Chapter 3

PATENTABILITY OF BIOTECHNOLOGY INVENTIONS

Inventions are patented on the basis of certain yardsticks. It is universally recognized that an invention must satisfy few requirements such as novelty, non-obviousness and industrial applications and written description before a patent is granted. It is important to note that the three universally recognized criteria of patentability namely; novelty, non-obviousness and industrial applicability or utility applies to all inventions including biotechnology inventions. However patenting of life or living beings produced through biotechnology concerns special attention due to inherent complexities of the nature of biotechnology inventions. Difficulty is felt in patenting living a being is felt mainly due to three reasons.

1) Since living matter is doubtful to be extended patent protection to?
2) Difficulty in describing biotechnology inventions.
3) Whether biotechnology inventions are to be considered as inventions or as discovery.

It is felt that the requirements the traditional patent law are not enough to test the patentability of the biotechnology inventions. In case of biotechnology inventions it is quiet difficult to differentiate between an invention and discovery. Since biotechnology inventions involve living beings it requires special attention before a patent is granted. Due to the inherent complexities and technicalities some times biotechnology inventions cannot be described in the written specification. To overcome this problem there evolved a solution in the form of deposit of the invention in any recognized depositories. The Budapest treaty recognizes international depositories where inventions related to living

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263 Swaminathan M.S, An introduction to the guiding principles in the decisions on patent law, Bahri brothers, Delhi, First edition, October 2000, Pg. No. 331.
264 Budapest treaty, 1977 provides for the establishment and recognition of international depositories to deposit inventions of life forms and other biotechnology inventions for the patent grant along with the patent application.
matter can be deposited and maintained for the purpose of patent protection. The deposit of the invention enables the patent examiner to test the genuineness of the invention, before the grant of a patent. It is recommended that in case of claiming of biotechnology inventions for patents the deposit of the invention shall accompany the patent application. Therefore a biotechnology invention must satisfy the requirement of deposit of the invention along with traditional patentability requirements. Hence it is inferred that patentability of biotechnology inventions depends on the satisfying of regular requirements under the patent laws along with the deposit of the invention. The essential requirements that a biotechnology invention or an invention involving living being must satisfy for patent grants are as follows.

1) Patentable subject matter.
2) Novelty.
3) Non-obviousness (inventive step)
4) Industrially applicable (utility)
5) Written description of disclosure of the invention and the deposit of the invention

**PATENTABLE SUBJECT MATTER**

The first and foremost requirement is that an invention should fall within the ambit of patentable subject matter. Inventions falling within the purview of patentable subject matter only eligible for patent protection. The components of patentable subject matter were not uniform in different Nations. However with the coming into being of TRIPS, there is uniformity in bringing inventions within the scope of patentable subject matter. Now all over the world biotechnology inventions involving living being are forming part of patentable subject matter. The TRIPS agreement speaks about the patentable subject matter in broad terms. It states that patents shall be made available for any invention, whether products or process, in all fields of technology provided that they are new involve an inventive step and are capable of industrial application. It further states that

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265 Budapest treaty was signed and done at Budapest, in 1977. Any member of the Paris Convention may become party as per article 15 of the treaty. See, Guide to patent law, Manish Arora, Universal publishing company private limited, Delhi, Edition 2002, Pg. No. 410.
266 See, Art: 27 of the TRIPS agreement
267 See: Ibid.
patents shall be available without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced. However members may exclude from patentability inventions, including inventions of life forms of biotechnology on the grounds of public order, morality, protection of human, animal or plant life or health or to avoid serious prejudice to the environment. Further members may exclude from patentability; diagnostic, therapeutic and surgical methods for the treatment of humans or animals; plants and animals and essentially biological process for the production of plants or animals. However it is believed that microorganisms, plants and animals produced through non-biological or microbiological processes could be patented under the agreement. Therefore it is inferred that biotechnology inventions resulted out of biotechnological processes, which does not come with in the meaning of essentially biological processes, are patentable.

**Invention Vs. Discovery**

It is universally accepted that patents are given for inventions and not for discoveries. It was long been established that discoveries are not patentable. Invention is something newly designed or created or the activity of designing or creating new things. Discovery is the act of finding something that had not been known before. The term invention is not defined under TRIPS or under other international conventions on patents like Paris convention or Patent cooperation treaty. Even the recent European Directive on biotechnology invention also does not define the term invention. The U.S...

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269 See: The TRIPS agreement sub clause (2) and (3) See generally, See, Jayashree Watal, Intellectual property rights in the WTO and developing countries, Oxford University press, New Delhi, First published 2001, Third impression 2002, Pg. No.461.

270 All unicellular organisms with dimensions beneath the limits of vision, which can be propagated and manipulated in a laboratory, are termed as microorganisms. Microorganism includes bacteria and yeasts but also fungi, algae, protozoa, plasmids, viruses and human animal and plants.

271 See: P.K. Vasudeva, patenting biotech products: complex issues, EPW, Commentary, October 14-20, 2000


275 See: European Directive on the legal protection of biotechnology inventions, 1998
patent statute defines the term invention to mean any “invention or discovery”. As per the US patent law there is no difference between an invention and discovery. However, discovery amounts to a finding of a thing that is existing in the nature not know before, whereas invention means creation of design of something totally new that was not there before.

The philosophy of patent law states that inventions can be living things. At the same time discoveries can also be living things. It is believed that discovery of living beings existing in the nature is not patentable but inventions of new living beings that do not exist in the nature are patentable. It is felt that a discovery does not involve creation or design of new thing hence not patentable. Almost all patent laws throughout the world say that discoveries or substances found in nature do not constitute an invention and are excludable from patent grant. Strictly speaking inventions of biotechnology are not totally new but are manipulated living beings found in the nature. Therefore there is a need to draw a distinguishing line between a discovery and an invention in the light of patenting products of biotechnology. The very first objection against patenting of living beings is that living beings are discoveries or products of nature existing and found in the nature. Infact biotechnology inventions are based on products found in the nature.

The starting point or raw material for these inventions is biological material found in the nature. It is believed that finding of biological things exist in the nature amounts to discovery. It is also believed that the manipulation of preexisting biological resources in the nature gives rise to biotechnology inventions. Perhaps human intervention differs a product of biotechnology with that of natural biological product. Human intervention to the biological resources yields new, non-natural, man made and hitherto not existed living beings. Here the distinction between a preexisting biological product and human intervened, human made biotechnological product is very thin. The distinction relevant to

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276 See: 35. United States patent Act, section: 100
277 Dr. Swaminathan K.V. An introduction to the guiding principles in the decisions on patent law, Bahri brothers, Delhi, First Edition, October 2000, Pg. No. 224.
278 A mere discovery of something that exists in nature, forming part of the state of the art (prior art) is not patentable.
patentability, between the ‘discovery’ of something that exists in nature and the invention and creation of something new, involving a pre-determined degree of human effort or invention is, in practice, difficult to make in the field of biotechnology. One of the contentious issue raised on aspect of biotechnology inventions is that of the extent to which the traditional concept of invention can be applied to protect these invention.

Biotechnology is notable for designing or creating new things that were not existed earlier. Biotechnology inventions are the result of the addition of human ingenuity and intellect to the existing natural resources. Finding of biological things found in the nature amounts to discovery, however adding human ingenuity to such biological things gives rise to an invention. Therefore till the addition of human ingenuity a biological product remains a discovery and after the addition of the human ingenuity it becomes invention. However the complexity arises due to the fact that it is increasingly becoming difficult to determine where ‘discovery’ ends and ‘invention’ begins. This issue is resolved more through judicial decisions and patent office practices on the facts and circumstances of each case rather than through clear-cut criteria laid down in law.

The case law pronouncements have made it clear that finding of a product of nature is a discovery. The product of nature becomes product of man due to the intervention of human being or due to the application of human ingenuity. In the sense a product of nature through some human intervention becomes product of man. This human intervention to the product of nature gives it a new existence, making it to possess some special features, which it was not earlier, renders it an invention. On the whole it creates a new living entity with some special characteristic features, which was not in existence earlier. Therefore product of nature through some human intervention becomes product of man, which does amount to an invention. It can be inferred that biotechnology inventions being products of man amounts to an invention and constitute patentable subject matter.

279 Dr. T. Ramakrishna, Biotechnology and intellectual property rights, Center for intellectual property rights research and advocacy (CIPRA), National Law School of India University, Bangalore, First Edition, 2003
280 Jayashree Watal, Intellectual property rights in the WTO and developing countries, Oxford University press, New Delhi, 2002, Pg. No. 132 & 133
281 Dr. Swaminathan K.V. An introduction to the guiding principles in the decisions on patent law, Bahni brothers, Delhi, First Edition, October 2000, Pg. No. 329.
Patentable subject matter in the United States:

The United States Patent Law states that any invention of new and useful process, machine, manufacture or composition of matter or any new and useful improvement thereof may constitute patentable subject matter. The United States patent law expressly does not state what constitute patentable subject matter and what does not. It outlines broad scope of subject matter that is patentable. Accordingly the threshold inquiry of all patent applications is whether the claimed invention can be classified within this range. Any subject matter that falls within the prescribed range is patentable. It implies that the patentable subject matter includes any method of manufacture, machine, composition of matter or process.

The United States patent law does say anything specifically about the biotechnology inventions involving life. However the judiciary in US has interpreted the patentable subject matter under the patent law to cover living beings. In Diamond V.Chakraburty for the first time US supreme Court was confronted with a question whether the patentable subject matter under the US patent law does cover living beings or not? The invention claimed was a genetically engineered microorganism. The inventor contended that the invention is a patentable subject matter as it is a composition of matter. The Supreme Court of US liberally interpreted the term “composition of matter” to include living beings also. It was held that living beings are patentable, as the patent law does not prohibit the same. It was observed that living beings produced through biotechnology involves re-composition of physical and chemical properties hence are composition of matter within the meaning of patentable subject matter under the patent law. After this decision Patent offices though out the world started issuing patents on living beings produced through biotechnology by considering as a composition of matter within the scope of patentable subject matter.

The decision of the Supreme Court was a trend setting decision in the history of patent law as it interpreted the patentable subject matter to include living beings produced through biotechnology. After the decision now patentable subject matter under the US patent law covers living beings also. As biotechnology inventions are concerned with life

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282 See: U.S.C Section: 101 Inventions patentable.
283 (1980) USSC 447 at 303
or living beings the decision had far reaching impact on the biotechnology inventions. In the latter decisions Supreme Court of US and as well as the US patent office interpreted the patentable subject matter to include living beings such as plants, animals and human genetic material. In Ex Parte Hibberd a plant was held to constitute patentable subject matter. In Harward oncomouse it was decided that a genetically engineered animal do constitute patentable subject matter. In Amezan Inc. Vs Chugai pharmaceuticals Co. human genetic material like DNA was held to form patentable subject matter. Again in In re Bell human DNA was held to constitute patentable subject matter.

Further human cloning methods were also held to constitute patentable subject matter. In all the above decisions the phrase composition of matter was interpreted to cover living beings, within the meaning of patentable subject matter. It is inferred that biotechnology processes and biotechnology products like; microorganisms, plants, animals and human genetic materials do constitute patentable subject matter in the United States and are patentable. However it is believed that human being does not constitute patentable subject matter under the US patent law, since cloning of human is punishable under The Human Cloning Prohibition Act. It is believed that human beings do not constitute patentable subject matter.

**Patentable subject matter in the European Union**

In the European Union inventions are patentable but discoveries or not. In the European Union any new, novel invention having industrial application is patentable. The European Patent Convention (EPC) says that invention such as; plants, animals other than microorganisms, essentially biological processes apart from microbiological and

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285 See: Harvard Oncomouse decision in 1988
286 *Amezan Inc. Vs Chugai pharmaceuticals Co. Ltd* 927 F.2d 1200.18 USPQ 2d 1016 (Fed.Cir.1991), *In re Bell*
287 *Pioneer Hi-bred International V. Holden Foundation seeds Inc.* 35 F 3d. 1226. 31 USPQ 2d. 1385 (8th Cir. 1994) as cited in Merges et al (1997) Pg. No. 68
288 See: The Human Cloning Prohibition Act, 2003
290 See: EPC: Article: 52
non-biological processes does not constitute patentable subject matter.\textsuperscript{291} Plant variety
means any plant grouping within a single botanical taxon of the lowest known rank
categorized by at least one single transmissible characteristic distinguishing it from
other plant groupings and which is sufficiently homogeneous and stable. Essentially
biological process\textsuperscript{292} was defined to mean a process that consists entirely of natural
phenomena such as crossing and selection.\textsuperscript{293} Microbiological process is defined to mean
a process involving technical activities, where microorganisms or their parts are used to
make or to modify products.\textsuperscript{294} It is a process to develop microorganisms for specific
uses.\textsuperscript{295} A microbiological process constitutes an exception to an essentially biological
process and the same is patentable.

It is inferred that under EPC plants and animals produced out of non-biological
processes and microbiological processes do constitute patentable subject matter.\textsuperscript{296}
However it was the decisions of the European Patent Office (EPO) and the Courts that
considered the biotechnology inventions as patentable subject matter. In the early
seventies five years before United States Supreme Court decision in Chakraburty case
German Federal Supreme Court upheld patent protection for new microorganisms as
constituting patentable subject matter.\textsuperscript{297} In \textit{Genentech-I/Polypeptide expression}\textsuperscript{298}
patentable subject matter was interpreted to include microorganisms. Further in \textit{Plant
Genetic Systems}\textsuperscript{299} plants, plant cells and seeds were viewed to constitute patentable
subject matter. It was viewed that plant cells and seeds are equivalent to microorganisms.
Besides in \textit{Harward oncomouse}\textsuperscript{300} a transgenic mammalian\textsuperscript{301} animal was held to

\begin{itemize}
  \item \textsuperscript{291} See: European Patent Convention (EPC) Article: 52 and 53. See also The European Union Directive on the legal protection of biotechnology inventions, 1988, Article: 4
  \item \textsuperscript{292} Essentially biological process is defined under the recently enacted directive on the legal protection of biotechnological inventions.
  \item \textsuperscript{293} See: The European Union Directive on the legal protection of biotechnology inventions, 1988, Article: 2(2)
  \item \textsuperscript{294} Gerald Karmstra, Mark Doring, Nick Scott-Ram Andrew Sheard, Henry Wixon, Patents on biotechnological inventions: The E.C.Directive, Sweet and Maxwell, London, 2002., Pg. No. 12-14
  \item \textsuperscript{295} See: Plant Genetic Systems/Glutamine Synthetase inhibitors (1993) 24 IIC 618. See also The European Union Directive on the legal protection of biotechnology inventions, 1988, Article: 2 (1)(b)
  \item \textsuperscript{296} See generally: P.K Vasudeva, Patenting biotech products: complex issues, EPW commentary, October 14-20, 2000.
  \item \textsuperscript{297} See: Wagner (1976), Pg. No. 335.
  \item \textsuperscript{298} T 292/85 (1989) O.J E.P.O 275
  \item \textsuperscript{299} Plant Genetic Systems/Glutamine Synthetase inhibitors (1993) 24 IIC 618.
  \item \textsuperscript{300} T 19/90 (1990) O.J. EPO 476, Tech. Bd App; (1991) E.P.O, R.525, Ex. D.
\end{itemize}
constitute patentable subject matter as against the exclusion of animal varieties from the purview of patentable subject matter. Going further in Relaxin case\textsuperscript{302} the EPO happened to decide that human genetic materials do constitute patentable subject matter. In Biogen Vs. Medeva\textsuperscript{303} again human genetic material were held to constitute patentable subject matter. The actual text of the EPC does not say that microorganisms, plants, animals and human genetic materials are patentable. However it was the interpretation of the provisions of the EPC, which rendered the above to constitute patentable subject matter. It seems the Europe is following the adoptive way of US in interpreting the patentable subject matter under the EPC to include living beings.

As far as patentable subject matter is concerned both US and Europe go hand in hand except on therapies. The US does not exclude therapies\textsuperscript{304} for curing diseases as a part of medical treatment from the purview of patentable subject matter unlike the European Union.\textsuperscript{305} The EPC excludes therapies for treating diseases from the purview of patentable subject matter and the European patent office rejected claims on therapies many a times. In Unilever Ltd (Davis's) Application\textsuperscript{306} the claim was for a method of immunizing poultry against the disease coccidiosis by using certain microorganisms as food additives. The immunization was for preventing the animals from catching the disease, not for curing the disease. The method claimed in patent was not on curing processes of a disease, but on a method of preventing the animals from catching disease. The question that arose was whether the method of preventing animal from catching disease is a therapy? It was viewed that therapy has a broader meaning than just preventing the animal from catching disease or curing of the diseases; it covers any form of medical treatment of disease\textsuperscript{307} Hence it was held that the claim for a method of

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  \item \textsuperscript{301} Mammalian is a living being, which breast-feeds its off spring. To put it otherwise breast feeding animals are called mammals. Human being is also a mammalian as human beings breast feed their off spring.
  \item \textsuperscript{303} (1997) R.P.C 1, HL
  \item \textsuperscript{304} US granted first patent on gene therapy in 1995 by this time the US patent office must have granted patents on dozens of therapies.
  \item \textsuperscript{305} See: EPC: Article: 53(4)
  \item \textsuperscript{306} (1983) R.P.C 219
  \item \textsuperscript{307} Holyoak and Torreman, Intellectual property law, Butterworths, London, Second edition, 1998, Pg No. 80
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preventing the animals from catching disease was held not to mean a therapy under the Act and hence is patentable.

The approach taken in the above case was followed in Starfford-Miller’s Applications. The claim was for a method of chemical treatment of a disease called healice. It was held that an infestation of healice may not be regarded as disease and thus its treatment does not constitute therapy. In the background of this decision contraceptives used for birth controls have been patented. Contraceptives in the form of birth control pills involve the use of chemicals in the body. Using of contraceptives for birth control was viewed as not amounting to treatment of disease and hence the same constitute patentable subject matter. On the same lines medical tests carried out to identify the presence of any disease constitute patentable subject matter. In Bruker’s Application the view of European Patent Office was that the method of identification of a disease does not amount to the treatment of disease hence constitute patentable subject matter. European Patent Office allows patents on any method of identification of disease but method of treatment of disease is not patentable. Further test to identify the presence of any disease not being a therapy is patentable. This prohibition is made in the interest of general public so as to keep the medical treatments within the reach of common man not being monopolized by private agencies.

