \textit{Ibid.}
\textsuperscript{44} Keith E. Maskus and Jerome H. Reichman (Ed.), \textit{International Public Goods and Transfer of Technology}, 1\textsuperscript{st} Ed., Cambridge University Press, London, 2005 at p.269
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satisfy the long-felt need of the consumers and to make quality products for the market. More so, it provides more businesses with a chance to mitigate the cost of the products and investment\textsuperscript{46}. The Patent system invites investment and foreign direct investment for the new technology which floods the market\textsuperscript{47}. Moreover, the primary objective of a stronger system of patent protection and enforcement is to maximize the competitive gains from additional innovation and technology acquisition. This will lead to more productivity and the result would be an increasing level of market autonomy.

6. **Patent Promotes Research and Development:**

Patent system protects a wide variety of technical inventions. It is presumed that the reasons for granting a patent are to create an incentive to research and to accelerate and aggregate innovations through disclosure of inventions. The research activity of innovators is undoubtedly influenced by the patent system as well as the industry structure. As a result almost all industries have established atleast a minimum level of infrastructural facilities for research and development programs. This is so that they are able to produce new products and processes so as to satisfy long-felt want of the society and to transfer new technology to the industry. Of course the patent system helps the inventor and the industry recoup the amount they spent and to give more opportunities at the market place to face competitors. Introduction of new products and processes considerably enhance technological development and make it necessary to relook the concept of ‘invention’ as patentable subject-matter. So it is apparent that the industries are making large-scale research efforts in the area of pharmaceutical inventions and biotechnology inventions. Finally, it is presumed that an inventor may recover R and D costs and investments by offering exclusive rights for a limited period. It also stimulates investment to commercialize and market new inventions so that the general public can enjoy the fruit of the innovation.

\textsuperscript{46} Adrian Sterling, *Perspectives on IP and Market Freedom*, Sweet & Maxwell, London, 1997 at p.70

\textsuperscript{47} Shahid Alikhan, *IP and Competitive Strategies in the 21\textsuperscript{st} Century*, 2\textsuperscript{nd} Ed., Wolters Kluwer, NewYork, 2009 at p.55
7. Patent Balance Public Interest:

In the course of time both individual and ‘public’ justifications have played prominent roles in the arguments in favor of patents for invention. There is an implied contract between the inventor and the society, that is, if the inventor invents a new and useful invention for the society, he has to be adequately rewarded and legally protected. Patent systems represent a complex balance of interests of the patentee and third parties including the consumers who look to the patent to provide new, cheaper or improved commodities and a general enhancement of the standard of living\textsuperscript{48}. The public also look for new activities and employment to replace ones which have become redundant, often as a result of innovations which reduce the direct labor content of product and services\textsuperscript{49}.

The presence of a strong and effective patent system may bring numerous benefits such as the dissemination of information and providing an incentive to invest in the development of new products and processes which will fall into the public domain\textsuperscript{50}. Patents are looked upon to provide two kinds of impetus 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\textsuperscript{51}.

Also, it is obvious that every invention exploited by the owner should be useful to the public at large unless the invention or the creation lose its validity. The patent systems encourage disclosure to achieve its primary purpose of advancing practical acts by increasing public knowledge too\textsuperscript{52}. In this respect, a balanced patent system is defined as one where social benefits exceed social costs and the system, therefore contributes to a nation's economic well being. Achieving balance in the system should therefore be the key objective of patent system.

\textsuperscript{49} Ibid.
\textsuperscript{50} Bainbridge, \textit{Intellectual Property Law}, 4\textsuperscript{th} Ed, Financial Time, PITMAN Pub., London, 1999 at p.325
2.7. **Concept of Invention:**

Invention is a highly creative process. An invention is the discovery or creation of a new configuration, composition of matter, device or process\(^{53}\). Some inventions are based on preexisting models or ideas. Others are radical breakthroughs, which may extend the boundaries of human knowledge or experience. Sometimes seeing a new possibility, a new connection or relationship can spark inventions. It is obvious that the main object behind the concept of invention is necessity. Necessity may be the mother of invention or invention may be the mother of necessity. It is based on the changing complexity of the society, especially due to the development of science and technology.

The Supreme Court of the US invoked the goal of invention and stated, “the patent monopoly was not designed to secure to the inventor his natural right in his discoveries rather, it was a reward, an inducement, to bring forth new knowledge\(^{54}\).

An invention that is novel and not obvious to those who are skilled in the same field may be able to obtain legal protection as patents. Historically, patents were granted to mechanical categories, such as the safety pin by Walter Hunt in 1849. Further patent protection was granted in the year 1893 to Whitcomb Judson for the zipper and locomotive steam engine for rail track to John Ruggles, which were granted patents in 1836, respectively\(^{55}\). Next patents were granted for electrical inventions in the year 1879 for electrical lamps. Later on patent was granted to Dupont in the year 1937 under the category of chemical inventions for inventing linear condensation polymers\(^{56}\). More so, recently, the scope has been widened in multifarious dimensions which include processes and products of genetic engineering, computer programs and so on.

2.8. **Statutory meaning of Invention under Indian Patent Act**

There is no general rule to determine what constitutes an invention under the Act. The more arrangement of two or more things without the exercise of


\(^{56}\) Ibid.
inventive ingenuity is not a subject matter for a patent. Simplicity is not necessarily an objection for securing a patent for an invention. The only thing that the inventor should keep in mind is whether the developed variant will render more useful results or not. The workshop improvements or change of materials, color or size of a material made in a well-known way are not patentable inventions. Under the UK Patent Act, the expression “patentable invention” is defined but there is no separate definition for invention. We have to infer from the said provision that the invention shall be new, involve inventive step and be capable of industrial application. If we look into Indian Patent Act, 1970, it defines “invention” as new and useful art, process, method or manner of manufacture, machine, apparatus or other article, substance produced by manufacture and includes any new and useful improvement of any of them and an alleged inventions. Further this definition was amended in 2002 in accordance with TRIPS Agreement. Accordingly, the term ‘invention’ means, any new process or product involving an inventive step and capable of industrial application. Here the researcher feels that this definition is too general and wide; it is not crystal clear. The term invention is therefore the production or introduction of a new thing for the first time by exercising one’s own mind, skill and labor.

The US patent law says that “whoever invents or discovers any new and useful process, machine manufacture or composition of matter or any new and useful improvement may obtain patents”. Furthermore, it was in order to comply with the TRIPS requirement and potentially face the developed countries at market based on the new dimension of the concept “invention”, that the Parliament amended the patent Act in the year 2005. Accordingly, the concept of invention was enlarged by defining the term ‘new invention’ as “any invention or technology which has not been anticipated by publication in any document or used in the document or used in the country or elsewhere in the world before the date of filing the patent application with complete specification, which means the subject-matter

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57 The UK Patent Act 1977, S. 1(1)
58 Indian Patents Act 1970, S. 2(1)(i); See also Thomson Brandi v. Controller of Patents and Designs, AIR 1986 Del 249
59 Indian Patents (Amendment) Act 2002, S. 2(j)
60 35 U.S.C. § 101
has not fallen in public domain or that it does not form part at the state of the art. Hence, it is understandable that the term invention obtained new decoration in the sphere of legislative framework.

2.9. Patentability Criteria

Every country across the globe recognizes three primary requirements for obtaining patent registration; which are as follows:

(1) Novelty – Newness of the invention

(2) Non-obviousness / Inventive step – Proof of inventor’s contribution of his ingenuity.

(3) Utility / Industrial application – Capable of being industrially made and used.

1. Novelty:

The first and foremost requirement for obtaining patent is novelty or newness: that means an invention must be new. It must not already have been available to the public. The question of novelty has a special meaning assigned to it under the U.K. Patent Act. It states that “an invention is new, if it does not form part of the state of the art”. It also describes that the “state of the art” as comprising all matter made available to the public before the priority date of the invention, whether by written or oral description by use or in any other way. This includes matter contained in other applications having an earlier prior art. Therefore novelty is really a question of whether the invention has been “anticipated” for example by previous patent or by publication or use could have occurred elsewhere in the world. So it is obvious that the standard adopted by the Patent Act and EPC is one of absolute novelty, there are no temporal or geographical restrictions on the prior art. It is matter available anywhere in the world at any time. It is essential for

61 Indian Patents (Amendment) Act 2005, S. 2(l)
63 Ibid. S. 2(2); See also EPC 1973, Art. 54
64 Ibid. S. 67
the validity of a patent that it must be the inventor’s own invention as opposed to mere verification of what was already known before the date of patent.\textsuperscript{65}

The manner of manufacture to be patented is publicly known, used and practiced in the country before or at the date of patent, then it amount to public knowledge, which would disqualify the grant of a patent. In other words for getting patent protection the new subject matter must involve invention over what is old.\textsuperscript{66} Also, the court expressed its view on novelty in a landmark case\textsuperscript{67}: “invention as is well known, is to find out something or discover something not found or discovered by any one before”. It is not necessary that the invention should be anything complicated. The essential thing is that the inventor was the first to adopt it. The principle therefore, is that every simple invention claimed, so long as it is something which is novel or new would be an invention. Finally, to decide whether an invention is new is a three step process. The first one is finding the state of the art, the second one is “interpreting the specification to establish the boundaries of the invention being claimed”, and the third step is “comparing the invention as claimed to the prior art on the priority date of the invention. Thus it is mandatory that in order to obtain patent the inventor shall prove the claimed invention is novel.

