INTRODUCTION:

Biotechnological Patent and its brief evolution:

“The patents add fuel of interest to the fire of genius.”

Abraham Lincoln

The inventions in biotechnology cut across issues related to science, ethics, legal and complexities of international trade. The term ‘biotechnology’ came into use in mid 1970s. Technology has a wider scope and hence biological resources can be patented. Biological resources of developing countries are used as raw materials and this is a serious threat to the developing countries. Moreover it has an adverse effect on ecological balance.

The CBD refers to sovereign rights over resources of countries. The TRIPS agreement refers to patent and monopoly rights for individual firms. Some of the provisions of CBD may clash with that of the TRIPS. Conserving biological diversity and using biological resources in a sustainable manner is very essential. The Biological Diversity Act, 2000 in conformity with CBD has been formed by the Indian Parliament.

The UN Declaration on human environment states that man has fundamental right to freedom, equality and adequate conditions of life in an environment of equality. Right to healthy environment is a basic human right.

“In no other area are patentability issues as controversial as in biotechnology.”

Biotechnology uses biological systems, living organisms or derivatives to modify products for specific use. In order for a patent to be issued, there are three requirements that must be

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2 WTO in the New Millennium at 738.
3 Sarat Sahu, *ENVIRONMENTAL PROTECTION IN RELATION TO PATENTABILITY OF BIOTECHNOLOGY* 243 (2000)
4 Benoît Battistelli, EPO President.
fulfilled: Inventive step, Novelty and Industrial application. Biotechnological patent is a patent relating to an invention in biology.

In 1873, Louis Pasteur got patent in yeast. In 1980, it was decided in Diamond Vs Chakrabarthy that all life forms under the sun are patentable if human intervention is present. In 1988, first entire animal to be patentable was discussed in Oncomouse case. Whether human genes are patentable or not was the issue considering Relaxin case in 1991.

The traditional biotechnology was largely confined to the plant and animal breeding and Industrial microbiology. All these have been making a rapid shift. Protoplast fusion, Hybridism technology and Recombinant DNA technology have changed the whole scenario of life forms. Human Genome Project which was launched in 1990 in one of the important landmarks in field of genetics. Successful cloning of mammals in another landmark. Howsoever cloning of human beings is still a gray area.

In 1962, Crick, Watson and Wilkins were awarded with Nobel Prize for deciphering the structure of DNA. This gave rise to the science of genetic engineering. In 1980s regular discussion took place regarding mapping of human genome. The Genome Project was formally chartered for better understanding of human health. Through research genes have been identified that are responsible for chronic diseases. Researchers have also learnt how to modify certain hereditary characteristics including human beings. It has been strongly advised by scientists that the Human Genome Project should not be patentable subject matter since it is a part of our universal heritage.

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5 Defined in the Convention of Biological Diversity.
LEGAL FRAMEWORK AND PROTECTION FOR BIOTECHNOLOGICAL INVENTIONS:


Biotechnology patent application poses several challenges, both legal and technical.\textsuperscript{11} All the requirements of biotechnology patents are mentioned in 35 U.S.C\textsuperscript{12}. For patent application to be considered as patent protection, it should be a patentable subject matter\textsuperscript{13}, novel\textsuperscript{14}, adequately disclosed\textsuperscript{15}, non obvious\textsuperscript{16} and useful.

Patentable subject matter

Asexually and sexually reproduced plant can be patentable. Plant breeders are given plant protection by Plants Variety Act, 1970\textsuperscript{17} and Plants Patent act 1930\textsuperscript{18}.

Novelty

"It is established patent practice to recognize to recognize the novelty for a natural substance which has been isolated for the first time and which had no previously recognized existence."\textsuperscript{19}

If it is in prior use, it cannot be patented. As of now, novelty is not that great an issue in patenting\textsuperscript{20}. This is because of the technical newness\textsuperscript{21}. Howsoever, once the technology matures, it will be a challenge.\textsuperscript{22}

Inventive step

"Whenever anything inventive is done for the first time it is the result of the new idea to the existing stock of knowledge. Sometimes, it is the idea of suing established techniques to do

\textsuperscript{11} Jeffrey G. Sheldon, \textit{How To Write Patent Application} 14-2 (1992) [Hereinafter as Sheldon]
\textsuperscript{12} Michael Eipsten, \textit{Modern Intellectual Property} 765 (1991) [Hereinafter as Modern Intellectual].
\textsuperscript{14} \textit{Patent Act}, \textit{Id.}, at 102.
\textsuperscript{15} \textit{Patent Act}, \textit{Id.}, at 112.
\textsuperscript{16} \textit{Patent Act}, \textit{Id.}, at 103.
\textsuperscript{17} 7 US.C 2321-2582(1988).
\textsuperscript{20} \textit{Modern Intellectual, supra} note 12.
\textsuperscript{21} \textit{Modern Intellectual, Id.}
\textsuperscript{22} \textit{Modern Intellectual, Id.}
something which no one had previously thought of doing. In that case, the inventive idea will be doing something which people had wanted to do but could not think how. The inventive idea would be the way of achieving the goal. In yet other cases, many people may have a general idea of how they might achieve a goal but not know how to solve a particular problem which stands in their way. If someone devises a way of solving the problem, his inventive step will be that solution, but not the goal itself or the general method of achieving it.”