The recently adopted directive on biotechnology inventions states that certain inventions of biotechnology such as; processes for cloning human beings; processes for modifying the germ line genetic identity of human beings; uses of human embryos for industrial or commercial purposes; and processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such process does not constitute patentable subject matter. Further human cloning, human body, at various stages of its formation and development, and the simple discovery of one of its elements, including

308 (1984) FSR 258
310 (1988) OJ EPO 308FN
the sequence or partial sequence of a gene, from the purview of patentable subject matter. However, an element isolated from the human body or otherwise produced by means of a technical process including the sequence or partial sequences of a gene may constitute a patentable subject matter even though its structure is identical with that of a natural element. The European Union Directive on the legal protection of biotechnology inventions must be taken as supplementary means for the interpretation of the relevant provisions of the EPC. As far as patenting of biotechnology inventions is concerned EPC must be read along with the Directive

**Patentable subject matter in India**

In India only inventions are patentable but not discoveries. There is a clear distinction between inventions and discoveries as the Act specifies that only inventions do constitute patentable subject matter. Indian patent law defines invention under section: 2(j) to mean: a new product or process involving an inventive step and capable of industrial application. Here inventive step means a feature that makes the invention not obvious to a person skilled in the art. Indian patent law does provide for subjects that are not patentable, instead it does provide what is not patentable. Indian patent law provides for an illustrative list where is has mentioned the subjects that are not patentable. Any subject matter, which does not fall within the purview of illustrated, list does constitute patentable subject matter. The list has been updated and modified to comply with the

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316 See: The patent Act of India (as amended in 2005) Section: 3
provisions of the TRIPS agreement. The Act states that following are not inventions and do not constitute patentable subject matter.

1. Inventions against natural laws
2. Inventions contrary to public order and morality.
3. Discovery of a living thing occurring in nature
4. A claim for a duplication of an earlier work.
5. Methods of treatment for human beings or animals.
6. Plants and animals in whole or in part, and essentially biological processes for the production of plants and animals.

However, microorganisms and living beings such as plants and animals produced through non-biological or microbiological processes such as biotechnological processes do constitute patentable subject matter. India has amended her patent law in 2002, to bring life and living beings created through biotechnology within the purview of patentable subject matter. The original patent Act states that chemical processes do form part of patentable subject matter. The term chemical process is redefined through amendments to include biochemical, biotechnological and microbiological process. As per the modified definition of the chemical process it is implied that biotechnological processes and products of such process are unambiguously patentable. However there are no decided case laws in India on the patentability of biotechnology inventions. Meanwhile universally patent laws exclude certain inventions from the purview of patentable subject matter. An invention, which falls within the purview of exclusions, cannot be patented though it satisfies the requirements of novelty, inventive step and

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317 See: Indian patent Act, as amended in 2002. India having signed TRIPS has made necessary amendments to her patent law to fulfill its obligations under the TRIPS agreement. The coming into being of the TRIPS agreement has made biotechnology inventions universally patentable.
319 Inserted by amendment in 2002, to comply with the provisions of the TRIPS.
320 See: section: 3 of Indian patent Act, as amended in 2002.
322 See: under section: 5 of the Indian patent Act as amended inn 2005
323 With the amendment in 2002 chemical processes is given meaning to include biochemical, biotechnological and microbiological processes. See explanation given for ‘Chemical process under section: 5 of the Act.
usefulness. The following inventions including certain biotechnology inventions do not constitute patentable subject matter.

1) Discoveries

2). Inventions against public order and morality, such as:
   a) Human body, discovery of its elements and genes in natural form (Isolation of human genes and gene sequences are patentable if isolated by technical means)
      Processes for cloning human beings;
   b) Processes for modifying the germ line genetic identity of human beings;
   c) Uses of human embryos for industrial or commercial purposes; and
   d) Processes for modifying the genetic identity of animals, which are likely to cause them, suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes.

3) Plants, animals and essentially biological processes. (Microbiological and non biological processes and products resulting from such processes are patentable.)

After the Chakraburty decision in the United States throughout the world living beings were recognized as patentable subject matter. As the biotechnology industry progressed and gave rise to modern day miracles of enormous human valued, there was a vehement demand to include biotechnology invented living matter within the realm of patentable subject matter. Due to the enormous impact of the field of biotechnology on the society and on the day-to-day life of human beings, it was considered necessary to include biotechnology inventions within the gamut of patentable subject matter. This proposal has got strong back push from the decisions of United States and Europe law courts and as well as from the practices of United States and European Union patent offices. This has been given the status of a canon of patent law by virtue of TRIPS.

Given the research in biotechnology is growing day by day promising many things to the mankind now patentable subject matter is believed to include novel, non-obvious microbes, plants, animals, natural and synthetic compounds, genes, proteins, DNA, RNA, recombinant cells, proteins expressed by genes in recombinant cell lines, methods of
expressing protein in animals and mammals. Methods of preparing proteins, processes for recovery of proteins, processes for medically delivering recombinant proteins and methods of altering natural properties of plants such as stress, decease or pest resistance are also recognized as patentable subject matter. The TRIPS agreement has changed the contours patent law, by recognizing biotechnology inventions as palatable subject matter.\textsuperscript{325} Now universally biotechnology inventions do constitute patentable subject matter.\textsuperscript{326} There are few universally accepted requirements such as novelty, inventive step, industrial application and written description\textsuperscript{327} on satisfaction of which biotechnology inventions are patentable.

**NOVELTY OF BIOTECHNOLOGY INVENTIONS**

If an invention falls within the scope of patentable subject matter, than the next step is to test its novelty. As per the first modern patent statute enacted in Venice in 1474, every person who shall build any new and ingenious device, not previously made shall be granted an exclusive right to use and operate the device.\textsuperscript{328} The TRIPS agreement says that\textsuperscript{329} patents shall be available for any inventions, whether products or processes in all fields of technology provided they are new. Any person who contributes some thing new to the society,\textsuperscript{330} who brings out something novel, hitherto not known to the society is eligible for patent grant.

**Novelty of biotechnology inventions in the United States**

The patent law of the United States, states that the invention shall be considered as novel if it is not known or used or described in any printed publication or patented in

324 See: Howard B. Rock man, Intellectual property law for engineers and scientists, Wiley interscience, A John Wiley and sons, inc., publication, New jersey, 2004
325 TRIPS agreement aims to make available patents irrespective of the inventions field or place of work, See: article; 27. Sub clause (1), See, European patent Convention Art: 52, See 35.U.S.C, section 101, See, U.K Patent Act 1977, and also Indian patent Act as amended in 2002
326 See: Ramappa, Intellectual property rights under WTO, Tasks before India, Wheeler publishing, New Delhi, Allahabad, First Edition 2000, Pg. No. 133 TRIPS came into force from 1-1-1995 for developed countries, for developing and least developed countries there was given a transition period of 10 years, which ended by 1-1-2005. Now TRIPS agreement is in force for all the member states through out the world
328 See: Chisum, Principles of patent law, Pg. No. 335
329 See: The TRIPS agreement: Article: 27 sub clause (1)
U.S.A or in any foreign country before.\textsuperscript{331} The invention shall be a novel step procuring a new thing, which is not existence hitherto. On the same lines an invention of biotechnology shall be a novel step, producing a new thing that was hitherto not in existence in the nature.\textsuperscript{332} But the basic problem with the patenting of biotechnology inventions is that biotechnology inventions are not totally new. Further one of the greatest challenges faced by the patent regimes has been the boundary between human invention and products existing in the nature. It is well known fact that biotechnology and its living inventions are based on pre-existing biological matter in the nature.\textsuperscript{333} Product existing in the nature does not satisfy the requirement of novelty. In general patents are granted only for inventions, which are novel, but not for things already existing in the nature. 

\textbf{The doctrine of “product of nature”}.

In the field of biotechnology, the issue of novelty is combined with the issue of patentable subject matter. Patentable subject matter does not include discoveries and products of nature as are not new or novel but exist in the nature. It is known fact that the raw material or feedstock in case of biotechnology inventions are biological products or products of nature which are not new. Therefore in order to claim novelty of a biotechnology product it has to be proved that it merits some improvement over the product of nature. Product of nature becomes biotechnology product that is a product of man only when there is some human intervention, which incorporates some novel features. The doctrine of “products of nature” creates an important restriction particularly in biotechnology. There are instances where patents were denied on the ground claims of product of nature hence are not patentable. In \textit{American Fruit Growers Vs. Brogdex}\textsuperscript{334} patent was denied on the basis of the doctrine of products of nature. The claim was for oranges coated with a preservative. It was viewed that the coated oranges

\textsuperscript{330} See: 35, U.S.C, Sec: 102, See, Chisum, Principles of patent law, Pg. No. 33
\textsuperscript{331} See: 35, U.S.C, Sec: 102
\textsuperscript{333} Lislei G Restaino, Steven E.Halpern and Dr. Eric L.Tang, Patenting DNA related inventions in the European Union, United States and Japan: A trilateral approach or a study in contrast?, ,UCLA Journal of Law and Technology, 2003
\textsuperscript{334} 283, U.S. 1.8, USPQ, 131 (1930))
were not sufficiently modified or there was no sufficient human hand to distinguish it from natural ones hence are not new.\textsuperscript{335}

This doctrine of product of nature\textsuperscript{336} was used to deny patents on products of nature or naturally existing living beings. In fact the philosophy prevailed in those days was that living things are not new and are not at all patentable. Another instance where this product of nature doctrine was used to prevent living being patented is that of \textit{Funk brothers seed co Vs Kalo Inoculant Co}\textsuperscript{337} The claim was a mixed culture of different strains, each of which was useful to inoculate the roots of different species of leguminous plants, assisting the plants in nitrogen fixation. Different species of root-nodule bacteria existed in nature. Applicants made efforts to combine the different species of bacteria in a mixed culture suitable for inoculating a range of crops. These attempts were failed because the different species inhibited each other’s effectiveness in combination, leaving plaintiff’s claim as a mere discovery. The Court held that patent claim invalid on the ground that patentee had not created any new bacteria. It was viewed that the bacteria is existent in nature and there is no efforts of the patentee to change its status of product of nature. Eventually the Court decided that products of nature are manifestations of nature belong to none, which are not new and cannot be patentable.

When we consider the above judgments of United States Supreme Court, it appears that products of nature being manifestation of nature does not satisfy the requirement of novelty and are not patentable. The observation is that products of nature creates an important restriction for patenting of life forms of biotechnology, because biotechnology products are based on compounds found in living organisms or produced by naturally occurring animals and plants which are not considered as novel.\textsuperscript{338} But argument in favor of patenting of life forms of biotechnology inventions is that: living beings produced through biotechnology do not exist in the nature but are new living beings. This argument

\textsuperscript{335} 35, U.S.C, Sec: 102, See, Chisum, Principles of patent law, Pg. No. 33
\textsuperscript{336} Dr. T. Ramakrishna, Biotechnology and Intellectual Property Rights, Center for Intellectual Property Rights and Advocacy, National Law School of India University, Bangalore, First Edition, Pg. No: 22.
\textsuperscript{337} 33 U.S 127 (1948)
was supported in *Merck & Co V. Olin Mathieson Chemical Corp*.\(^3\)\(^3\)\(^9\) The claim was for an isolated and purified vitamin B\(^{12}\).\(^3\)\(^9\) Inventors isolated and purified vitamin B\(^{12}\) from fermentation process and claimed patent. \(^1\)\(^2\)\(^4\) In fact vitamin B\(^{12}\) is produced naturally in minute quantities in the livers of cattle and in certain microorganisms. The Court held that patents must not be denied on the ground of product of nature when the product is produced through different means. It was identified that the claimed vitamin is not available naturally in its purified form. By reversing the stand on the doctrine of products of nature the court held that; there can be a patent on products of nature if it is a “new and useful composition of matter.”\(^3\)\(^4\)\(^0\)

Infact all the inventions of biotechnology are initially products of nature. If we apply the doctrine of products of nature in its strict sense, the life forms of biotechnology may not get patent protection. There was a fear that claims for life forms of biotechnology would be rejected because they were products of nature. It was contended that, when some improvement is made over the existing products of nature it is no more a product of nature but a novel product of man. Here human ingenuity is added to products of nature and such human effort in adding ingenuity differs it from natural product and renders it a novel product of man. This addition of human ingenuity to the natural products makes it possess some special features, which it was naturally possessing earlier. The inventions of biotechnology were not existed earlier in the nature hence are novel. This argument was put forward in *Diamond Vs. Chakraburty*\(^3\)\(^4\)\(^1\) to claim a patent on non-naturally occurring, genetically engineered bacteria. Initially patent office rejected patent on the ground of product of nature. When the case reached Supreme Court by overruling Patent offices stand on product of nature held that the claim is not a product of nature but is a product of human ingenuity, which does not exist in the nature. It was viewed that the invention does not naturally exist but is a man made novel organism hence is not a product of nature but a product of man. The Supreme Court of America upheld the contention of Chakraburty in holding that his invention is not a product of nature but is a product of man, as it does not exist in nature. The decision has virtually

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\(^3\)\(^9\) 253 F. 2d 156 (4th Cir. 1958)
\(^3\)\(^4\)\(^0\) Dr. T. Ramakrishna, Biotechnology and Intellectual Property Rights, Center for Intellectual Property Rights and Advocacy, National Law School of India University, Bangalore, First Edition, Pg. No: 22.
overruled the product of nature doctrine by holding the claimed biotechnology invention as new.

The trend that this decision had set is that “non naturally produced, human made living beings are new and are undoubtedly patentable.” Now a natural product is patentable provided there is some human intervention or addition of human ingenuity, which renders it novel. Basically all biotechnology inventions are depending on products of nature, but the human ingenuity or human intervention, which makes a particular organism or article possess some special feature renders a biotechnology invention distinct and novel from biological product or a product of nature. If an organism is given a new form, quality, properties or combination not present in the original article existing in nature is novel. Therefore biotechnology products distinct from biological products are novel products and patentable in accordance with the existing patent law. The very fact that there is some human intervention or addition of human ingenuity renders a biotechnology product new.

It is accepted that transgenic plants and animals modified microorganisms and isolated and purified DNA sequences are the results of human intervention to the biological products and are new hence are patentable. The opinion of the European patent office is that the isolated and purified sequences of genes and DNA are not available in such form naturally, hence are novel. One might advocate the view that transgenic living beings are new, in the sense of having no previous existence in the state of the art. Further, mere finding of a product in the nature is not patentable because products of nature are not new. However if there is enough role played by the human agency in isolating and in manipulating a product of nature to processes special characteristic features which it was not earlier, renders the product of nature a new product of man and the same is patentable.

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341 447 U.S 303(1980), See, Chisum, Pg. No: 772 to 778.
342 923, F. 2d 920, (Fed. Cir. 1991)
343 The availability of a full-length gene does not preclude the novelty of a DNA fragment coding for such gene. See: Lislei G Restaino, Steven E.Halpern and Dr. Eric L.Tang, Patenting DNA related inventions in the European Union, United States and Japan: A trilateral approach or a study in contrast?, UCLA Journal of Law and Technology, 2003
344 Ibid
Novelty in biotechnology inventions in the European Union

Inventions are patentable in the European Union only if they are new.\(^{345}\) An invention should not form part of the state of the art or knowledge in the public domain in order to consider it as a novel or new invention.\(^ {346}\) The state of the art comprises of everything made available to the public by means of a written or oral description, by use or in any other way before the date of filing of the European patent application. The European Patent Convention (EPC) states that; European patents shall be granted for any invention, which is new.\(^ {347}\) The invention shall be considered as novel if it is not known or used or described in any printed publication or patented.

Unlike U.S.A in Europe novelty of biotechnology inventions was not a contentious issue. As even before the Chakraburty decision in the U.S.A in Europe there witnessed claims on living matter. In 1969 in Red dove case in Germany a patent was claimed on a method for breeding doves with red plumage.\(^ {348}\) The patent was rejected on the ground that the invention is not repeatable, but the novelty of the invention was neither contested not discussed. It seems novelty of biotechnology inventions is accepted in the European Union. Meanwhile the European Union adopted the European Patent Convention in 1973 which states that microbiological processes and products thereof such as microorganisms are patentable. It implies that the novelty of biotechnology inventions was accepted in the European Union and the same was given statutory support through the EPC. The convention excludes plants animals and essentially biological processes for the production of plants and animals from patenting.\(^ {349}\) Later on the above provision of EPC was interpreted to include plant, animal and human genetic material produced through non-biological processes or biotechnological processes without much debate on the novelty.\(^ {350}\)

Infact strong moves to patent biotechnological inventions in Europe were made only after the novelty of biotechnology inventions was almost settled in the U.S. The US

\(^{345}\) See: The E.U directive on biotechnology inventions: Article: 3  
\(^{346}\) See: EPC: Article: 54  
\(^{348}\) See Adelman et al. (1998), Pg. No. 156  
\(^{349}\) See: EPC: Article: 53  
\(^{350}\) See decisions in oncomouse, plant genetic systems, novarties and biogen.
Supreme Court and the patent offices decisions have debated discussed and convinced that biotechnology inventions are new. It might be the reason why novelty of biotechnology inventions was not given much attention to. An invention, which does not form part of the prior art, which is hitherto not known, published or claimed, is considered to be novel. It is believed in general that idea of the invention does not preclude the novelty of actual invention. The availability of an invention does not preclude the novelty of the invention of its new use. In particular with reference to the novelty of DNA sequences or gene fragments the opinion of the European patent office is that the isolated and purified sequences of genes are novel being not available naturally in such form. However certain inventions exploitation of which is against public order or morality or prejudicial to the health of animal or human or environment are not patentable in the European Union though are novel.

**Novelty of biotechnology inventions in India**

Novelty is not defined in the Patent law of India. But invention is defined to mean a new product or process involving an inventive step and capable of industrial application. The Indian patent Act defines inventive step and industrial application but it does not define the term novelty. Hence it is left to the patent office and the Courts to define and mean the term novelty. As per the definition given to the term invention a subject matter must be new to constitute an invention. The Patent Act specifically states that certain subject matter are not inventions, in doing so it indirectly states that certain subject matters are not novel or new. In particular subject matters such as discoveries and finding of a living thing or substances occurring in the nature are considered as not new and does not constitute an invention. Further plant, animal and essentially biological processes are not considered as new and do not constitute an invention.

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351 The availability of a full-length gene does not preclude the novelty of a DNA fragment coding for such gene. See: Lislei G Restaino, Steven E Halpem and Dr. Eric L Tang, Patenting DNA related inventions in the European Union, United States and Japan: A trilateral approach or a study in contrast?, UCLA Journal of Law and Technology, 2003.

352 See: Section: 2(1)(j) of the patent Act of India as amended in 2005.

353 See: The patent Act as amended in 2005, Section: 3(c)

354 Ibid: Section: 3(j)
However microorganisms, plant, animal produced through non-biological or biotechnological processes are considered as new and can be patented. Further human genetic material in isolated and purified form is also considered as new invention. For the first time in the history of Indian patent law a living process was claimed for patent. The process was useful in preparation of a vaccine against infectious decease in poultry. The applicants contended that the process is new and is patentable. The patent office initially rejected patent on the ground that it is a living process, which is not new, and the same does not constitute invention. In appeal the Calcutta High Court held that there is no bar in the patent Act to patent a new living process or living product.\textsuperscript{355} The High Court accepted the contention of the applicant that the claimed living process is new and directed the patent office to grant patent on the invention.

