Chapter 6

ETHICS IN PATENTING BIOTECHNOLOGY INVENTIONS

Ethics is a study of what is normally right and what is wrong or a set of belief about what is morally right and wrong. Morality is a belief that doing some thing is good and doing something is bad. Biotechnology is one of the fastest growing areas of scientific, technical and industrial innovation of recent times, and it is also one of the most prominent in public discussion especially the ethical values associated with biotechnology. Assumptions and convictions of a strongly ethical nature underpin the chief policy and indeed political questions that have been at the center of debates on biotechnology in recent times. The discovery of recombination techniques in the beginning of nineteen seventies opening extraordinary new possibilities for the biological modification of organisms. The potential dynamics in this field prompted profound ethical concerns. The most obvious difference between the patenting of biotechnology and the patenting of other forms of technology is that it has led to the introduction of ethics into patent law. There is a series of profound ethical and moral questions raised by the specter of patenting life forms. Ethical considerations do object the patenting of living beings.

Ethically speaking living beings are creation of God, which cannot be owned by human being through patents. God is the only owner of all the living being on this planet. Living beings are vested with inherent dignity and integrity, which shall be protected and guaranteed. Human being cannot play with the wisdom of God by manipulating living beings. Manipulation of living beings hits at the dignity and integrity of living beings. Genetic manipulation of organisms and its protection by the patent system had always

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950 H.L.A Hart, Law, Liberty and morality, Oxford University Press, New Haven, 1921, Pg. No. 104-105
952 Sivaramaiah Shantaram, Biotechnology, Biosafety and Biodiversity, Pg. No.161
953 Lionel Blenty and spyrous M. Maniatis, Intellectual property and ethics, Sweet and Maxwell, London, 1998 Pg. No. 111
954 K.R.G Nair and Ashok Kumar, Intellectual property rights, Allied Publishers Limited, New Delhi, 1994Pg. No. 264 and 276
raised hue and cry on moral and ethical issues. It is quite obvious that patent law cannot protect immoral inventions on the question of ethics and morality. Patent is a private right, which excludes all others except the owner from working or using a particular invention. Patenting life amounts to privatizing and owing life as a property, which is considered as immoral.

**Natural law principles**

The fundamental principles of natural law are pre moral and universal in character. A jurisprudential enquiry into the concept of life reveals that there are few intrinsic values attached to life. The conceptual framework of life is connected to natural law which postulate for the inherent values of life like; dignity, integrity, sustenance, survival and self-preservation. Nature has provided every living being a right to self-dignity and integrity. Every living being deserves a drive for self preservation of natural features attributed to it by the nature. Every living being has right to preserve the intrinsic values of life, which should not be disturbed or tampered with. Biotechnology is capable of removing certain natural features and incorporating certain novel features into living beings. Manipulation of living beings, hits at the inherent dignity, integrity and natural set up of living being. Further such manipulation disturbs the sustenance and self-preservation of natural features of life. Patenting of biotechnology inventions is in a way an incentive for the manipulation of living beings. Nature is integral part of every living beings life. Living beings are associated and forming part of the nature. Any alteration or manipulation of any living being like plant, animal or invisible microorganisms strike not only at the integrity of such living beings but also at the integrity and balance of the nature. In this background it is felt that scientific and technological developments should not disturb or destroy the values of life.

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955 Dr. L. Ramakrishna, Intellectual property rights, National Law School of India University, Bangalore, First edition, 2003, Pg. No. 40
957 See generally A.H Chrost, An introduction to Aquinas, 1974, 19 A.M.J of Jurisprudence 1
958 M.D.A Freeman (Ed) Lloyd’s Introduction to Jurisprudence, Sweet and Maxwell, Sixth edition, 1994, Pg. No. 81
959 See generally, H.L.A Hart, The concept of law, Oxford University Press, 1992, Pg. No.188
960 H.L.A Hart, The concept of law, Oxford University Press, 1992, Pg. No.188
961 See generally Roberto Unger, Knowledge and politics, as cited in M.D.A Freedman (Ed) Lloyds Introduction to Jurisprudence, Sweet and Maxwell, sixth Edition, 1994, Pg. No. 595to597
Ethics versus Biotechnology

The argument in support of patenting of life quotes John Locks labor theory, which says that the one who labors for an invention deserves an exclusive right over it. One who labors gifts the society a certain thing against the grant of certain exclusive rights there by establishing a social contract deserving exclusive right over the result of his labor. Further they quote John Bantam’s utilitarian theory, which states that maximum benefit to the maximum members of the society should be considered. They say that the utility that biotechnology and patenting of life fetches to the society should be considered. Society at large is going to benefit from biotechnology inventions involving manipulation of life; hence maximum benefit of maximum members of the society is being served. Therefore the efforts in bringing maximum benefits to the society deserve certain exclusive fights for a temporary period of time. However the question here is whether John Locks labor theory or Bantam’s Utilitarian theory postulate for patenting of life as a reward for laboring in manipulating a living being to do something new or to produce something new in bringing certain utility to the society. While ethicists and fundamentalists answer negatively to the question, the scientific community answers positively.

Argument against patenting of life states that John Lock’s theory does not postulate for patenting of life. Patent is a private property, which can be owned transferred or sold just like goods. It is viewed that patenting of life amounts owning private property rights over life making life as a market commodity. Hence patenting of life is nothing but commodification and marketing of life, which is a gross violation of dignity of life. Therefore patents cannot be granted on life giving rise to property rights in life. They further say that labor in manipulating and disturbing the integrity of living beings should not be encouraged through patents. Labor in creation of non-natural life forms is not backed by Locks theory since it involves distortion of intrinsic values of life.

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965 See generally, Robert Nozick, State anarchy and utopia, Oxford University Press, 1998
Further they state that utilitarian theory does not envisage for patenting life. Maximum benefit to the maximum members of the society should not be at the cost of ethics, which are manifestation of consciousness of maximum members of the society.

Further they argue that nature has provided equal rights to all living beings. Human beings do not have rights over other living beings. Rights of human beings are not superior to the rights of other living beings. Hence human beings cannot take other living beings for granted and they cannot play with the dignity and integrity of such living beings by manipulating them. In particular it is argued that manipulation of animals capable of expressing feelings is morally not right. Causing sufferings to animals for the purpose using in experiments in the field of biotechnology is ethically questionable.

According to the ethicists patenting and owning human beings and genetic material of human beings amounts to holding them in slavery. Slavery hits at the dignity of human beings, which is guaranteed under different international covenants and declarations. Human dignity is reaffirmed in the charter of United Nations. Universal declaration of human rights envisages for the recognition of the inherent dignity of human beings. The declaration says that all human beings are born with dignity and holding them in slavery shall deprive of such dignity. The declaration postulates for the promotion of inherent dignity and values in life. The understanding is that scientific experimentations should not subject living beings to torture, inhuman or degrading treatment. The United States patent offices view is that granting patents on human being would violate thirteenth amendment to the U.S constitution, which prohibits slavery. Therefore ethicists say that since, no human being shall be subjected to

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967 See: Preamble to the Charter of United Nations 1945
968 See: Preamble to the Universal Declaration of Human Rights (UDHR) 1948
969 See: UDHR Article: 1 and 4
970 See: International covenant on civil and political rights (ICCPR) 1966, Article: 7
slavery. It is felt that patenting of human being or human genetic material should not be allowed otherwise it violates inherent dignity and integrity of human life.

However argument in support of patenting of life or patenting of biotechnology inventions is that keeping in mind enormous benefit that the science called biotechnology has brought to the modern world and potential utility of the patenting of life ethics could be sidelined. Scientific communities along with the supporters of life patenting say that manipulation of living beings is done in order to improve their efficiency. Manipulation intends to incorporate certain features, which are beneficial, or to remove certain features, which are not beneficial. The intention is not to disturb integrity or dignity but to bring some benefit to the society. They further say that biotechnology has invented countless number of non-natural living beings or inventions involving life by the manipulation of existing living beings, which have served and are serving the society. With its potential to manipulate living beings in a way to benefit the society biotechnology is promising to be capable of catering the needs of the society.

The inventions of biotechnology though involve manipulation of livings have application in diverse fields yielding enormous benefit to the society. The enormous capacity of biotechnology to isolate and commercially produce natural compounds found inside the body of living beings cannot be undermined. Such compounds produced through biotechnology are useful in producing medicines to cure conical diseases in a way promising to cater the health needs of society. The manipulation of existing crops and animals resulted in crops and animals giving high yields at low production cost promising to feed the hunger needs of the society. Further, biotechnology living inventions are crucial in the protection of environment and also in improving the yield in livestock production. Therefore they say that in the light of potential benefits of biotechnology inventions patents can be granted though there are certain ethical objections in order to reap the fruits of biotechnology. In this background it would be proper to discuss ethics in patenting of life in U.S.A where modern biotechnology and life patenting could be traced.

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972 See: International covenant on civil and political rights (ICCPR) 1966, Article 8
973 See: Preamble to the International covenant on civil and political rights (ICCPR) 1966 and International Covenant on economical and cultural Rights (ICECR) 1966.
Ethics in patenting life: An U.S perspective

Moral standards differ from person to person and place to place. However, patenting of life is universally considered as immoral and unethical. American Bill or Rights postulate for due respect of inherent dignity and intrinsic values of life. The constitution of America envisages for equal treatment of all and guarantees human dignity. At the same time it prohibits slavery and commodification of life in order to guarantee human dignity. However, the American society is adoptive and flexible. It quickly adjusts to the changing conditions. According to the United States patent law “anything under the sun made by man is patentable”. There is no provision under the U.S patent law that speaks about ethics and morality. Probably that was the reason behind interpreting the U.S patent law to patent anything under the sun made by man.