Obviousness

Whether biotechnological inventions are subject to same standard of obviousness as inventions is a question raised because of its newness. There is no change in legal standard of obviousness though the practitioners may be highly skilled or howsoever sophisticated the invention is.

Adequate disclosure

The description, enablement and the best mode of requirements are to be disclosed according to the title in USC. Inadequate disclosure is considered as bad faith or fraud. It can be invalidated on that ground. But it is very difficult to disclose everything in detail. In 1970 it was decided that all in public depository, there should be disclosure. The public should have idea about this to raise any opinion and for the sake of transparency.

Utility

There should be some practical use and commercial markability is not required. This criterion is not difficult to demonstrate but applications have been rejected on this ground and that is very common. Claims regarding treatment of human body, or animal by therapy, surgery or diagnosis do not have industrial application. The UK Patent Office would be swayed by the views expressed by the US Patent Office, that there requires to be disclosed a “specific, substantial and credible utility”.

23 Biogen Inc v Medeva plc (197) R.PC. 1 [Hereinafter as BIOGEN CASE]
24 BIOGEN CASE, Id.
25 BIOGEN CASE, Id.
26 In re Argaudelis, 434, F. 2d.1216 (Fed Circuit. 1985).
27 Barmag Barmer v. Murata Machinery Ltd, 731 F. 2d 831 (Fed Cir. 1984)
28 SHELDON, supra note 11.
29 Section 4(2), The Patents Act 1977 [Hereinafter as THE ACT].
The biotechnology sector has been identified as one of the most promising sectors for economic development by Stockholm European Council.  

“It is easy to focus on the contentious issues surrounding biotechnology patenting, such as the criteria for patenting plants and animals, the patenting of gene sequences and morality issues and forget that the majority of biotechnology patent applications will be decided on the basic issues of novelty, inventive step and industrial application.”

It was difficult for the authorities to keep pace because the research was at a very great pace. Agreement on the European Patent Convention in 1970s resulted in harmonization of requirements of patentability. During 1980 and 1990s it became clear that the law was interpreted differently. This resulted in the Directive being proposed. The directive gave a clear distinction about what is patentable and what is not. Only inventions that combine a natural element with a technical process, and is isolated or produced for industrial application can be patentable. Patents may claim plant genera or species but cannot claim individual varieties.

Publicly funded science should be commercialized according to U.S Congress. Thus in 1980s intellectual property rights were decentralized from government to research institutions. There is a global agreement with Article 4 of the Universal Declaration on the Human Genome and Human Rights which states ‘The human genome in its natural state shall not give rise to financial gain.’ Still patenting is a contentious issue because there are several interpretations about what natural state means.

In the United Nations Declaration of Human Rights, Article 27 there is two commitments that many countries in the world have agreed to observe.

34 The ACT, supra note 29, Para 5 of Sch. A2.
35 The ACT, supra note 29, Para 4.
(1) Everyone has the right to participate freely in the cultural life of the community.

(2) Everyone who is the author has the right to the protection of the moral and material interests resulting from any scientific, literary or artistic production.  

The UPOV Convention governs plant variety rights, which allows the breeder to market the crop variety.  
The rule in USA states that unless there is a strong offence to public sensitivity, the commercialization of human cells and tissues are permissible. The European Parliament ‘Human Genome Analysis’ program stated that "there shall be no right to exploit on an exclusive basis any property rights in respect of human DNA".  

Section 101 and Section 103 states the TRIPS Provisions on Biotechnology. Article 27.1 of the TRIPS Agreement sets out those members shall provide patent protection to inventions in all fields of technology. Article 27.2 deals with also exclusions pertaining to public order, morality, health and environment. Article 27.3 lays down some exclusion from the purview of patent protection that members may provide.

Patenting would encourage commercial developing of genetic engineering. A written description of invention and how to make and use it must accompany the claim. This is called specification. It is very difficult to distinguish between micro organisms. They are complicated and not very easy to decipher. The invention should be defined and it should have utility. Specification according to Section 112 enables person skilled in art to make and use the invention.

The EC Biotechnology Patents Directive started life as a proposal in 1988. The aim was to establish improved and harmonized standard for protecting biotechnological inventions. Claims to proteins produced by recombinant DNA technology, together with associated processes have

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41 Saltus, R., BIOTECH FIRMS COMPETE IN GENETIC DIAGNOSIS 234 (12th Dec., 1986).
44 35 U.S.C 112(1976).
45 Id.
46 Id.
been the main subject of UK biotechnological patent litigation. One such subject has been mentioned in Genentech’s Patent.\textsuperscript{48} The DNA sequence for therapeutic protein has been discussed in Amgen v Transkaryotic Therapies.\textsuperscript{49} Article 53(a) EPC has been pressed into service as a basis for attacking biotechnological patents.

In T 19/90 Harvard/Oncomouse, the ethical issues were considered and certain guidelines were established involving suffering of animals and risks to the environment. Here such objections failed as also in Howard Florey Institute/Relaxin and Plant genetic systems/ Glutamine synthase inhibitors. In Leland Standford/Modified animal, one of the first EPO decisions applying and upheld a patent to a modified. There has been little scope for non-infringement arguments since biotechnological claims are functionally defined. KirinAmgen v Transkaryotic Therapies\textsuperscript{50} is one of the exceptions.