2. Non-obviousness / Inventive step:

Inventive step means, “a feature of an invention that involves technical advance as compared to the existing knowledge or having economic significance or both and that makes the invention non-obvious to a person skilled in the art.\textsuperscript{68} It is said that inventive step measures technical accomplishment reflected in an invention. It attempts to measure an even more abstract quality than novelty and utility. The underlying principle behind the doctrine of obviousness is that the public should not be prevented from doing anything which was merely an obvious extension or workshop variation of what was already known at the priority date.\textsuperscript{69}

The obviousness inquiry encourages people to carry out research they may not

\textsuperscript{65} Bishwanath Prasad Radhey Sham v. Hindustan Metal Industries, 1979 (2) SCC 511
\textsuperscript{66} Blanky and Co., v. Lathern and Co., 6 RPC 1889
\textsuperscript{67} Raj Prakash v. Mangat Ram, AIR 1978 Del 1
\textsuperscript{68} Indian Patents Act 1970, S. 2(ja)
\textsuperscript{69} PLG Research v. Ardon International, 1999 FSR 116, 136
otherwise be undertaken more specifically, the fact that patents are not granted for obvious invention encourages speculative or risky research.

Patent law rewards the discovery and disclosure of inventions that are new useful and non-obvious advances. Patent rights are not available for new advances that are merely obvious extensions or modifications of prior designs that could be achieved without the lure of patent rights. The EPC also requires that an invention shall be considered as involving an inventive step, if having regard to the state of the art, if is not obvious to a person skilled in the art.\textsuperscript{70}

The word ‘obvious’ does not have any special legal meaning and it has been said that it is not necessary to go beyond the dictionary definition but to take it to mean “very plain”\textsuperscript{71}. The person skilled in the art is simply someone with a wide knowledge of the technology with in which the invention. The notional skilled workers do not have inventive ability but he does have knowledge common to the particular are. That is, he possesses common general knowledge and this is the basis for determining whether in the light of that knowledge, an invention is obvious. In order to determine whether an invention is obvious at the time of its invention, the court sets out a tripartite test for obviousness.\textsuperscript{72}

\begin{enumerate}
\item The scope and content of the prior art.
\item The difference between the prior art and the claimed invention, and
\item The level of ordinary skill in the pertinent art.
\end{enumerate}

Unlike novelty, where the claimed invention is compared with a single prior art, non-obviousness compares the relevant invention with the prior art as a whole. The US Supreme Court articulated about non-obviousness in a famous case\textsuperscript{73} that, “patentability requires something more than novelty”. The invention also must represent enough of a qualitative advance over earlier technology. So the test is to determine the technical advance incorporated is whether obvious to

\begin{itemize}
\item EPC 1973, Art.56
\item Graham v. John Deere Co., 383 US 1 (1966)
\item Hotchkiss v. Greenwood, 52 US 248 (1850)
\end{itemize}
Persons Having Ordinary Skill In The Art (PHOSITA). Also the Federal Circuit Court sets forth the following factors for defining PHOSITA as 74,

1. The inventors’ educational background.
2. The kinds of problems confronted in the art
3. Finding solutions for existing problems
4. The level of sophistication of the technology.
5. The speed of invention in the art, and
6. The educational level of workers in the field.

All the above said factors are also considered, for determining persons having ordinary skill in the art.

Thus, it is said that the inventor should show what kind of improvement made by contributing his ingenuity it the invention. The court also held that for an 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 75. So, it is apparent that the invention claimed by the inventor should not be obvious to the person skilled in art, and only then is he entitled to patent protection for his invention.

3. Industrial Application / Utility:

The third and most important requirement of patentability concerning commercial exploitation is utility or industrial application. It means the invention must be capable of industrial application and must perform some function which is of benefit to the society Industrial applicability means, according to its nature; it can be made or used in any kind of industry 76 including agriculture 77. The invention must be industrially applicable, meaning that the invention should have industrial utility. Industrial applicability means it must perform some function of “positive benefit” to the society 78. To comply with utility requirement an invention

74 Environmental Designs v. Union Oil Co, 713 F.2d. 693, 697 (Fed. Gd. 1983)
75 M/s. Bishwanath Prasad Radhey Shyam v. M/s Hindustan Metal, 1979 (2) SCC 571
76 PCT 1977, Art. 33; See also Indian Patents Act 1970, S. 2(a) (c)
78 Bedford v. Hunt, 3 F. Cas. 37 (C.C. Mass. 1817); Cross v. Lizuka, 753 F 2d 1040 Fed. Cir. 1985
need not be superior to existing product or process. And it is also not necessary to establish the commercial success of the product or process\textsuperscript{79}, but the patented invention should be available at market for public consumption\textsuperscript{80}.

The patent law requires that patentable inventions must possess ‘practical utility’\textsuperscript{81}. In other words to be patentable an invention must have some ‘real world use’ ‘Practical use’ does not necessarily mean “significant or extensive”. Even a chemical intermediate which exists only for an instant of time when it is produced during the course of a chemical reaction is useful because it is a tool that allows researchers to develop other chemicals that have useful therapeutic properties\textsuperscript{82}. Even a small degree of utility is sufficient to satisfy utility requirement. It is also said that the quantum of utility required for the purpose of granting patent protection was explained in a case as, if the object sought to be attained by the patentee can be attained that too practically be useful at the time when it is granted and then the test of utility complied with\textsuperscript{83}. So, it is apparent that the law is least bothered about the degree of utility. Finally the researcher opines that the great majority of inventions are never challenged as lacking ability. The utility requirement simply ensures that the invention works on some minimum level of its own nature.

4. **Inventions that are not patentable:**

The inventions which satisfy the essential criteria of patentability namely novelty, inventive, step and industrial application, may not be patentable due to the policy of the government. In India, sections 3 and 4 of the Patent Act stipulate the inventions for which patents cannot be secured though they satisfy all the essential requirements of patentability. The object of this exclusion is because some of the inventions, if protected will hamper further growth of development in the technical field and some inventions if protected will pragmatically affect the welfare of the people or be against public policy and morality.

\textsuperscript{79} Barmag Machinery Fabric A.G. v. Murata Machinery Ltd. 731., F.2d 831 (Fed Cir. 1984)
\textsuperscript{80} Harward/Onco Mouse, (2005) O.J. EPO 473, 494
\textsuperscript{81} Re Brana, 51, F3d. 1560 Fed.Cir. 1995
\textsuperscript{82} Re Joly, 753 USPQ 45 CCPA (1967)
\textsuperscript{83} Lane Fox v. Kenigston and Knightsbridge Electric Lighting Co, (1892) 3 Ch. 424
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According to Indian Patent Act, the inventions which are frivolous or which is anything obviously contrary to well established natural laws are not patentable.\(^{84}\) It is also said that the government of a country has a great sense of responsibility to safeguard and protect the health, environment and maintain public order.\(^{85}\) Also, mere discovery of scientific principles or the formulation of an abstract theory or discovery of any living thing on non-living substance occurring in nature cannot entitle patent.\(^{86}\) The mere discovery of a new property or mere 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.\(^{87}\) In this respect the Court has also confirmed that a patent for a mere use of a known contrivance without any additional ingenuity in overcoming fresh difficulties was considered bad.\(^{88}\) Moreover, the mere admixture resulting only in the aggregation of the properties and arrangement and rearrangement or duplication of features of known devices cannot entitle patent protection. Also, the method of agriculture, horticulture, the process for medicinal, surgical, curative, prophylactic or treatment of human etc. are not patentable. More particularly plants and animals other than micro-organisms in whole or any part there of including seed varieties and species and essentially trio logical processes for production or propagation of plants and animals cannot constitute patentable invention, patent Act also excludes computer program per se, mathematical and business methods, literary, dramatic, musical, artistic and cinematographic works and mere scheme or game or method of performing mental.

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\(^{84}\) Indian Patents Act 1970, S. 3(a) reads, “An invention which is frivolous or which claim anything obviously contrary to well established natural laws”.

\(^{85}\) Ibid. s. 3(b) states that, ”an invention, the primary or intended use or commercial exploitation of which would be contrary to law or morality or which causes serious prejudice to human, animal or plant life of health or to the environment”.

\(^{86}\) Ibid. S. 3(c)

\(^{87}\) Ibid. S. 3(d)

\(^{88}\) Standipack Pvt. Ltd v. Oswal Trading Co., Ltd, 1999 PTC (19) 479 (Del)

\(^{89}\) Indian Patents Act 1970, S. 3(e) reads, “A substance obtained by mere admixture resulting only in the aggregation of the properties of the components thereof or a process for producing such substance.”

\(^{90}\) Ibid. S. 3(f) says, “The mere arrangement and rearrangement or duplication of features of known devices each functioning independently of one another in a known way”; See also Franz Xaver Huemer v. New Yash Engineers, AIR 1977 Del 79

\(^{91}\) Indian Patents Act 1970, s. 3(h)

\(^{92}\) Ibid. S. 3(i)

\(^{93}\) Ibid. S. 3(j)

\(^{94}\) Ibid. S. 3(k)

\(^{95}\) Ibid. S. 3(ka)

\(^{96}\) Ibid. S. 3(l)
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act\textsuperscript{97}, presentation of information\textsuperscript{98} topography of integrated circuit\textsuperscript{99} and the inventions based on traditional knowledge\textsuperscript{100} cannot be considered as patentable subject-matters.

The Act also stipulates that no patent shall be granted in respect of an invention relating to atomic energy\textsuperscript{101} in line withSec 20(1) of Atomic Energy Act 1962. In case a patent has been granted for invention relating to atomic energy, the central government may direct the controller of patents to revoke the patent under the Act\textsuperscript{102}.