The decision of U.S Supreme Court in Diamond vs. Anandha Chakraburty for the first time raised ethical and moral consideration in patenting living organisms. The claims were for microorganism capable of eating oil spills. Initially the patent was rejected on the ground that the invention is not patentable. But the inventor did not give up and appealed to the Supreme Court of America. In appeal the Supreme Court viewed the invention as non-natural human made invention, which was not existed before. It was held that patent could be granted on living organism by liberally interpreting the language of the U.S patent law. The entire world was shocked with this decision and there raised eyebrows over the sanctity of the decision in the light of ethics and morality.

The decision of the Supreme Court was intensively criticized as against the ethical and moral standards of the society. There were intensive debates all over the world and critics...

972 See: International covenant on civil and political rights (ICCPR) 1966, Article: 8
973 See: The opinion of judges in Diamond Vs Chakraburty (447 U.S 303 (1980)) while interpreting the patent law of America in order to grant patent on living organism for the first time in the history.
from different corners of the world viewing the patenting of living organism as against ethical and morality. There opined that patent law should respect ethics and morality but should not go against. However after the decision of Chakraburty there was plethora of patent applications claiming different non-natural human made life. There started undermining ethics while focusing on the benefits of such inventions. The U.S Patent Office by following the suit of the Supreme Court granted innumerable patents on different microorganisms giving rise to debates on ethics in patenting life.

**Ethics in patenting plants**

After the decision of Chakraburty giving green signal to patent single celled microorganisms, there expressed doubts that the US patent office may extend patent protection to multi-cellular living organisms such as plants and animals. Bringing into reality such doubts and adding fuel to the debates on ethics in patenting life in 1985 in *Ex parte Hibberd* there granted a patent on a plant. It was the first instance where a multi-cellular living organism was claimed and patented. The claims were to a plant genetically engineered to possess an abnormally high level of amino acid tryptophan. The United States patent offices Board of Patents Appeals and Interferences decided a genetically modified plant as patentable.\(^{980}\)

The Board primarily relied on Chakraburty, placing little emphasis on ethical and social policies underlying the patenting of plants.\(^{981}\) The decision attracted severe criticism and initiated strong debates on the ethics in patenting plants. The central issues involved in the debates were that plants are creation of god and human being cannot own the Gods wisdom. God is the only owner and it is unethical to privatize Gods creation. Manipulation of plants itself is unethical since it disturbs the integrity and violates the rights to self-preservation. There started speculating about the next reach of the voyage of patenting of life exploding the ethical and moral standards of the society. Following the decision of Board for patent appeals many plants were patented giving little or no

\(^{980}\) K.R.G. NAIR AND ASHOIK KUMAR, INTELLECTUAL PROPERTY RIGHTS, ALLIED PUBLISHERS LIMITED, New Delhi, 1994, Pg. No.282.

emphasis on the ethics involved there in. Shortly in Pioneer Hibred International Vs. JEM AG Supply the U.S Court of Appeals for the Federal Circuit upheld patents on engineered plants taking patenting of plants away from ethical and moral considerations. Now there is no doubt that plants could be patented without any ethical or moral restrictions.

Ethics in patenting animals

Animals are considered as higher life forms due to the fact that animals can suffer and express feelings unlike plants or other living beings like microorganisms known as lower life forms. The ethical concerns raised were more vehement in case of patenting animal than plants due to the above reason. However in Exparte Allen there claimed an engineered animal for patent. The invention was genetically engineered oyster an animal possessing extra set of chromosomes. The patent was rejected on the ground of obviousness, however the case opened the gates for patenting of animals. The US patent office was of the opinion that ethics could not prevent animal patenting. Shortly after the decision in Exparte Allen U.S patent office issued a notice indicating, “the US patent office now consider non-naturally occurring, non-human multicultural living organisms, including animals, to be patent–eligible.” The notice of the U.S patent office

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984 1987 2 USPQ 2d 1425
985 The claimed oyster was edible all year around because it did not devolve body weight to reproduction during the breeding season. The applicant sought to patent a method of inducing polyploidy in oysters as well as resulting oysters as products by process. The United States patent office found the oysters to be obvious and rejected the patent. Nonetheless, the polyploid oysters paved the way for the patenting of other non-naturally occurring animals. Following the reasoning of Chakraburty the United States patent office concluded that such organisms are eligible for patenting. The patent office gave much weight to the reasoning of Chakraburty than the ethical concerns.
989 See generally: K.R.G. NAIR AND ASHOIK KUMAR, INTELLECTUAL PROPERTY RIGHTS, ALLIED PUBLISHERS LIMIKTED, New Delhi, 1994, Pg. No.277
990 Animal patentability notice issued by the U.S patent office on April 21, 1987
991 Manu Luv Shahalia, Intellectual property rights: Many sides to a coin, Universal law publishing company, New Delhi, 2003 Edition. Pg. No.173, See also Jasmine Chambers, Patent eligibility of
sets out its intention to patent animals without any ambiguity. It implies that US patent office has decided that ethical and moral considerations can be undermined in patenting animal. Besides the notice of the US patent office added fuel to the ongoing debate of the ethics in patenting life. There was vehement opposition to the notice issued by the U.S patent office. Animal League Defense Fund and several animal and farmers rights groups brought suit challenging the U.S patent offices authority to issue notice encouraging and giving green signal to animal patenting. They claimed that general public has got interest in the decisions of the patent office and patent office should not undermine the interest of the general public by overweighing ethical considerations. They argued that playing with the life of animals is unethical. Making animal susceptible for diseases and causing them suffering is inhuman and immoral. It was also argued that animals have every right to preserve integrity and natural characteristics. Manipulating animals to alter natural set up and owing them through patents is unethical and against the wisdom of God.

Meanwhile the scientific community states that the potential benefits that manipulation brings in should be considered over and above ethics. Further they say, “we are not trying to own Gods wisdom but we are claiming for non-natural and human made inventions having potential to benefit the society at large”. We are claiming our labor and intellectual effort, which is not against ethics. Approximately one year after the notice was issued the U.S patent office granted its first patent of the kind on a transgenic mouse useful in cancer testing. In Harvard oncomouse the claim was for a genetically engineered mouse susceptible to cancer. The mouse was containing a cancer-causing gene inserted by genetic engineering, which made the mouse susceptible to cancer. The patent was opposed strongly as immoral and unethical. Opponents of patent argued that

Biotechnological inventions in the U.S Europe and Japan: How much patent policy is public policy? George Washington International Law review, 2002
994 Ibid
996 Dr. T. Ramakrishna, Biotechnology and intellectual property rights, Center fir Intellectual Property Rights and Advocacy (CIPRA), National Law School of India University, Bangalore, First Edition, 2003. Pg. No.24
patenting of an animal parse is unethical and it may leas one day to cloning and patenting of human. They say that owing an animal capable of expressing is against public policy, which should not be allowed.

Infact the ethical and moral concerns raised against patenting animals were vehement compared to plants and other lower life. However the view of the patent office was that the benefits of the invention should be considered over and above ethical concerns. It was reasoned that cancer is one such major disease in the world, which is suffered, by millions of people. As the invention helps in testing cancer it carries a hope therefore its potential benefit should be given importance to and eventually patent was granted. However the scientific community was pro-aggressive in stating that; in the light of debate on human cloning, the policy statement issued by the U.S patent office on April 21 1987 was short lived as it is confined to non-human multi-cellular living organisms.

Ethics in patenting human cell lines

Biotechnology is capable of manipulating any living being including human being. It is capable of isolating, removing, suppressing, or incorporating genes from and to human body. Further it made possible to identify, isolate and commercially produce proteins, hormones that human body produces naturally. It was felt that the alteration of natural set of human body would go against its integrity. Ethicists say that patenting of human genetic material such as cells, DNA, genes and amounts to owing human body or human life as private property. Private property in human body or human life amounts to slavery, which violates the inherent dignity. Debates on ethics in manipulating human body and patents on human body ware started as early as patenting of living beings was started as manipulation of human being and patenting of human genetic material was predicted at that time. Bringing predictions into reality manipulation of human body by way of isolation or removal or genetic material such genes and DNA or incorporation of

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997 See: WWW. Bioethics.gov, for details on ethics in biotechnology inventions.
1000 See: Patricia A Rac, “patentability of living subject matter”, 10 CIPR 41 (1993)
foreign genetic material into the body was made possible. Eventually patents being claimed on human genetic material giving rise to nerve tightening and heated debates on the ethics in manipulating human body and morality in owning human genetic material. For the first time in *John Moore case*\(^{1001}\) a patent was claimed on a cell line of a human being. John Moore a leukemia patient from California underwent a medical treatment for hairy cell leukemia. While treating him, his physicians found his cell lines useful in preparing a specific medicine and obtained patented on the same in 1984.