**Impact of Biotechnology Directive:**

Article 6.2 of the Directive provides a non-exhaustive list of material that is unpatentable on public policy or morality grounds. Article 8 to 11 of the Directive establishes special instances of infringement thought to be appropriate to ‘biological material’ as defined. Article 8.1 relates to product protection and Article 9 makes it clear that under no circumstances protection extends to those matters declared to be unpatentable under Article 5.1, namely ‘the human body, at the various stages of its formation and development, and the simple discovery of one of its elements including partial sequence of a gene’. Article 8 addresses the issue of the protection afforded the direct product of certain processes.\textsuperscript{51} Articles 2 and 4 provide that plant and animal varieties and essentially biological procedures for plant and animal breeding are not patentable. Article 3 and 5 of the Directive address the ‘product of nature’ issue. Article 3 explains the principles in Article 52 of EPC are to be applied in case of biological material. Article 5 of the Directive further refines in relation to biological material found in human body.\textsuperscript{52}

\textsuperscript{48} (1989) RPC 147 203.
\textsuperscript{49} (1995) OJEPO 388.
\textsuperscript{51} See Ch 6.
\textsuperscript{52} Trevor Cook, A USER’S GUIDE TO PATENTS, The EC Biotechnology Patents Directive (2002).
The issue of patenting human genes caused religious, political and legal debates all around. The conclusion of advocate general recommended that the action for annulment be dismissed and the ECJ upheld the conclusions and dismissed the action.

**DIAMOND VS CHAKRABATHY AND BEYOND:**

**Pre Chakrabarthy**
Importance of bacteria was discovered for the first time by Louis Pasteur in 1870. Penicillin which has antibacterial properties was a fungus and it was also discovered. Alexander Fleming got first patent for microorganisms for this. Patent is not for organism but for resultant. Louis Pasteur got patent for process of fermenting beer claim. Later there was a case of challenging grant of such patents saying it went against natural law. Vaccines usually have microbes in weaker form. After 1970s, there came up the concept of genetically modified bacteria, recombinant DNA Technology etc. In case of cross breeding of two or more varieties, you are never certain as to whether you will get the desirable traits but in case of recombinant DNA technology, your expected result is always certain. After this importance of microbiology increased. First patent on microbiology was filed in 1972. Before 1980, patents were given for inventions based on microbiological processes. Patents not granted for living entities per se as they were considered products of nature.

**Present case:**
In the case of Diamond Vs Chakrabarthy, live organisms were patentable for the first time. Chakrabarthy created an oil eating bacteria to be used in case of oil spills to decompose and hence clear out the oil spread. The code here in question was USC 35.

Article 101 states that whoever invents or discovers any new or useful process, machine, manufacture or composition of matter which kind of invention is particular in US, or any new or useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title.

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54 Case C-377/98.
Patent in this case was filed for three things

- Process patent for method of producing
- Patent for inoculums comprised of carrier material floating on water, such as straw.
- Patent for bacteria itself

Name and Composition of the bacteria is derived from pseudomonas genus and called as pseudomonas peptide. It contained at least two stable energy generating plasmids, each of the plasmids providing a separate hydrocarbon derivative pathway. US patent office gave patent on the first two things only. So appeal was for the last thing. In 1930, US legislated Plant act and it was thought that patent would be given to living things.

Chakrabarthy argued that intention of legislature was to grant for living things. Court agreed but said that living things did not mean microbes. Present law in US - Article 1, section 8 clause 8 includes both invention and discovery but then this cannot be patented.

**Aftermath**

It became a settled law after this case to grant patent to microorganisms. It worked as incentive to researchers to invent more. Law developed as microorganisms per se could be patented provided it is a result of human intervention. After this even EU started granting patents on microbes. But law was not settled. Discretion with the jurisdiction. Law developed case by case. There was no ‘non patentable subject matter’ for living things.

Before 1990, biological resources were common heritage of mankind. So nay country could use your resources and take benefit out of it. After 1992, countries came together and changed common heritage of mankind principle to national sovereignty principle, i.e., you need permission of the country concerned to use their resources. This concept was included in TRIPS too. Concept of Biological Diversity Authority also came into existence.

Two approaches exist when it comes to patentability of plants and animals and other life forms. The first approach favors patent protection for animal and plant inventions should be accorded adequate patent protection in the same way as inventions in other fields of technology. This would solve problems in developing countries. Patent protection for them transfers the technology and dissemination of state of art on plant and animals inventions. The second
approach denies patent protection for plant and animal inventions. Patent on life forms give rise to various concerns. With regard to micro organism, there is no rationale for distinguishing between plants and animals on one hand and micro organisms on the other. Since both are living things which cannot be invented but only discovered hence both should not be patentable.\textsuperscript{56}

The courts had not revived the older idea that some kinds of inventions should not be patented. Patent law says that any new or useful “process, machine, manufacture or composition of matter” can be protected by a patent. Some believe that the 1952 Patent Act abolished the exceptions stated. In the 1970s, inventors began filing more applications for biotech inventions. The public and some experts feared the idea of genetic engineering, and hence opposed patenting biotechnology.