In the light of the TRIPS agreement considering biotechnology inventions as new being a signatory to the agreement India amended its patent law to implement the agreement. Now with the amendments to the patent Act biotechnology inventions like; living beings and living processes are considered as new. There was no strong debate in India unlike in US on the novelty of biotechnology inventions. As the matter is settled in developed countries like U.S and in the European Union that biotechnology inventions are novel over and above the pre existing biological products there was no difficulty for India to follow the suit.

\textit{NON-OBVIOUSNESS}

\textbf{The ultimate condition of patentability}

Not all subject matters, which are new, are patentable. The invention must involve an inventive step in order to be patented. The invention must be a leap forward by the inventor that puts him ahead of the pack and which justifies patent grant.\textsuperscript{356} The TRIPS agreement states that “patents shall be available for any invention, whether products or

\textsuperscript{355} See: Dr Ramakrishna.T (edited) \textit{Biotechnology and Intellectual Property Rights}, Center for Intellectual Property rights and Advocacy (CIPRA), National Law School of India University, Bangalore, First Edition, 2003, Pg. No. 38

processes, in all fields of technology provided that they are new, involve an inventive step and capable of industrial application”. The expression inventive step is deemed to be equivalent to the requirement of non-obviousness. The demand for inventive step has great potential to act as a hurdle for patentability. The issue of whether an application should be rejected or a patent held invalid on the ground that what is claimed was obvious, has come recently in the biotechnology area.

It is felt that the inventive step involved in a biotechnology invention is very difficult to prove. In the last thirty years, great strides have been made in the field of biotechnology, particularly recombinant DNA research, with this progress has come a degree of uncertainty regarding the obviousness of certain biotechnology inventions. The requirement of inventive step also constitutes one of the most complex questions in biotechnology. Many judges and scholars regard non-obviousness as the key requirement, in part, because it is frequently the most challenging to prove. Obviousness is a technical question that involves consideration of different technical aspects. The invention must be a step further than the existing knowledge in the public domain. What amounts to must to be decided from the angle of a skilled person in the field of the invention.

**The quest for inventive step**

The quest for inventive step is perhaps the most difficult aspect of the patent procedure. A patent may not be granted if the differences between the subject matter sought to be patented and the prior art (knowledge in the public domain) are such that the subject matter as a whole would have been obvious at the time the invention was made to

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357 Dr. T. Ramakrishna, Biotechnology and Intellectual property rights, Center for intellectual property rights research and advocacy (CIPRA), National School of India University, Bangalore, First Edition, 2003, Pg. No. 24
a person having ordinary skill in the art to which said subject matter pertains.\textsuperscript{363} The invention should represent a significant advance over previously discovered information existing at the time the invention was made.\textsuperscript{364} It is believed that innovations of biotechnology are as capable of as those in any other field being useful, novel and non-obvious. Perhaps many biotechnology advances are capable of satisfying the requirements for patentability.\textsuperscript{365} The complexity involved in testing the inventive step in biotechnology invention is that: all the inventions of biotechnology are biological products in the beginning and were having prior existence in the nature. The patent law states that any material, which forms part of the prior art, is not an invention and the same is not patentable. Therefore a biotechnology invention must prove beyond doubt, that it involves an inventive step. The inventor must prove that his invention merits a leap forward from the existing prior art.

There is no doubt in saying that most of the biotechnology inventions such as genes, gene sequences, DNA, DNA sequences and the like, involves biological material existing in the nature. Identification of biological material existing in the nature, amounts to a discovery, which involves no inventive step. It is not a mere discovery of existing gene that is patentable, but an isolated and purified gene from human, animal or plant body that is patentable. Hence any invention relating to genes, a gene sequence etc., produced through biotechnology must prove beyond doubt that it is not a mere discovery. The fact remains that genes and DNA are not available to be easily isolated and purified. There requires lot of effort and ingenuity to isolate and purify genes or DNA. It is believed that the efforts of ingenuity in isolating and purifying genes or DNA signifies a leap forward from the prior art comprising of naturally existing un isolated and unpurified genes.

The requirement of non-obviousness in U.S

Obviousness is a question of law. The patent examiner bears the burden of establishing a prima facie case of obviousness. If examiner establishes prima facie case of obviousness, then burden shift to the applicant to rebut it. The current practice of the U.S Courts, in testing the non-obviousness of the invention has been laid down in famous Graham case. The Court of Federal Circuit in the above case has clarified the meaning of the term ‘non-obviousness’ under the U.S patent code by stating that non-obviousness involves a leap forward by the invention over and above the existing knowledge in the prior art. The Court has set forth a test for deciding the non-obviousness of an invention. The test imposes three requirements to be fulfilled by an invention in order to get patent. The Court laid down that:

1) The Courts must survey the scope and content of the prior art.
2) It must examine the differences between the prior art and the claimed invention.
3) There shall be a determination as to the level of ordinary skill in the art.

In addition to these three elements the Court of Federal circuit has added a forth element to the test. The Court states that the Courts may use secondary considerations such as commercial success, long felt but unsolved needs, or the failure of others to shed light on the circumstances surrounding the origin of the invented subject matter to test the obviousness of an invention. These considerations are not by themselves dispositive but

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they are highly persuasive of non-obviousness. In determining whether biotechnological invention meets the non-obviousness requirements for patentability, Courts consider the Graham factor as well as other factors. Obviousness of the invention is tested on the basis of the prior art that existed at the time of filing of patent application. The state of prior existed at the time of examination of the application or at the time of grant of the patent is not considered in testing the non-obviousness of the invention.

The first non-obvious case involving a biotechnology invention came to the forefronets of judiciary in *Hybertech, Inc V. Monoclonal Antibodies, Inc.* The invention was an immunoassay that utilized monoclonal antibodies to measure the concentration of certain antigens. Immunoassay means a method for detecting or measuring antigens by using antibodies. Antibodies are proteins produced inside the body of living beings. The inventors’ goal was to evolve a process for measuring the quantity of certain antigens in a given solution. Inventors produced a method to detect antigens by employing antibodies. The invention was first of its kind in developing a method to employ antibodies against antigens. This case was the Courts first attempt to test and analyze the obviousness of a biotechnology invention.

Initially patent was granted later it was declared as invalid on the ground of prior anticipation in the prior art and for obviousness. In appeal the Court of Federal Circuit tested the state of the art in determining the obviousness of the invention. The Court relied on Graham factors in deciding non-obviousness of the invention. First the court examined a series of four articles that predicted the using of monoclonal antibodies as immunoassays. Secondly the Court evaluated the original monoclonal antibody, an article

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374 Hybertech’s invention was an immunoassay that utilized monoclonal antibodies. Immunoassay means “a method of raising antibodies against targeted antigens. Monoclonal antibodies are “the antibodies raised from a single cell inside the body to fight against targeted antigens. Antibodies are proteins produced by immune system inside our body to fight against antigens. Antigens are disease-causing insecticides.
discussing antibody assays, and an existing patent for a polyclonal antibody\textsuperscript{378} sandwich assay. Thirdly the Court compared the monoclonal antibodies described in an article with the monoclonal antibodies in the present invention.\textsuperscript{379} By considering these three factors, Court held that; bare predictions in the prior art do not suggest how that end might be accomplished. The Court viewed that the articles in the prior art suggested immunoassay invention but they have not revealed any scientific methods to create the invention. It was viewed that due to the predictions in the prior art the concept of an immunoassay may have been obvious to try, but the actual invention is not obvious without predictable, and successful techniques.

The Court opined that obvious to try is an improper consideration in adjudicating the obviousness issue.\textsuperscript{380} The federal Court found that all the references including the method of producing monoclonal antibodies, the usefulness of monoclonal antibodies in the characterization, and localization of a peptide and sandwich immunoassays with polyclonal antibodies, did not suggest the claimed invention.\textsuperscript{381} The Court viewed the references in the prior art at the most as an invitation to try monoclonal antibodies in immunoassays.\textsuperscript{382} The Court observed that there was no reasonable expectation of success by those skilled in the art.\textsuperscript{383} Eventually the Court concluded that the present immunoassay was not obvious in the light of the prior art.\textsuperscript{384} There must be a reasonable expectation of success for in the invention in the prior art to hold the invention obvious. The case reveals that prior art must contain a suggestion for the invention and it must

\textsuperscript{377} Monoclonal antibodies are antibodies raised by cloning a single cell.
\textsuperscript{378} Polyclonal antibodies are antibodies raised by cloning different cells.
\textsuperscript{380} Ibid
\textsuperscript{382} Ibid
\textsuperscript{384} In reaching its decision the Court has taken into account the secondary consideration laid down in the Graham case. The Court used objective evidence of commercial success to bolster the finding that the immunoassay techniques were unavailable in the prior art.
reveal predictable techniques that allow for successful realization of the invention in order to determine that the claimed invention is obvious or does not involve an inventive step.\textsuperscript{385}

**Prior art**

In the light of the fact that obviousness of biotechnology inventions is decided on the basis of the knowledge in the prior art it is necessary to know what exactly is meant by prior art. Prior art can be defined as the knowledge or information or technology, existing in the public domain or known, published or used in any form in any part of the world. It is the knowledge existed in the society prior at the time of the invention. Present day Intellectual property rights frameworks consider documented knowledge as prior art.\textsuperscript{386} Defining what constitutes prior art and establishing the state of knowledge at any point of time, would be a major challenge.\textsuperscript{387} An invention in the public domain is nothing new and known and it would be obvious to any person skilled in the art to practice the same.

United States patent law states\textsuperscript{388} that for an invention known or used or patented or described in a printed publication or in public use before in America or in a foreign country, no patent shall be granted.\textsuperscript{389} Here printed publication includes single copies of doctoral dissertations catalogued in University libraries, and single copies of grant proposals indexed and publicly available on file with the National science foundation. The phrase printed publication has been meant also to include specimen sheets from the museum.\textsuperscript{390} Therefore an invention that already known or in use or published becomes

\textsuperscript{386} Prabudha Ganguli, Intellectual property rights, Unleashing the knowledge economy, Tate McGraw-Hill publishing company limited, New Delhi, 2002, Pg. No. 136.
\textsuperscript{387} Ibid.
\textsuperscript{388} See, United States Patent Code, Section: 102
\textsuperscript{389} See, 35. U.S.C Sec: 102, Sub clause (a) to (g)
\textsuperscript{390} On November 3 1999, United States patents and trademarks office rejected a patent on the basis of accessioned specimen sheets in the museum in Chicago. The claim was for some invention on Davine plants, who’s major defining characteristic was its flower color, patent office concluded that there is no distinction between Davine’s specimen sheets and B-caapi specimen sheets in the museum in Chicago. Both having its flower color as defining character but patent office concluded that there is no distinction between Davine’s and B-caapi specimen sheets. Patent office recognized specimen sheets in the museum as “printed publication” under section 102(b) of United States patent code. Patent office confirmed in its rejection that such sheets qualify as “printed publications” for the purpose of determining patentability. In fact it was the first time the patent office has interpreted printed publication to include specimen sheets
part of the state of the art or prior art. An invention part of prior art does not involve any inventive step and is obvious to a person skilled in the relevant art hence and it does not entitle itself for the patent grant.

**Person having ordinary skill in the art**

Obviousness is not judged from the angle of the inventor, rather, it is judged from the angle of an imaginary legal construct, the Person Having Ordinary Skill In The Art (PHOSITA), who is imagined to know all the relevant prior art. In *In re o Farrell* the Federal Circuit Court considered the knowledge in the prior art in deciding the obviousness of the invention. The invention was a method to produce a foreign protein in a transformed species of bacteria. The process involved isolating and inserting the stretch of DNA coding for the protein into the bacterium. The Court laid down following test to be satisfied by a biotechnology invention satisfies in order to satisfy the requirement of non-obviousness

(1) There must be no expectation of success.


392 853 F.2d 894 (Fed.Cir. 1988)

393 Proteins are biological molecules, they are chemicals produced inside the cell of living organisms. Proteins are the living blood for any organism. Protein includes enzymes that catalyze biochemical reactions, major structural materials of the animal body, and many hormones. Many valuable proteins occur in nature only in minute quantities, or are difficult to purify from natural sources. Many biotechnology projects intend to device methods to synthesize useful quantities of specific proteins by controlling the mechanism by which living cells make proteins. See, Donald S. Chisum, Craig Allen Nard, Herbert F. Schwartz, Pauline Newman, F. Scott kieff, Cases and materials on Principles of Patent Law, New York Foundation Press, New York, 1998, Pg. No. 670.

394 A bacterium is a single celled organism that can be seen with the help of microscope. Bacteria’s are also known as microscopic organisms existing in the nature. It is a protein expressed in other species. Through biotechnology when such protein is made to be expressed, in any species, which originally it was not, such protein is a foreign protein in that particular species.

395 DNA stands for deoxyribonucleic acid. It is a molecule inside the cell of a living thing, which pairs along with RNA (ribonucleic acid).

396 It was an appeal from the decision of United States patent and trademark office board of patent appeal and interferences which affirmed the patent examiner’s final rejection of patent application on the ground that the invention would have been obvious to a person skilled in the art under section 103 of United States patent code, in view of prior art. Donald S. Chisum, Craig Allen Nard, Herbert F. Schwartz, Pauline Newman, F. Scott kieff, Cases and materials “Principles of Patent Law, New York Foundation Press, New York, 1998, Pg. No. 669.

(2) There must be no indication in the prior art disclosing what was necessary to vary in order to reach the desired result, and

(3) There must be only general guidance in the prior art.

In the present case it was argued that the invention is obvious in the light of the prior art containing applicant’s prior publications.\(^{398}\) Prior art constituted of an article by the co-inventor that described a method for making a cloning vector with a regulated indigenous gene. The prior art suggested a procedure and technique for producing foreign protein in the genetically engineered bacterium with a reasonable expectation of success. Two out of three inventors published earlier giving details regarding the method of producing foreign protein in the host bacteria.\(^{399}\) The Federal Circuit evaluated the prior art consisting of prior procedures, methods and the available scientific procedures.\(^{400}\) It was observed that the co-inventors publication has revealed the detailed methods and techniques to produce foreign protein in the host bacteria, which would have been obvious to a person skilled in the art. The Court found that:

(1) There is a suggestion in the prior art for the invention with a reasonable expectation of success.
(2) The prior art explicitly suggested the invention and
(3) The suggestion provided explicit and detailed methodology, which is not a general guidance.

The Federal Circuit concluded that in the light of the findings made the present invention has not passed the test non-obviousness test. Further the Court analyzed that mere suggestion for the invention finds it obvious to try but not obvious.\(^{401}\) It was held that every obvious invention is obvious to try but every obvious to try invention is not obvious. It was viewed that obvious to try refers to a mere suggestion for invention. A mere suggestion is not enough to find an invention as obvious without reasonable expectation of success.

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\(^{398}\) See: Dr. T. Ramakrishna, Biotechnology and intellectual property rights, Pg. No. 26.

\(^{399}\) Ibid.


\(^{401}\) See: 853 F.2d 894 (Fed. Cir 1988)
Suggestion for invention and reasonable expectation of invention

Obviousness does not require absolute predictability of success but merely a reasonable expectation of success.\textsuperscript{402} The inventive step in this research is not the product but the innovative techniques necessary for its discovery.\textsuperscript{403} In the absence of no reasonable expectation of success, the Courts focus on the scientific methods techniques and procedures available to try the invention. In \textit{Amezan Inc. Vs Chugai Pharmaceuticals Co. Ltd}\textsuperscript{404} the claim was a DNA sequence coding human protein erythropoietin (EPO) and the protein itself, in a highly purified form.\textsuperscript{405} Erythropoietin is a protein that boosts red blood cell production. Amgen scientists claimed isolated and purified the stretch of human DNA that codes for erythropoietin. Defendants argued that on the date of invention, one of ordinary skill in the art would have had a reasonable expectation of success in obtaining EPO through the method, which the inventor has claimed. However no one had successfully obtained EPO by using the inventor’s method.

In the light of the above fact the Court viewed that the procedure followed by the inventor was obvious to try but it would not have been obvious at the time of the invention.\textsuperscript{406} Defendants further claimed that their scientist was the first to conceive the probing strategy of using two sets of probes; therefore they should be entitled to the patent. However it was the Amgen scientist, who actually conceived the erythropoietin DNA sequence.\textsuperscript{407} The Court here defined the term conception to mean the knowledge of actual sequence with a reasonable expectation of success. Having mere idea does not amount to conception but evolving technical methods to put the idea into practice amounts to conception. The Court opined that he who first conceived an invention and then reduce it to practice is the first inventor and is eligible for patent.\textsuperscript{408}

\textsuperscript{404} 927 F.2d 1200.18 USPQ 2d 1016 (Fed.Cir.1991)
\textsuperscript{405} See: Dr. T. Ramakrishna, Biotechnology and intellectual property rights, Pg. No. 26.
\textsuperscript{407} Supra Note. No. 403
\textsuperscript{408} Ibid
The Court viewed that defendants have not had complete mental conception of purified and isolated DNA sequences encoding EPO. The actual scientific methods to isolate DNA sequence were not known in the prior art. The prior art suggested the probing strategy but it was without reasonable expectation of success therefore it was obvious to try but not obvious. Moreover witness testimony suggested that; on the prior art, the chances of success are not more than fifty percent. Here defendants might have an idea but petitioners are the first persons to evolve technical method and reduce the idea into practice. It was viewed that the prior art including defendant’s idea contained just an idea or a mere suggestion for DNA sequence encoding EPO. But the invention evolved practical methods to isolate and purify DNA sequence encoding EPO hence is not obvious under section: 103 in the light of prior art and is patentable. Hence it was held that the petitioners conceived the invention hence they are eligible for a patent on both the claims; for DNA sequence and for protein itself. The approach of the Court in the above case on conception is a guiding principle for the obviousness analyses.

The federal Circuit has retained the same approach in *In re vaeck* where in it decided an invention of chimeric gene as non-obvious in the light of the prior art that was containing neither “implicit suggestion nor a “reasonable chances of success.” Further in *In re Bell* the claims were to nucleic acid molecules i.e., DNA and RNA containing human sequences, proteins, amino acid sequences coding for human insulin like growth factors, that a play a role in the mediation of somatic cell growth on the administration of growth hormones. The prior art constituted of two publications disclosing amino acid sequences for growth factor II and I and also there existed a patent on a “method for cloning genes.” The patent disclosed a general method for cloning genes but it specifically described the isolation of a gene, which codes for a protein unrelated to insulin growth factor. The patent examiner rejected claims as obvious on the basis of publications and the existing patent. Examiner viewed that it would have been obvious on the part of a person skilled ion the art to find nucleic acid in the light of known amino acids.

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409 Ibid
410 991 F.2d 781 (Fed. Cir. 1993)
411 Initially the Patent examiner rejected the claims as obvious under United States patent code. Section: 103 on the basis of prior art. USPTO Board for Patent appeal affirmed the same. An appeal was raised to the Court of Federal Circuit.
acid sequences. The Board affirmed examiners rejection even though there was no structural similarity between DNA coded for insulin growth factor-I and amino acid sequence. In appeal the Federal Circuit viewed that amino acid sequences could be coded for different nucleotide sequences but the present inventor claiming only few among them. It was observed that the prior art is suggesting for infinite number of nucleotide sequences in general, but the present application is for human sequences coding for insulin growth factor, which was not been described by the prior art. Therefore it was held that the invention is specifically providing for nuclide acid molecules (DNA and RNA) containing human sequence coding for insulin like growth factor is not obvious in the light of prior art describing a general method for isolation of genes and amino acid sequences in general.