Moore challenged patenting of his cell line in the Supreme Court of California. He argued that patented cells are from his body; it is his property therefore he has got rights over it. He stated that he is the one who can own patents on the components of his body. However irrespective of Moore’ contention there questioned the morality of patenting a cell line which is a part of human body. It was argued that owing a part of human body through patent is a gross violation of human dignity and it strikes at the moral standards of the society. The Court rejected moor’s argument and held that there cannot be any property rights over ones body, which is against dignity of human being. However while addressing the morality and ethics involved in patenting human cell line the court took the view that; cell lines are not readily available to be isolated, it involves Herculean task to isolate the same. Further it was viewed that patent was not claimed on the natural cell lines in the body but on the isolated cell lines out side the body. Hence such isolated cells a result of laborious research deserves patent. It was further held that the use of the inventions could override the ethical concerns involved therein. Eventually the court gave green signal to patenting of human cells, genes and DNA in an isolated form out side the body thereby sidelining the ethical concerns.

However the debate continued and further intensified after the decision of the Supreme Court of California. Again in 1993 a patent on human cell lines was claimed before the patent office.\(^{1002}\) The cell line was developed from here blood, which was found to be useful in research on AIDS and cancer. This time it was not private individual who claimed the patent but it was the government of the United States of America, which claimed cell lines of women from the guayami Indian tribe of Panama.

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\(^{1001}\) Supreme Court of California, July 9, 1990  
\(^{1002}\) Patent application No. 9208784 A 1, 1993
South America. It shows that the government of America itself is in favor of and interested in patenting human cells and genetic material by undermining the ethics involved therein. There were protests before the US patent and trademarks office against patenting of cell lines of human beings. Non-governmental organizations such as RAFI (Rural Advancement Foundation International) and tribal communities strongly objected and questioned ethics in patenting a cell of a tribal woman. The government of America contended that; patent could be granted, as the cell line is useful in research in AIDS and cancer the two most threatening diseases in the world. The application claiming the human cell line of tribal women was attracted international criticism centering on ethics and morality involved thereby. As the Government of America itself involved in the patent opponents criticized the stand of the government in claming a cell line that it would lead to commodification of life. Yielding to the high pressure, vehement oppositions and international criticism the government of America was forced to withdraw the patent application.

**The TRIPS agreement and ethics**

With the coming into being of TRIPS agreement now universally ethics, morality and public order forms a restriction to the patentability of inventions. The agreement says that inventions, which are against public order or morality can be excluded from the purview of patentability. Being a signatory to the agreement now the United States can exclude inventions from patenting on the grounds of ethics and morality. The agreement further states that inventions, which may be detrimental to the health of human, animal or plants or to the environment, may also be excluded from the scope of patentability. In the light of ethical and moral standards of the society the agreement excludes natural plants, animals and essentially biological processes from the purview of

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1004 See: RAFI press release on October 26, 1993 on ‘patenting the primitive, anthropological and ethical reflections on indigenous peoples and the human genome project” paper presented at
1005 Lionel Blenty and Spyros M Maniatis, Intellectual property and ethics, Sweet and Maxwell, London, 1998
1006 See: The TRIPS agreement, Article: 27(2) and (3)
1007 For the United States the TRIPS agreement came into being on 1-1-1995
1008 See: The TRIPS agreement, Article: 27(2) and (3)
patentability. Further the agreement considers unethical to patent surgical and therapeutic and diagnostic methods for the treatment of human beings or animals.\footnote{See: The TRIPS agreement, Article: 27(2) and (3) However patenting of surgical, therapeutic and diagnostic method for the treatment of plants are considered not to go against the ethical standards of the society.}

People who argue against life patenting say that the TRIPS agreement excludes animal, plant and human being from patenting on ethical grounds. Hence patenting of plant, animal, human being including human genetic material does violate the TRIPS agreement in the light of ethical standards prescribed in the agreement. However people in support life patenting say that the TRIPS agreement prohibits patenting of natural plant, animal and human genetic material but it does not prohibit non-natural human made or genetically engineered plant, animal and isolated and purified human genetic material in its non-natural form. Meanwhile there is no dispute in considering patenting of human being and patenting of surgical, therapeutic and diagnostic method for the treatment of human and animal as unethical.

In the mean time there was a major advancement in biotechnology in nineteen nineties. In the United States there is a major upsurge in the research on human genetic material, the result being number of patents on human genetic material such as human DNA and genes. Once the ethical boundaries were exploded and patents on human cells and genetic material were allowed there was a plethora of patent applications claiming human genetic material. To quote few; In \textit{Amgen Vs. Chugai} the claim was for a DNA, in \textit{In re Bell} there claimed DNA, again in \textit{In re Deuel} the invention related to an isolated and purified DNA. In \textit{In re o Farrell} the invention was a method to produce a foreign protein in a transformed species of bacteria. Innumerable number of genes and DNA have been patented since the beginning of nineteen nineties. Every day many genes, DNA and other human genetic material are being patented. Thousands of patent applications are pending before the United States patent office claiming different biotechnology inventions, majority being claims on human genetic material. Reportedly in the year 2001 alone United States patent office awarded 20,000 gene patents and

\footnote{927 F.2d 1200, 18 USPQ 2d 1016 (Fed. Cir. 1991)}\footnote{991. F.2d 781 (Fed. Cir. 1993)}\footnote{51 F. 3d1552(Fed.Cir.1995)}\footnote{853 F.2d 894 (Fed. Cir. 1988)
another 25,000 were pending. Most of the genes and DNA patented are coding some proteins, which are useful in the medical field in the preparation of some kind of medicine, drug or vaccine.

Research in biotechnology and genetics took an interesting dimension with the invention of techniques of cloning. The entire world was shocked with the news with the birth of Dolly, the cloned sheep in 1997. Dolly was a clone of a six-year-old sheep, which resembles its predecessor. Dolly raised immense debates over the ethics involved in research in biotechnology. There raised voices that biotechnology is destroying the ethical cover in the society. Cloning of few other mammals like, rabbit, monkey, and cow followed cloning of sheep raising doubts about cloning of human being in the future.

**Ethics in human cloning**

In the United States of America judiciary is very active and innovative. Whatever judiciary decides while interpreting the existing law or while filing the vacuum of law is having binding force. As the patent law of America does not provide for restriction on patenting on the grounds of ethics and morality the judiciary was free enough to extend patent protection starting from microorganisms till human genetic material. However though ethics and morality restrictions are not provided expressly in the US patent law the judiciary could have taken the initiative to impose the same by its interpretation. But judiciary thought otherwise not to impose ethical restriction in the light of potential benefits of biotechnology and patenting of genetically engineered living beings.

Adding additional fuel to the debate on ethics in patenting living beings, a patent application was filed in the US claiming non-human chimera. Stuart Newman claimed a patent on the invention where he incorporated a human gene into an animal, which

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1016 Cloning is the process of producing identical organisms, through the division of a single embryo or through nuclear transfer or replacement of a nucleus in an egg by a foreign nucleus. It is a method of reproduction involving the copying of a cell or an individual from its DNA. See: Ethical and legal implications of human cloning, The ICFAI Journal of Health and Law, Volume. II, No. 2, May 2004, Pg. No. 65
resulted in an invention, which is neither animal nor a human. The patent office for the first time happened to consider ethical standards in the society and held that the invention could not be patented, as it would outrage the public order and morality. The patent office believes that transgenic human beings are not patentable by virtue of thirteenth amendment to the US constitution. Therefore patent was rejected and made it clear that human beings are prohibited from patenting on ethical grounds. Besides the U.S judiciary and as well as U.S patent office believe that cloning of human being and patenting the same are totally excluded under the constitution of America as well as under the patent law. Cloning is a general term that explains any procedure that produces a precise genetic replica of a biological object including a DNA sequence, a cell or an organism. As thirteenth amendment to the constitution prohibits slavery in human beings the same was taken to restrict human cloning and patenting of human being.

Both the judiciary and the patent office stand on equal footing in viewing that “cloning of human being violates the inherent dignity of human life and patenting of human being amounts to slavery”. This stand was highlighted in In Pioneer Hibred International where in it was held that human cloning is prohibited as it is against ethics morality and public policy. This implies that inventions relating to transgenic humans are prohibited. At last the judiciary of America and the U.S patent office accepted the ethical and moral standards of the society, which are expressly not provided under the patent law. But raising certain doubts about the actual stand of US on the issue of human cloning it was further held that processes or methods for human cloning are patentable. The logic behind allowing patenting of methods of human cloning is

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1018 Jasmine Chambers.
1019 Cloning is the process of producing identical organisms, through the division of a single embryo or through nuclear transfer or replacement of a nucleus in an egg by a foreign nucleus. It is a method of reproduction involving the copying of a cell or an individual from its DNA. See: Ethical and legal implications of human cloning, The ICFAI Journal of Health and Law, Volume. II, No. 2, May 2004, Pg. No. 65
1021 One method of cloning involves removal of the nucleus of a mature, unfertilized egg an replacement with a nucleus obtained from a specialized cell of an adult organism. The nucleus of a cell contains all the hereditary material so the renucleated egg and individual into which the egg develops are genetically identical to the organism that was the source of the transferred nucleus. Because of nuclear transfer an unlimited number of clones will be produced. It is possible to clone even the dead because of laboratory cultivation and storage of tissues with cells.
questionable. The purpose of a method of human cloning might be to clone human being. When human cloning and patenting of human being is prohibited on ethical grounds in what way it is ethical to patent human cloning methods. This issue needs to be considered in the light of possibilities of human cloning in the future.