Thus the inventions, which do not fall under above specifically excluded categories are patentable under the Act. Also the concept of ‘invention’ itself got a new face or new dimension. Traditionally the inventors produced new plastic items, machine apparatus, manufacturing processes, pharmaceutical products and sometime later inventors started producing, altering, isolating, purifying new life forms and obtained patent over life forms as well. Moreover, copyrightable subject-matter i.e. the software is now transformed into a patentable subject matter\textsuperscript{103}. Thus, due to the advent of science and technology, the concept of ‘invention’ is enhancing day by day. The researcher in this work wants to focus and discuss the patentability of life forms and its origin, development and the positive as well as negative impacts on the society.

2.10. Historical Evolution of Patent on Life Forms

It is obvious that the history of life on earth, organisms have made use of each other in sophisticated ways. Interaction between organisms constitutes a global natural economy for survival. The advent of industrial revolution toppled this prime factor of dependence by introducing novel technical systems to fulfill the human needs. Until recently our history relied primarily on non-biological technology, the industrial revolution was built primarily on fire, minerals and chemistry. Now the inventors contribute their ingenuity to produce, and alter new

\begin{itemize}
\item \textsuperscript{97} Ibid. S. 3(m)
\item \textsuperscript{98} Ibid. S. 3(n)
\item \textsuperscript{99} Ibid. S. 3(o)
\item \textsuperscript{100} Ibid. S. 3(p)
\item \textsuperscript{101} Ibid. S. 4
\item \textsuperscript{102} Ibid. S. 65
\item \textsuperscript{103} Diamond v. Diehr, 450 US 175 (1981)
\end{itemize}
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organisms. This novel technology rapidly attracted business venture and develop is to sector of prime value in 1960’s and 1970’s. So the researchers and investors started filing patents in order to prevent others from using their technology.

At present biotech engineers started inventing many products and processes based on biological materials. The term ‘biotechnology’ has no universally accepted definition and it is defined in numeral ways, the reason is that biotechnology is not static but dynamic in nature. The term biotechnology is a combination of two words ‘bio’, which means ‘life’ and ‘technology’ means application of scientific knowledge in practical purposes to get desired result. Thus, ‘biotechnology’ means the scientific knowledge that uses life or living entities like micro-organisms, plants and animals for practical and commercial purposes to get desired end results. In recent years, natural sciences have developed rapidly in the area of biotechnology. So the term ‘biotechnology’ can be broadly defined as “any technique that uses living organisms, (part of organisms) to make or modify products, to improve plants or animals or to develop microorganisms for specific uses”. The main value of biotechnology is twofold. First, scientists can take useful cells from plant and animal cells and transfer them to micro-organisms such as yeast and bacteria that are easy to grow in large quantities. Products that once were available only in small amounts from an animal or plant are then available in large quantities from rapidly growing microbes. The second benefit holds particular promise for plant and animal breeders. Genetic Engineering allows desirable gene from one plant, animal or microorganism to be incorporated into an unrelated species, thus avoiding the constraints of normal cross-breeding. Thus, before discussing the modern biotechnology the researcher must discuss and analyze the traditional nature of biotechnology.

104 The term biotechnology was coined by a Hungarian engineer named Karl Erkay in the year 1919.
105 Dr. Sreenivasalu N.S. and Dr. Raju C.B, Biotechnology and Patent Law (Patenting Living Beings), 1st Ed, Manupatra Pub, Delhi, 2008 at p.2
107 Micro-organism is an organism that is microscopic and which can be seen only with microscope; Micro organisms include bacteria, fungi, archaea and protists, yeasts.
109 Ibid.
2.11. Prior to Diamond v. Chakraborthy

The ancient Egyptians made wine by using fermentation techniques based on an understanding of the micro-biological processes that occur in the absence of oxygen. They also applied fermentation technologies to produce dough rise during bread making. Based on this process they were able to produce almost 50 varieties of bread in Egypt more than 4000 years ago. More so history says, that Sumerians introduced ‘baking technology’ with yeast and the Egyptians produced the wine brewing technology by fermenting grape juice. These techniques were passed on from generation to generation. Baking and wine making were considered to be normal household works until science lime lighted the technological processes involved in it. Sometime later, due to the rapid development of science and technology, bio-engineers proved that the process of fermentation occurred because of micro-organisms present in the atmosphere. This discovery received the first patent on life form in Finland in 1843. In 1873, patent was granted to Louis Paster for the process of isolation of yeast. Comparatively these technologies were primitive based on the present day technologies, yet patents were granted in order to stimulate, innovation and grant, protection to the inventions.

In the mid 1800s, an Australian monk, botanist and plant scientist Gregor Mendel carefully studied the principle of heredity by experimenting with garden peas. In this way Mendel successfully crossbred ‘traits’ such as color, plant height and pod size. Mendel showed that differences such as a plant height or color could be attributed to the passing of traits and genes i.e. the basic building blocks of life.

The second generation biotechnology patent, which begins with the mass microbiological applications discovered by Louis Pasteur in day today life and developed to an extent when the great discoveries like ‘genes’ and ‘chromosomes’, transferrable genetic material in DNA and RNA, ‘codon’,

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110 A gene is a stretch of genetic material (DNA or RNA) with a defined function in the organisms or cells. It usually codes for a protein. There are many genes within a genome, for example, the human genome is now found to contain about 30,000 genes.

111 Chromosomes are made of DNA and proteins. In prokaryotes, the intact DNA molecule containing the genome in eukaryotes, a DNA molecule complexes with RNA and protein into a thread like structure containing a linear array of genes.

112 Codons are tri-nucleotides, that is a series of three chemical bases linked together in a specific order. It is that order that determines the amino acid will be added to the protein under construction. Each codon carries the code for a specific amino acid.
isolation and purification of genes sequencing DNA, synthetic insulin were made. The human urge to patent these technologies also increased and patent applications were filed for patenting these technologies and either the patent office or the court rejected many applications raising the issue of invention or discovery. But the patent applications were mainly rejected on the ground that they were the products of nature\textsuperscript{113}.

In 1953, J.D. Watson and France Crick discovered the structure of DNA. Undoubtedly this was the most significant biological discovery since Darwin’s theory of evolution. For their work Watson and Crick received the Nobel Prize in 1962 for medicine. Today, researchers are increasingly and energetically involved in applying Watson and Crick’s discovery to the development of commercially useful products. The discovery of the structure of the DNA molecule which might be thought of as the genetic code of life has created new frontiers in the world of science\textsuperscript{114}. These frontiers include frontiers of fear, frontiers of fact, frontiers of fantasy and frontiers of law. Today the test-tube embryo of George Orwell’s 1984 is fact not science fiction. Man can now genetically alter animals and create new animals not already existing, such as the cross between the sheep and the goat known as the “geep”\textsuperscript{115}. Applied biotechnology has already provided us with an economical way of producing “insulin” and will no doubt allow economical production of many other valuable industrial products. Applied biotechnology also offers such exciting opportunities as new life forms and altered life forms of benefit to man, new plants which may create high yield row crops and improved varieties of known plants which will be resisted to traditional pathogens etc.

Essentially today biotechnology is the science of gene splicing otherwise known as ‘genetic engineering’ or the recombinant DNA (rDNA) technique. The process involves combining genes of different organisms for the purpose of introducing new properties into the host organism. Otherwise, it is nothing but manipulation of genetic materials of a living being to get desired results. In fact, it

\textsuperscript{113} Re Mancy, 499, F2d, 1289, 1291 (CCPA, 1974); American Fruit Growers, Inc v. Brogdex, 283 US 1 1931; Re Merat.519, F.2d at 1392 (CCPA 1975)

\textsuperscript{114} Edmund J. Sease, From Microbes, To Corn Seeds, To Oysters, To Mice: Patentability of New Life Forms, Available at www.NationalAgLawCenter.org. Accessed on 14\textsuperscript{th} March 2012

\textsuperscript{115} Ibid.
was recombination technology which made public attention focus on biotechnology.

Recombinant DNA (rDNA) technology creates new DNA sequences by joining pieces of DNA from different organisms together. Bacterial enzymes known as nucleases, a specific DNA sequence and other enzymes known as ligases are all reconnected into several DNA stands. This splicing and recombination of the DNA sequences results in totally new DNA in the host organism or cell. The host cell or organism may then express the foreign DNA by creating the desired proteins that would not have been produced had the DNA not been altered. This sort of technology allows the genes responsible for the production of such proteins as insulin or human growth hormone to be introduced into bacteria or other hosts so that the host will produce the desired product.

In agriculture through genetic engineering now-a-days it is possible to engineer any crop or plant by manipulating the genome so that the genes coding for certain features like resistance to pests, weeds, herbicides and tolerance to drought conditions high-yielding genes would be isolated and incorporated. These genetically engineered plants or crops therefore possess the qualities such as high yield, capacity to resist pests, insects, and weeds and also capacity to withstand drought condition. Thus, there is a solution for the demand for increased production in the agriculture sector.

Similarly the application of biotechnology in the field of animal husbandry tends to produce high yield of milk, flesh and coral through tissue culture, cloning and genetic engineering. Now there can be an animal which posses both the features of resisting diseases and of giving high yields. Besides these, Genetically Engineered animals are used in testing drugs, medicines and therapies and they can also be used as bio-reactors to produce human metabolic products.

1.12. Invention v. Discovery

When the object of patentability is an invention concerning biotechnological matter, patent law distinguishes between invention and discovery.

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This legal construction makes the distinction which in theory has a clear dividing line, fundamental to patent eligibility. In classical mechanical science and technology this issue posed no problem yet with biotechnological inventions, the situation is different.