In Diamond v. Chakrabarthy, the Supreme Court ruled that unforeseen new technology was not patentable and this made little sense, because patents were intended to protect unforeseen advances. The statement that the Patent Act covers “anything under the sun that is made by man,” comes from the legislative history of the 1952 Patent Act. The patent office after this case expanded the kinds of inventions it was willing to patent, to include plants, animals, some computer technology, and business methods. Neither the Supreme Court nor other courts have stopped this expansion.\textsuperscript{57}

PTO clarified what had been an inconsistent approach to patent living organisms. It was later clarified in Ex parte Allen case. The PTO stated that

“non naturally occurring non human multicellular living organisms, including animals to be patented subject matter within 35 USC 101”.

The PTO issued the first patent to transgenic animal, Harvard Oncomouse. Biotechnology was new then at the time of Chakrabarthy case and no one could predict that it would grow so exponentially in the next 25 years, the filing and granting of patents has increased tremendously since then.

\textsuperscript{56} Biotechnology Inventions and The Trips Agreement.
Polymerase Chain Reaction
It is hailed as one of the most important scientific technology to have been developed. It is used for detecting and cloning DNA sequence.

Genetically Engineered Crops
The herbicides are used in such a way that they do not kill the crops but they control and kill the weeds.

Primate Embryonic Stem Cells
Pluripotent is something that can develop into organ or tissue. The cells are isolated and sustain embryonic stem cells so that cell lines contain to proliferate in undifferentiated shell.

POST DIAMOND VS CHAKRABARTHY EXPERIENCE:
Ex Parte Allen Case
This case was decided by the BPAI. Because of disclosed unpatentable subject matter, the specification was rejected. BPAI stated that

“the examiner has presented no evidence that the claimed polyploid oysters occur naturally without human intervention neither do they occur naturally. The record leads to no conclusion other then that the oysters are non naturally occurring manufactures or composition of matter within the confines of patentable subject matter under 35 U.S.C101”.

It was obvious to one skilled in art and hence not patentable. Non naturally occurring, non human multicellular living organisms are patentable subject matter if they are not obvious to one skilled in art.

Claims encompassing human beings will not be granted patent protection. ‘Since the grant of limited, but exclusive property right in a human being is prohibited by the Constitution’. In 1987, the House of Representatives sought to place moratorium on the issuance of patents claiming genetically altered animals.

58 2 USPQ 2d. 1427 (BPAI 1987).
59 Id.
60 Id.
61 Id.
62 H.R. 3119, 100th Cong, 1st Session. 133 CONG REC H7206(1987).
Ex Parte Hibberd

Patent asked for a corn plant containing an increased level of an amino acid. It was held to be patented subject matter U/USC section 101. Since this ruling, utility patents are being granted to plants even though protection under PPA or PVPA is already available. No statutory exemptions in case of utility patents unlike PVPA where there is research exemption and farmers’ exemption. US statute grants to plant patentees the right to exclude others from asexually reproducing the plant or selling or using the plant so reproduced. Plant patent only protects clones or in other words, asexual progeny of a particular plant. A breeder through no particular efforts of his other than by accident develops a new plant which is nevertheless due to his activity should be entitled to patent as though he had deliberately planned the result achieved. Any use of plant which does not directly/indirectly involve asexual reproduction cannot be deemed to be infringement as patent on plant as a whole. So, sale of fruit is permissible.

Ex Parte Vanover Case

Petitioner here had asked for both product and process patent. Question here was that the legislation had protected plant variety and not method. Court denied process patent saying legislature had not talked about it anywhere. It was improper to talk about process patent in case of plant. Patent here had to be on plant as a whole and not parts as such even.

Ex Parte Foster

It is related to invention and discovery and its meaning within plant law. Appeal before court asking for patent over a patent already existing in nature. Plaintiff was a plant cultivator who had travelled all over the world. On his way to Columbia, he had found the Sin gonium plant and started budding process. He brought it back to US where it was considered a new variety discovered by him. Examiner rejected. Board dismissed. Asexual reproduction had taken place here. It was said that the interpretation should be done as in other acts/statutes relating to patents. Court said only thing petitioner had done was taken something already existing in nature and cultivated and thus nothing is new. No human intervention was present and hence no patent can be granted.

Ex Parte Moore

It is almost similar to Foster case. Here, Miller had built a house, when he moved in, he got new kind of peach tree. He lived there for 12 years and used it but never realized it was new. When Moore saw it he realized immediately. With Miller’s permission, he took 10 scions for budding.
purposes. He grafted these scions with wild variety. Moore applied for plant patent of new variety. In this case, what Moore has done will result in another new variety with combined traits of wild and new variety. So he should get patent.

Patent office had rejected application because discovery means finds and Miller had discovered in this case. The arguments raised in the appeal were, Miller cannot be discoverer as he did not know it was new variety and Miller did not asexually reproduce the trees.