Again in In re Deuel obviousness of a biotechnology invention was tested. The invention related to an isolated and purified DNA and cDNA (complete DNA molecules encoding Heparin-Binding Growth Factors (HBGF)) The Heparin-Binding Growth Factors are proteins that stimulate cell division and facilitate the repair or replacement of damaged or diseased tissue. Initially the application was rejected for a patent by the examiner and it was confirmed by the PTO Board, as unpateble on the ground of obviousness under 35 U.S.C section: 103 in the light of the prior art. The Prior art comprised of a reference teaching a method of gene cloning and a reference disclosing a partial amino acid sequence of a heparin protein in the light of which the invention was held obvious. In fact, the crux of the issue was whether the combination of a prior art reference teaching a method of gene cloning together with a reference disclosing a partial amino acid sequence of a protein may render DNA and DNA molecules encoding protein prima case obvious or not.

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412 See generally: Dr. T. Ramakrishna, Biotechnology and intellectual property rights, Pg. No.26.
414 51 F.3d 1552 (Fed.Cir.1995)
416 See: Dr. T. Ramakrishna, Biotechnology and intellectual property rights, Pg. No.27.
However it was observed that the prior art does not disclose any relevant cDNA (complementary DNA) molecules. It simply teaches a method of gene cloning. In fact the claimed molecules are not contemplated or conceived in the prior art. *What is not contemplated or conceived cant be obvious*". On the same lines knowledge of a protein does not give one a conception of a particular DNA encoding it, because it does not provide the detailed structure of the genetic code. Conception of a molecule requires conception of its structure, name, formula or definitive chemical or physical properties.\(^{418}\) Moreover a disclosure of amino acid sequence of a protein does not make DNA sequences coding for such protein obvious.\(^{419}\) The reason is that one can hypothesize enormous number of DNA sequences coding for a single protein.\(^{420}\) Therefore the invention cannot be held as obvious because in the light of prior art not contemplating the invention.

The second reference disclosed a general method for cloning a gene. It discloses a method of isolating DNA or cDNA by screening a DNA or cDNA library with a gene probe. It does not describe the method of isolation of a particular DNA or cDNA (complementary DNA) molecule. The Court affirming In re Bells decision held that; the existence of a general method of isolating cDNA or DNA molecules would not render the isolation of specific molecules obvious.\(^{421}\) In the sense a general method to isolate any DNA or a gene would not render a specific method obvious. The fact is that a broad genus does not necessarily render obvious each compound within its scope. Similarly knowledge of a protein does not give one the conception of a particular DNA encoding it.\(^{422}\)


\(^{421}\) See: Dr. T. Ramakrishna, Biotechnology and intellectual property rights, Pg. No.27

\(^{422}\) 71See, In re Baird, 16 F.3d 380, 29 USPQ 2d 1550 (Fed. Cir. 1994)
After observing the prior art the Federal Circuit concluded that the references do not teach or suggest the claimed cDNA (complementary DNA) molecules. The Court viewed that “one reference in the prior art just discloses heparin protein another reference discloses a general method for isolating DNA or cDNA, but the claimed DNA molecules have not been specifically taught or suggested. Therefore the invention is not obvious in the light of prior art.

However when we observe the journey of federal circuit from Hybertech till In re Deuel reveals that the law relating to patentability of biotechnology inventions is not certain. While adjudicating the cases the Courts have evolved few principles on the basis of which obviousness of biotech inventions can be decided. It is inferred that the mere knowledge of a protein and its amino acid sequences would not render the isolation of the DNA or gene, which codes for such proteins obvious. Protein is a product that a particular gene or a DNA codes for. The knowledge of protein can be gained by knowing its amino acid sequences. But the knowledge of a gene or DNA can be gained only when its nucleotides are known. The reason is that the conception of an invention involves conception of its physical and chemical properties. The chemical and physical properties of proteins, genes and DNA are different; hence the conception of protein would not amount to the conception of gene or DNA, which codes such protein.

**Obviousness of a process of making a new product.**

In the field of biotechnology sometimes known processes are used with different new raw materials giving rise to new products. It is an obvious test before the law Courts to decide whether a known process can be patented if the starting materials used and the end product is new”? In re Durden\(^{423}\) the Federal Circuit was confronted with the above question. The claim was for an old process of making a new product by using new raw material. The appellants used new and non-obvious starting material to produce a new and non-obvious end product through an old and known process in the prior art. Appellants contended that the starting material and end products are new and non-obvious; hence the claim is patentable though they used an old and known process. Prior art was consisting of a patent disclosing a very similar process. It was observed that the

\(^{423}\) (763 F.2d 1406 (Fed. Cir. 1985)
process and its end result were predictable by a person having ordinary skill in the art. The Federal Circuit rejecting the appellant’s proposition held that the claimed process was predictable by a person having skill in the art and obvious in the light of prior art.\textsuperscript{424} Further it viewed that using of an unobvious starting material with unobvious end product will not render a known process unobvious.\textsuperscript{425} However the Court rejected to set a general rule to judge obviousness of above like cases and held that to days rule would likely be regretted in tomorrow’s case. Hence each case should be decided on the basis of its own fact situation. So when the process is old and known, than claim to the process shall not be entertained though the starting material used and the end products are new and unobvious. This decision was not favorable to the biotechnology industry and has generated chaos and confusion in the industry. The reason is that scientists will be experimenting with the old and known process with new products to bring something new.

Again in \textit{In re Pleuddemann}\textsuperscript{426} the Federal Circuit confronted with another important question whether method for using a product is patentable. The claim was for a method for making use of novel agents for a particular use. Initially patent examiner as well as PTO relying on the Durden decision rejected the claim as obvious on the ground that claimed patent teaches the same process on which there is an existing patent. Following the rationality of \textit{In re Huchl} the Federal Circuit reversed the examiners rejection\textsuperscript{427} and held that the claim in \textit{In re Durden} on which examiner relied in reaching his decision to reject the claim was for a method of making a compound. But here the claims are for methods of using a compound. So the relevant case here is not \textit{In re Durden}, but \textit{In re Kuchl}, where exist same fact situation similar to the present case. The Court held that the process or method of making the compound is quite different from a process or method of using a compound.\textsuperscript{428} The Federal Circuit viewed that the obviousness of methods of using depends upon the obviousness of using new compounds. The method of using

\begin{itemize}
  \item Federal circuit relied on \textit{In re Albertson} 332 F. 2d 379, 141 USPQ 730 (CCPA 1964)
  \item 910 F.2d 823 (Fed. Cir. 1990).
  \item 475 F.2d, 658, 177 USPQ 250 (Ccpa1973)
\end{itemize}
compound has been held as non-obvious when the compound itself is new and non-obvious. The Court reasoned that prior art doesn’t contain the new compound; hence the obviousness of the method of making use of the new and unobvious compound can’t be established.

The biotechnology industry was blossoming when these judgments have come. There was expectation of even more favorable approach from judiciary as well as from congress in facilitating patent grants. Biotechnology industry seeks process patents for its invention more than product patents. The biotech industry considered the judgment of the Court of Federal Circuit in *In re Durden* as a check for its development. In fact obviousness has been a sticky subject in the realm of biotechnology because scientists use similar techniques to isolate different gene sequences, even though the gene sequence may be new. In its various decisions the Court of Federal Circuit has laid down an uncertain law on biotechnology patents. In some cases Federal Circuit has relaxed the requirement of obviousness by liberal interpretation.\(^{429}\) In some cases it tightened the requirement of obviousness by strict interpretation. In a significant attempt to revamp the non-obviousness requirement to biotechnology inventions congress brought an amendment to the United States Patent Code and as well as enacted a new Act by name Biotechnology process patents Act.\(^ {430}\) In the light of these legislative efforts now patent is granted on a biotech invention only if both the invention and the process to produce such invention shall be non-obvious.\(^ {431}\)

**The requirement of inventive step (non-obviousness) in the European Union**

In the European countries inventive step is referred to as equaling to the issue of non-obvious in United States. The European Patent Convention (EPC) states that; an

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\(^{429}\) See: *In re O’Farrell, In re Deuel*


invention shall be considered to involve an inventive step if, having regard to the state of the art it is not obvious to a person skilled in the art.\textsuperscript{432} The State of the art shall be held to comprise everything made available to the public by means of a written or oral description by use or in any other way before the date of filing of the patent application.\textsuperscript{433} The quest for inventive step is perhaps the most difficult aspect of the patent application procedure.\textsuperscript{434} The patent office shall decide whether an invention involves an inventive step, whether it contributes to the existing knowledge in the society or it forms part of the existing knowledge in the society.\textsuperscript{435} In Europe an invention must satisfy the requirement of inventive step before the grant of patent. In *Windsurfing International Inc* for the first time Court considered inventive step as a requirement of patentability.\textsuperscript{436} The Court laid foundation for a clear test of inventive step through evolving a four-prong test.\textsuperscript{437} The test involves:

1. Identification of the inventive concept embodied in the patent suit.
2. Assessment of prior art on the date of patent application through the eyes of normally skilled but unimaginative addressee in the prior art.
3. Identification of difference between the generally known matter i.e., prior art and the claimed invention in the patent application.
4. Assessment of the claimed invention whether it would have been obvious to a person skilled in the art in the light of prior art.

An invention must to pass through the test to obtain patent. However testing of inventive step in the biotechnology invention was a major concern for the English law courts. Due to the enormity of patent applications claiming genetically engineered products and due to the complexity involved in producing and patenting these products, the issue has raised interest in the law fraternity. For the first time in Europe the inventive step involved in a biotechnology invention was tested in *Genentech Inc Vs*
Welcome foundation Ltd. The claim was for a human tissue plasminogen activator (t-pa) produced using recombinant DNA technology (genetic engineering). It was the first time that this technology has been used to synthesize t-pa, though the technology had been used for synthesizing a variety of other substances. The issue was whether the invention involves an inventive step. The Court examined whether synthesis of t-pa deserves patent protection or it is just a mere new application of existing technology. It was observed by the House of Lords that at the time of the inventor’s research, DNA technology existed and at least in theory could be adapted to produce t-pa. Further the same technology is being used to produce growth hormones, insulin and other valuable products of similar nature. The claimed invention involves the use of recombinant techniques in yeast, which had previously been used to express genes in bacteria.

There was reasonable expectation of success in the application of recombinant technique in bacteria. In the light of above factors it was held that producing human tissue plasminogen activator (t-pa) in bacteria using recombinant technology does not involve an inventive step and patent was rejected. The Court was strict in applying inventive step requirement to the biotech inventions. In the view of the Court if there is a suggestion in the prior art for the invention the invention does not involve inventive step. The biotech industry in United Kingdom feared that the Genentec decision has created an anti biotech atmosphere that may effect the development of the industry.

However the fears of the biotech industry were removed with the decision of Court of appeal In Chiron Corporation Vs. Murex Diagnostics Ltd and Organon Teknika Ltd. The invention involved was a virus responsible for causing non-A non-B Hepatitis (NANBH) known as Hepatitis virus and also an immunoassay kit for detecting antibodies against Hepatitis-C virus. The detection involves screening of blood for the identification

439 See: Dr. T. Ramakrishna, Biotechnology and intellectual property rights, Pg. No. 28
of Hepatitis-C infection, the production of a vaccine and a method of cultivating Hepatitis-C cells.\textsuperscript{444} Defendants produced their own immunoassay kit for detecting Hepatitis-C virus. The petitioners alleged the defendants for infringing their patent and they wanted to prevent the defendants from selling their own immunoassay kits. In counter, defendants challenged the validity of the petitioner’s invention by contending the obviousness of the invention in the light of the prior art.

It was viewed that the invention involves the identification and sequencing of a specific stretch of genetic material responsible for causing Hepatitis-C virus. The invention was not general in nature, it was specific and having substantial utility in identifying virus-causing Hepatitis-C, which the prior art did not, consisted of. There was no evidence in the prior art suggesting the subject matter of invention prior to the date of the patent application. The House of Lords located inventive step in sequencing of specific genetic material. The invention was considered as an improvement over the prior art, as there was no such genetic material available in the prior art earlier to the invention. Eventually the invention was held as involving an inventive step and patent was declared valid. Further in \textit{Biogen Vs Medeva}\textsuperscript{445} again inventive step involved in the invention of recombinant DNA molecules coding for Hepatitis-B virus was tested.\textsuperscript{446} The observations made by Lord Hoffman on the quest of inventive step have had a great impact on the patenting of biotechnology inventions.

House of Lords speaking through Lord Hoffman state that whenever anything inventive is done for the first time, it is the result of the addition of a new idea to the existing stock of knowledge. Sometimes it is the idea of using established techniques to do something, which no one had previously thought of doing. In that case, the inventive idea will be doing the new thing. Sometimes it is finding a way of doing something,

\textsuperscript{444} See: Dr. T. Ramakrishna, Biotechnology and intellectual property rights, Pg. No. 29

\textsuperscript{445} (1997) R.P.C.1

\textsuperscript{446} A patent was granted in 1990. Later respondents, i.e., Medeva have produced their own Hepatitis-B vaccine through recombinant DNA technology and they described it as a third-generation Hepatitis-B vaccine. In 1992 Biogen began infringement proceedings against the respondent Medeva Plc. Medeva counterclaimed for revocation, alleging the Biogen’s patent as invalid. They contended that the invention was obvious at the time of application. They submitted that the steps taken by Biogen were one that was obvious to try. An expert in the field, enabling the direct expression of a eukaryotic protein in a prokaryotic cell, published it in a paper.
which people had wanted to do but could not think now. Many people may have a
general idea to achieve a goal or to solve a particular problem. If someone devices a way
of solving the problem, his inventive step will be a solution. In the present case to decide
whether the invention constituted inventive step or not we have to leek into the prior art
in 1978. Whether the invention was obvious in view of the matter made available to the
public before. His Lordship said that the idea of producing Hepatitis-B virus by
recombinant DNA technology was known by everyone in 1978 and there was no doubt
on this among the others working in the field.\footnote{447}

House of Lords has made specific enquiry into the prior art in holding the invention
as obvious.\footnote{448} It was held that Biogen had used available techniques and materials in
research and they had not developed any new processes or had not discovered anything
about those processes.\footnote{449} The knowledge in the prior art with regard to the invention was
suggesting the invention. Moreover the inventors have utilized available techniques in
reaching at the claimed invention. Therefore an invention, which is a result of known
techniques, does not involve an inventive step. Further an invention suggested by the
prior art cannot pass the test of inventive step.

Meanwhile biotechnology industry urges that the production of known products
having fine levels of purity requires immense research effort. Though the product is
known, increasing the level of its purity is a Herculean task. It was thought that Biogen
decision might create difficulties in the biotechnology industry. However at the same
time EPO Technical Board of Appeal held the same invention as involving an inventive
step. Accepting the urges of the biotech industry the Board felt that the production of
known products with increased levels involves an inventive step. The Board considered
the invention as a major break through in Hepatitis-B for which many people are working
in the field to achieve the same result but Biogen did it. Unlike the United States of
America in the European Union the law relating to biotechnology is not been stabilized.
The decisions of the European technical Board of Appeal and also the decisions of House
of Lords does provide for the present law on the issue.

\footnote{447} Manu Luv Shahalia, “Perspectives in intellectual property law, many sides to a coin,” Universal Law
\footnote{448} Ibid, Pg. No. 182.
However in the light of the fluctuating decisions of the Board it cannot be predicted that the stand of the Board on the determination of inventive step of biotechnology inventions remains same. Sometimes the decisions of the House of Lord and the Board do contradict with each other as it was in Biogen Case. However the decisions of the Board are binding on all the member states of European Union. But House of Lords happened to adjudicate certain important issues in particular on the inventive step involved in biotechnology inventions. Therefore both the decisions of House of Lords and as well as the Board are relevant in deciding the inventive step involved in biotechnology invention.

**Inventive step of biotechnology inventions in India**

In India patents are granted for inventions involving an inventive step.\(^{450}\) Inventive step is defined to mean a feature that makes the invention not obvious to a person skilled in the art.\(^{451}\) Any new product or process that involves an inventive step is patentable in India. In India the patent law\(^{452}\) provides that when an application for patent is made, the patent examiner\(^{453}\) will have to conduct an investigation to find the relevant prior art. If in the investigation it is found that the invention has been anticipated by publication in India or elsewhere before the date of the applicants filing of complete specification than patent shall not be granted. In such circumstances the invention falls within the realm of prior art, the knowledge in the public domain involving no inventive step. Such knowledge in the public domain being obvious to a person skilled in the relevant art shall not be given patent.\(^{454}\) The requirement is no different with reference to biotechnology inventions. However there is no substantive case law development with regard to inventive step in the biotechnology inventions in India.

For the first time in India inventive step involved in a biotechnology invention had come before the forefronts of the Courts. In *Dimminaco A.G V. Controller of Patents* 449 See: Dr. T. Ramakrishna, Biotechnology and intellectual property rights, Pg. No.30
450 See: Patents Act as amended in 2005, Section: 2(j) Invention
451 See: Ibid: Section: 2(ja) Inventive step
453 Under Indian patent Act, examiner is a person to who will scrutinize the patent application and conduct patent search to find relevant prior art.
Designs & others the Calcutta High Court confronted with a question whether the claimed invention relating to a process for preparation of infectious Bursitis Vaccine does involve inventive step and whether the claimed subject matter constitutes invention under the patent Act of India. The vaccine was useful for protecting poultry against contagious bursitis infection. The inventors contended that the process claimed involves certain chemical steps under specific scientific conditions. The Patent office initially rejected the patent application by stating that living virus or living process does not constitute invention under the patent Act. However the Calcutta High Court held that there is no statutory bar to patent living processes or product that involve inventive step. In the present case the process claimed does involve certain inventive step, as it requires certain chemical steps to be taken in the production of the vaccine. The High Court directed the patent office to grant patent on the claimed process. Therefore as per the decision of the Calcutta High Court a biotechnology invention involving a new process or product can be patented if it involves an inventive step. Further as per the patent law if the invention is anticipated in the prior art or is published, used, patented it does not involve an inventive step. In case of biotechnology inventions also the claimed invention does not constitute an inventive step if is anticipated or published or used or patented earlier or in any way forms part of the prior art.