The fact is that patents cannot be granted for discoveries while at the same time biotechnological inventions consisting of gene sequences are patented. For the purpose of discussion in this context should be emphasized that the legal construction of invention could well differ from the linguistic understanding of the word. The basic notion of discovery is new knowledge of something already existing in nature, which means that the phenomenon pre-exists and is just waiting to be discovered. This understanding of discovery sets against the legal concept of an invention indicates the difference between them an invention is a new product or process with no previous existence.

2.13. Invention in general

Only a few countries have, in their respective domestic laws relating to patent, set forth a positive definition of the subject-matter considered to be an invention under the legal concept. In fact, the US patent law is an exception in this respect stating that, “whoever invents or discovers any new and useful process.........”117. The TRIPS provides no definition of an ‘invention’ with the consequence that in principle it does not prevent the exclusion of naturally occurring substances such as microorganisms, genes and cells from patent protection. Also in the extension that TRIPS Agreement apparently says invention either process or product in all field of technology is entitled to get protection118. The same situation as with the TRIPS holds good for the EC Directive on the legal protection of biotechnological invention119. The EC Directive does not set forth a positive definition of the concept but explicitly holds biotechnological inventions

118 TRIPS Agreement 1994, Art.27
patentable\textsuperscript{120}. With eligibility as viewed by the EPC, it is clear that inventions such as gene sequences are patentable subject-matter\textsuperscript{121}.

2.14. Invention as Opposed to Discovery

By considering the object of patentability, doctrines have been developed that exclude certain subject-matter from the patent protection as regards discoveries under European laws and products of nature under US patent Law. As the legal concept of invention has developed in countries of the EPO\textsuperscript{122} and the US however patent law covers subject-matter that could also be found in nature. This obscure distinction between inventions and discoveries of something already existing is essential for patent law and the possibility of protecting developments made.

For biological phenomena, which to a certain extent “exist in nature,” the invention concept had to be somewhat extended in order to cover these types of inventions. Obviously, this concept has continuously evolved through judicial decisions to include biological organisms and parts of biological materials, cell lines etc. occurring in nature. Much of the discussion has focused upon the notion that it is not possible to speak of an ‘invention’ where products of nature or living forms are concerned.

In Europe, the eligibility question in the biotechnological field has been firmly settled by the EC Directive, which confirms EPC case law on this point of law. US law has established that modified living forms, are patentable as ‘composition matter’. Products of nature are generally considered inventions when some human intervention has been necessary to make them available. The patenting of high life forms however is still being contested for ethical concerns in Europe and even though in principle they are eligible for protection, the matter has yet to be completely settled.

\textsuperscript{120} Ibid. Art. 1
\textsuperscript{121} Ibid. Art. 5(2)
\textsuperscript{122} European Patent Convention (EPC) 1973, Art. 52(2)
2.15. New Scope of the Concepts

Modern biotechnology extends humanity’s reach over the forces of nature as no other technology in history. DNA’s and proteins can be conceived by performing minor modifications on prior art DNA’s and proteins. As this group shows similarities to traditional chemicals in their mode of conception, they can be categorized as “molecular modification products.” Also, the last group concerns the DNA’s formed by the combination of both unexpressed, functional regulatory sequences and expressed coding sequences and which usually are used as vectors. In fact this group includes second generation DNAs that code for protein composed from several functional sites each having an autonomous functional meaning. Comparable to this group of DNA products is mechanical devices made by combining prior art elements and because of this resemblance they can be characterized as ‘combination’ products.

In conclusion, the mode of conception of “molecular modification” products and ‘combination’ products is fairly similar to that of traditional chemical compounds and mechanical devices respectively. The mode of conception in translation and invention differs from traditional mechanics and chemistry, yet reliable enterprise in unexpected discovery.

The basis of modern biotechnology is the ability to cause genetic recombination using molecular means as opposed to sexual means. Foreign genes can be inserted into cells, permitting them to make proteins, they have never been able to make before. Also, patenting of gene sequences is quite controversial because they represent the very basis for all sorts of deliberate changes in any material capable of self-reproduction or capable of being reproduced in a biological system. Obviously speaking, biotechnological products and processes closely related to phenomena existing in nature and contradicts the patentability of

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biological phenomena. But patent has been granted to end products of biotechnology, if it satisfies certain conditions.

2.16. **Natural Technological Processes**

Patent on life forms really crossed number of barriers i.e. either legislative issues or judicial interpretations, however both these institutions showed green signals based on the significance of utility of biotechnology inventions. The first decision internationally broadening the concepts of invention was the 1984 ‘Red Dove’ decision in the German Federal Supreme Court\(^\text{126}\). Its conclusion was relevant in that invention in its patent-legal meaning could encompass animal-breeding methods if it was shown to utilize controllable natural forces to achieve a casual perceivable result.

It is understood that the invention concept covered thereby a biological method and in this case, it was cross-breeding. The technique at issue was not that of recombinant DNA but a classical cross-breeding method\(^\text{127}\). In spite of the fact that the breeding method encompassed pure biological steps it does not as such occur naturally. The argument is that the ‘method was not ‘natural’ and therefore the finding agrees with the laws of logic. Although the different steps may be biological in the patent law context processes that per se do not exist in nature is therefore not the matter of discovery but of technical inventions. In this basis it must be emphasized, however that under EPC essentially biological processes are not patentable anyhow, due to an explicit exclusion from patentability\(^\text{128}\). In the absence of such an exception and assuming they met the basic patentability criteria those processes would be patentable inventions.

2.17. **“Product of Nature” Doctrine**

Even though under US law discoveries are not explicitly held non-eligible, for patent in the beginning, it was believed that the living organisms and their parts were non-patentable products of nature. Thus, it is understood that living things were not considered patentable subject-matter. As the concept of invention has

\(^{126}\) Red Dove Case, II C 138, 1970

\(^{127}\) Under European Patent Convention (EPC) such a method would probably not be patentable because of the exclusion from patentability of essentially biological process under Art. 53(b).

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evolved through judicial decisions and doctrinal understandings of the natural product doctrine has acquired the exception that significantly broaden the possibility of patent protection.

The earlier cases leading to Diamond v. Chakrabarty\textsuperscript{129}, require a fundamental appreciation of the “product of nature” doctrine. Only new, useful and non-obvious things are patentable\textsuperscript{130}. Something cannot be ‘new’ or ‘novel’ if it already exists naturally. Thus, products of nature cannot be patented.

If the product of nature distinction seems clear, its application has been anything but; the line between organisms which are products of nature and altered organisms which are not products of nature is no clearer than the legal line between life and death. The following case laws illustrate this proposition nicely. For example, the doctrine is sometimes traced to the 1874 US case decided by the US Supreme Court\textsuperscript{131}.

In this case US Supreme Court considered a claim for chemically treated wood pulp and rejected the patent for want of novelty. Because the case featured natural materials and was extensively cited in later decision about extraction and purification, commentators have periodically leapt to the conclusion that it turned on the un-patentability of naturally existing cellulose. In fact, the court found that cellulose from vegetable fiber has been “produced and used in the manufacture of paper long before the date of the patent”. Invalidity resulted from the human prior art rather than from anything to do with the natural existence of cellulose in wood.

Furthermore, the US Court once again emphatically discussed the same subject- matter, in a case\textsuperscript{132}. There the notion of an operative product of nature would initially seem to be on more solid ground. The German Chemical Firm BASF held an extremely valuable US patent for synthetic alizarine, a red dye

\textsuperscript{129} 447 US 303 (1980)
\textsuperscript{130} 35 U.S.C. §§ 101, 102 & 103
\textsuperscript{131} American Wood Paper Co. v. Fibre Disintegrating Co., 90 US (23 Wall) 566 (1874)
\textsuperscript{132} American Wood Paper Co. v. Fibre Disintegrating Co., 90 US (23 Wall) 566 (1874)
produced from coal tar. Alizarine has long been obtained in natural forms from the root of the madder plant. Accordingly the defendants at the Supreme Court argued inter alia, that alizarine is a natural product having a well-known definite constitution that it is not composition of matter within the meaning of the statute but has been well-known in the arts from time immemorial for the purpose of dyeing. This was a novelty defense that overlapped with a ‘product of nature’ argument, artificial alizarine was not new because it was chemically, identical to the natural dye in the prior art.

The product of nature doctrine was emphatically analyzed in the ‘Orange rind’ case. On March 10, 1925 Messars Brogden and Crows bridge received United States Letters Patent for the discovery that impregnation of the rind of oranges with very small amounts of borax rendered the orange resistant to blue mold decay. Patent claim 26 covered, “Fresh citrus fruit of which the rind or skins carries borax in amount that is very small, but sufficient to render the fruit resistant to blue mold decay”. Both the district court and the court of appeals held that this claim was valid and infringed. The defendant used the borax impregnation process but argued that claim 26 defined nothing more than a natural fruit. The patentee argued that since the product was a combination of natural fruit and the borax carried by the rind or skin, the complete article was not found in nature and was properly patentable. The United States Supreme Court reversed the opinion of Court of appeals and found the product not patentable. The court stated;

“Addition of Borax to the rind of natural fruit does not produce from the raw material an article for use which possesses a new or distinctive form, quality, or property. The added substance only protects the natural article against deterioration by inhibiting development of extraneous spores upon the rind. There is no change in the name, appearance or general character at the fruit. It remains a fresh orange, fit only for the same beneficial uses as theretofore”.