**Dunn Vs Ragin**

The case involved three way interference and was related to a new variety of seedless orange originating as a mutation. Employee discovered new variety and told Dunn who asked Carlile to asexually reproduce it. The tree and related rights were sold to Carlile. Carlile applied for patent but before his tests were successful 3-4 years. Earlier, Dunn had asked Ragin to asexually reproduce any tree from his grove. Ragin ha reproduced this particular variety in 1936 itself while Carlile was still testing in 1937. So Carlile application was in interference with that of Ragin. Learning this, Dunn filed his own application saying he discovered it first and had asked Carlile to reduce it for practice for him. Ragin contends that mere knowledge does not amount to discovery as referred to in plant statute. Also, Carlile was not Dunn’s agent. Court awarded priority to Ragin. Carlile’s application was invalid as successful testing had not yet finished when he filed the application.

**BIOTECHNOLOGICAL CHALLENGES: SOCIO ETHICAL CONSIDERATIONS**

**Legal Issue**

In US, until 1980s the eligibility of all life form for patent rights was denied. In Funk Bros v. Kalo Inoculant Co, Court held that

"he who discover a hither of unknown phenomenon of nature has no claim to a monopoly of it which the law recognizes. If there is to be invention from such a discovery it must come from the application of law of nature to a new and useful end. Even though it may have been the product of skill, it certainly was not product of invention".


63 333 U.S. 127 (1948).
Ethical Issues
Many believe that patent reduces God’s creature to mere material objects, degrades God given dignity of life forms. This was addressed by the European Court in Relaxin case.\(^{64}\) Order public was defined as ‘relating to protection of public security and environment’ and morality was described as ‘relating to the belief in European society as some behaviour as right and acceptable where as other behaviors as wrong’.

Environmental Issues
Some of the concerns about the new technology include its potential adverse effects on environment and potential risks to human health. However, in Onco-Mouse case, the risk of uncontrolled release is limited to intentional misuse. Hence, environmental standards are for legislature or executive to frame.

There are certain issues that need to be focused upon. The patent should be encouraged by public research organizations. The government needs to increase its knowledge for market for technology. The government should encourage alternative means of disseminating knowledge now. The role of the patents in expanded world of open source software needs to be focused\(^{65}\). One of the most important issues is that patenting of little novelty or excessive breadth has been granted. The public research is difficult to research and costly even. The negative effect on computer and technology difference is hampering patent innovation. The patents crate temporary monopoly. It all depends on particular features of patent regime\(^{66}\).

Patentable subject matter, patenting requirements and patent breeding are the three basic tools in designing of patents like for example enhancing diffusion and innovation. The weak and narrow patents should encourage secrecy at expense of publicity, harm markets for technology and hinder in diffusion of technology. On the other hand, strong and broad patent opens door for undesired strategic behavior.

EPO has experienced high growth since its first application in 1978\(^{67}\). The total number of claims has increased even. The increase in expenditure has contributed to surge in patent

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\(^{64}\) 14. 1995 OJEPO 588.
\(^{67}\) OECD (2003).
Innovative one has been turned into globalised patenting. Innovation is central to business state. There should be greater collaboration. There should be expanse of innovation and new technology plays very important role. There should be enforcement of patent policy which is responsible for powerful governing bodies. IPR should have extended coverage. The filing procedure should be flexible and cheap. The rights of patent holder are frequent and strongly enforced in courts. Restriction on exemption for research use. Patent covers broader usage.

Research institutes are now allowed for patenting. This has been inspired for US. Public Research Organizations should be given priority and not individual research. The mixture of exclusive and non exclusive license granting by public research organization is fairly balanced. More applied research is done. Discussion and deliberation should be done in academic patenting. There should be pressure on government to clarify scope of research exemption in research to research and innovation.

Biotechnology, Patent and Diffusion
Genes, gene fragments etc are included now under the broader scope. The importance of patent protection for public sector research is controversial. Difference occurs through license negotiation, and alters access solution. Constitutional rights are necessary. Both public and private licensing should be encouraged. Research exemption should be clarified and exempted. The quality of patent issued should be improved. The emerging access challenges should be monitored. There should be economic analysis of transfer mechanism. Software is pervasive and hence quality of software related patent should be altered.

A- Discovery v Invention
Discovery means which already existed in nature but was noticed for the first time while invention means which did not exist before but was made with human

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70 Kortum S. and J.Lerner, what is behind the recent surge in patenting? 1-22 (1999).
intervention. The naturally occurring microbes, genes, nucleic acid, carbohydrates etc should be kept out of intellectual property protection. There should be a clear demarcation between discovery and invention.

B- Ethical dilemma

i. Is life a patentable commodity?

ii. Does it serve human and animal welfare?

iii. Is it moral and ethical to give patent over humans and other living beings?

iv. How is the public and the private interest articulated?

v. Something that already exists in nature, can its access be limited?

vi. By patent of biotechnological invention majority of developing countries would be benefitted?

vii. If there is no benefit to human welfare and if it’s leading to cruelty of animals, such inventions are patented?

viii. Does developing and under developed countries have the ability to benefit from the biotechnological invention?

ix. What yardstick should be applied to patentable and non patentable invention?

x. Is the principle of beneficence served more by having research than by not having research?

xi. Is justice served by systems of intellectual property protection?

xii. What are the limits of doing harm by research subject?

xiii. Ethically can anyone own a product of their mind, a product of nature, a product of a designed process, a discovery or even an invention?

xiv. Does it make any difference whether the product or process involves living organisms or not?