However nowhere in the United States patent law or in the Indian patent law the term prior art is used or defined. The European Patent Conventions uses the term state of the art which is equivalent to prior art and states that state of the art comprises everything that is made available to the public by means of a written or oral description by use of in any other way before the date of filing of the European patent application. The United States patent law the European Patent Convention and as well patent law in India state that any invention which is known or published or patented being part of the prior art is obvious and does not involve inventive step. Therefore an invention, which is a part of the prior art does not involve inventive step and is not patentable. The invention shall be a leap further from the state of the art or it shall be a step forward from the

455 See: Dr. T. Ramakrishna, Biotechnology and intellectual property rights, Pg. No. 38
already existing knowledge that is prior art. It shall be advancement of existing knowledge in the public domain. It implies that courts while determining the obviousness of any invention shall have to consider the scope of the prior art. Infact, law courts have taken into consideration the knowledge in the public domain or the state of the art in deciding the obviousness of an invention. The presumption is that on the basis of prior art, if an invention becomes obvious to the person having skill in the relevant art, such invention does not constitute an inventive step and must not be patented.

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UTILITY OR INDUSTRIAL APPLICATION

An invention must be useful and must be capable of industrial application in order to be patented. There must be some demonstrable utility or specific benefit from an invention. The invention must have some practical utility in the form of immediate benefit to the public. As regards the conditions of industrial applicability, no special considerations should apply to biotechnology inventions. The requirement of industrial applicability shall be satisfied not at the time of filing of patent application but at the time of grant of the patent. It implies that; at the time of filing the patent application if the invention has no practical utility or industrial application, nevertheless patent shall be granted, if the inventor could establish the utility before the date of the grant of patent.

Utility of biotechnology inventions

Utility poses a greater concern for chemical and biological inventions. The utility of the invention shall be described in a written form along with the written specification of the invention. The utility of biotechnology inventions is almost undisputed except few overtones. To illustrate genetically engineered plants gives benefits such as high yield, resistance to pests, weeds and herbicides. On the same lines a genetically engineered

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458 Novelty and non-obviousness shall be established at the time of filing of application but industrial application shall be established at the time of granting of patent, See: Dr. K.V. Swaminathan, An introduction to the guiding principles on the decisions on Patent Law, Bahri brothers, Delhi, First Edition, October 2000, Pg. No: 330.
animal gives benefits such as high yield of milk, woolen or flesh. However the utility of biotechnological inventions such as DNA or gene remains unknown until the gene’s function is characterized and the activity of its product is determined. Hence it is a difficult task to identify the utility of a gene or DNA.

**Utility under the U.S patent law**

Under the U.S patent law there was no requirement of utility for an invention to be patented. Section 100 of the US patent law speaks about the utility of inventions. This requirement of utility is a new phenomenon. Courts have started imposing utility requirement on inventions recently. For the first time United States Supreme Court stressing on the requirement of utility rejected an invention due to the lack of utility in *Brenner Vs Manson*. The Court stated that the invention shall be useful and it shall bring certain benefit to the society otherwise no patent shall be granted. The Court laid down guidelines for identifying the utility of an invention. The guidelines states that:

1) The term “useful” is not so broad to include any invention not harmful.

2) Utility shall be established before the grant of patent. Mere fact that the invention is an object of scientific enquiry did not establish utility.

3) The function of the invention shall be made known. Patent shall not be granted to an invention whose function is not known.

The quid pro quo of the view of Court is that monopoly shall not be granted on an invention without function or any benefit. Mere producing of something that may be an object of scientific research can’t justify patent grant with out specific and definite benefits in currently available form. The utility must be substantial utility. In the sense the utility, must be useful in the real world. To put it otherwise there shall be some practical utility of the invention. An invention either a product or a process if it is useful or if it is industrially applicable benefits the society. Before patenting an invention it

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460 Ibid


shall be made sure that it fetches something to the industry or to the society. The requirement of utility is no different to biotechnology inventions.

Patent examiners while patenting biotechnology inventions were requiring in many cases, the submission of clinical data in support of the utility of the invention. In many instances patent applications have been rejected due to the failure on the part of the inventor to submit the clinical data and the result of the clinical trials conducted on the invention. Failure to submit clinical data was considered as non-fulfillment of utility requirement. Many applicants felt difficulty with this approach of the patent examiners in seeking clinical trials data. In this background by identifying the necessity of specific framework to determine the utility of the inventions, in particular to determine the utility of biotechnology inventions especially utility of gene and DNA inventions the US patent office issued “utility examination guidelines.” The guidelines issued in 2001 reflect the intentions of the patent office. The guidelines are very much relevant to biotechnological inventions, especially to inventions relating to genes, DNA. The utility guidelines 2001 prescribe for following four-prong test to evaluate the utility of the inventions.

1) Does an invention have a well-established utility?
2) Does an invention have a specific utility?
3) Does an invention have a substantial utility?
4) Does an invention have a credible utility?

An invention, which satisfies above test, is said to have satisfied the utility requirement. As per the guidelines the examiner must adhere to the following procedure.

1) There shall be determination of specific claim as the invention.
2) There shall be determined whether the specification and claims made in the application disclose any credible utility of the invention.

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464 See: USPTO new “utility examination guidelines” 2001
465 See: USPTO guidelines issued in 1995, revised and issued in 2001
466 Earlier utility guidelines 1995 were providing for two prong test to test the utility of inventions.
3) If no credibility is disclosed or asserted and if such utility would not have been readily apparent to one of normal skill in the art, the application should be rejected for lack of utility.

4) If the utility would be credible to a person of ordinary skill in the art in view of the evidence submitted on record the application should not be rejected.

The examiner must to put forward evidence and sound reasoning in case of rejection of patent on the ground of lack of utility. The burden lies on the examiner to prove the lack of utility beyond doubt. Once the lack of utility is established than the burden to rebut it shifts to the applicant to prove the utility of the claimed invention. As per the utility guidelines a biotechnology invention should have specific, substantial, credible and well-established utility in the eyes of a person having skill in the art. 467

**Specific utility:**

Specific utility has been defined to mean an “utility that is applicable specifically to a particular subject matter.” Any utility, which is generally applicable to broad class of the invention, would not be considered specific. For example a general method to isolate genes is not having any specific utility. If the method is to isolate any specific gene, such method can be said to have a specific utility. 468

**Substantial utility**

An invention, which does not require any further research to prove its utility, to confirm its use, is said to be have substantial utility or real world utility. An invention having substantial utility can be practically applicable for the needs of the society. The invention shall be complete in itself at the same time the utility shall be substantial. 469

**Credible utility:**

Credibility refers to reliability of the invention. If the Utility is reliable then such utility is credible. Credibility of any invention depends upon the evidence in support of

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467 See: Utility examination guidelines issued by the USPTO in 1995, revised in 2001
469 See: Swaminathan, An introduction to the guiding principles on the decisions on Patent Law, Bahni brothers, Delhi, First Edition, October 2000, Pg. No: 344 & 345. See also, Leslie G Restaino, Steven E. Halpen and Dr. Eric L, Tang, “Patenting DNA-related inventions in the European Union, United States and
its assertion. If the inventor could bring enough support or evidence in favor of his claim, such a claim can’t be rejected. The credibility of the invention can be established through evidence comprising of expert statements, reports of clinical trials and laboratory records. The assumption is that an assertion is credible unless, the logic underlying the assertion is seriously flawed or the facts upon which such assertion is based are inconsistent with the logic underlying the assertion. The credibility of the invention shall be judged from the angle from a person having ordinary skill in the art. The invention utility shall be believable by a person having ordinary skill in the art.470

Well-established utility

In general any utility, which is specific, substantial and credible, is called as well-established utility. It is a utility supported by enough evidence disclosed in the specification. It is an utility that would be demonstrable by the inventor and identifiable by a person of ordinary skill in the art. This utility can’t be question or disputed. Well established utility is established where the utility is specific, substantial and credible. The utility guidelines set out different procedures to be followed for various claims of inventions.471 The patent office shall follow the procedure set forth in under the utility guidelines for testing the utility of any invention. The guidelines set out different procedure for different inventions. The procedure is as follows:

Utility of Process claims:

Process claims that recite more than one utility, if at least one utility is credible, specific and substantial the application should not be rejected. If any utility in such claim is not specific, credible and substantial than the application should be rejected.

Utility of Product claims:

Product claims that do not recite any specific, credible and substantial utility a rejection under section: 101 would be proper. If cure or prevention claims are not credible to one of skill in the art shall not be patented. However documentary evidence or

sound technical reasoning must support any rejection on the basis of lack of credible utility.

**Utility of Treatment claims and vaccines**

For treatment claims rejection for lack of utility shall be rarely made, because most diseases or conditions can be treated. In general it is presumed that treatments are specific to particular diseases and are credible in the eyes of a person having ordinary skill in the art. Claims on vaccines regularly prepared to combat various viruses and organisms, and would have a credible utility. One of ordinary skill in the art would appreciate such utility so rejection for lack of utility shall not be raised in case of vaccines.

**Claims on materials and methods**

In case of claims on materials or methods to be used for research raises issue whether the utility require any further research to confirm a ‘real world’ utility. The reason is that research utility was not considered as a substantial utility.” If the invention requires further research to confirm a real world utility than the invention can be rejected for lack of utility.

**Utility in the eyes of person skilled in the art**

According to the utility examination guidelines, the utility of the invention is judged through the eyes of a person skilled in the relevant art. If the utility of the invention is credible and substantial in the eyes of a person having ordinary skill in the art, than it can be said that the invention has satisfied the requirement of utility under the.472 An examiner must not reject the patent application if the applicant could establish that invention would be specific, substantial and credible to a person of ordinary skill in the art.

As far as the utility of biotechnology inventions are concerned the approach of the US patent office is liberal. Most of the biotechnology inventions are concerned with isolation of DNA sequences, DNA, genes, gene sequences coding for specific proteins.

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471 See: The US patent office Utility examination guidelines 2001
Proteins produced through biotechnology are useful in producing pharmaceutical products. Therefore the utility of such invention is undisputed. According to the patent office if the asserted utility of any biotechnological invention is in general, such utility is not specific and it will not satisfy the requirement of utility. For example: if the asserted utility of the isolated DNA fragment is not specific, due to the fact that asserted utility would apply to the general class of all DNA will not satisfy the requirement utility. On the same lines the isolation of a specific protein without function of without the demonstration of its specific use does not satisfy the requirement of utility.

It is believed that mere isolation of a DNA or DNA sequence is not enough; the utility of such DNA or DNA sequence must be established. The inventor must demonstrate the role of the gene or DNA or protein. Without asserting the specific utility no patent can be claimed on any gene or DNA or protein. Such utility of shall be specific, substantial and credible, but not speculative or prospective. If a DNA sequence is manipulated in order to make it express differently form the way it used to earlier then it can be said that a new DNA sequence has been invented. Its utility depends on the way it expresses itself in the phenotype of the organism that has it. On the whole manipulation of a single DNA sequence causes a particular cell to function differently in producing intended protein. Here the purpose behind manipulation of is get a particular gene to express in a different manner in producing intended protein which it was not earlier. The objective behind such manipulation is to derive a particular benefit.

Utility has only recently emerged as an issue for biotechnology patent applications. Previous issues, such as the discovery of human protein erythropoietin reached the Courts in large part because of the vast commercial potential and utility of the product. Most of the biotechnology inventions objective is to produce desired protein in a host organism at molecular level. The function that such inventions perform

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473 If a DNA sequenced is manipulated to help it express differently. Infact the manipulated DNA sequence caused corresponding gene coding for a specific protein to express differently. In turn the gene causes corresponding chromosome to express differently. At last it makes the respective cell to function differently by expressing intended protein


renders the invention useful that satisfies the requirement of utility. Therefore most of the biotechnology inventions are assumed to satisfy the requirement of utility. Here the utility of the biotechnology inventions is specific in manipulating specific genes or DNA, it is substantial in producing certain protein that can be industrially applicable. A person having ordinary skill in the art would believe that the inventions of genes and DNA to have certain utility like producing of protein, hence the utility of the invention is credible. 

**Utility of Essential Sequence Tags (EST): A case study**

However the credibility of biotechnological inventions such as partial DNA sequences such as essential sequence tags (EST) has been doubted. An EST is a part/fragment of a DNA molecule, which is used to identify and locate an expressed gene.\(^ {476}\) It is used as probe in identifying genes and DNA. However patenting of EST is controversial, as it has been challenged by a variety of societies like the Human Genome Organization (HUGO). HUGO also believes that EST lack substantial and credible utility.\(^ {477}\) There were other comments, which stated that sufficient utility is not disclosed in case of EST, as probe its sole function is to identify other nuclear acids and genetic material whose utility is not known and also the function of the corresponding gene is not known. Some comments suggested that the utility of an EST is not established when its corresponding gene is unknown. Even if an EST is sufficiently described as a DNA sequence, it might not be useful for specific mapping of a gene.

It is an open question whether a partial DNA sequence such as an EST, which an applicant asserts to have utility as a probe to isolate a gene or as a tag for an expressed gene of unknown function, is totally incapable of achieving a useful result. According to the US patent office an asserted utility of an EST, as a probe in isolating DNA is not ‘specific’ because that asserted utility would apply to the general class of all DNA. The general concern was that: if patent is allowed on EST, patent would be granted for nonspecific, non-substantial utilities contrary to the established case law. The patent office has recognized that it is now technically quite routine to clone DNA that encodes

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\(^{476}\) Leslie G Restaino, Steven E. Halpen and Dr. Eric L. Tang, “Patenting DNA-related inventions in the European Union, United States and Japan: A trilateral approach or a study in contrast? UCLA Journal of Law & Technology. (J.L & Tech 2)

\(^{477}\) HUGO views an EST as obvious and does not involve any inventive step. HUGO vies that routine steps will be followed in isolating EST. Moreover
particular known protein sequences. Moreover it has become ‘routine to clone DNA’s that encode homologous protein from a number of different species or strains. For example today it would be trivial to clone human insulin DNA if one possessed rat insulin DNA.\textsuperscript{478} The patent office was not in favor of granting patents to EST. But there was strong demand from the biotech industry to grant patent to these EST. However it remains to be seen how the Federal Circuit responses towards the practice of PTO on the utility of DNA sequences.

Indeed, the sequencing of any gene involves the sequencing of individual, small fragments. Moreover, the sequencing of fragments of genes has long been used as a rapid tool for the characterization of genes. Through using partial gene sequences such as EST to find full length cDNA and genomic sequences is an important research activity which is routinely performed in many laboratories, is still remains a task that is troubled with uncertainty. It was argued that to realize the utility of EST further research has to be done. For example, to use DNA fragments for tissue typing one must first establish that a particular fragment or set of fragments provides a sufficiently discriminatory signature of a particular tissue type or state. However in 1997 a policy decision was made to allow patents on EST. In 1997 it was announced that the patent office would allow patents on EST based on their utility as probes. Accordingly the first patent on EST was granted on October 6, 1998. There was a plethora of applications before the PTO subsequent to the grant of first patent on an EST. By the end of 2000, the USPTO received patent applications on millions of gene fragments. (EST) Now the situation is such that probably every human gene at least in part might already be subject to a patent application.\textsuperscript{479} However a mere assertion of the utility of an EST as a probe without further disclosure of its specific function is considered not enough to satisfy utility requirement.

The utility of genetically engineered living being is beyond doubt but the utility of EST is doubted. Under the new utility guidelines biotechnology inventions like: gene,

\textsuperscript{478}Rat is considered very much similar to human in its biological set up. So also the molecular set up is same in rat as well as human being. So once you know the cDNA coding for a specific protein in rat, it would be easy to clone human cDNA coding for the same protein.
DNA, including EST are undoubtedly patentable provided have well established utility. If there is well-established utility but specific and substantial utility is not asserted patent must not be given. At the same time if specific and substantial utility is asserted but there is no well-established utility, than also patent must be granted. Moreover the utility of the invention shall be credible in the eyes of a person skilled in the art.

The requirement of Industrial application of biotechnology inventions in Europe

According to European Patent Office utility is defined as industrial applicability, which includes any kind of industry inclusive of the industry of agriculture. The European Patent Convention states that in order to be patented an invention must be capable of industrial application. Only that which is usable or to be precise capable of industrial use is regarded as deserving of the protection afforded by the grant of a patent. As far as utility of industrial application of biotech inventions is concerned Europe is no different from US. In both the regions patent law stands on same footing concerning the utility of biotechnology inventions. However Europe prohibits patenting of therapies though have certain utility but US does not.


By considering the enormity of biotechnological inventions, in the background of plethora of patent applications on inventions such as DNA and EST, United States of America, European Union and Japan patent offices known as “trilateral patent offices’ have undertaken a comparative study on patent practices on biotechnology. In particular the study focused on the utility and patentability of DNA fragments and EST’s. The trilateral project recommended as follows.

1) A mere DNA fragments without indication of a function or specific asserted utility is not a patentable invention.

479 Leslie G Restaino, Steven E. Halpen and Dr. Eric L, Tang, “Patenting DNA-related inventions in the European Union, United States and “Japan: A trilateral approach or a study in contrast? UCLA Journal of Law & Technology. (J.L & Tech 2) 2003

480 Ibid

481 In June 2000 a technical meeting of Trilateral Patent Offices was taken place. There held consensus on the patenting practice of biotechnological inventions. As a result of this meeting following conclusions were made. The same were added final report of the project.
2) A DNA fragment, of which specific utility, such as; use as a probe to diagnose a specific disease, is disclosed is a patentable invention as long as there are no other reasons for rejection.

3) A DNA fragment showing no expected effect, obtained by conventional method, which is assumed to be part of a certain structural gene based on its high homology with a known DNA encoding protein with a known function, is not a patentable invention as per the practice of European Patent Office and Japan Patent Office practice.

4) A DNA fragment is not patentable if the specification fails to indicate an asserted utility as per the practice of the patent office.

5) The mere fact that DNA fragments are derived from the same source is not sufficient to meet the requirement for unity of invention.

The study states that all nucleic acid molecules related inventions, including full-length cDNA without indication of function or specific, substantial and credible utility do not satisfy industrial applicability, enablement or written description requirements. Further it is believed that an isolated and purified nucleic acid molecule related inventions, including full-length cDNA of which function or specific, substantial and credible utility is disclosed, which satisfy industrial applicability, enablement, definiteness and written description requirements would be patentable as long as there is no prior art or other reasons for rejection such as, lack of best mode disclosure or ethical grounds.

**The requirement of Industrial application of biotechnology inventions in India**

The patent law of India states that any new product or process involving inventive step and capable of industrial application does constitute an invention and is patentable. Capable of industrial application in relation to an invention means that the invention is capable of being made or used in an industry. The requirement of industrial application of inventions in India is no different from the industrial requirement of Europe or utility requirement of US. However there is no substantial case law

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482 See: The patent Act of India as amended in 2005, Section: 2(j)
483 See: The patent Act of India as amended in 2005, Section: 2(ac)
development with regard to the industrial application of biotechnology inventions in India as the industry is at infant stage. In *Dimminaco A.G V. Controller of Patents Designs & others* \(^{484}\) for the first time utility of a biotechnology invention was demonstrated. The invention relating to a process for preparation of infectious Bursitis Vaccine. The vaccine was useful for protecting poultry against contagious bursitis infection. Initially the patent office rejected the patent application on the ground that the claim does not constitute invention. But the utility of the invention was not disputed.