The court seemed to hold that to avoid application of the product of nature doctrine, the product must possess a new and distinctive form, quality or property, it mush exhibit a change in name, appearance or general character. However, the

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133 American Fruit Growers Inc v. Brogden, 283 US I (1931)
Court’s actual decision concluded that borax impregnated orange was not a new article at manufacture but only a ‘product of nature’. Thus it could be argued that the orange was not changed in ‘general character’ but in reality it was, since it was combined with borax a non-natural substance.

A similar yard stick was used in another case\textsuperscript{134}, wherein, the patent application claim covered fresh shrimp from which the head and sand vein had been removed. The patent examiner rejected the claim on the ground that the product did not differ from ordinary shrimp of commerce. The patent applicant argued that the removal of the sand vein rendered his deveined shrimp different from those ordinarily available. Citing American Fruit Growers\textsuperscript{135}, the Board of Appeal stated that applicant is not claiming the whole shrimp. However, the part he is claiming is still in its natural state, which has been changed in no manner. Thus the applicant could not entitle patent over a product of nature.

Presumably, a shrimp with some parts removed still had all of its remaining parts intact as they existed in nature. Nothing which remained was unchanged in its general character from its natural state. This decision really seems more defensible than the orange rind case because man later intervened and added borax to the orange rind. Here, however, man intervened only to eliminate something from the shrimp carcass; the flesh of the shrimp remained natural. Thus there was no novel combination.

### 2.18. Chakrabarty’s\textsuperscript{136} Legacy

For many years the ‘product of nature’ doctrine was used as a bar to patents pertaining to living matter. The product of a nature doctrine was purportedly overturned by the landmark decision in Chakrabarty’s case.

The development of recombinant DNA technology in the 1970s made it possible to cut and splice genetic material from any organism to create new genes which could then be transferred into different organisms. This technology, with its far-reaching implications, positively forced the courts to interpret the broad language of the patent law to determine, whether new and improved life forms

\textsuperscript{134} Ex parte Grayson, 51 U.S.P.Q (BNA) 413 (PTO Bd App. 1941)
\textsuperscript{135} \textit{Ibid.}
\textsuperscript{136} \textit{Supra} note 129
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could be patented. The issue was discussed in Chakrabarty’s case, which is described below. This case law had made it clear that in order to be patentable; an invention must be a non-naturally occurring product of human ingenuity rather than an undiscovered natural phenomenon or law of nature.

This case involved an application for a patent on a bacterial organism that was genetically modified to degrade multiple ingredients in crude oil which was created by Anand Chakrabarty. This property was not possessed by any bacterium found in nature and could be used for cleaning up oil spills. The patent application claimed a method of producing the modified bacterial organism, an inoculum comprising a carrier material containing the bacteria and the bacterial organism itself. Here the crucial question arises, whether the living matter was patentable or not. The patent office allowed claims to the process of making the bacteria and the inoculum be patented, but the claim to the organism was denied by the PTO on the grounds that bacteria’s were products of nature and living things could not be patented. But Mr. Chakrabarty contended that, because of the capability to break down crude oil, his bacterium possessed a trait, which was not found in naturally occurring bacteria and therefore, sought patent protection.

Chakrabarty appealed to the Patent Office Board of Appeals, where the decision of Patent Office was upheld. The Board concluded that patentable subject-matter as enshrined under section 101 of the United States Patent Act, did not encompass living things such as microorganisms. Thus, the appeal was rejected by the Board because living things are not patentable subject-matters. Several appeals were brought, and the case was finally heard by the U.S. Supreme Court. In a 5:4 decision the court held that Congress intended the statutory definition of patentable subject-matter to be broadly interpreted to include organisms that were made with human intervention, whether living or not. In essence, court opined that, “anything under the sun that is made by man” was potentially patentable. The court further decided that the language of 35 U.S.C. Section 101 was sufficiently broad to encompass the living microorganism, thus signaling the expansion of patent law to living matter also. The court interpreted the phrase, “composition of matter” under section 101 to encompass living matter produced through biotechnology. The court observed that the claimed bacterium was a composite mixture of the features of
known species. It was viewed that Chakrabarty had genetically modified the natural bacterium to possess capacity to eat crude oil spills.

The court held that the inventor, by putting all those enzymes in one single organism had created, “a non-naturally occurring manufacture or composition matter – a product of human ingenuity, having a distinct name, character and use”. The oft-quoted statement from the court is its reasoning that, “Congress plainly contemplated that the patent laws would be given wide scope”, and had intended patentable subject-matter to include anything under the sun that is made by man”. The relevant distinction for eligibility was set, ‘not between living and inanimate things, but between products of nature, whether living or not and human-made inventions.

The court accepted that the starting point of the invention was a product of nature but the inventor had added his ingenuity in making the bacterium to possess the capacity to eat up oil spills with accuracy and pace. The bacterium was a product of nature until there is human intervention after which it turned to be a product of man. The court further rejected the arguments that microorganisms cannot qualify as patentable subject-matter until the Congress expressly authorized such protection and held that biotechnology was unforeseen by the Congress when it enacted section 101 on patentable subject-matter. Even then the Congress employed broad general language in drafting section 101 precisely because such inventions were often unforeseeable. More so, the court highlighted the constitutional objective of promoting the progress of science and thus interpreting the patentable subject-matter to encompass living matter.

This decision is a turning point in the history of biotech patent. After this decision, Patent Offices throughout the world started issuing patents on living organisms. The court in this case held that the invention was a result of human ingenuity and intellectual labor which should receive liberal encouragement. The court held that Chakrabarty’s invention was not a product of nature, the human role involved in the invention differentiates it from a product of nature.

Amicus briefs that were filed with the court warned of potentially hazardous effects of genetically modified organisms on the environment, and ethical issues would be raised if patenting of living organisms was allowed, but court declined to consider these arguments. The court believed that the grant or denial of patents on microorganisms was not likely to put an end to genetic research or its attendant risks. Furthermore the court believed that the role was to interpret the language of the statute not to make political judgments about competing values and interests. It was up to congress to amend the patent Act to exclude genetically engineered organisms from patent protection or to enact new legislation that would specifically apply to living organisms.
beings produced through biotechnology by considering them as a composition of matter within the scope of patentable subject matter. Patentable subject-matter is thus interpreted, in subsequent decisions to include living beings such as plants, animals and human genetic materials.

(1) **No New Properties:**

The finding of non-eligibility can be explained by the fact that ‘no new properties’ were created in any of the bacteria, which is why the court regarded the mixture of naturally occurring bacteria as a product of nature rather than an invention. But in the Funk Bros decision\(^ {139}\), what the inventors had done was to simply recognize the natural properties of the bacteria and take advantage of them. Therefore the mixture was not an invention within the legal meaning of the term.

Subsequently, under US law at this time the invention concepts did not encompass naturally occurring living subjects matter. The fact that human beings had to put the four different bacteria together, in a mixture—which as such could not be found in nature in order to obtain its usefulness and to solve the technical problem of fixing nitrogen did not change this interpretations.

(2) **Creation by Man:**

The notion that living things created by man could be patented also stems from the famous ‘Red Dove’ decision\(^ {140}\). Not only did the German Supreme Court, hold biological processes eligible for patents, in addition, it indicated that animals produced by such methods were also patentable. This finding challenged that previous notion that animals had been excluded from the possibility of patent protection because living organisms and their parts were non-patentable products of nature. Before this the conviction had been that a patent granted for living organisms produced by biological methods would remove from the public domain something produced by nature to be equally for the use of all men. The indication is that invention could include such phenomena, therefore implied a broadening of the concept compared to its previous application. The breeding method which required man’s interference to make the phenomenon did not already exist. The

\(^{139}\) Funk Bros Seed Co. v. Kabo Innoculant Co., 333 US 127 (1948)

\(^{140}\) II C 137 (1990)
animal is still a natural product produced by a process, in which biological steps are used even though man accomplished this particular process. The argument against this interpretation of invention would be that the animal is a product of nature and has simply been discovered by man. To this one can oppose that the animals concerned would not have existed if they had not been produced by this method invented by man. Thus, it is apparent that if man creates new character or phenomena over an existing living being is well patentable subject-matter.

(3) **Technical means:**

As the technology used biological subject-matters were created that even though composed of biological material, they had no previous natural existence. The landmark decision for such inventions came in Diamond v. Chakrabarty\textsuperscript{141}, handed down by the US Supreme Court. The decision ushered in an interpretation which extended patent protection to cover new organisms. Obviously the economic incentive behind the system is evident from the reasoning. The court recognized that the capacity to exclude was not the capacity to make, use or sell and that those potentially valuable innovations would not have otherwise come into existence.

The patentability issue concerned a Genetically Engineered bacterium capable of degrading crude oil. Putting into a single organism cDNA’s that coded for four different enzymes each of which could degrade different types of oil made the invention. The court held that the invention by putting all those enzymes in one single organism had created, “a non-naturally occurring manufacture or composition of matter, a product of human ingenuity having a distinctive name, character and use”\textsuperscript{142}. The well-quoted statement from the court is its reasoning that, Congress plainly contemplated that the patent laws would be given wide scope and had intended patentable subject-matter to “include anything under the sun that is made by man”. The relevant distinction for eligibility was set not between living and inanimate things but between products of nature, whether living or not and human-made inventions.

\begin{footnotes}
\item[141] Supra note 129
\item[142] Ibid.
\end{footnotes}
These two decisions firmly set the applicability of the invention concept to biotechnological inventions. The court positively held patent on plants to be generally allowed\textsuperscript{143} and also found that multi-cellular organisms were patentable subject-matter\textsuperscript{144}. Soon thereafter the USPTO announced that applications for patents for naturally occurring non-human multi-cellular living organisms including animals were going to be accepted. As a general rule for the grant of a patent it was noticed that an animal must be given a new form, quality properties of combination not present in the original article existing in nature. Because of the gradual development towards considering as patentable subject-matter all life forms except human beings under US Laws, living matter became eligible for patent protection. The first animal patent concerned a mouse in which onco genes\textsuperscript{145} were inserted in order to make it more prone to developing cancer which was used for experimental purposes to fight the disease of cancer\textsuperscript{146}.