**Ethics in human genetic research**

The story does not stop there but continues in search of unforeseen ends proving to be yielding miracles as per the biotechnologists. Research in genetics made it possible to produce human organs for the purpose of transplanting into the body of needy suffering of improper working or failure of organs. Irrespective of ethical objections to cloning and production of human organs and their transplantation into the bodies of living human beings, biotechnology is poised to serve the purpose of the needy. Research in human genetics exploded the boundaries of ethics and morality intending to unravel the genetic structure of human body in order to cure genetic diseases.

Further human genetic research gave rise to research in human genome, human embryonic research, and stem cell research where serious ethical concerns are involved. Human genomic research involves manipulating with the genetic set up of the individual, which is highly controversial in the light of ethical objections. Embryo research involves manipulation of embryos capable developing into a complete human being. Manipulating the embryo or fetus and removal of stem cells of such embryo in the initial stages of development of a human being is strongly objected. Genetic research further made it possible to bigot children through assisted reproduction to the benefit of infertile couple. It is even possible to have children with desired characteristics through assistance of biotechnology.

In the light of above developments in the human genetics there adopted a Declaration on Human Genome and Human Rights. The convention says that research

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1022 Cloning of human genetic material such as cells, genes, DNA in order to produce human organs for the purpose of transplantation to the body of needy has become a reality irrespective of the ethical considerations involved in cloning a part of the body.

1023 Genetic research yielded cures for genetic or heredity diseases by removing, suppressing the gene causing certain hereditary disease or by incorporating a foreign gene to suppress the gene causing the hereditary gene.

in human genome shall respect ethical standards of the society.\textsuperscript{1025} The declaration promotes the development of ethical studies in the light of scientific and technological progress in the field of biology and genetics.\textsuperscript{1026} No research in the fields of biology and medicine should prevail over the respect for human rights and human dignity.\textsuperscript{1027} The declaration recognizes freedom of research as a part of freedom of thought. It encourages research in the field of biology, genetics and medicine in order to guarantee right to health and relief from sufferings.\textsuperscript{1028} The declaration directs the member states to establish ethics committees\textsuperscript{1029} to assess the ethical, legal and social issues raised by research on human genome and its applications and also to promote education in bioethics.\textsuperscript{1030} The declaration intends to identify practices that could be contrary to human dignity and ethics in particular such as germ line intervention.\textsuperscript{1031} The declaration further directs the member states to come with proper legal measures to respect ethics and human rights.\textsuperscript{1032}

**Ethics committees**

In order to fulfill its obligations that have arisen under the declaration the Government of U.S did set up a committee by name National Bioethics Advisory Commission in 1997. The primary job of the commission was to report on the ethics involved in research in biology and medicine especially research in human genome and human cloning. In its report submitted in the year 1997 the committee called for further consideration of the ethical and social questions raised by cloning. Another report by National Academy of Sciences (NAS) also called for further consideration of the ethical questions raised by cloning. However both the reports concluded that attempts to clone human being would be unethical.

Adding enough fuel to the debates on ethics in human cloning in 1998 scientists were able to isolate human embryonic stem cells from fetus in the womb of a pregnant women. Subsequently in 2001 American researches claimed to have produced the first

\textsuperscript{1025} See: Ibid: Article: 13 and 14
\textsuperscript{1026} See: Preamble to the declaration.
\textsuperscript{1027} See: Article: 10 of the declaration.
\textsuperscript{1028} See: Article: 20
\textsuperscript{1029} See: Article: 16
\textsuperscript{1030} See: Article: 20
\textsuperscript{1031} See: Article: 26
cloned human embryos.\textsuperscript{1033} These developments warranted the government of America to set up a committee by name Presidents Committee on Bioethics to advice on the bioethical issues related to advances in biomedical science and technology.\textsuperscript{1034} In its inquiry into the ethics in human cloning and human dignity, the committee found that to day more routine biological research and many important pharmaceutical applications depend on cloning, which involves many ethical dilemmas. The committee in its first report submitted in July 2002 recommended for the prohibition of human cloning.

In the realm of possibility of cloning a human being and in the light of reports of National Bioethics Advisory Committee and The presidents committee on bioethics concluding that human cloning as unethical the government of America tried to enact legislation to prohibit human cloning. The efforts tasted success, when the congress passed legislation by name Human cloning prohibition Act, 2003. The Act defines human cloning to mean asexual reproduction, (reproduction not initiated by the union of oocyte and sperm) accomplished by introducing nuclear material from one or more human somatic cells into a fertilized or unfertilized oocyte whose nuclear material has been removed or inactivated so as to produce a living organism at any stage of development that is genetically virtually identical to an existing or previously existing human organism.\textsuperscript{1035} The Act distinguishes between reproductive cloning and therapeutic cloning. Reproductive cloning purpose is to reproduce a human being. Therapeutic cloning purpose is to produce any tissue or organ of a human being to replace it with the one that got damaged. The Act prohibits reproductive cloning on ethical considerations, however it does allow therapeutic cloning.\textsuperscript{1036}

\textsuperscript{1034} The committee was set up on November 28, 2001 by means of executive order 13237
\textsuperscript{1035} See: Section: 301 of the Act
\textsuperscript{1036} As per the Human tissue Act, 1961, any organ or tissue of a dead person could be used for research if the dead person consented when he was alive. There is a fear that if human cloning is allowed there may be pressure on persons to sign written consents or there is possibility of development of a doctrine of implied consent to donate organs and tissues. Further, dealing in human organs is prohibited under Human Organ Transplantation Act, 1989, but embryo does not form a part of human body hence prohibition does not apply to embryo. However storage and use of human embryos for research purpose could be done only on a license from Human Fertilization and Embryology Authority under the Human Fertilization and Embryology Act, 1990.
Further it states that any attempts of cloning human being or to deal in an embryo produced by human cloning and dealing with any product derived from such embryo is prohibited and made punishable under the Act. Human cloning or any attempt to do so is punishable with ten years imprisonment and fine not less than $1,000,000. The Act intends to study and assess ethical and legal implications of new developments in medical technology concerning human cloning.

**Ethics in manipulation of human bodies and embryos in pursuit of happiness**

The potential of biotechnology in having better children, ageless bodies and happy souls cannot be undermined. During the time of pregnancy through manipulation of embryo desired characteristic features could be incorporated and unwanted characteristics could be removed. Old bodies could be injected activeness in order to make them feel younger; better performing traits could be injected into the body through biotechnology-assisted manipulation. Even individual’s mood could be cheered up with mood brightener and memory could be improved with memory helper in order to enlighten their soul. The presidents committee on bioethics submitted its second report in October 2003 focusing on the ethics in manipulation of human embryos and use of biotechnology in pursuit of happiness. The report did not totally oppose manipulation of human body or embryo for desired results but it inquires into the ethics of such biotechnology pursuit. The committee fears that such pursuits should be closely monitored; otherwise it may create havoc in the society if every body goes behind it.

**Ethics in biotechnology assisted reproduction (AST)**

Assistance of biotechnology is sought in procreating children. Biotechnology is capable of blessing infertile couple to have children through artificial fertilization. New biotechnologies such as pre-implantation genetic diagnosis including sex selection,

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1037 See: Section: 302 of the Act
1038 See: Section: 3 of Act: Study by the general accounting officer.
1039 Ibid: Better children; superior performance, Pg. No. 27-157
1040 Ibid: Ageless bodies, Pg. No. 159-204
1041 Ibid: Happy souls, Pg. No. 205-274
1044 Ibid: Pg. No. 90 and 177
germ line genetic modification, human embryo research, in vitro fertilization and development of human life in vitro (outside the mother womb) have generated a hope in infertile couple to have children. These technologies used to assist reproduction may affect health of the child and the mother. Further large number embryos capable of becoming human being die in assisted reproduction raising serious ethical concerns. However it is observed that assisted reproduction causes death of large number of human embryos, which is a major serious concern. In the light of the above developments the presidents committee on bioethics submitted its report investigating into the assisted reproduction techniques (AST) of biotechnology. The committee doubts that increased control in AST over the characteristics of the child may curb natural characteristics.

The committee questions ethics in in vitro fertilization and embryo research affects the dignity of human being. The committee probes into the safety, ethical issues involved in the assisted reproduction and recommends for a study on the impact of assisted reproduction. Until the completion of a comprehensive study the committee recommends for the prohibition of fusing, buying, selling, transfer of human embryos into non-humans and patenting of human embryos. As there is no law on the regulation of assisted reproduction the committee stress on the need of regulatory mechanism to monitor assisted reproduction and use of human embryos.