On appeal the Calcutta high Court decided that the claims constitute invention as it involves certain chemical steps to be taken under certain scientific conditions. At no stage the utility of the invention was questioned implying the fact that almost all the biotechnology inventions are having certain utility of industrial application. Like wise the utility of biotechnology inventions like genetically engineered plants, animal gene, DNA and the like is undisputable. Therefore the utility or industrial application of biotechnology inventions is accepted and assumed in India.

The inventions of biotechnology are very much useful in different sectors specifically and substantially. Biotechnology is being vastly used in different sectors such as the agriculture, medical, chemical industry animal husbandry and many. Biotechnology produced genetically engineered plants and animals having increased potentials. Biotechnology has brought up innovative medical treatments, surgical processes that are very much useful in the society. Biotechnology inventions are useful in treating pollution, poultry, fisheries, forestry, and many. This technology has got enormous importance in the present day life. Such being the case the question of utility of biotechnology arises very rarely. The presumption is that the inventions of biotechnology have got enough utility

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\(^{484}\) See: Dr. T. Ramakrishna, Biotechnology and intellectual property rights, Pg. No. 38
WRITTEN DESCRIPTION

An invention must be described in a written form as a necessary condition to be satisfied to grant patent. In addition to satisfying requirements such as novelty, non-obviousness and industrial application an inventor must adequately disclose the invention in written form.\(^{485}\) The TRIPS agreement states that the patent application shall disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art and shall disclose the best mode for carrying out the invention known to the inventor.\(^{486}\) The written description\(^{487}\) shall provide the details of the invention, in a complete, clear and concise manner and shall disclose the best mode of processing, making and using the invention to enable a person skilled in the art to practice the invention. The disclosure shall enable a person skilled in the art to make and use the invention.

The objective of the written description requirement

In general terms the requirement is to disclose “how to make” the invention and “how to use the invention.”\(^{488}\) The requirement of written description of the invention serves the purpose in evaluating the inventor whether he does possess the invention at the time of filing the patent application.\(^{489}\) Written description is a public notice that the inventor possesses the invention.\(^{490}\) The development of law relating to written description is a public notice that the inventor possesses the invention.

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\(^{486}\) See: The TRIPS agreement: Article: 29: Conditions on patent applicants.

\(^{487}\) United States patent code Section: 112 of the United States patent code provides for the disclosure requirement of the inventions.


\(^{490}\) In *Vas catch* it was held that written description requirement serves the purpose to put the public on notice of the specific, the requirement also prevents the applicants from claiming more than what he invented and described.\(^{490}\) The description provided should be sufficient enough to inform one skilled in the art that the applicant was in possession of the claimed invention at the time of the application. The objectives of the written description can be summarized as follows.

- Ensuring that the inventor was in possession of the invention at the time of application
- Notice to the public regarding the invention
- Defines the boundaries and limitations of the invention
- Enables the person skilled in the art to practice the invention after the term of the patent
- Ensures fair play by the inventor in disclosing the best mode to the public against monopoly
- Ensures Quid pro quo knowledge to the society against private monopoly.
description requirement is of recent origin.\textsuperscript{491} The requirement of written description was historically not well delineated.\textsuperscript{492} It has recently come to represent a heightening of the patentability bar with respect to biotechnology inventions. For many years the requirement was interpreted to mean description to enable a person skilled in the art to practice. With the advent of biotechnology patent offices and Law Courts started interpreting the requirement of written description stringently to check the scope of inventions of biotechnology. In particular Federal Circuit has used this requirement to restrict the biotechnology patent applications. The requirement of written description is strictly imposed.\textsuperscript{493} in order to confine and limit the scope of the invention to what is described in the application.

\textbf{The requirement of written description in U.S}

The United States patent Act states, “the invention shall be described in such full, clear, concise and exact terms as to enable any person skilled in the art to which it pertains or with which it is most nearly connected to make and use the same.”\textsuperscript{494} The requirement of written description is enshrined under section 112 of the US patent law. The Federal Circuit, the final appeal Court for patent applicants in United States has


\textsuperscript{492} Historically speaking the patent Act of 1790 established original requirement for specification of the invention in the patent application. Subsequently the patent Act of 1793 replaced the term “specification” with “written description”. The requirement was to give full, clear and exact description of the invention to give notice to the public about the possession of the invention. Wood V. Underhill, See, Debra Z. Anderson, \textit{HOW TO ENABLE YOUR BIOTECH DISCLOSURE FOR UNITED STATES PATENT APPLICATION}, lawyers Journal, Allegheny County Bar Association, July 11, 2003.

In the mid 1800, the Supreme Court determined that a disclosure, which requires one skilled in the art to experiment in order to practice the claimed, is defective. Later it was decided that some experimentation was acceptable but it must not be undue. Held in Minoral Separation V. Hyde, See, Debra Z. Anderson, \textit{HOW TO ENABLE YOUR BIOTECH DISCLOSURE FOR UNITED STATES PATENT APPLICATION}, lawyers Journal, Allegheny County Bar Association, July 11, 2003. The Federal Circuit for biotechnology inventions is applying the same standard. See \textit{In re Wands}, 858 F2d, 731 (Fed Cir. 1998) The premise of the patent system is that an inventor having taught the world something it did not know, is encouraged to make the product available for public and commercial benefit, by governmental grant of the right to exclude others from practice of that which the inventor has disclosed. The boundary defining the excludable subject matter must be carefully set; it must protect the inventor, so that commercial development is encouraged” but the claims must be commensurable with the inventors contribution. Thus the specification and claims must meet the requirement of 35 U.S. C section; 112. Donald S. Chisum, Craig Allen Nard, Herbert F. Schwartz, Pauline Newman, F. Scott kieff, \textit{Cases and materials “ Principles of Patent Law}, New York Foundation Press, New York, 1998, Pg. No.302. The current written description requirement was enshrined in the patent Act 1952.

\textsuperscript{493} The later claim over and above the earlier claim will not receive the benefit of the earlier filing date.
clarified the written description requirement applies in the field of biotechnology. At the same time United States Patent and Trademark Office has interpreted section: 112 to consist three dimensions as follows:

1) Written description.
2) Enablement.
3) Best mode & deposit of the invention

**Written description and enablement of biotechnology inventions**

There is no peculiar difference between the written description of other invention and the written description of biotechnology inventions. However the Court of Federal Circuit intends to strictly apply the written description requirement to biotechnology inventions. The Federal Circuit the final appeal Court for patent appeals in United States has clarified how the written description requirement applies in the field of biotechnology. For the first time in *Hybertech Inc., V Monoclonal Antibodies, Inc* the Court of Federal Circuit applied the written description requirement to a biotechnology invention. The invention was “an immunoassay that utilized monoclonal antibodies having high affinity for certain antigens”. Immunoassay the subject matter of patent is a diagnostic method for determining the presence of amount of antigen in body fluids such as blood or urine by employing the ability of an antibody to recognize and bind to an antigen.

The patent was challenged on the ground of non-fulfillment of written description requirement. The District Court opined that the patent fails to disclose How to make and screen monoclonal antibodies and how to measure monoclonal antibody affinity.

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494 See: The U.S patent Code: Section: 112
497 Same standards of written description are applied to biotechnology inventions.
498 802 F.2d 1367 (Fe. Cir. 1986)
499 Hibertech was the first biotech case decided by the Federal Circuit
was viewed that the specification is non-enabling and does not satisfy the best mode requirement. Further it was observed that the “enablement is a legal determination of whether a patent enables one skilled in the art to make and use the claimed invention”. It was also observed that enablement is not precluded even if some experimentation is necessary but such experimentation must not be unduly expensive. In the present case there is no evidence that there required undue experimentation, hence the patent was held to be enabling.

With regard to the disclosure of best mode of practicing the invention the Fed Circuit observed that ‘not complying with the best mode requirement amounts to concealing the preferred mode contemplated by the applicant. There was a testimony by Hybertech employees alleging concealment of best mode by the inventor. The testimony states that screening process disclosed by the inventor is intensive and time consuming. Federal Circuit rejected to relay on this testimony to say that the inventor concealed the best mode and held that if the process is intensive and time consuming it does not mean that it is not a best mode.\textsuperscript{501} Eventually Federal Circuit held that the inventor satisfies the disclosure, enablement and best more requirements.

It was the Federal Circuits first attempt to discuss and lay down law relating to written description of Biotechnology inventions. In its first attempt itself the Federal Circuit has discussed in detail and applied the requirement of written description to biotechnology inventions in an innovative way. The Court has thrown light on all the dimensions of written description requirement with regard to biotechnology inventions. Infact the Court has made very important observations, which have great impact on its subsequent decisions. On the basis of this decision, Federal Circuit has applied the written description requirement to biotechnology inventions in various subsequent cases.

\textbf{Reasonable experimentation and undue experimentation}

When an invention is described in a written form it shall to be decided whether such description provides enough details of the invention, whether it enables a person skilled in the art to practice the invention, whether the inventor has disclosed the best

\textsuperscript{501} With reference to indefinite of claims alleged against the inventor, the Court held that “the claims read in the light of specification reasonably appraise those skilled in the art both at the utilization and scope of the invention”. More over the language is precise. The Courts cannot demand more.
mode of practicing the invention. But a question arises as to what is the standard of
description that enables a person skilled in the art to practice the invention. If the
description requires a person skilled in the art to experiment in order to reduce the
invention to practice, in such cases it is a moot question whether such experimentation
constitutes insufficient description of the invention. If such experimentation does not
amount to insufficient description what is the extent of experimentation that is allowed?
However enablement is not precluded by the necessity for some experimentation such as
routine screening, but it must not be undue. But what amounts to reasonable
experimentation and undue experimentation depends on the factual situation of the case.
Here one must consider the nature of the invention and state of the art. 502

In In re Wands 503 the invention was an “immunoassay” utilizing monoclonal high
affinity IGM (immunoglobulin) antibody methods for the detection of hepatitis-B surface
antigen. An antibody does bind with a particular antigen to fight against. The affinity is a
quantitative measure of the strength and highness with which they bind to the
determinant antigens with difficult antibodies. Usually an antibody with a higher affinity
for an antigen is more useful for immunological diagnostic tests than one with a lower
affinity. There are several immunoglobulin classes or isotopes. And immunoglobulin G
(IgG) is the most common isotype in serum. Another isotype, immunoglobulin M (IgM)
is prominent early in the immune response. One of the major factors is that IgM
molecules are larger than IgG molecules and moreover IgM molecules have 10 antigen
binding sites but IgG has got 2 sites. Most of the immunoassay methods use IgG, but the
claimed invention uses only IgM antibodies. The present invention yields both IgG and
IgM antibodies.

To comply with the best mode requirement inventor deposited IgM antibodies having
high affinity than IgG at a cell depository. A deposit of the invention can serve the best
mode requirement. Especially when the invention is relating to a living matter, which is
not publicly available than deposit of invention helps the inventor in fulfilling the written

502 See generally, Ansul Co. V Uniroyal Inc. 448 F.2d 872, 878, 79, 169 USPQ 759, 762, 63 (2d Cir. 1971)
cert, denied, 404 U.S 1018, 92 S. Ct 680, 30 L.Ed 2d 666(1972)
503 858 F.2d 731 (Fed. cir. 1988) See generally, Debra Z. Anderson. HOW TO ENABLE YOUR
BIOTECH DISCLOSURE FOR UNITED STATES PATENT APPLICATION, lawyers Journal, Allegheny
County Bar Association, July11, 2003.
description requirement. However, a deposit is always not necessary to satisfy the enablement requirement in particular when the invention does not require undue experimentation. Wands the applicants states that application of monoclonal antibody technically to make high affinity IgM anti HBsAG antibodies requires only routine screening it does not amount to undue experimentation.

The Court did probe into the method of making monoclonal antibodies as described in the invention. The first step for making monoclonal antibodies is to immunize an animal. The present patent provided a detailed description for immunizing a specific strain of mice against Hepatitis-B surface antigen. The patent described entire procedure of making antibodies starting from immunizing mice to produce monoclonal antibodies after cloning. The Court took the view that the disclosure would enable a person skilled in the art to practice the invention without undue experimentation. It was observed that if the data provided by Wands in support of his claim if interpreted in a reasonable manner it leads to the conclusion that undue experimentation is not required to practice the invention. Wands disclosure provides considerable direction and guidance on how to practice the invention and presents working examples.

Further Wands record says that in the production of high affinity IgM antibodies against HBsAG the amount of effort needed to obtain such antibodies is not excessive. Eventually Federal Circuit held that Wands invention would not require any undue experimentation to practice the invention. The Federal Circuit laying down clear guidelines for the determination of reasonableness of experiments to reduce a biotechnology invention to practice held that; when the description of the invention requires undue experimentation it does not enable person skilled in the art to practice the

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504 The Court while deciding the reasonability of the experimentation involved in the Wands invention considered the guidelines laid down in In re Forman (230 USPQ at 547) In this case few guidelines were laid to test the reasonability of experimentation. The guidelines are as follows.

1. The amount of direction or guidance presented.
2. The presence or absence of working examples.
3. The nature of the invention.
4. The state of the prior art.
5. The relative skill of those in the art.
6. The predictability or unpredictability of the art and the breadth of the claims.

invention does not satisfy the written description requirement. It was concluded that a description of the invention, which requires some reasonable experimentation, in order to reduce it to practice does not constitute insufficient written description.

Best mode of practicing the invention

The requirement of written description states that the inventor shall disclose the best mode of practicing the invention in order to enable a person skilled in the art to practice the invention. In fact, a mode that is not a best mode can also enable a person skilled in the art to practice the invention. However, United States Patent Act states that application shall disclose the best mode of practicing the invention. The rationality behind best mode requirement is that inventor should not be allowed to take monopoly rights without disclosing the best mode. The inventor shall not conceal from the public method, which he prefers to be the best mode. If the inventor had a preferred mode than the one he disclosed in the application it does constitute violation of the requirement description of best mode of practicing the invention.

However, if the inventor does not consider a mode to be the best mode, which a third party considers to be, it does not amount to violation of the best mode requirement. Therefore enabling a skilled person to practice the invention by a mode is not enough, the description has to enable him to carry out the invention in the preferred best mode.

However the requirement of best mode is not new. The passage of patent Act 1870 brought the best mode requirement as a necessary condition for the patent grant. The best mode requirement was applied only in case of patents on machines. Later on it was applied to all types of inventions. With the advent of biotechnology best mode requirement was applied also to inventions involving living matter. The best mode requirement serves following purposes. It prevents the invention from concealing from the public preferred embodiments of invention, which they have conceived. It enables a person skilled in the art to practice in the best-contemplated and preferred mode by the inventor. It reveals the state of mind of the inventor at the time of the filing of patent application.


As the disclosure of the best mode is compulsory, the Courts use a two-step analysis to determine the compliance with the best mode requirement. Court use to test the compliance of the best mode requirement through subjective and objective analysis. The subjective inquiry assesses the inventor's state of mind at the time of the filing of the application to determine whether the inventor had a preferred mode of carrying out the invention. The objective inquiry assesses whether the contemplated mode described by the inventor was sufficient enough to enable a person skilled in the art to practice the invention in the preferred best mode. See Chemcast Corp V. Arco industries Corp See Tressa Jennifer James, Implications of the best mode requirement on patents involving biotechnology, Houston Business and tax Law Journal, University of Houston Law Center, 2001-2002.
*Hybertech V. Monoclonal antibodies*\(^5^0^9\) it was held that if the recreation of the best mode is labor intensive and time consuming, it does not mean that the inventor concealed the best mode. It was held that practically speaking it might not be possible to duplicate the invention exactly by following the contemplated best mode. It is not necessary that best mode should enable a skilled person to duplicate the invention exactly. In *Amgen V. Chugai*\(^5^1^0\) the Court held that it might not be possible to exactly duplicate the best mode contemplated by the inventor. When inventor does not comply with the best mode requirement, it suggests that he has concealed a preferred best mode from the public by not disclosing it.

However In *Mycogen V. Monsanto*\(^5^1^1\) It was held that if the inventor does not consider a mode as a best mode failure to disclose the same does not constitute violation of best mode of describing the invention. The state of mind of the inventor should signal a mode as a best mode, which if he does not disclose it does constitute violation of best mode. However if the inventor not considered a mode to be the best mode, which a third party considers in such cases there, is no violation of the best mode. The state of mind of the inventor is the deciding factor in determining the compliance with best mode.

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\(^{5^0^9}\) 802 F.2d 1367 (Fe. Cir. 1986)  
\(^{5^1^0}\) 927 F.2d 1200 (Fed. Cir. 1991)  
\(^{5^1^1}\) The claim was for a method to modify the structure of the gene in order to express a protein, which is responsible for insect death. Mycogen the inventors intended to insert this gene into plant cells so that the intended plant procedures a protein which if eat by any insect causes its death. Inventors brought an infringement claim against defendants Monsanto who claimed to invent the same method. Defendants counterclaimed invalidity and failure to satisfy the best mode by the inventors. Inventors have removed few sequences from the gene so as to make it function properly in producing targeted protein, when it is inserted in an intended plant. In particular a sequence of ATTTA was removed by the inventor, which was preventing the gene for performing intended function. But the inventor did not disclose this in the patent application. Defendants argued that inventor has concealed this information; hence they violated the best mode requirement. Meanwhile it was observed that inventors were aware of the negative inputs of ATTTA sequence and they had the idea of removing ATTTA sequence. Moreover, Adang one among the inventor admitted that the removal of the ATTTA sequence should have been documented in the application. However Court ruled that defendants had not provided sufficient evidence to conclude that the inventor considered the removal of ATTTA sequence as the best mode of their invention. Infact Court accepted Murry another inventor’s testimony that removal of AT (adenine, tenine) sequence was the best mode and removal of ATTTA (adenine, tenine, tenine, tenine, adenine) was a natural consequence of this approach. Court concluded that the inventors have not violated best mode requirement in not describing the removal of ATTTA sequences as they have not had the state of mind to conceal it and moreover they did not consider it to be the best mode. Infact eh removal of ATTTA sequence was a natural consequence of the practice of the best mode as contemplated by the inventor.
requirement. The intention of the inventor is immaterial in concealing the best mode.\textsuperscript{512} As long as the inventor know of a better mode than the one he disclosed irrespective of his intention he violates the requirement under section: 112. Violation of the best mode requirement will have following consequences:

1) Invalidation of patent.
2) Liability for antitrust violations
3) No protection for the patentees trade secrets and
4) Complete defense for infringement

Generally a patent, which has failed to disclose the best mode of practicing the invention, will receive the blow of sward in the form of patent invalidation. The best mode violation invalidates a patent even though the patent provides an enabling disclosure.\textsuperscript{513} Further the patentee will be held liable for concealment and antitrust violations. Besides Courts may refuse to protect the patentees’ trade secrets. Ultimately failure to comply with the best mode requirement gives a complete defense for those who have infringed the patent.