(4) Living Organisms and their Parts as Patentable:

US patent law clearly abandoned the standpoint that living organisms and their parts were non-patentable products of nature\textsuperscript{147}. Once the basic patentability criteria are met as for any other technological inventions living matter can be patented. In Chakrabarty’s decision the court established that the relevant distinction between invention and product of nature and man-made invention. The above case concerns subject-matter that has in some way been modified or altered although form the decision it could be inferred that human intervention suffices. If so, the Chakrabarty’s decision opens the way to still further expansion of the concept. Therefore the invention concept would also encompass the kinds of subject-matter that require human intervention in order to make them available in a useful form by way of isolating or purifying naturally occurring products.

Another consequence is that as transgenic organisms become common place the possibility increases that a patented organism will accidently become either the building block of a patentable transgenic organisms or a component of a

\textsuperscript{143} Exparte Hibberd, 227 U.S.P.Q. 443 (Bd. Pat. App. 1985)
\textsuperscript{144} Exparte Allen 2 USPQ2d 1425 (Bd. Pat. App. & Inter. 1987)
\textsuperscript{146} Ibid.
\textsuperscript{147} Supra note 129 at 306
breeding program. Because the majority of the world’s grain crops are wind pollinated, this scenario is far from unlikely as it makes prevention from spreading into the environment almost impossible. Even sexually reproducible plants for instance transgenic ones could spread into the environment and also transgenic animals.

With respect to transgenic organisms from a biological perspective the difference between an invention and a discovery is to some extent an illusion. From a policy perspective the evident difficulty is how to justify the insertion of one or some genes into an animal making the transgenic animal invented. The plain argument is that even if the desired function obtained by the insertion of an onco gene into mouse can only function inside the animal. This does not change the fact that the animal as such has not been invented or conceived by the inventor. From the invention’s perspective the animal has definitely been given new qualities not present in the original mouse as it existed in nature. Because eligibility is settled in this respect, the key policy issue is the scope of patent protection given to these inventions.

(5) Prepared in non-Natural Forms:

Another argument is that in its natural form materials might exist in nature but could not be used to solve particular technical problems. If however naturally occurring material is prepared in a novel non-natural form or used in a non-obvious way it may be eligible for patent protection. The policy explanation supporting this understanding of the invention concept is the useful ends and one good example in this respect is prostaglandin. “Prostaglandin” is a hormone present in small quantities in most animal tissues. Because of its low concentration in the naturally occurring fluids, the prostaglandin was useless for medical purposes. The Court of Claims and Patent Appeals found that the invention patentable because the material was purified sufficiently to make it useful in treating human disease i.e. the “created form” of the material was sufficiently new in the context of not having previously existed per se148. The court further opined that, “by definition pure materials necessarily differ from less pure or impure materials and if the later are

148 Re Bergstrom, 427 F.2d. 1394 166 USPQ 256 (CCDA, 1970)
the only one existing as available as a standard of reference-perforce the ‘pure’ materials are new with respect to them.

(6) Not freely Occurring in Nature:

The finding of a substance freely occurring in nature and is a more discovery and as such is not patentable. It is really reflected in a provision of biotechnology directive\textsuperscript{149}.

As the definition of the concept stands the explanation for coverage in this respect in that isolation from its surroundings makes the substance into something not freely occurring per se in nature. Thus, distinguished from discoveries those products in the patent legal context are inventions. The answer to the question why the mere fact of isolating a substance from its natural environment or purifying it turns the substance per se from a discovery into an invention rests on its particular realization. This kinds of inventions analyzed in this section are those that consist of naturally occurring DNA’s or parts of them and which can be characterized as ‘translation invention’. Obviously this category consists of recombinant inventions of naturally occurring DNA’s retrieved by starting from the corresponding natural protein sequence. The use of natural DNA is the first step on the path towards the production of any recombinant protein, as explained in man’s contribution consists in the discovery of a “naturally occurring structure\textsuperscript{150}, rather than in the creation de novo of a new structure or a part of it. The difficulty of incorporating these kinds of subject-matter into the concept of an invention is that instead of making incremental modification to natural molecules, the making of a translation DNA starts from the molecular information contained in a natural protein in order to retrieve the corresponding DNA. In this case both the starting material and the regulating product have a similar informational content but which is encoded in different molecules.

\textsuperscript{149} Art. 5(1) of the EC Biotechnology Directive reads as, “the human body, at the various stages of its formation and development and the simple discovery of one of its elements, including sequences or partial sequence of a gene cannot constitute a patentable discovery”.

\textsuperscript{150} Strictly speaking not all DNA’s encoding for natural proteins do occur in nature, due to the presence of introns in the genome of eukaryotic organisms. However most occur in nature in the form of mRNA easily converted in cDNA.
From the definition of the invention concept as discussed above it follows that the relevant point at which the subject-matter is excluded from its scope is that where it occurs freely in nature. Because these translation inventions are not available in their form in nature which follows that the retrieved translation DNA are inventions in the legal sense provided they have a function or use.

Further it is discussed that the prohibition against patenting of natural product does not apply to cDNA because with the rare exceptions of retroviruses, cDNA as such does not exist in nature. More so, the naturally occurring retroviral cDNA molecules do not code for any these reasons the invention concept has applied to cDNA molecules\textsuperscript{151}. When patents are sought for genes they are actually sought on cDNA sequence, which are “new creations” in a biological sense and is very rare to use the genomic DNA.

Rather the process relies on the fact that cells normally make a large number of different proteins each of which being translated to form the specific mRNA molecule. Thus the cells make the mRNA which can be extracted, purified and used to make ‘complementary DNA’ (cDNA). Biologically the cDNA thus obtained is not a genome DNA comprises the protein coding “exons”\textsuperscript{152} interspersed with the non-coding “introns”\textsuperscript{153} which are usually removed by the RNA processing steps that occur in the nucleus. Subsequently, the cDNA is “new” within the meaning of it per se having no previously existence. In other words since cDNA arises only with the process of ‘reverse transcription’\textsuperscript{154} of mRNA which is usually not natural, the cDNA itself is not natural. However a cDNA sequence as such may be biologically novel.

In fact, this position is affirmed by the biotechnology directive, which reads as,, “biological material that is isolated from its natural environment or produced by means of a technical process may be subject of invention even if it is previously

\textsuperscript{151} Borson D.B., The Human Genome Projects: Patenting Human Genes, IDEA, vol. 35. No:4
\textsuperscript{152} ‘Exon’ means a polynucleotide sequence in a nucleic acid that codes information for protein synthesis and that is copied and spliced together with other such sequences to form messenger RNA. Available at http://www.merriam-webster.com/dictionary/exon Accessed on 26\textsuperscript{th} March 2011
\textsuperscript{153} ‘Intron’ means a polynucleotide sequence in a nucleic acid that does not code information for protein synthesis and is removed before translation of messenger RNA. Available at http://www.merriam-webster.com/dictionary/intron Accessed on 26\textsuperscript{th} March 2011
\textsuperscript{154} ‘Reverse transcription’ is the process of synthesizing DNA using RNA as a template and reverse transcriptase as a catalyst. Available at http://www.merriam-webster.com/dictionary/reverse%20transcription Accessed on 26\textsuperscript{th} March 2011
occurred in nature\textsuperscript{155}. Court has also accepted the same view and held that gene sequence contains information about genetic material and therefore it is a mere, discovery and not an invention, but the process of isolating the gene sequence is patentable\textsuperscript{156}.

\textbf{(7) A Technical Solution:}

One basic precondition in Europe for patent protection is that the said phenomenon is technical solution to a specific technical problem. As the Opposition Division stated in the Relaxin decision,\textsuperscript{157} the mere finding of something freely occurring in nature is not an invention since an invention must have technical character, i.e. would constitute a industrially applicable technical solution to a technical problem and reproducibly obtainable without undue burden. This basic condition of an invention suggests or recommends the following theoretical definition of its concept. “The concept of invention as used in patent law means a technical solution”. The main criterion for this definition is that the subject-matter represents a technical solution. In practice, the notion of ‘technical’ has no clear boundaries as to its precise meaning. In addition its understanding seems to differ somewhat between countries. The so-called ‘technical field’ covered by the EPC for instance includes some subject-matter outside the conventional industries held such as agriculture and forestry, fishing, trade, commerce, medical etc.

It is also noted that the guidelines for the examination in the European Patent Office were revised in February 2000 which reads as, “To find a previously unrecognized substance occurring in nature is also a mere discovery and therefore unpatentable. However, if a substance found in nature can be shown to produce a technical effect, it may be patentable”. An example of such case is that if a substance occurring in nature which is found to have an antibiotic effect. In addition, if a micro-organism is discovered to exist in nature and to produce an antibiotic, the micro-organism itself may be patentable as one aspect of invention. Similarly, a gene which is discovered to exist in nature may be patentable if a

\textsuperscript{155} Biotechnology Directive, Supra note 119, Art. 3(2)
\textsuperscript{156} Kinin Amgen Inc. v. Hoeenst Manoi Roussel, (2004) UKHL 46
\textsuperscript{157} T 0272/95 (Relaxin/Howard Florsey Institute) of 23.10.2002, ECLI:EP:BA:2002: T0272 95.20021023
technical effect is revealed. Thus if it is showed that the end-product when looked as a whole, an application that incorporates a discovery brings about a technical change, it may be patentable, thus technical solution is a significant criteria in differentiating whether an end-product is an invention or discovery.