Ethics in stem cell research

Stem cells are multi-potent cells capable of developing into any organ in whole body. Stem cells are derived from human embryos living or dead at the stage of four to eight cells from the time of fertilization and forming of zygote. Stem cells can also be derived from bone marrow. Further for the purpose of deriving stem cells embryos are

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1045 Ibid: Pg. No. 123-146 and 178
1047 Ibid, Pg. No. 126 and 158
1048 Ibid: Pg. No. 205-228 for recommendations of the committee
1049 To some extent The Fertility clinic Success rate and Certification Act, 1992 and Food and Drug Authority (FDA) regulate assisted reproduction
1050 The committee intends to strengthen the fertility clinic success rate and certification Act, 1992 to regulate assisted reproduction.
1051 Zygote is a fertile egg which develops into fetus
created artificially through In Vitro Fertilization (IVF) of through embryo cloning.\textsuperscript{1052} Stem research helps in producing tissues useful in organ transplantation and it is useful in finding cures to diseases. Stem cells can be used to test potential drugs more effectively and used as models to understand how certain diseases are caused.\textsuperscript{1053} A study finds that stem cells taken from cloned embryos are likely to be safe when used for therapeutic purposes.\textsuperscript{1054}

Stem cell research is also useful in drug development and for treating patients suffering from cell based diseases such as diabetes, Parkinson’s Alzheimer’s and spinal cord injury.\textsuperscript{1055} Organ transplantation may fail some times if the body does not accept the organ. In order to transplant organs into the body of the needy successfully, tissue produced through stem cell research is being used. As stem cells can develop into any organ of human body, tissue that suits and matches both the transplanted organ and the body could be produced through stem cell research. Stem cell research can help in curing heart ailments. Through stem cell research healthy heart muscle cells can be produced to replace damaged cells.\textsuperscript{1056} Research in stem cell involves isolation of stem cells from human embryos, which some time causes the destruction of embryos.\textsuperscript{1057} This give rise to serious ethical concerns as stem cells are capable of developing into a human being and embryo is the initial stage of a human being.\textsuperscript{1058} Ethicists opine that destruction of embryos is nothing but killing the future human being which is equal to murder.

Ethical objections find that we cannot end some lives for the sake of biomedical research. Further it is argued that stem cell research using embryos is nothing but commodification of human embryos. Here the moral status of the embryos needs to be determined before deciding whether use and destruction of embryos is ethically and legally right or wrong. Different bodies have expressed concern over the moral status of

\textsuperscript{1052} See: MONITERING STEM CELL RESEARCH Report by the presidents council on bioethics, submitted in January 2004, Pg. No. 30- 48 and 74-97
\textsuperscript{1053} See: The Hindu daily, December 29, 2005 Pg. No. 16
\textsuperscript{1054} \url{http://www.bioethics.com/}, last visited 23-01-06
\textsuperscript{1055} \url{http://apnews.myway.com/article/20060111/38F24NBO4.html}, last visited 23-01-06
\textsuperscript{1056} See: Stem Cell technology can help cure heart ailments, The Hindu daily, dated March 13, 2006, Pg. No. 3
\textsuperscript{1057} Ibid
\textsuperscript{1058} MONITERING STEM CELL RESEARCH Report by the president’s council on bioethics, submitted in January 2004, Pg. No: Pg. No. 5-7 and 237-272
the embryo and ethics involved in using human embryos in stem cell research. The Ethics Advisory Board of the Geron Corporation says that moral status of the embryos forms the basic ethical question involved over the objection to stem cell research. The American Association for the Advancement of Science (AAAS) states that disagreement over the status of the embryo is the burning point in solving ethical issues involved in embryonic stem cell research. National Bioethics Advisory Committee (NABC) describes the ethical issues raised by stem cell research as principally related to the current sources and methods of deriving stem cells. The National academy of Science states that basic ethical objection in stem cell research using embryos is that it deprives a human embryo of any further potential to develop into a complete human being.

However National Institute of Health (NIH) a federally funded agency through its Human Embryonic Research Panel (HERP) states that isolation of human embryonic stem cells is an area of research that might yield significant scientific benefit, which could be considered for federal funding. In the light of controversies over stem cell research and unresolved status of human embryo, the Bush administration issues NIH guidelines over stem cell research. The NIH guidelines postulate for respect to and observance of high standard of ethics and morality in human genetic research. The guidelines say that federal funding shall be given to research in stem cells derived from the embryo, which no longer had the possibility of development as a human being. Further the guidelines states that informed consent for the donation without any financial inducement must have been obtained for the donation of the embryo. In the light of guidelines, stem cells could be derived from dead embryos but there is no specific measure to decide the death of an embryo. When it can be said that an embryo is dead, whether seizure of capacity to replicate amounts to death of an embryo is further a debatable question. Further it is felt that deriving stem cells from a living embryo may

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1060 See: Policy brief from the American Association for the Advancement of Science (AAAS), 1999, Pg. No. 11
1061 See: National Bioethics Advisory Committee report, 1999, Pg. No. 45
1062 See: Report of the National academy of Science, 2002, Pg. No. 44
1063 See: NIH Human Embryonic Research Panel (HERP) Report, 1994, Chapter.2
hurt the development of the embryo into a complete human being. Therefore deriving of stem cells from living embryos is considered unethical.\textsuperscript{1065}

Research will continue whether government funds it or not, if government confines its funding to embryos derived in specific ways research may continue by using embryos derived in other ways without any government funding. The solution is not fixing criteria for federal government funding but to evolve certain measures to control and regulate stem cell research with due respect to ethical concerns. Moreover exclusively for the purpose of stem research embryos are created with inbuilt defects and insufficient genetic structure. As a consequence the embryo lacks ability to develop into a complete human being.\textsuperscript{1066} This kind of creation of defective embryos also raises serious ethical questions. The deliberate creation of defective or sick or disabled embryos by tampering with human genome and putting something destructive is ethically not acceptable and it is being severally criticized.\textsuperscript{1067}

The creation of defective embryos involves donation of woman egg and artificial fertilization of it. There is a possibility of forcing or coercing women to donate eggs involuntarily breaking ethical boundaries. Reportedly one of the professor from University of Pittsburg has collected eggs to use in research involuntarily by paying them against the principles of morality set under the NIH guidelines.\textsuperscript{1068} The Seoul National University (SNU) report states\textsuperscript{1069} that the research conducted by the professor of the Pittsburg University has raised huge controversy as he claimed to have produced cloned human embryos.\textsuperscript{1070} In the light of increasing controversies in the stem cell research, Federal States have enacted separate laws to regulate stem cell research. These laws say that stem cells could be derived from In Vitro Fertilized embryos only before

\begin{footnotesize}
\textsuperscript{1064} See: Bush administration NIH guidelines for embryonic stem cell funding released on November 7, 2001. Earlier Clinton administration Issued NIG guidelines for embryonic stem cell funding on August 17, 2000
\textsuperscript{1065} See: MONITORING STEM CELL RESEARCH Report by the president’s council on bioethics, submitted in January 2004, Pg. No.23-35
\textsuperscript{1066} This kind of defective embryo is called as biological artifact deliberately created embryos with inbuilt defects in order to use stem cell research.
\textsuperscript{1067} Ibid: Pg. No. 36-49
\textsuperscript{1068} See: The report sent by the Seoul National University (SNU) investigation committee report sent to the Journal Science on December 23, 2005
\textsuperscript{1069} http://apnews.myway.com/article/20060111/D8F24NBO4.html, last visited 23-01-06
\textsuperscript{1070} See: Prof. Hwang Woo Sulks paper published in Science June 2005
\end{footnotesize}
the fourteenth day of conception and before the embryo is implanted into the mother womb. Once the embryos become fourteen days old irrespective of the nature of fertilization no stem cells can be derived. However few states altogether ban In Vitro Fertilization for creating embryos to derive stem cell. There is no uniformity of understanding in the Federal States on stem cells research. Therefore there is an urgent need to enact a central law on the issue in order to balance biotechnology developments and the ethical concerns involved in such developments.

Ethics in patenting biotechnology inventions in the European Union

Natural law principles are universal but ethics and morality differs from person to person and place to place. However regarding ethics in patenting biotechnology inventions Europe is having a comprehensive framework unlike U.S. Ethical and moral considerations have been given statutory and legal support in the European Union. In Europe existing patent laws expressly prohibit certain biotechnological inventions on ethical grounds. The European Patents Convention (EPC) specifically speaks about ethics in patenting inventions. The convention states that inventions, which are against public order and morality shall not be patented. Patenting of plant, animal and essentially biological processes to produce plants and animals is not allowed under the EPC. Further methods for treatment of the human or animal body by surgery or therapy and diagnostic methods are not considered as inventions and excluded from the purview of patenting in the light of ethical and moral standards of the society. In the interest of public surgical and diagnostic methods are kept away patent monopolies. On the same lines living things found in the nature in the original form

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1072 Ibid
1074 See: EPC: Article: 53: Exceptions to patentability
1075 Ibid
1076 See: EPC: Article: 52: Inventions patentable
are also considered as unethical under the convention. The TRIPS agreement echoes the same language of EPC in providing for exclusions from patentability.\textsuperscript{1077}

Further the recent Directive on biotechnology inventions does prohibit patenting of certain biotechnology inventions on ethical grounds.\textsuperscript{1078} For the first time in the European Union ethics and morality in patenting biotechnology inventions was discussed in \textit{Genentech-I/Polypeptide expression}.\textsuperscript{1079} The invention was a plasmid, a genetically engineered microorganism. The EPO Technical Board while addressing the morality in at patenting of living matter like microorganism held that patenting of microorganism does not violate public order and morality. It was the first time that EPO addressed ethics and morality involved in patenting biotechnology inventions. However patenting of microorganisms did not raise serious ethical concerns in the European Union and there were no serious objections to it. However the decision of granting patent on microorganism stimulated claims for patents on other living things such as plant and animal. However even before the adoption of the convention plants and propagating materials of plants were claimed for patents, but at that time there was no serious awareness on its implications on ethics and morality.