xv. Should the practical law be expected to have the same goals as that of ethics?

xvi. By incentive system of patents, do we encourage more research into more beneficial areas of science than we would by not having patents?
Public opinion matters a lot in this context. The UN panel on Medical Ethics in the Age of Genetic Engineering attempted to explore on to how these researches will benefit human beings.\(^75\) It is only through global debate and strong political stand, the damages suffered by the developing countries can be mitigated. Many organizations started filing patent applications before even knowing what role they play in the body. The court had given the decision in several cases that a gene can be patented if it has been isolated and purified in a way that is not found in nature.\(^76\) Many of the scientists left their research work in public domain by various means. There were two big problems in trying to patent human genome, “The first is moral. You can’t patent something that belongs to everyone. It’s like patenting the stars. The second is economic. By patenting something without knowing the use of it, you inhibit industry. That would be catastrophe.”\(^77\)

The UK Medical Research Centre covered all bases by going ahead and filing an application for patents on over 1000 gene sequences of its own.\(^78\) The USPTO rejected the NIH application and NIH did not appeal back. It was argued by the international community’s that the NIH filed for patent application even without knowing the genes functions in the body. The gene might be credited to another researcher.\(^79\)

“A partially sequenced gene has no meaning. The specific protein which a gene encodes must be determined. The patent filings are premature. We need to encourage and not discourage international collaboration in mapping the human genome”\(^80\) referring to the Japanese filing.

Human DNA sequences do not have a utility. But the researches contended that these help them in decoding the genetic codes of their respective genes\(^81\). But SC rejected this in 1966.\(^82\) But if they are incorporated in living organisms to create recombinant materials, then they can be patentable.\(^83\) To confirm with the USPTOs policy, many applications disclosing and claiming individual DNA sequences are likely to be rejected. This will send a message to the scientific

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\(^{75}\) U.N News letter No. 17-23 (May 2003).
\(^{76}\) Amgen Inc v. Chugai Pharmaceutical Co., 13 USPQ2d, 1737.
\(^{77}\) Christin Gorman, *The Race To Map Our Genes* 141.
\(^{78}\) Aya Furuta, *Japan Jumps Into Gene Patent Fray* 13 (1993) [Hereinafter as FURUTA].
\(^{79}\) *Supra* note 76.
\(^{80}\) FURUTA, *supra* note 78.
\(^{83}\) *Id.*
community that no one can claim proprietary rights by comprising the human genetic code. The door for communication for the researchers will be opened up. Information will be free flowing and the targeted goals can be achieved soon. There might be issues of multicellular organisms and certain social issues. It is seen that in the near future the patent office will give patent to several genetically engineered multicellular cell. Researchers from all around the world will transfer their research to others and industry will grow at a very quick pace if by following the USPTO path, patents are being rejected. Not all that is humanly possible is bioethically acceptable. Although the benefits of granting patents are known, morality and dignity of not only of humans but of all living beings should be valued.  

The direct use of products is well established. The genetic information can also be used to cure a disease. There are two basic approaches to apply patent law to biotechnology inventions. One is that the normal patentability criteria shall apply to everything. Secondly, there should be specific exclusion on certain types of invention.

Some ethical issues in patenting in scientific research include Patent law regulates inventiveness, rewards innovation; useful information will become trade secrets if patenting is not allowed. If the biotechnology industry is to compete, our country needs to compete because other countries support patent. The arguments against patenting include some countries do not permit similar patents. Increased use of animals means more animal research which may be against animal welfare, patenting promotes inappropriate human control over information that is common heritage.

The issue remains contentious because different countries have conflicting policy. Rewarding an inventor creates a positive environment for progress of research. The financial interest in a free market creates more funding for research. Medical and agricultural products are needed, but they are not always the most efficient processes. In terms of distributive justice, the amount of money people use in developed countries is a waste of research investment.


The end is open to all. If restrictions are applied to the general access to information, then there is different short-term end. After the period of patent exclusion than the direct result is the same.\textsuperscript{87} The intangible must be placed in a format that it can be repeated again but at the same time, it should be stable and precise. The modern registration system and the detailed rules that regulated the way the intangible was represented\textsuperscript{88}.

Biological inventions have always been volatile, unstable and dynamic. Court ordered that the defendant cannot deprive the plaintiff from its exclusive right to use plants which the defendants know. The defendants were required to pay the damages. Exemplary damages were denied to the plaintiff.\textsuperscript{89} Though aspects of the Monsanto case are vague yet there has been passive infringement of biological invention. There are two factors that combine together to create the problems associated with it. It is well settled that infringement is any act that interferes with the full enjoyment of the monopoly rights of the patentee\textsuperscript{90}. Moreover, intention is immaterial for “infringement occurs when the essence of an invention is taken”, regardless of the intention of the infringer.\textsuperscript{91}

The first principle is to allow the patentee full enjoyment of their monopoly rights.\textsuperscript{92} This can be traced to the so called reverse infringement test which is sometimes used to determine whether an invention is novel or not.\textsuperscript{93} On the basis that novelty and infringement are mirrors of each other, it is thus suggested that infringement should also be decided objectively. The existence of patent register and the information function performed by the patent system is focused. The third parties get harmed and infringement is absolute and invention is made available to the public. But in biological inventions, infringement can be hardly avoided.