(8) **The utilization of Natural Forces:**

In order to devise a technical solution to a technical problem man has to use the natural forces from the natural world. In reality, therefore a technical solution inevitably involves the use of natural forces.

In its Red Dove\textsuperscript{158} decision the German Supreme Court suggested a definition of the phenomena regarded as inventions. Legally, ‘a technical instruction’ to man, “how to methodically utilize controllable natural forces to achieve a casually predicable result”. This result in turn referred to the direct result of the said controllable natural forces without the necessity of the interference of human ingenuity. The phenomenon in suit was a classical breeding method which thus in principle qualified as “invention”.

The development of US case law supports the conclusion derived from the Red Dove decision, that the making use of natural forces should be incorporated under the definition. Also the US court stated that if there was to be an invention from such a discovery it must come from the application of the law of nature to a new and useful end\textsuperscript{159}.

Thus, in this context the notion of invention as used in patent law means a technical solution which utilizes a law of nature or controllable natural forces. From this interpretation follows that classical breeding methods do have a certain degree of technical character in that they make use of natural forces. Thereby, those methods are technical solution in the strict sense of patent law which is legally significant in view of the fact that otherwise those would be considered purely biological and be non-patentable discoveries. It should be pointed out that although because of its technical content such a process qualifies as an invention, it

\textsuperscript{158} Red Dove Case, II C 138, 1970

\textsuperscript{159} Funk Bros Seed Co. v. Kabo Innoculant Co., 333 US 127 (1948)
still might not be patentable under the EPC.\textsuperscript{160} The reason is that it would often come under the notion of essentially biological process and as such be explicitly excluded from patent protection.

\textit{(9) The necessity of Human Intervention:}

Another aspect that comes into play for considering a subject-matter an invention is the necessity of human intervention. Consistent with the basic theory, discoveries belong to the domain of improving the objective world by human efforts. Thereby the policy issue of exclusivity and free use was set by the legal understanding of inventions to be constructions, yet for the purpose of patent law. In constructing a theory incorporating the relevant aspect of the invention concept, it would prove useful to focus on a relatively strict definition of its constituent parts for the purpose of creating an eligibility standards, the two contradictory concepts of invention and discovery must be clearly distinguished. Discoveries are new knowledge of natural laws, natural phenomena or natural substances occurring or existing in nature yet unknown to man. In contrast, an invention must include as a part of it something not existing in nature but created or altered, isolated and purified by human efforts. The court is also having positive stand in this regard and found that the invention patentable because the material was purified sufficiently to make it useful in treating human disease i.e. the created form of the material was sufficiently new within the meaning of previous existence per se.\textsuperscript{161} This basic approach can be read from the Chakrabarty’s decision, where the court held that the inventors by putting all of the enzymes in one single organisms had created a ‘non-naturally occurring manufacture or composition of matter, a product of human ingenuity having a distinctive name, character and use’. The relevant distinction was not between living and in animate things but between products of nature whether living or not, and human made inventions. It was eligible because in nature the creation had no prior existence per se.

\textit{(10) The Result of Human Ingenuity:}

For the purpose of correctly and consistently carrying out the assessment we have to elucidate the essential distinction between a discovery and a patentable

\textsuperscript{160} EPC 1973, Art. 53(b)
\textsuperscript{161} Supra note 148
invention. The general feature is that all inventions are the result of human ingenuity. The central point is therefore, whether the completed invention depends on or rather is a result of mental activities of the person who actually carries it out. For a process this means that mental activities are necessary to make it happen and for products the involvement of mental activities is necessary during the procedure of making. The general conclusion can be drawn that a phenomenon is not a discovery of it could be obtained as such solely by the intervention of human ingenuity.

This understanding of the concept as a minimum suggests that if one essential step to achieve a particular product includes something created by human effort i.e. an invention. The basis for this conclusion is the need for human assistance at some point to facilitate the accomplishment of the intended product. Provided that the legal distinction between discovery and invention for biotechnological products is located at this point, this would explain why elements isolated from human or other organisms by means of a technical process qualify as inventions. Their realization per se requires technical solutions invented by man to solve the technical problem for which they are desired. Without such utilization of human ingenuity the substance could not exist as such, or in a useful form and thereby serve to solve the precise problem. From a policy perspective, therefore this understanding makes sense as an explanation of how the invention concept could include substance already existing in nature. In point of fact it means that the material can be found in nature but not in that specific form.

For an object to qualify an invention within the concept’s legal meaning, the required utilization of natural force does not have to be directly derived from human intervention. Based on the definition it follows that the necessity of human interference has to indirectly effect the result which in turn is a direct result of the use of those natural force brought about through intellectual activities. That is to say, human activity is needed for making use of the relevant natural forces and thereby the concept establishes the pre-condition of human interference for the achievement of the desired end result.
(11) **Existing in nature:**

For biological inventions the main point of issue is how to establish the legal meaning of “existing in nature”. This matters because many of the substances that are patented can be found in nature, and the issue particularly concerns those substances that are isolated from naturally existing plants and animals or from other sources. The resulting products are often without substantial changes compared with what exists in nature except for purity or stability.

The EPO Guidelines,\(^{162}\) confine the meaning of “existing in nature” within narrow limits so as only to cover the substances freely occurring in nature. The Guidelines settle the matter by declaring substances found in nature which must first be isolated from their surroundings, which can be properly characterized and which are ‘new’ in the absolute sense of having no previously recognized existence, eligible per se for protection. Particularly for biological materials the precondition that the inventor discloses the matter of how to obtain it in a repeatable way is important and the required characterization can be by its structure, by the process through which it is obtained or any other parameters. For the sake of clarity in this context, a distinction must be made between, “having no previous existence” and the novelty requirement.

2.19. **Basic Patentability Criteria**

**Novelty:**

The basic patentability criteria of novelty is satisfied if the subject-matter does not form part of the state of the art.\(^{163}\) The meaning of novelty under patent law therefore has different meaning from what it may be commonly taken to have i.e., something new is something that was not there before. In respect of patent over biotechnology inventions, many issues are going on relating to novelty requirement. Many argued that biotechnology inventions are discoveries not inventions. But the US Supreme Court at the first time in Chakrabarty’s decision very liberally interpreted the concept of novelty in respect of biotech inventions

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\(^{162}\) EPO Examination Guidelines Part C IV 23  
\(^{163}\) EPC 1973, Art. 52
and rejected the argument of “products of nature”. In the above case, the inventor made following claims:

(i) Process of producing the bacteria.

(ii) Claim for the innoculam comprises of a carrier material floating on a water, and,

(iii) The bacteria itself.

The USPTO (The United States Patent and Trademark Office) accepted first two claims, but rejected the third claim. The Supreme Court reversed this and laid down the new proposition that, “anything under the sun made by man can be patentable subject-matter”.

In USA, a patent was granted for pure adrenalin isolated from the adrenal gland tissue.\(^{164}\)

The argument of product of nature obviously fails to recognize the many ways in which biotechnology alters naturally existing organisms as they differ dramatically from naturally occurring organisms. It is very clear that, the SC decision in Chakrabarty became apparent that non-naturally occurring organisms that have been ‘man-made’ or ‘man altered’, satisfy the novelty criteria.

The discovery of a micro-organism, protein or antibiotic in nature can be claimed in its isolated form or as substantially free of impurities. Also a gene can be claimed as the gene per se as long as the claim does not include within its scope the native chromosome of which the gene forms part or as the recombinant or isolated or purified gene.\(^{165}\) In this case the patent office decided that:

(a) No objection can be taken to a claim to a new organism on the ground that it is something living.

(b) Any new variants claimed must have improved or altered useful properties and not merely have changed morphological characteristics which have no effect on the working of the organisms, and

\(^{164}\) Parke Davis v. H.K. Mulford, 196 F. 496 (2\(^{nd}\) Cir.1912)

\(^{165}\) Ranks Hovis McDougall Ltd’s Application, 1976 AOJP 3915
(c) Naturally occurring micro-organisms per se are not patentable as they represent a discovery and not an invention but a claim to a pure culture in the presence of some specified ingredients would satisfy the requirements of a technical intervention.

When a transgenic plant or animal is created, it is a product of human ingenuity and it qualifies as patentable under the standard of novelty. By issuing its decision contemplating animals as patentable subject-matter the PTO strengthened the position stated in Chakrabarty.

In case of novelty in human gene sequences are slightly different instead patenting new animals with genetic material different from that which is found in nature. Genes may be patented if they are an isolated and purified form but not if they are simply the form in which the scientists discovered the sequence. Gene sequences contain a great deal of extraneous information, because they are comprised of sections which codes for proteins as well as sections do not. When scientists alone sequences they isolate only the protein coding portions thus isolating and purified gene sequences. Applying these standards of novelty it is appropriate that isolated and purified gene sequences be awarded patent protection in accordance with the novelty standard.

Thus, it is apparent that novelty requirement not a great challenge in respect of patent on life forms because the courts started interpreting the concept very liberally by evolving new principles like ‘man made’, ‘human intervention’ etc.

Inventive step / Non-obviousness:

The 1995 amendment to 35 U.S.C. 103, comes what revamped the non-obviousness requirement in order to incorporate biotechnology. The basic tenets have remained the same however, in order to ascertain the obviousness of an invention, the invention must be viewed in light of other inventions in the prior art. If the new invention is one which could be easily accomplished by one with skill in the prior art, the invention will not be granted a patent. Obviousness has been a sticky subject in the realm of biotechnology because scientists use similar

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techniques to isolate different gene sequences even though the gene sequences may be new.