\textbf{Ethics in patenting animals}

The suit of allowing patents on microorganisms was followed by the claims for patents on animals. In contrast to the patenting of microorganisms there raised serious ethical concerns against patenting animals. For the first time in \textit{oncomouse case}\textsuperscript{1080} ethics in patenting an animal had come to the fore fronts law Courts in Europe. It was the first time that an animal was claimed for patent before the EPO where vehement oppositions were raised against patenting an animal. Major part of the objections focused on the ethics in causing suffering to the animal and the possible risks associated with the release of genetically engineered organisms into the environment.

Many animal welfare associations by joining their hands with the opponents of life patenting say; that innocent animals’ life could not be taken for granted. It was contended that in the name of benefit to the society animals should not be subjected to

\textsuperscript{1077} See: TRIPS: Article: 27(2) and (3)
\textsuperscript{1078} See: The European Union Directive on the legal protection of biotechnology inventions, 1988
\textsuperscript{1079} (T 292/85) (1989) OJ E.P.O 275
risks and sufferings. They argued that animals are living beings created by God, human being could not manipulate animals as per his wish. Human being cannot own animals as a commodity in the market, which is immoral and against the public order. Further it was doubted that release of genetically engineered organisms might bring unforeseen and irreversible risks to the environment. In the light of the EPC stating that invention exploitation of which is contrary to public order and morality cannot be patented it was argued that the invention couldn’t be patented as it is against public order and morality.

However applicants were able to convince the patent office that potential benefit of the invention in cancer testing could be considered over and above ethical concerns. Further the EPO Board viewed that the intention in manipulating an animal is not to damage ethical standards but to yield benefit to the society. Therefore it was held that there is nothing wrong in patenting an animal in the light of the potential benefit that it may fetch. The Board has tried to do the balancing act between ethics and benefit to the society and held that the benefit that mankind going to derive by way of cancer testing, the sole purpose of the invention should be considered in granting patent grant. The EPC was convinced that the intention of the applicants was not to disturb ethical standards and not to cause risks or suffering to the animal, but to do research on a chronic disease suffered by millions of people around the world. The EPO considered the invention as not against public order and morality in the light of its utility. It was concluded that it is not unethical or immoral to patent inventions having definite utility and eventually patent was granted.

Later the same EPO Board again happened to again balance the ethical standards of the society and the benefits of a biotechnology invention. The invention was a mouse...
that was inserted a gene to which made it susceptible to hair loss. Applicants contended that the invention is useful in research on hair loss and baldness in the human being. The applicants relying on the oncomouse decision argued that the benefit that the invention brings to the society could be considered over and above ethics. However in contrast to its decision in oncomouse case the EPO held that the benefits that the present invention might bring to the society couldn’t be balanced with the possible risks and sufferings to the animals. The possibility of research in hair loss and baldness cannot be compared with research in cancer therefore the case is different from oncomouse and the same rationality cannot be applied here. The EPO concluded that patent on engineered mouse susceptible to hair loss would be unethical and against public order and EPC does not grant patent protection to such inventions.

**Ethics in patenting plants**

The decision of EPO in oncomouse in allowing patent on an animal had far reaching impact in the European Union. Many patent applications were filed claiming different biotechnology inventions claiming genetically engineered animals. Mean while for the first time in *Green peace V. Plant Genetic System* a plant was claimed for patent. The EPO happened to decide on the issue whether patents on seeds and plants goes against public order and morality. The Board defined the phrase public order to cover the protection of public security, physical integrity of individuals and also the protection of the environment. In the sense any invention the exploitation of which is likely to breach public peace or social order threatening the public security or seriously prejudice the environment are to be excluded from patentability as being contrary to order public.

It was opined that seeds and plants parse shall not constitute an exception to patentability under EPC merely because they represent ‘living matter’ on the ground that plant genetic resources should remain the “common heritage of mankind”. The Board noted that plant biotechnology parse cannot be regarded as being more contrary to

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1086 Lionel Bentley and Spyros M. Maniatis, Intellectual property and ethics, Sweet and Maxwell, London, 1998, Pg. No.113
1087 See: The Independent, February 2, 1992
1088 But what is public order and morality is not defined and hence it depends upon factual circumstances.
morality than traditional selective breeding because both traditional breeders and molecular biologists or biotechnologists objective is to change the property of a plant by introducing novel genetic material into it in order to obtain a new and possibly improved plant. Discussing on the concept of ‘morality’ it was held that ‘morality is related to the belief that some behavior is right and acceptable, whereas other behavior is wrong. This belief being founded on the totality of the accepted norms which are deeply rooted in a particular culture.

Therefore any invention which is not in conformity with the conventionally accepted standards of conduct pertaining to this culture are to be excluded from patentability being contrary to morality. Public order and morality under the EPC does not imply public order and morality in any one particular region or Nation but throughout the European Union as a whole. An invention is not against public order or morality just because law in some or all of the contracting states prohibits it. The EPO was reluctant to consider ethical issues on routine basis. It was viewed that it is not necessary to consider moral and ethical standards every time. This decision was stumbling block to the inclusion of ethical standards into patent law.

**Ethics in patenting human genetic material**

The stand of the EPO state that patenting of microorganisms, animals and plants does not parse constitute violation of ethics and morality. However patents were also claimed on human genetic material on the basis of the stand of the EPO there by once again throwing the ball into the Court of EPO to decide on the ethics and morality of patenting human genetic material. For the first time in Relaxin case the EPO happened to decide on the ethics and morality in patenting human genetic material. The claim was for a gene coding for a hormone called Relaxin. The hormone is expressed in the body of women during the time of delivery to relax the body that labored and suffered pain in delivering baby. The patent was opposed on following grounds.

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1089 EPO Technical Board decision T 356/93, See also International Review of industrial property and copyright 618, L. Blenty, “Sowing seeds of doubt on oncomouse (1994-95) kings college law journal, 188.
1091 See generally Modern law review, Pg. No 675
1092 Dr. K.V Swaminathan, An introduction to the guiding principles of patent law, Bahri Brother, New Delhi, 2000. Pg. No. 356-357
1. That the patenting of human gene offends morality or order public and it is against human dignity as it involves taking of tissue from human body.

2. That the patenting of human genes amounts to modern slavery since it involves the dismemberment of women and their piecemeal role to commercial enterprises.

However it was viewed that taking of tissue from human body was nothing immoral as it is standard practice in medical procedure. Responding to the argument that patenting gene amounts to slavery of human beings it was held that since patenting of human genes does not grant any rights to individual human beings, no question of slavery arises. Finally by rejecting the opposition it was concluded that patenting of genes does not amount to patenting of human life hence is not unethical or immoral.\textsuperscript{1093} Further streamlining its approach on patenting living beings and ethics involved there in the EPO Board in \textit{Novarties},\textsuperscript{1094} held that genetic material such as cells and parts thereof are considered as microorganisms. It was viewed that as microorganisms are patentable in the European Union therefore genetic material such as cells and parts thereof, genes, and parts thereof being considered, as microorganisms are also eligible for patent protection without any ethical objections.

In the light of the stand of the EPO it is inferred that in the European Union there find difficulties in incorporating ethics into the patent law. It seems EPO considered the potential benefits of biotechnology inventions over and above ethics. Though protested by strong opposition patenting of biotechnology inventions traveled a long way from patenting of microorganisms till patenting of human genetic materials. In the recent past in Europe, there was a major growth in human genetic research and as a result more and more human genetic material being claimed for patents. There expressed fears that the trend may lead to patenting of human being. As the patenting of human genetic material was on great scale it was doubted that claims for human being is not too far. At this juncture the mandates of the European Union Convention for the protection of Human Rights and Fundamental Freedoms are significant.\textsuperscript{1095} The convention standing in line with the Universal Declaration of Human Rights and such other human rights

\textsuperscript{1093} See generally, Lionel Bentley and Spyros M. Maniatis, Intellectual property and ethics, Sweet and Maxwell, London, 1998, Pg. No. 114 and 115
\textsuperscript{1094} EPO technical Board of Appeals decision 20\textsuperscript{th} December, 1999
conventions postulates for the inherent dignity of human beings.\textsuperscript{1096} Patents in violation of human dignity and freedom are considered as unethical under the convention. The convention intends to guarantee human rights, human dignity in the light of developments in the field of biotechnology.