\textit{“Liability for infringement is, as I have said, absolute. It depends upon whether the act in question falls within the claims and pays no attention to the alleged infringer’s state of mind. But this doctrine may be difficult to apply to a patent for the use of a known substance in a known

\textsuperscript{89}Monsanto v. Schmeiser,2001 FCT 256,para 131.
\textsuperscript{90}Lishman v. Erom Roche,(1996) 68 CPR (3d) 72,77 (FCTD).
\textsuperscript{91}Computalog v. Comtech Logging, (1992) 44 CPR (3d) 77,88 (FCA).
\textsuperscript{92}Lishman v. Erom Roche,(1996) 68 CPR (3d) 72 at 77 (FCTD).
\textsuperscript{93}Robert Alfred Young and Robert Neilson v Rosenthal, (1884) 29 RPC 31-3.
way for a new purpose. How does one tell whether the person putting the additive into his engine is legitimately using it to inhibit rust or infringing by using it to reduce friction.\textsuperscript{94}"

The prior user might be denied his right to work on discovery of a new thing and hence differentiating the old from the new. The inherent conflict between the physical nature of infringement and the mental nature of novelty of purpose patents gives rise to real problems. If novelty of purpose patents are no to impinge upon the legitimate activities of third parties, it may be necessary to limit the scope of monopoly.\textsuperscript{95}

A change is represented the way property rights are prioritizing and new relationship is created between the tangible and intangible property. To the extent that passive infringement is allowed, it raises questions about the relationship between intellectual property and physical property. The patents may become a much more dominant and powerful form of property.\textsuperscript{96}

**PATENT REGIME: COMPARATIVE STUDY OF PROTECTION OF BIOTECHNOLOGICAL INVENTIONS**

**Global Scenario**

OECD published the first investigation of international patent protection for biotechnology.\textsuperscript{97} At the same time, through its committee of experts WIPO began a wide study.\textsuperscript{98} In 1988, The European Commission also made a study.

(i) Patenting of life forms

Micro organisms as per the definition are too small to be visible to the naked eye. They are produced under abnormal stress conditions or human intervention. The cells and tissues of higher life forms are kept out of definition while defining micro organisms.\textsuperscript{99}

(ii) WTO-IPR Mandate

Article 27 of the TRIPS require the member states to grant patent in all fields of technology provided they are new, inventive and has an industrial application. Although

\textsuperscript{94} Merrel Dow Pahramaceuticals v Norton (1996) RPC 76,92(HL).
\textsuperscript{95} Friction Reducing Additive G 2/88(1990) EPOR 73,80-1.
\textsuperscript{96} Monsanto v. Schmeiser,2001 FCT 256.

\textsuperscript{98} WIPO (1988), Industrial Property Protection of Biotechnological Invention, Documents BIOT/CE/IV/2 and 3.

\textsuperscript{99} JPR ISSUES IN BIOTECHNOLOGY, *supra* note 1.
exception is stated, micro organisms have been included in the subject of patent under section 273(b).

(iii) US Law - the trendsetter

In the case of Diamond Vs Chakrabarthy, it was decided that patent can be allowed for nay thing, under the sun that is made by man.\textsuperscript{100} The US patent law has even allowed patent for non naturally occurring non human multicellular living organisms including animals.\textsuperscript{101}

(iv) Japanese Law

Japanese patent law concerning micro organism and plant varieties known as seed and seedling has some provisions for grant of patent to micro organisms in plants and animals.

(v) European law

This is restrictive in scope. Article 53(b) of the European Patent Convention excludes patenting of plants and animal varieties and essentially biological processes for production of plants and animals.

(vi) Budapest Treaty

For the purpose of patent procedure, the Budapest Treaty on the International Recognition of Deposit of micro organisms works. In International Depository Authorities is any one of which a new stain of micro organisms can be deposited of a patent application in any members state.\textsuperscript{102}

\textbf{Standards of Patentability of Biotechnological Invention in US and UK}

In Amgen v. Chugai pharmaceuticals,\textsuperscript{103} the issue was regarding two patents - one claiming the gene encoding a protein and another claiming the protein itself in a highly purified form. Amgen got patent in 1987 October and for Chugai June 1987. But Amgen was the first to conceive the DNA sequence simultaneous in the production of purified EPO. But in the case of Chugai an inventive concept for its isolation was there, but its DNA sequence was never known till the Amgen made it. The Court held Amgen's invention as novel.

\textsuperscript{100} Diamond V. Chakrabarthy, 447 US 3.3 ,1980.
\textsuperscript{102} Article 6,para 1(a)
\textsuperscript{103} 927, F.2d 1200 ( 1991).
The approach followed by the UK Court is reflected in Biogen v. Medeva where court held that "even though Biogen had taken the initiative something unanticipated by others; it used available techniques and methods in research. They had not developed a new inventive process or had not discovered anything about those processes and it was only a business decision to carry out research to pursue an identifiable goal by known means". Held, Biogen's patent as invalid.

Recently, in KSR Intl' Co. v. Teleflex Inc, the Court observed that 'When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill in the art has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product is not of innovation but of ordinary skill and common sense'.