**Deposit of the invention in lieu of description, enablement and best mode**

In case of biotechnology inventions some times it may not be possible to describe the invention with its chemical and physical properties detailing its structure and sequences. In such circumstances depositing the invention in a recognized depositaries is deemed to satisfy the written description requirement. There are International depositaries established and recognized for the purpose of facilitating the deposit of living material for the purpose of patent procedure.\textsuperscript{514} The Budapest treaty provides for the establishment of depositaries all over the world to acknowledge and accept the deposits of microorganisms and living material for the purpose of patent protection. Depositaries provide an accession number for every deposit of the invention for reference. Besides the deposit of invention gives additional security to the biotechnology patent applicants, in describing

\textsuperscript{512} Randomex Inc, V. Scopus Corp, See, Tressa Jennifer James, Implications of the best mode requirement on patents involving biotechnology, Houston Business and tax Law Journal, University of Houston Law Center, 2001-2002.
\textsuperscript{513} See: Spectra physics Inc., V. Coherent Inc
\textsuperscript{514} See: Budapest treaty for the international deposits of microorganisms, 1977.
the invention and also in defending the validity of the invention. The deposit of the invention serves following purposes.

1) Helps inventor to fulfill the written description requirement when it is difficult to describe the invention verbally.
2) Insures against possible factual errors made in the application.
3) Assists the inventor in rebutting challenges on the invalidity of the claims.
4) Insures against improper or vague descriptions
5) Helps inventor in rebutting claims against validity for failure to fulfill written description requirement.

In case of biotechnology inventions involving living matters it is not possible to describe the invention in a clear and precise manner. This situation is practically relevant for inventions of DNA and protein sequences, where errors in the description of a sequence or inadequate description are common. In such cases a deposit of the invention helps the inventor to fulfill the written description requirement. It is universally accepted to accept the deposit of the invention where it is difficult to describe the invention.515 In Amgen Inc., V. Chugai Pharmaceuticals Co., Ltd.,516 the claims were for DNA sequences encoding erythropoietin and host cells transformed with a DNA sequence. Defendants asserted that the failure of Amgen to deposit the best mode host cells was a violation of the best mode requirement.517 The inventor disclosed the mode and he did not know better mode than the one that he disclosed.518 Defendants contended that in the field of living materials it is required to deposit the invention to fulfill the written description requirement.519

515 See Budapest Treaty for the international deposit of microorganisms for the purpose of patent protection, 1977.
516 (927 F.2d 1200 (Fed. Cir. 1991)
517 The District Court found that the best mode of practicing the claimed invention was by use of a specific genetically heterogeneous strain of Chinese hamster ovary (CHO) cells, which produced EPO at a rate greater than that of other cells.
519 See generally In re Argoudelios 434 F.2d 1390, 168 USPQ 99CCPA 1970.
The Court observed that if the material in the invention is not readily available to the public such as microorganisms obtained from soil samples, the deposit of the invention is necessary to enable public. Because written description may not be sufficient to describe the invention and to enable the person skilled in the art to practice the invention. It was held that: the present invention involves using of biological materials that can be produced in the laboratory using the description or the method disclosed in the patent application. So the question of non-availability of materials does not exists. What is required in the present case is the description of the best mode to carryout the invention not the deposit of the invention. Meanwhile written description guidelines also suggest that a deposit is not necessary when the biological material used is known and readily available to the public, which can be isolated without undue experimentation. While deciding on the enablement of claims it was viewed that to enable a skilled person in the art to practice the invention, patent must contain a description to make and use the invention. It was opined that if the description requires some experimentation to practice the invention, it does not. It was observed that: what is necessary is that a disclosure sufficient to enable one skilled in the art to carry out the invention commensurate with the scope of his claims. In particular for DNA sequences, description means disclosing how to make and use enough sequences to justify grant of the claims sought.

Responding to the contention that the invention cannot be practiced exactly as described, it was held that no scientist could ever duplicate exactly the best mode described in any patent application. Here it is not possible to give guarantee to duplicate

520 See generally, FN See generally In re Argoudelios 434 F.2d 1390, 168 USPQ 99 CCPA 1970.
521 See generally In re Lundark, 773 F.2d 12216, 1220, 227 USPQ 90, 93 (Fed. Cir. 1985)
523 See generally Feldman V. Arunstrup, 517 F.2d 1351, 1354 186 USPQ 108, 111 (CCPA 1975)
the invention exactly what is required is best mode contemplated by the inventor. The Court concluded that when the application describes the best mode to practice the invention without undue experimentation it is not necessary to deposit the invention. In *Enzo Biochem, Inc V. Gen-Probe Inc* the inventors deposited the invention comprising of at least one nucleotide sequence, which the nucleic acid probes, in the form of a rDNA (recombinant DNA) molecule. The question here was whether a deposit of the invention necessarily satisfies written description requirement. The Federal Circuit held that “a deposit of the invention may be sufficient to satisfy the written description requirement.” The Court took the view that a person skilled in the art could obtain the acclaimed invention from a public depository by reading the accession numbers given to the deposit. Moreover by following the appropriate techniques the invention can be practiced.

The Court opined that; though the structure or exact nucleotide sequences are not explicitly set out in the description, the requirement is deemed to be complied with the deposit of the invention. Further it was opined that the written description requirement should be met by the disclosure of functional characteristic with a disclosed correlation between that function and a sufficiently known or disclosed structure. It was held that not all-functional description of genetic material necessarily fails to meet the written description requirement. The Court concluded that neither proof of possession of an invention nor proof of its reduction to practice necessarily satisfies the written description requirement. In the present case the requirement was met not because *Enzo* possessed the claimed invention and reduced it to practice but because deposits of the claimed invention had been made and is referenced by an accession number in specification which made the deposit accessible to the public.

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527 See: In re gay, 309 F.2d 769, 773, 135 USPQ 311,316,50 CCPA 725 (1962)
528 U.S Patent No. 4,900,659, 2002. The claim was a “composition of matter” containing nucleic acid probes specific for Neisseria gonorrhoea that hybridize selectively with strains of the bacterium Neisseria meningitides.
The Courts viewed the actual deposit of the invention as satisfying the written description requirement. The description of nucleotide sequences or physical properties were not given importance but the deposit was viewed as necessary. Therefore it can be inferred that the deposit of the invention is preferred in case of biotechnological inventions to be at safer side. Any failure to describe the invention with necessary details or disclosure of best mode of practicing the invention could be compensated by the deposit of the invention. Deposit is also encouraged especially when the biological material used for the invention is not know and not publicly available or if such matter cannot be isolated or purified without undue experimentation.

Further state of mind of the inventor is important in determining the best mode of practicing the invention. In Regents of the University of California V. Oncor it was held that the state of mind of the inventor at the time of the filing the patent application is

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531 With accession numbers referred in the specification, which makes the invention accessible to public, and to practice by following appropriate techniques.
532 See Budapest Treaty for the international deposit of microorganisms for the purpose of patent protection, 1977.
533 U.S. patent No. 5,477,841 (841 patent) the invention was relating to a process frequently used to bind identify the specific location of targeted DNA sequences on chromosomes know as in situ hybridization. Two researchers from University of California Dr. Gray and Dr. Pinkel developed a method for improving the specificity of the process and got patent in 1995. Prior to Gray and Pikel in situ hybridization was an imprecise process where a large number of nucleic acid sequences, known as “probes” were used to bind and identify the location of DNA sequences. The probes, which are labeled, bind or hybridize to the targeted sequences. Once hybridization taken place, location of the target DNA can be determined. Unfortunately the probes would also frequently bind to non-targeted sequences Grey and Pinkel improved this process by adding unlabeled sequences to the mixture, which would bind to the non-targeted sequences. This effectively blocked the real probe from binding with sequences similar to the target. As a result the process was less likely to detect non-targeted sequences.
Patentee’s filed infringement suit against Oncor a Maryland Corporation that sells DNA probes for use in situ hybridization, began selling and marketing the blocking probes to customers. Oncor counterclaimed the invalidity of patent due to violation of the best mode requirement. They contended that two years before inventors specifically stated that single stranded RNA are the way to go. But they failed to disclose in the patent that the probes in use should be single stranded. They got different patent for using single standard probes increase the efficiency and specificity of hybridization. Court disregarded Oncor’s arguments regarding single standard probes by holding that inventors notes where in they stated simple standard probes are the way to go as only a supported argument at one time they considered. However it did not state the mind of the inventor as these notes were sufficiently removed from the time period when the application was filed. Court viewed that inventor’s state of mind was not signaling the use of single standard probe, hence best mode description of their invention does not require of the use of single standard probe. Another argument against the inventor was that they concealed information regarding the use of Rnase treatment as the preferred method of practicing the patent. The inventors made no attempt to explain in the application why Rnase was used as standard protocol in the experiment. It was contended that Rnase was not needed all the time. It was not the best mode for the patented process. Hence, Court did not accept the University’s contention and held that if Rnase is needed in some cases, but not all. In cases where the
relevant in determining the best mode of practicing the invention. The frame of mind of the inventor regarding his contemplated mode of practicing the invention decides it all. If at the time of filing of patent application the inventor had in mind any better mode than the one he described in the application it amounts to concealment of the best mode to practice the invention. Such situation leads to non-fulfillment of the requirement of written description. However In *Evans medical V. American Cyramid* it was held that failure to describe the best of practicing the invention in the patent application could be compensated by depositing the invention before the grant of patent. The Court has considered the date of patent grant as the right time to determine the state of mind of the inventor, instead of the date of filing the patent application. Therefore if the initial patent application did not comply with the best mode requirement, later but before the grant of the patent the inventor can amend the application or may prefer to deposit the invention to comply with the best mode requirement.

In case of biotechnology inventions it may not be accurately possible to describe the invention and to disclose the best mode of practicing the invention. Therefore the deposit of invention is deemed to serve the purpose of satisfying the requirement of description and best mode of practicing the invention. Hitherto the law relating to written description state of mind of the inventor is unclear at the time of the filing of the patent, it may still be necessary to explain the exceptional situation in order to fulfill the best mode requirement.

534 The patent was on a procedure for the development of an cellular antigen which could be used in vaccines for Bordetella pertussis (B pertussis) otherwise know as whooping cough. Plaintiffs brought infringement suit against defendants for infringing their patent. Defendants counterclaimed that the patent has not satisfied best mode requirement. Defendants contended that plaintiffs have concealed a best mode of practicing the invention by not describing Bbos. Bbos was the best antibody for the purification process described in the application. Initially in the patent application the inventor described the antibody that they used as “a monoclonal immunoglobulin specific for Adenglate cyclase associated protein (ACAP).” Later inventors made a biomaterial deposit. It became apparent that the antibody Novotny actually used was “BBos”, a specific antibody belonging to the ACAP class. Defendants stated that inventors know that BBos was the best antibody suitable for the process they described in the invention. Hence they intentionally concealed the best mode of practicing the invention.

The argument of the inventors was that biomaterial deposit that they made afterwards and amendments made to patent application before the grant of the patent has satisfied best mode requirement. Court rejected defendant’s argument by saying that defendants have not proved with evidence that the inventor’s state of mind at the time of filing patent application was signaling Bbos use. However inventors deposited biomaterial used for the invention before the grant of patent, that is sufficient to satisfy the best mode requirement. The defendants have not proved that the inventors had no state of mind to use Bbos at the time of filing the patent application. The Court concluded that the deposit of the invention and the amendments made to the patent application before the grant of the patent fulfilled the requirement of best mode. See Tressa Jennifer James, Implications of the best mode requirement on patents involving biotechnology, Houston Business and tax Law Journal, University of Houston Law Center, 2001-2002.
was shaped in a traditional way. However the approach of the Federal Circuit in the decisions that it has made in the recent times reflects its intention to modify the existing patent law in order to protect modern technological innovation. Federal Circuit has set new trends in applying written description standards to biotechnological inventions. 

**Departure from old practices of written description and new approaches in patent law: the current status.**

The current state of the written description requirement with respect to biotechnology has been shaped in large part by two recent decisions of the Federal Circuit. The first of these cases, *Fiers V. Ravel*\(^{535}\) decided in 1993. This decision served as the starting point for modern written description jurisprudence. The invention relates to a DNA coding for human fibroblast beta interferon (IF), a protein that promotes viral resistance in human tissue. Three persons filed patent application for the same invention in the United States. Before filing patent application in the United States all the three filed patent application in different countries. On the basis of their prior patent application all the three who filed application in the United States claimed priority.

Priority will be given to a person who filed the patent application with complete disclosure of the invention. Here the issue before the Court was to decide who first filed patent application with complete disclosure of the invention. Person who able to describe the invention with completes disclosure would get priority. It was observed that Sugano one of the applicants has disclosed the complete DNA, sequence of the protein as well as a method for obtaining the DNA in his application filed in Japan on March 19, 1980. Ravel another applicant filed his first application on 21\(^{st}\) November 1979 in Israel earlier to Sugano and Fiers. But he did not disclose the complete sequence in that application. Fiers also did not disclose complete sequence for DNA in his first application.

The assumption is that whoever discloses the complete structure of a DNA can be said to have invented the DNA by isolating and purifying it. Mere identification of DNA is not enough; the written description must detail the structure of the DNA with its specific functions. Moreover the disclosure should detail the methods of making and using of the invention. The patent office decided that Sugano’s patent application

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\(^{535}\) 984 F.2d 1164 (Fed. Cir. 1993)
describing complete DNA sequence was eligible to be given priority above Fiers and Ravels applications. The Federal Circuit affirming the patent office decision articulated several important principles relating to the written description requirement. Federal Circuit took this opportunity to evolve modern standards of the written. The Court has laid down following standards of written description with reference to biotechnology inventions.

a) Merely claiming DNA and a method for isolating it did not demonstrate that the inventor is in the “position of the DNA”.

b) Disclosure that represents a wish or arguably a plan for obtaining the DNA does not satisfy written description requirement.

c) Adequate disclosure of DNA requires a precise definition, such as by structure, formula chemical name or physical properties.

d) Only the person who conceived an invention could disclose the invention in such manner to satisfy the written description requirement.

e) What is not conceived cannot be described and for an invention, which does not satisfy written description requirement, no patent can be granted.

f) The description must reasonably convey that the inventor is in the possession of the invention at the time of patent application.

It was observed that Ravel and Fiers have not described the invention in their patent applications in order to satisfy the written description requirement. Hence they are not eligible to get priority of such patent application. But Sugano did satisfy the written description requirement by clearly describing the complete and correct DNA sequence coding for human fibroblast interferon in his patent application. Sugano was held entitled to claim the priority of his earlier application. In the true sense written description requirement will only be satisfied when the inventor describes the invention in clear and


complete manner along with methods of making and using it. It was held that an adequate description of biotechnology inventions like gene, DNA, recombinant plasmids and microorganisms requires a precise definition, structure, formula, chemical name or physical properties of the invention.

It is felt that the Court of Federal Circuit has structured this new standard of law on written description to strengthen the patent law on biotechnological inventions. The Court has established an extremely high standard of specificity necessary to satisfy written description requirement. In fact this strict standard of written description was required to check the biotechnology patent applications. This standard has been evolved to prevent patent applications claiming genetic material by providing mere information as to the invention. This standard was very much required keeping in mind the enormity of patent applications claimed genetic materials such as DNA. After this decision the written description standard has been strengthened particularly with reference to biotechnological inventions. Now patent offices have adopted these standards in screening the patent applications claiming biotechnological inventions. Inventor who describes the complete structure and sequence of the invention in a clear and comprehensive manner along with the method of making and using it is said to have satisfied the written description requirement.

The Federal Circuit in has continued the same approach in *The Regents of the University of California V. Eli Lilly and Company* 539 The invention was relating to recombinant plasmids and microorganisms that produce human insulin: a protein involved in the regulation of sugar metabolism. The patent describes the cDNA (complementary DNA) sequence of rat insulin. However the claim in the patent claims was directed to vertebrate and mammalian and human cDNA coding for insulin. It was argued that rat and human genes are very similar therefore in the light of knowledge of a gene or cDNA coding for insulin in rat it would be easy to obtain corresponding gene of cDNA coding for insulin in human. It was contended that the disclose of insulin cDNA in a simple species necessarily implicated the possession of the insulin, cDNA of all species

539 119 F.3d 1559 (Fed. Cir. 1997)
within the genus of the disclosed species.\textsuperscript{540} Even the method to obtain cDNA coding for insulin in both rat and human are similar. The validity of the patent was challenged by Lilly for failure to provide an adequate written description of the invention.\textsuperscript{541}

It was observed that the patent application discloses a general method to obtain cDNA coding for insulin in human along with amino acid sequences of human insulin, but it did not describe human cDNA and its relevant structural or physical characteristics. The Court of Federal Circuit held that a general method of producing human insulin cDNA and a description of the protein it encodes i.e., insulin along with amino acid sequences, does not provide a written description of claimed human insulin cDNA\textsuperscript{542} Therefore the application does not give description of human cDNA structural or physical characteristics. There is no sequence information indicating which nucleotides constitute human cDNA. It was further held that for the same reasons, the specification also contained inadequate written description to support genus claims covering cDNA of vertebrates or mammals which otherwise could have been supported by describing the sequence of a representative number of cDNA falling within the scope of the genus, or by describing structural features common to the genes.

The Court viewed that claimed genera of vertebrate and mammalian insulin cDNA were not described by the listing of a single specific nucleotide sequence, that of rat insulin cDNA\textsuperscript{543} The Court concluded: “an adequate description requires a kind of specificity usually achieved by means of the recitation of the sequences of nucleotides that make up the cDNA.” A patent application claiming biotechnology invention in particular an invention relating to genetic material such as DNA, must describe the structural and physical properties of the invention with precise definition, structure, protein it encodes, amino acid sequences and also its nucleotide sequences in order to satisfy the written description requirement. With respect to DNA sequence claims the


\textsuperscript{543} Ibid
written description requirement is only satisfied where there is a disclosure of the precise sequence of nucleotide comprising that DNA.

Going a step ahead from *Fiers V Ravel* the Court standardized the written description requirement by holding that the written description requirement is only satisfied when the precise sequence of nucleotide comprising that DNA along with its physical and chemical properties. To claim cDNA its physical and chemical properties must be described, describing a general method to produce cDNA does not describe the cDNA. At the same time describing the protein that a cDNA encodes does not describe the cDNA. What is required is the description of the cDNA itself with its physical and chemical properties. The invention in Lilly describes the method of producing cDNA and the protein that it encodes. But the claim was for cDNA itself, whose physical and chemical properties and corresponding nucleotide sequences are described. Hence it was held that the application fails to give complete description of the invention claimed.

However in *Amgen Inc. V. Hoechst Marion Roussel, Inc*, the invention concerned recombinant technology related to the production of non-naturally occurring Erythropoietin (EPO) and to vertebrate cells and mammalian cells used in the production of EPO. The patent disclosed methods of producing EPO using hamster and monkey cells adequately described. Amgen has described the production of EPO using hamster and monkey cells and claimed patent on the production of EPO using any vertebrate or mammalian cells. Testimony of witness in support of the claims says that; though there might be variations in applying the disclosed methods to other vertebrate or mammalian cells, a person skilled in the art would have found the differences to be minor.