Further United Nations Declaration on Human Genome and Human Rights\textsuperscript{1097} says that research in human genome and human genetics shall respect ethical standards of the society.\textsuperscript{1098} The declaration promotes the development of ethical studies in the light of scientific and technological progress in the field of biology and genetics.\textsuperscript{1099} It states that no research in the fields of biology and medicine should prevail over the respect for human rights and human dignity.\textsuperscript{1100} The declaration recognizes freedom of research as a part of freedom of thought and encourages research in the field of biology, genetics and medicine as a necessary means to guarantee right to health and relief from sufferings to the mankind.\textsuperscript{1101} The declaration directs the member states to establish ethics committees\textsuperscript{1102} to assess the ethical, legal and social issues raised by research in human genome and its applications. The ethics committees established should take initiative to promote education in bioethics.\textsuperscript{1103} Further the declaration intends to identify the practices that could be contrary to human dignity and ethics in particular such as germ line intervention.\textsuperscript{1104} Further it mandates the member states to come with proper legal measures to respect ethics and human rights in the light of advancements in the fields of human genetic research.\textsuperscript{1105}

\textsuperscript{1095} See: European Convention for the protection of human rights and fundamental freedoms  
\textsuperscript{1096} International convention for civil and political rights and International convention for economic and cultural rights.  
\textsuperscript{1097} See: United Nations Universal convention on Human Genome and Human Rights, 1997  
\textsuperscript{1098} See: Ibid, Article: 13 and 14  
\textsuperscript{1099} See: Preamble to the declaration.  
\textsuperscript{1100} See: Article: 10 of the declaration.  
\textsuperscript{1101} See: Article: 20 of the declaration  
\textsuperscript{1102} See: Ibid: Article: 16  
\textsuperscript{1103} See: Ibid: Article: 20  
\textsuperscript{1104} See: Ibid: Article: 26  
Mean while the European Union adopted a “Convention on Human Rights and Biomedicine” which is worth discussing.\(^{1106}\) The convention intends to protect human dignity in the light of human being, being made subject of research\(^{1107}\) in biomedical sciences.\(^{1108}\) The convention says that research in human being, tissue, organ or human genome\(^{1109}\) shall be undertaken only after informed consent of the person concerned after disclosing possible risks associated.\(^{1110}\) The interest and welfare of the human being shall prevail over the sole interest of society or science.\(^{1111}\) Using of human body and its parts for financial gain is prohibited under the convention.\(^{1112}\) Keeping in mind the recent development in embryonic research the convention intends to provide adequate protection for human embryos from being misused. Besides creation of human embryos solely for research purpose is considered unethical and the same is prohibited under the convention.\(^{1113}\) Besides the convention encourages debates over the ethics in the developments of biomedical field.\(^{1114}\)

### Ethics Groups and Committees

It is an established fact that the advancements in the genetic and bio-medical research are associated with ethics and morality. Since genetic and bio-medical research raises serious ethical concerns it is important to assess the ethical and social consequences of such research.\(^{1115}\) In the European Union there established few groups to advice on the ethics in the latest developments of biomedical research. The drive of these groups was to investigate into the ethical implications of biomedical research. The

\(^{1106}\) See: The convention for the protection for the protection of human rights and dignity of the human being with regard to the application of biology and medicine.

\(^{1107}\) See: Chapter: V: Article: 15 to 17 Scientific research

\(^{1108}\) See: Article: 1 of the convention.

\(^{1109}\) See: Article: 13 Interventions on the human genome

\(^{1110}\) See: Chapter VII of the convention: Article: 21 and 22: Prohibition of financial gain and disposal of a part of the human being

\(^{1111}\) See: Article: 5 of the convention.

\(^{1112}\) See: Article: 2 Primacy of the human being.

\(^{1113}\) See: Article: 18 Research on embryo in vitro

\(^{1114}\) See: Chapter: X Article: 28: Public debate. New insights into the structure, function and control of genes and how they influence our health have produced a dramatic expansion in our understanding of what causes disease. The application of genetic technologies can be used to advance medical research and clinical care, including for example the discovery and development of new pharmaceuticals, vaccines and diagnostic tests. Although the technology offers much promise, some developments have also raised wider concerns. Given the huge potential of genetic advances it is important to consider the ethical and social consequences. See: Colin Campbell, A commission for the 21\textsuperscript{st} century, Modern law review, Pg. No. 598

\(^{1115}\) See: Colin Campbell, A commission for the 21\textsuperscript{st} century, Modern law review, Pg. No. 598
European Group on Ethics in Science and Technologies states that human dignity and integrity shall be ensured while using human tissues in biomedical and genetic research.\textsuperscript{1116} The Group of Advisors on the ethical implications of biotechnology\textsuperscript{1117} opines that no patent should be granted on the human body at different stages of its constitution and development or on its elements.\textsuperscript{1118} Both the groups recommends for the guaranteeing of human dignity in the light of developments in the biomedical research.\textsuperscript{1119} It is recommended that research in human genetics especially on human body shall be conducted only for therapeutic purpose only after obtaining informed consent of the person concerned.

Besides in the United Kingdom there established different committees to address and advice on biomedical and human genetic research. The Nullified Council on Bioethics\textsuperscript{1120} states\textsuperscript{1121} that there shall be generic debate on human genetics and use of human tissues in the bio-medical research.\textsuperscript{1122} Further the Human Genetic Advisory Committee (HBAC)\textsuperscript{1123} is established with a sole objective to address ethics involved in research in human genetics. The committee reviews the progress in the field of human genetics and reports on the wider social, ethical and economic consequences as a result of such developments. Besides the Advisory Committee on Genetic Testing (ACGT) advises on the ethics in genetic testing of human beings, fetus and embryos. Meanwhile the Gene Therapy Advisory Committee (GATC) advises on the ethics associated with removal, suppression and incorporating of genes from and to human body through gene therapy in order to curb genetic diseases. Both AGGT and GATC are represented and

\textsuperscript{1116} See opinion of the European Group on ethics in science and new technologies rendered to the European Commission, 21\textsuperscript{st} July 1998.
\textsuperscript{1117} The group of advisors on the ethical implications of biotechnology submitted its report on ethical aspects of patenting inventions involving elements of human origin on September 25, 1996.
\textsuperscript{1119} See also the opinion of the economic and social committee of the economic and social committee of the European Commission, See Gerald Karmstra, Mark Doring, Nick Scott-Ram Andrew Sheard, Herry Wixon, Patents on biotechnological inventions: The E.C.Directive, Sweet and Maxwell, London, 2002., Pg. No. 20
\textsuperscript{1120} In the light of serious ethical concerns associated with the latest advancements in biomedical research the government of United Kingdom established Nullified Council on Bioethics and Human Genetic Advisory Committee (HBAC) to advice on the latest developments in the human genetic research.
\textsuperscript{1121} The council submitted its first report in 1993 and second in 1995
\textsuperscript{1122} See generally modern law review, 1998 Pg. No. 594
\textsuperscript{1123} HBAC a no-statutory body was established in December 1996
taken for assistance by the HBAC in advising the Government of United Kingdom on the ethical issues involved in research in human genetics.\textsuperscript{1124} These committees and groups have been established for the purpose of assuring the maintenance of ethical standards in the conduct of research in human genetics. These committee assesses evaluates the researches in human genetics in the light of seriousness of ethical concerns that it gives rise to.

Today biotechnology is being taken for assistance in reproduction and we find fertility clinics to assist infertile couple to have children. In the light of increasing number of fertility clinics and also increased research in the field of embryology the Government of United Kingdom enacted Human Fertilization and Embryology Act. The Act establishes Human Fertilization and Embryology Authority to monitor the working of fertility clinics in helping parents to have children and to regulate assisted reproduction. The authority also regulates human embryo research in the light of latest advancements in the field of human embryology, which involve serious ethical concerns. Embryo research basically confined to therapeutic purpose focusing on the finding of cures and medicines for many diseases. However research in embryo raises serious ethical questions. In view of the fact, the authority probes into the ethics in cloning and using of human embryos for therapeutic purposes and assesses the consequences.

**European Union Directive on biotechnology inventions**

The drive for a comprehensive mechanism on the regulation of biotechnology got accomplished with the adoption of Directive on biotechnology invention. The directive\textsuperscript{1125} addresses ethical issues associated with the developments in biotechnology. The Directive tries to balance ethics with the latest advancements in biotechnology like, human genetic research embryo cloning and stem cell research. The Directive empowers the European Group on Ethics in Science and New Technologies to evaluate ethical aspects in biotechnology from to time to time.\textsuperscript{1126} The directive prohibits patenting of certain biotechnology inventions on ethical grounds. The directive reaffirms the

\textsuperscript{1124} See generally, Colin Campbell, A commission for the 21\textsuperscript{st} century, Modern law review, Pg. No. 598
\textsuperscript{1125} The Directive came into being in 2000
\textsuperscript{1126} See: Article: 7 of the Directive.
exclusion of plants animals and essentially biological processes from patenting.\textsuperscript{1127} Going a step ahead the Directive excludes certain inventions in the field of human genetics on ethical grounds\textsuperscript{1128}

1. The human body at the various stages of its formation and development and the simple discovery of one of its elements including the sequence or partial sequence of a gene.

2. Inventions, which are contrary to public order and morality such as;
   a) Processes for cloning of human embryos
   b) Processes for modifying the germ line genetic identity of human beings
   c) Use of human embryos for industrial or commercial purposes.
   d) Processes for modifying the genetic identity of animals that are likely to cause them suffering without any substantial medical benefit to man or animal and also animals resulting from such processes.

Compared to the United States of America ethical standards in the European Union are well founded. Ethics and morality are being addressed specifically in the patent laws in the Union. European Patent Convention and the recent Directive both specifically addresses ethics involved in biotechnology inventions. Unlike U.S the E.U has streamlined the ethical standards and incorporated into the patent law. In the European Union though human cloning is not directly prohibited certain inventions in the field of human genetics are excluded on ethical grounds.

**Ethics in patenting biotechnology inventions in India**

India is a country where ethics and morality are respected and adhered to at par with law. Ethics and morality play a vital role in the life an Indian. Indian tradition is well known for worshipping animals and plants. Indians worship cow and plants such as tulsi, neem etc., Indians consider certain plants and animals as a resemblance of God. For an Indian patenting of such plants and animals would be like patenting and owning of God. Therefore patenting of plants, animals and other living beings are considered as unethical.