In Tissue Plasminogen Activator case, the important claims were directed to the recombinant protein itself. But the inventive step was argued as based on the discovery of the DNA sequence and deduced amino acid sequence of human t-PA. The Court of Appeal held that the discovery of the amino-acid sequence for the substance t-PA, when incorporated into a process for the commercial manufacture of t-PA using conventional techniques lead to a valid claim. The court reached the conclusion that the claims were not based on the discovery of the sequences as such but to a practical application of the discovery in the production of, t-PA.

Prima facie obviousness is a procedural tool of patent examination which allocates the burden of going forward with production of evidence in each step by the examination process. In the field of biotechnology structural similarities between claimed chemical compounds and prior art compounds can lead to a prima facie obviousness rejection by an examiner. For example, the invention is established relationship in the genetic code between a nuclease acid and the protein. The Federal Court rejected the proposition that it encodes also makes a gene prima facie obvious over its corresponding protein. In this case, the patent application claiming DNA and RNA sequences containing human sequences coding for human insulin-like growth factors I and II, single chain serum proteins that assist in mediating somatic cell growth hormones have been admitted, was held to be obvious over the prior art by the examiner. The court found that the prior art disclosure of a protein sequence suggested over different DNA sequences that could encode for the protein. The applicant claimed as his invention a few of those sequences, those that actually encode the human protein IGF. The court held that although the prior art suggested an enormous number of DNA sequences that could code for the protein, including the applicant’s sequences the art provided no teaching to suggest which of the vast number of sequences encoded the human protein. Thus, the applicant’s invention was not obvious over the prior art because

167 Genentech v. Wellcome Foundation, 1989 RPC 147
168 Re Bell, 991 F.2d 781 (Fed.Cir.1993)
the art did not teach or suggest that the sequences claimed by the applicants would encode the human protein.

This decision was also followed by the Federal Court in another case,\footnote{Re Deuel, 51 F.3d 1552 (Fed.Cir.1995)} which directly dealt with the obviousness requirement for biotechnology. The court seemed to relax the obviousness standard by stating that general motivation to search for some gene that exists does not necessarily make obvious, a specifically defined gene that is subsequently obtained as a result of that search. More is needed and it is not found here. This decision allowed patents to be granted for DNA molecules even if the method for finding the DNA was obvious and seemed inconsistent with previous understanding of the non-obvious requirement. The 1995 amendment of 35 USC 103, however seems to require that both the process and the molecule be non-obvious to satisfy the non-obviousness requirement.

Clearly many biotech advances are capable of satisfying the requirement for patentability. From a purely legal standpoint innovation in biotechnology are as capable as those in any other field of being useful, novel and non-obvious. For example, under the American system, which recognizes the “sweat of the brow”\footnote{The sweat of the brow doctrine encompasses the concept that an invention patentable, if it would take painstaking efforts or extensive experimentation above and beyond, the existing art to achieve the inventive results.} doctrine, the lack of an inventive step has never really been an obstacle since plant breeding is quite laborious even if a ‘flash-of-genius’ is not present, section 103 (C) indicates that patentability shall not be negative by the manner in which the invention was made. In other words inventions inspired by a ‘flash of genius’ are on the same footing with “those created through the plodding path of exhaustive research and development, is to be considered.

**Utility / Industrial Application:**

The utility requirement referred to earlier in seeking patent protection on biotechnology and pharmaceutical inventions. Unlike many countries, the USA has always taken a broad view of what is useful.\footnote{35 U.S.C. § 101} Significantly in Nelson v. Bowler,\footnote{626 F.2d 853, 856, 206 USPO 881, 883 (CCPA 1980)} the court held that the question was whether the products had been
showed to have any practical utility. The question therefore is to be considered is whether the biotechnological invention has any direct therapeutic utility. So that the inventions need to exhibit a useful purpose is particularly important in relation to biological research. The reason for this is that although researchers have been successful in ascertaining what many of these genes do. Unless a useful purpose can be found for these genes they will not be industrially applicable as such not patentable. This position is reinforced by the biotechnology directive in so far as it attempts to clarify the inventions industrial applicability requirement in relation to biological inventions.

The Federal Circuit in a particular case approved the PTO standards for assessing specific and substantial utility. For example, when a specification discloses a protein having a particular nucleic acid sequence which can be made using techniques known in the art but which is solely disclosed as binding with a second specific protein of unknown utility, when contacted with whole blood the utility requirement is not met. In such instances the showing of a specific utility (binding to a particular protein) would be met, but there would not be a disclosure of substantial utility (real world use). In Chakrabarty’s case also, it is proved that the inventor created an oil extracting micro-organisms, itself is having its utility.

Under the European Patent Law, the claimed phenomenon should be a technical solution to a particular technical problem, which is the fundamental requisite for patentability. The notion of invention as used in patent laws means almost the technical solution, for example in Chakrabarty’s case the inventor invented a new character of naturally occurring microorganisms i.e. the new microorganism is capable of extracting oil spills. More so, in the re Relaxin case the court held that a substance freely occurring in nature is discovery. The invention must be of a technical nature which means that it would reprint an industrially applicable technical solution to technical problem and be reproducibly accessible and obtainable without undue burden.

174 Re Fisher, 421 F.3d at 1372
175 Brenner v. Manson, 383 US 519 (1966)
176 EPC 1973, Art. 52, 54 & 56
177 Supra note 157
Also it is enlightened that the use of recombinant DNA technology in various fields made tremendous changes in such fields. The ability of the recipient organism to produce compounds is one of the foremost benefits of the recombinant DNA technology. Moreover, the methods involved in DNA manipulation are viable for treatments of the micro-organisms significant in farming and are possible to be remarkably improved rapidly for new genetic characters in plants and animal. The operation of multifaceted gene and its characters such as photosynthesis and habitat variation that involve expression of various genes is challenging and currently it is not exactly achievable.

Agricultural progresses due to DNA technology include disease resistance in plants and animals, enhanced crops and improved nutrition. A transgenic plant contains a gene or genes that have been artificially inserted. The inserted gene sequence known as transgene may come from an unrelated plant or from a completely different species. One of the purposes of inserting a combination of genes in a plant is to make it useful and productive as possible. This process provides advantages such as higher yield, improved quality, pest or disease resistance and tolerance to heat, cold and drought. However, transgenic plants can also be produced in such a way that they express foreign proteins with industrial or pharmaceutical value. Transgenic plants represent an economical alternative to fermentation based production systems. Thus, it is obvious that the requirement of industrial application / utility is really dominating in respect of patentability of biotech inventions. For example, Harvard Mouse will be used in breast cancer research and so on.

2.20. Disclosure

In order to obtain patent the inventor is required to submit detailed written description in respect of the inventions. The problem in written description with regard to living organisms is that it is often not possible to provide a sufficiently detailed, reproducible written description for living organisms.\textsuperscript{178} The difficulty arises because living organisms express different characteristics in different environment and because both scientists and patent examiners have incomplete

\textsuperscript{178} If such inventions cannot be reproduced from the patent application, then those inventions fail the enablement requirement.
knowledge of biophysical and biochemical reactions. But the scientific knowledge of genes and the mechanisms by which they work increases and thus this may no longer pose a significant problem for inventors of transgenic plants and animals.\textsuperscript{179}

However patent Acts are not enacted or designed to highlight the problems of living organisms especially genetically modified organisms. So the written description requirement in these patent Acts are not adequate in case of transgenic plants and animals, which leads to description and enablement problems of these both plants and animals. In some cases, the patent examiner may require deposited for a modes, specimen or ingredients either at the patent office or a public depository. This deposit requirement applies in case of transgenic plants and animals. Even then considerable problems prevent in this inventions.

Deposit of biological material or organisms in a depository that can assure at least thirty years storage access to the material by patent examination while the application is pending and ready accessibility to the public once the patent is granted are the criteria must be met to comply with the statutory description requirement.\textsuperscript{180} These requirements may be adequate for bacteria or recombinant DNA sequences, but they are not adequate for multi-cellular animals. It is both impractical and prohibitively expensive to maintain depositories for transgenic animals unless deposit is limited to storage of frozen embryos. Even if deposit was limited to embryos significant technical problems concerning viability and reproducibility would remain. Currently no depositories are willing to accept animals for deposit due to productive maintenance costs, possible adverse publicity and impracticality of keeping samples alive for lengthy time periods, in case of Harvard Mouse only the recombinant DNA was deposited.

In respect of plants the solution for written description problem was arrived by means of PPA and PVPA in US. Both the PPA and the PVPA were drafted in order to deal specifically with the problems of living plants in the concept of

\textsuperscript{179} According to Dr. George Piezenik, molecule of DNA are generally definable and enumerable chemical compounds. In addition composition of matter, such as recombinant DNA, arguably remains chemically definable whether they exist inanimate in a test tube or function within a living cell. Furthermore, living cells are identifiable and describable entities that can be distinguished by a combination of physical, chemical and functional criteria. Although these arguments were drafted to support the patenting of genetically engineered bacteria, they can be applied to plants and animals etc.

\textsuperscript{180} Disclosure, embodies the requirement of description, enablement and deposit under 35 U.S.C. §§ 112 & 114
products of nature and in the written description. These Acts provide alternative protection to applicants enable to provide an enabling description for their plants. Hence, it is necessary to enact a separate legislation to address the similar description and enablement problems of transgenic animals.