Thus, by comparing the standards followed in the US and UK in patenting biotechnology inventions, it could be seen that in US the private interest is given more priority. But the recent decision of US Supreme Court in KSR Intl' Co. v. Teleflex Inc. gives a clear indication of change in their attitude by setting higher standards of patentability. But in UK such flexibility could not be seen and their priority seems to be more towards the public interest.

**Indian Stand**

A- Legislative Changes incorporated

India has made certain amendments in 1999 and 2002. As such India is under obligation to bring its patent law in conformity with the TRIPS and other International treaties and thus legislative changes are brought about. Section 27(3)(b) of TRIPS Agreement provided for protection of patent varieties either by patent or by an effective sui generis system or both. India has enacted Protection of Plant Varieties and Farmer’s Rights Act, 2001.

B- Judicial Initiative

The high court in a particular case held that

- Controller erred himself in law by holding that merely because product contain live virus, the process involved is not an invention
- Applying the vendibility test, the vaccine was treated as substance
- The claim of patent should have been considered by Controller on principles of section 3 of the Patent Act. No objection was raised by examiners under section 3.\textsuperscript{104} This judgment has opened new opportunities for obtaining patents on microorganisms’ related inventions.

C-Administrative support

The Indian Government has announced fiscal incentives and support measures realizing the urgent need of biotechnological inventions.

Before 2002 there was no patent protection for invention relating to life forms in India. But in Dimminaco A.G v. Controller of patent and design, the High Court held that a process for preparation of vaccine containing live virus is patentable since the term "manufacture" covers even living organism.

In the light of Article 27 of TRIPS the Section 3 of Patent Act, 1970 has been amended. In the absence of definition for ‘plant’, ‘animal’, ‘micro organism’ etc, its interpretation by the patent office becomes crucial. Since the term micro-organism can have a variety of definition, it is safer to place reliance upon the guiding provision in TRIPS agreement. Failure of others, long felt need, commercial success, complex work, cheaper and more economical product and simplicity of the technological solution are indicators of inventive step in 2008 draft Manual of Patent Practice and Procedure.\textsuperscript{105} Since there is no litigation in the field of biotechnology, we have to wait for the kind of standard the judiciary follows.\textsuperscript{106}

\textsuperscript{104} Dimminaco A.G. v. Controller of Patents Designs and Trademarks (September 2002).
\textsuperscript{106} Miss Rujitha, \textit{Conceptual Issues In Biotech Patenting}. 

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CONCLUSION
For the commercial advantages of technology the political system and the public at large are to work together. But harmonization of patenting rights with national interests also needs to be done. Article 27(2) provides ample scope to forbid patenting of inventions, “to protect public order or morality including, protection of human, animal or plant life or health or to avoid serious prejudice to the environment...”\(^\text{107}\) of research and innovation is the brighter aspect of granting patent. While the darker side is favorism for the developed countries. Paucity of economic evaluation of patent is required. There was no hard evidence. There should be experience sharing among countries. Developing countries should be focused. There should be development of market for technology. Access to incentive should be ensured. There should be protection and clarification of exemption for research use. It should also be ensured that patentability does not reduce incentive. The quality of patenting should be seen. Centralized court system is necessary. International co operation for promotion of quality at lowest cost should be present. The opposition system should be efficient. Patentees should self select their application.\(^\text{108}\)

New challenges will be faced in future. There is growing role of markets in production and increased globalization now.\(^\text{109}\) There should be convergence of various technological domains and promotion of public domain in internet. Policy oriented economic analysis is required.\(^\text{110}\) A Variety of new problems will arise from attempts to apply the traditional rules of patent law to this nontraditional invention. PTO and courts try to resolve these problems, but they should consider the effect of their decision in future technology. Culture deposition might be necessary to subjects ad should be available to public on expiry of patent.\(^\text{111}\)


\(^{109}\) *Genetic Inventions, Ips And Licensing Practices: Evidence And Policies*.

\(^{110}\) *Patents and Innovation: Trends and Policy Challenges* by OECD.

The issues in Chakrabarty were narrow but it removed the barrier of patent for wide variety of biotechnological inventions. The role of the Patent Office is to determine novelty, obviousness etc and hence it is deserved to be addressed by other organizations.\textsuperscript{112}

Though self-interests are considered for researcher’s autonomy but there will be more rapid progress if data is shared among all researchers. Only instruments and products used in diagnosis or treatment have been patented, actual procedures have been left open for all to use free of patent liability in accord with the principle of beneficence.\textsuperscript{113} The benefits should be in terms of general medical or agricultural development, rather than economic. We should reflect on how a possible further Bioethics Convention could meet the challenges that ethical patenting faces from biotechnology. The patent situation will also depend upon the relationship between TRIPS, UPOV Convention and the Convention on Biological Diversity.\textsuperscript{114} The knowledge gained should be considered as the common property of humanity. Utilization must be peaceful, access should be equally open to all and common welfare should be promoted. If we consider education to be a basic moral good we can claim that to perform, research has a positive effect on the teaching standard which may be a more significant benefit in small countries than the direct results of research.\textsuperscript{115} National pride is one of the reasons to promote research .People want those of other countries to have a high opinion of their country.\textsuperscript{116}

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