The Court took the view that vertebrate and mammalian are known biological materials and ordinary skilled person could easily comprehend the invention. Amgen’s claims referring to cells of vertebrate and mammalian that produce EPO provided sufficient information to a person skilled in the art to recognize and identify the members of the genera of vertebrate cells and mammalian cells. The Court concluded that description of a process of producing the claimed EPO in two species of vertebrate or

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544 314 F. 3d 1313 (Fed. Cir.2003)
mammalian cells constituted adequate written description of the claimed EPO made using any member of the genus of vertebrate or the genes of mammalian cells. The Court observed that the description enables one skilled in the art to practice the invention.

The Federal Circuit by diverging from its earlier decision of *Lilly* where it held by disclosing production of a protein in the cell of one mammalian inventor cannot claim all the vertebrate or mammalian cells held that description of the production of EPO using monkey and hamster cells is adequate enough to enable one skilled in the art to practice the invention by using the cells of other vertebrate or mammalian cells. 546 Cases such as *Eli Lilly*, *Enzo* and *Amgen* have clarified the subject of written description. It is now clear that proper deposit of biological material could adequately describe the invention in fulfillment of the written description requirement. The objective behind the written description requirement is that the description of the invention should enable a person skilled in the art to recognize what is claimed and to practice the same. As far as biotechnology inventions are concerned it is a settled principle that proper deposit of the invention should adequately describe such invention. Hence the deposit of the invention is considered as necessary in order to satisfy the written description.

**Written description of biotechnology patents in the European Union**

In the European Union the EPC states that patent applications must disclose the invention in a complete and clear manner to enable a person skilled in the art to reduce the same to practice. The convention 547 says that the claims in the patent application must be supported by the description. The claim to the invention needs support in the form of written description disclosing the method to make and use the invention. The approach of the Europe is no different with that of the U.S. 548 The patent application must give complete specification of the invention in order to ascertain the nature of the invention. 549

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548 See section: 83&84 of EPC

The description must be such that a person of ordinary knowledge of the subject would at once perceive, understand and be able practically to apply the discovery without the necessity for making further experimentations.\textsuperscript{550}

In the early days of European patent Convention there was little case law on the issue of adequate or sufficient disclosure of the invention. In the past few years there have been a number of cases that show development of law in this area.\textsuperscript{551} The requirement of sufficiency of disclosure is being applied to biotechnology inventions. The first biotech case where sufficiently of disclosure of the biotechnological invention was considered is that of Genentech v. Welcome foundation.\textsuperscript{552} This case is of significance in the area of biotech patents as it laid down some important principles with regard to the fulfillment of the requirement of sufficiency of disclosure in the European Union. The invention claimed was a plasmid suitable for transforming a bacterial host, which included an expression control sequence, or “regulon” which could enable the expression of foreign DNA as a recoverable polypeptide. The inventor has described a method to enable plasmids to control the expression of polypeptides in bacteria. However the claim was for the method to control the expression of polypeptides in the general class. Inventors argued that the method is of general application in the general class applicable to other bacteria and plasmids.

Objections of insufficiency of disclosure were raised to the broad term ‘bacteria’ which it was felt, could include unsuitable species or variants. Opponents contended that the description was only with regard to enabling plasmids express polypeptide in bacteria, the inventor have not described how it can be done in case of other bacteria or plasmids in the general class, which they claimed. The Board took the view that the unsuitability of unspecified variants was immaterial as long as the skilled person through the disclosure or on the basis of common knowledge knew suitable variants. It was held that one need to describe only one way to put the invention into practice as long as that method is of general application through out the full scope of the claim. It was held that there was no reason to believe that the general method described in the application would

\textsuperscript{550} See Hills V. Evans (1862) L.J. Ch. 457, 463
\textsuperscript{551} See Dr. Swaminathan, K.V, An introduction to the guiding principles in the decisions on patents law, Bahri brothers, Delhi, First Edition, October 2000. Pg. No. 348
not work equally with any plasmids, bacteria in the general class. It was concluded that the invention had sufficiently disclosed at least one way in which skilled person could carry out the invention. The Board laid down following important principles to be considered in determining the sufficiency of disclosure of biotech inventions.

1) The extent of monopoly claimed should correspond to the technical contribution made to the art to justify his claim.

2) General method applicable to whole class need not described with reference to particular case.

3) When there is no reason to believe that the general method would not work equally with other members of the general class, a patent cannot be reject for the lack of sufficiency of the disclosure.

When a general method applicable equally to the whole class the inventor need not described the method with respect to every member of the class. The evolving of a general method itself is a contribution to the state of the art which entitles the inventor to claim monopoly over such general method. In Harvard Onco-mouse that runs on parallel lines with Genentech case agian the sufficiency of disclosure of the biotechnology inventions was discussed. The invention was a method for producing a transgenic non-human mammalian animal having an increased probability of developing neoplasm by introducing an activated oncogene sequence into a non-human mammalian animal at a stage no later than the eight-cell stage. The applicant also claimed oncomouse; the transgenic non-human animal resulted from the above method. Applicants in support of their claim cited Genetech’s case, where the invention

553 By rejecting the opponent’s contention it was viewed that the inventors made a significant contribution to the state of the art in evolving a method applicable to the general class in expressing polypeptide that makes them eligible to the patent.
555 The examining division held that the claimed invention refers to all non-human mammalian animals, whereas the invention described in the examples has been performed only on mice. The division refused the claims on the ground that one skilled person cannot practice the invention on all other kinds of non-human mammalian by following the description in the patent application. The division opined the claims as broadly covering all non-human mammals without adequate and sufficient disclosure as required under article: 83 and 84 of the European Patent Convention.
described a general method to express polypeptide in bacteria and claimed the method to be applicable to all other class of species of bacteria.\(^{556}\)

There was opposition to the patent contending that the claim is too broad. It was argued that inventors are claiming method for producing a transgenic non-human mammalian by disclosing the method of producing mice. It was also argued that the inventors did not disclose the method of practicing the invention in other mammals. The Board of Appeals viewed that the mere fact that a claim is broad is not a ground to refuse the patent considering the application as not complying with the requirement for sufficient disclosure, unless there exist some serious doubts on the invention based on verifiable facts. The Board considered Genentech’s case as cited by the applicants as relevant in the present case. The Board identified the similarity between two cases; The Board convinced that the invention clearly indicates how the skilled person can practice the invention by incorporating an activated oncogene sequence into the genome of a non-human mammalian, disclosed as it does in case of mouse.

The Board viewed that the invention describes the method of incorporating and expressing an oncogene to produce oncomouse. It ensures that invention can be practiced successfully on mice. The described method can be applied in producing other non-human mammalian in the same fashion. To claim other non-human mammalian the inventor need not describe with reference to particular non-human animals. The description with reference to mice is enough to achieve the invention on other non-human mammalians. The Board took support of at least one evidence (palmiter & Brinster, (1986) 20 Ann. Rev. Genet. 465-499) which suggested that one skilled in the art might very well be able to carryout the invention on non-human mammals other than mice. Finally the Board concluded that the description of producing onco mouse is adequate and sufficient disclosure to practice the invention on other non-human mammalians.\(^{557}\)

Therefore it can be said that when a general method has been described that is applicable to a class generally, the inventor need not describe the practice of the

\(^{556}\) The examining division held that Genentech decision is irreverent in the present case and refused to grant patent on the ground of inadequate and insufficient disclosure.

invention with respect to every member in the class. It is a well-established principle in Europe that patent monopoly should correspond to the technical contribution to the society. At the same time it is also a well-established principle in Europe that description of practicing the invention with respect to any one or two members of the class is enough to claim monopoly over the class. This approach has been followed in several cases. Many a times EPO has reasserted the above said principle. In Exxon/Fuel oils\textsuperscript{558} the Technical Board of Appeal held that the claims in the application must be supported by the description of the invention and also the method to make and use it. The Board reiterated the above well-established principle in saying that “the extent of the patent monopoly should correspond to the technical contribution to the art in order to justify the claims.”\textsuperscript{559}

**Enabling disclosure and priority date**

Patent applications may claim priority of earlier patent applications on the same subject matter. However priority date of the earlier application shall be given only when the earlier application describes the inventions in a sufficient manner to enable a skilled person in the art to practice the invention. Inventors are entitled to claim the priority only for what they have disclosed in the earlier application. What they have not disclosed for that no priority shall be given. The reason is that what is not conceived that cannot be described, what is not described for that no priority can be claimed. Further if the earlier application does not provide adequate description of the invention than also no priority will be given though the later application claims exactly what is defined in the earlier application. The features of the invention must be described in the prior application adequately and unambiguously in order to claim the priority of the prior application in the later application. In *Collaborative research application*\textsuperscript{560} it was held that a patent application is entitled to priority with respect to an invention, which was adequately disclosed in the prior application. It was viewed that the subject matter of both the

\textsuperscript{558} (T/409/91) (1994) O.J. EPO 653
\textsuperscript{560} Decision T81/87 (1990) O J EPO 250.
applications must be clearly identified though identical wording is not required. Priority can be only claimed to what is adequately defined in the earlier application.\textsuperscript{561}

Again in \textit{Asahi Kasu Kogyo’s application}\textsuperscript{562} the question of priority had come to the fore fronts. The claim was for a protein known as Human Tissue Necrosis Factor (HTNF) produced through recombinant DNA technology. This protein is useful in reducing tumors in humans. Applicants filed an application for patent in EPO for which they claimed priority of their earlier Japanese application, which did not provide any description of method to obtain it. Lord Oliver speaking for the House of Lords took the view that in order to claim priority, Japanese application should have described the invention enabling the skilled person in the art to practice the invention, which it did not therefore no priority could be claimed. It was further viewed that if the earlier application describes a part of the invention and the remaining part is described in the later application in such cases also having not described the invention adequately no priority of the earlier application can be given. In the present case Japanese application has not described the invention adequately, it was not an enabling disclosure. Therefore it was concluded that the Asahi Kasai Kogyo’s EPO application couldn’t claim Japanese application, as Japanese application has not made an enabling disclosure of the invention.

The written description of the invention plays an important role in determining the priority of the application. The disclosure of biotechnology inventions was elaborately discussed in \textit{Biogen V. Medeva}.\textsuperscript{563} The claims were for genetically engineered DNA molecules coding for a protein crucial in producing vaccine against the Hepatitis B virus. Inventors produced recombinant DNA molecule coding for a protein useful in the production of vaccine for Hepatitis in the host bacterium. Since the coding sequence was not known, inventors used large fragments of Hepatitis virus (Dane particle) to produce recombinant DNA. Applicants filed their first application (Biogen 1) in Britain. On the basis of first application they claimed priority in the EPO application filed later. The

\textsuperscript{562} (1991) R.P.C. 485. HL
\textsuperscript{563} (1997) R.P.C 1. H.L
issue here was whether the first filed application adequately described the invention in order to claim priority of it in the later application.

The Biogen1 application has described the method to produce the said recombinant DNA coding for a protein useful in preparing a vaccine against Hepatitis virus. Meanwhile the applicant’s claim in the later application was broad enough to cover any recombinant DNA molecule, which expresses Hepatitis-B virus antigen genes in any host bacterium. Infact the application also claims any method of manufacture to achieve the expression that the inventors obtained. Lord Hoffman speaking for the House of Lord took the view that “the concept of an enabling disclosure as the core principle of patent law.” His Lordship has set forth the present law on the adequate disclosure of inventions in highlighting the implications of enabling disclosure. In the views of Lord Hoffman disclosure of inventions has got following implications.

1. Firstly it provides support to the claim of the invention
2. It fulfills an essential requirement for the validity of the patent application
3. It enables a skilled person to perform the invention as described by the inventor.
4. If the disclosure is not enabling, it is a valid ground to the revocation of patent
5. At the same time non-enablement is a valid ground for refusal of patent grant.

Therefore inventor must adequately describe the invention in a clear and complete manner, which shall be sufficient enough to a person skilled to practice the invention. The Court States that the monopoly claimed shall be weighed with the Contribution to the state of the art. Further the claims should be supported by an adequate, clear and complete disclosure that is sufficient enough to enable a person skilled in the art to perform the invention. Lord Hoffman said;

“Considering the technical contribution to the art, which Professor Murray made in 1978 and disclosed in Biogen1, it seems to me that it consisted in showing that despite the uncertainties which then existed over the DNA of the (Dane particle) Hepatitis virus in particular, whether it included recombinant techniques could nevertheless be used to make the antigens in a prokaryotic host cell. I accept that the method was shown to be capable of making both antigen and I am willing to accept that it would work in any otherwise suitable host cell. Does this contribution justify a claim to a monopoly of any recombinant method of making the antigens? In my view does not the claimed invention
is too broad? Its excessive breadth is due, not to the inability of the teaching to produce all the promised results, but to the fact that the same results could be produced by different means”.

Eventually it was held that Biogen 1 did not support the invention as claimed in the European patent and that it is therefore not entitled to the priority date of Biogen1. It was held that the specification must disclose the invention in a clear, complete manner, which is sufficient enough to enable a person skilled in the art to practice the invention. In the present case Biogen1 application description was not sufficient enough to enable a person skilled in the art to practice the invention on any recombinant DNA molecule to express the genes of any Hepatitis B virus antigen in any host cell. The Court concluded that the compliance with the adequate disclosure should be made on the date of the application, not on the date of the publication of the application. On the basis of above discussion principles relating the written description in the European Union can be summarized as follows.

1) The extent of the monopoly should correspond to the contribution made by the inventor to the state of the art in order to justify the claims. 564
2) There shall be some support to the invention in the form of written description. 565
3) The written description should enable a person skilled in the art to practice the invention without any under experimentation. 566
4) Priority of earlier application can be claimed only when earlier application adequately describes the invention referred in the later application. 567
5) What is described adequately in the prior application for that only priority can be claimed, what is not described for that no priority can be claimed. 568

Written description of biotechnology inventions in India.

India is no different as far as written description of biotechnology inventions are concerned. The patent Act states that the patent application shall be accompanied by the complete specification or provisional specification of the invention. The application must be accompanied by provisional or complete specification. The specification must describe the invention, its operation or use with the help of drawings if necessary. If the applicant does not give complete specification of the invention at the time of filing the application within twelve months he can file complete specification. Further the specification must disclose the best mode method of performing the invention, which is known to the applicant. In case of claiming the priority of an earlier filed application, priority shall be given only when the earlier application does give the complete specification of the invention to enable a person skilled in the art to practice the invention in the best possible way. Further the specification shall define the scope of the claimed invention with claim or claims on the invention.

The patent Act was amended in 2002 keeping in mind the necessity of deposit of invention in case of biotechnology patents. The amendment recognizes identifies the Budapest Treaty for facilitating the deposit of biotechnology inventions for the sake of patent procedure. A biotechnology patent application must be accompanied by a deposit of the invention in any recognized depositary institutions as recognized by the government of India through notification in the official gazette. The name address of the depository institution and the date of the deposit shall be mentioned in the application. Further the access number issued to the deposited invention shall also be mentioned in the application. There is no case law development with regard to the fulfillment of written description requirement by biotechnology inventions in India. Since the biotechnology industry is in infant stage in India and only since 2005 India is granting

569 Ibid: Section: 9 Provisional and complete specification.
570 See: The patent Act of India, Section: 10 Contents of specification
571 Ibid: Sub clause: 4(b)
572 See: Supra Note. No. 89: Section: 11 Priority dates of claims of a complete specification.
573 See Patents amendment Act 2002.
patents on biotechnology invention there is no substantive development of law in this regard. However the disclosure of the invention through specification while making the patent application is a prerequisite for the grant of patent.\footnote{574 See: Dr. Ramakrishna, Biotechnology & Intellectual property rights, National Law school of India University, Bangalore, First edition, 2003, Pg. No. 38-39}

In contrast to the patent law of the United States of America and the European Union the patent Act of India mandates the disclosure of source and geographical origin of the biological material used in producing the claimed biotechnology invention.\footnote{575 The biological diversity Act\footnote{576 See: Biological diversity Act, 2001} read with the patents Act\footnote{577 Patents Act of India as amended in 2002} states that the use of biological resource in producing the claimed biotechnology invention shall be disclosed and mentioned in the patent application in order to share the benefits of the patents to the geographical regions, which conserved the source. The TRIPS agreement does not require the mentioning of the origin of the resources, however the convention of the biological diversity (CBD) states that the origin of the biological resources used shall be acknowledged and the geographical regions shall be given a share in the benefits of such usage. In fact it is crucial issue where the CBD and the TRIPS do contradict. However being ratified both the agreement India does provide in its patents law that the patent application claiming a biotechnology invention is complete only when it discloses the source of the resources used.

Written description of the invention is a core principle of patent law. An invention shall be described in a clear and comprehensive manner in order to enable a skilled person in the art to practice the invention. The requirement of written description has been applied to biotechnological invention in varied form. In case of biotechnological invention the written description has to describe the chemical and physical properties of the inventions along with its structure and sequences. However, in every case, it is not possible to describe a biotechnological invention in a clear and comprehensive manner. Due to the fact biotechnological inventions are living beings it may not be possible to give describe the invention as required under the patent laws. So the practice of depositing the claimed invention has been adopted to satisfy the written description.
requirement. It is accepted that deposit of the invention fulfills the requirement of written description requirement. A deposit of the invention serves as an additional security to the inventor in claiming the patent and also helps in rebutting claims invalidity against the patent.

A biotechnology invention, which satisfies the requirements of novelty, non-obviousness, utility and written description is patentable provided the invention falls within the range of matters, which are patentable. The patent law states that a biotechnology invention, which is not a patentable subject matter, cannot be patented through it satisfy the requirements of patentablity. It is a settled principle in the patent law that a biotechnology invention is patentable only when it does fall within the purview of patentable subject matter. There arise difficulties in determining the novelty and non-obviousness of biotechnology inventions. The fact that biotechnology inventions are living beings, which are manipulated from their earlier natural existence position to possess certain, desired characteristics gives rise to certain difficulties. As per the present patent law it is believed that things or living beings existing in the nature are products of nature, which are not patentable. It is also believed that addition of human ingenuity to these products of nature renders them products of man. Therefore the difference between products of nature and product of man and the point from where a product of nature becomes product of man is very significant in deciding the novelty and non-obviousness of biotechnology inventions. However the utility of biotechnology inventions is undisputed. Further the satisfaction of the requirement of written description is also problematic in case of biotechnology inventions. It is felt that it may not be possible to describe a biotechnology invention in a clear and complete manner. Therefore there felt difficulty in satisfying the requirement of written description. Hence in order to compensate the non-fulfillment of written description requirement deposit of the invention is recommended. It is believed that deposit of the invention serves the purpose of describing the invention in order to enable the person skilled in the art to practice the invention in the best possible way. With the coming into being of the TRIPS agreement throughout the world patent laws have been harmonized. Now in all the member states of the TRIPS agreement the requirements of patentability of biotechnology inventions are uniform. Therefore a biotechnology invention satisfying the requirements of novelty,
non-obviousness, industrial application and written description or deposit of the invention is patentable throughout the world.