\textsuperscript{1127} See: Article: 4 of the Directive where it reaffirms the provisions of EPC: Article: 52 and 53, TRIPS: Article: 27
\textsuperscript{1128} See Article: 5 of the Directive
in India. The patent Act of India\textsuperscript{1129} addresses ethics in patenting inventions in general.\textsuperscript{1130} Following the suit of the TRIPS agreement in addressing ethical issues in patenting inventions,\textsuperscript{1131} India brought amendments to the patent Act. The amended patent Act states that invention exploitation of which is against public order, morality and inventions that may cause serious prejudice to the health of human, animal or to the environment cannot be patented.\textsuperscript{1132} Further plant animal and essentially biological processes for production of plants and animals are excluded from patenting on ethical grounds.\textsuperscript{1133}

However with the coming into being of the TRIPS agreement universally now inventions like; plants, animals and microorganisms produced through microbiological or non-biological or biotechnological processes are patentable.\textsuperscript{1134} Being a member to the TRIPS agreement India does adhere to it, in patenting above inventions. Patenting of such living beings goes against the customary practices and ethical standards in India. However as it is mandatory on the part of India to grant patent on inventions which TRIPS do intend to provide patent for. Meanwhile India started granting patents for plants, animals and microorganisms produced through microbiological or non-biological or biotechnological processes since January 2005.\textsuperscript{1135} Till the time no patent is granted therefore there is no serious discussion on ethics involved in patenting biotechnology inventions has taken place. In future some serious ethical debates are expected in India on patenting of living beings of biotechnology in the light of its seriousness over ethics and morality.

Infact India began patenting of biotechnology patents after it is universally settled that living beings could be patented except human being. A patent was granted on a

\textsuperscript{1129} See The Patent Act of India, as amended in March, 2005
\textsuperscript{1130} See: Chapter: II of the patent Act: Inventions not patentable.
\textsuperscript{1131} See: TRIPS Article: 27
\textsuperscript{1132} See: Section: 3(b)
\textsuperscript{1133} Ibid sub clause: (i)
\textsuperscript{1134} The exclusion of plants, animals and essentially biological processes to produce plants and animals has been interpreted to mean plants and animals produced through other than essentially biological processes as patentable. See: Article: 27 of the TRIPS agreement.
\textsuperscript{1135} India was given ten years transmission period to modify its intellectual property laws to bring in conformity with the provisions of the TRIPS agreement. The transmission period ended by 1-1-2005 and from the same date India accepting applications claiming different living beings produced through biotechnology.
living process on the direction of the Calcutta High Court.\(^{1136}\) The Court held that there is no bar for patenting living beings or living processes under the patents Act. However no ethical or moral issues involved therein were considered in the case. However ethical objections should not undermine the potential benefits of inventions. We cannot forgo the utility of biotechnology inventions by strictly implementing ethical standards. Former Chief Justice of Supreme Court of India says; research, which promises to mankind the great blessings of science, should not be stifled by too restrictive approaches.\(^{1137}\)

**ICMR guidelines on ethics in human genetics**

Though not many patents are granted on living beings in India research is on the go in different spears of biotechnology. In particular research in human genetics is not lagging behind too far compared to developed countries. In the light of increasing research in human genetics, the Indian Council of Medical Research issued guidelines to evaluate ethics involved in human genetics.\(^{1138}\) In the light of latest advancements in human genetics such as human genome mapping, genetic recombinant engineering, assisted reproduction technology, stem cell research involving serious ethical questions the guidelines are very significant. As the effect of ethical issues raised by research in human genetics is acute as a sense of urgency these guidelines have been issued. The guidelines admit that ethical considerations in human genetic research are more serious compared to research in plants and animals. The guidelines intend to guarantee human rights and dignity in the light of human genetic research where human being, human tissues, cells and genetic material is being used as subjects.\(^{1139}\)

The present guidelines acknowledge international conventions on human rights and fundamental freedoms. Further respect is shown towards “international ethical guidelines for biomedical research involving human subjects” issued by Council for international organizations of medical science (CIOM) in 1993 and general principles of

\(^{1136}\) See: Dr T. Ramakrishna, BIOTECHNOLOGY AND INTELLECTUAL PROPERTY RIGHTS, National Law School of India University, Bangalore, First Edition, 2003.

\(^{1137}\) See: Foreword to the Indian Council of Medical Research (ICMR) guidelines, 2000

\(^{1138}\) See: ICMR ethical guidelines, 2000

\(^{1139}\) Earlier to the 2000 guidelines there were proposals to frame guidelines in order to regulate and to address ethical concerns in human genetic research.
World Medical Association issued in 1964. The Helsinki declaration of world medical association on research in human subjects was also adhered to by the guidelines. The present guidelines states that research on human subject shall be done only after informed consent (Voluntary participation) after explaining him possible risks associated with. The guidelines intend to protect participants from physical or psychological harm or risk. The Guidelines State that the institutional ethical committees established with necessary expertise for the purpose should scrutinize research proposals on human genetics. The guidelines intend to establish Central Ethics Committee (DBT) and National Bioethics Committee (CET) to take initiative in organizing debates on ethics in human genetics. The guidelines prohibits misuse of results of human genetic research against ethical standards such as for identification of sex of the child or to enhance capacity of the child etc.,

However genetic screening to identification and curing of genetic diseases is considered as not unethical and practice of gene therapy to cure genetic diseases is allowed. Further patenting of gene therapies is allowed under the guidelines subject to the approval of National Bioethics Committee and Central Ethics Committee. However the use of genetic research or gene therapy to enhance genetic characteristics like; intelligence, memory is considered as unethical. Further gene therapy to alter germ line genetic set up is also considered as unethical and the same is prohibited. The guidelines do not consider assisted reproduction as unethical and there is no objection for in vitro fertilization with the help of biotechnology. But creating, using of embryos and fetus for commercial purposes is prohibited on ethical grounds. Using of embryos of fourteen days of age is considered unethical and encouraging abortions for research purpose is also prohibited on ethical grounds. Using of foetal tissue for the purpose of organ

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1140 See: Helsinki declaration of world medical association, Hong Kong, 41st world medical assembly, 1989.
1141 In the light of genetic research including developments of recombinant DNA technology having potential to unravel the mystery of human genome the guidelines states that; there shall be voluntary participation of individuals in genetic research.
1143 At the age of fourteen days the nervous system starts to develop in the embryo, therefore it is unethical to use such embryos in research disturbing its overall development.
1144 Foetal tissues or cells multiply rapidly and adopt easily to the signals received from surrounding tissue in a host. Hence transplantation could be success. Or body rejects any foreign material that is against the genetic make up of our body therefore transplantation of organs is not assured with hundred percent
transplantation is not considered as unethical provided the tissue is obtained from a dead embryo and the ethics committee approves the same. The guidelines say that Removal of tissue from embryo is unethical if it hurts the overall development of the child. Therefore while obtaining tissue from fetus the overall development of the fetus and health of the mother shall be taken care of.

The patent Act of India in line with the TRIPS agreement excludes certain inventions from patenting on ethical grounds. However the Patent Act and as well as the TRIPS agreement does not address the serious ethical implications of different biotechnology inventions. The TRIPS agreement leaves it to the member states to exclude inventions on the grounds of ethics and morality. The Patent Act of India states that inventions, which are against public order and morality, are excluded from patenting. As far as research in human genetics is concerned the European Union was able to introduce ethics into the patent law but U.S.A and India have not been very successful in introducing ethics into patent law. European Patent Law specifically excludes certain inventions of human genetic research from patenting unlike U.S and India. In this background the ethical guidelines issued by ICMR on human genetic research holds good in the absence of legislative efforts to address ethics in biotechnology and human genetic research completely. As far as ethics in human genetics is concerned the guidelines present the present law. However there is a move to enact a central law on the basis of the guidelines. Lets hope that in future there may be comprehensive efforts to address ethics involved in biotechnology and human genetics in India.

In the light of potential benefits brought by biotechnology it is not possible to undermine or neglect the developments in the field. However there is no uniform understanding over the ethical issues involved in research in biotechnology. There is no doubt that research in biotechnology involves tampering with life. Such tempering of life may result in benefit to the society but is should not at the cost of ethics and morality. Every thing that comes from biotechnology is not acceptable but few developments are inevitable. It requires a balancing approach here to respect ethical concerns and at the same time to encourage developments in the field of biotechnology. There should be successes. In such cases using the tissues from fetus, organs could be transferred and implanted as the foetal tissue adopts to any part of the body quickly.
uniformity of understanding with regard to ethics in research in biotechnology starting from manipulation of microorganisms till manipulation of embryos. In future developments in the field may further give rise to more serious ethical and legal objections. Therefore there is a need to set a platform for assessing, evaluating and respecting the ethical and moral standards.

**International bioethics committee**

There is a global form to discuss and evaluate ethics in biotechnology by name Global Form on Bioethics in Research came into being in 1983. The committee works under the auspices of UNESCO. It is an informal partnership established by a number of organizations with a shared interest in ethics in conducting research involving human beings in developing countries. The forum provides for a universal platform to debate on ethics involved in research in biotechnology and life sciences. The forum first met in 1999 and till the time it met seven times where it attempted to evolve international consensus on bioethics in the light of developments in life sciences and biotechnology. The last meeting of the forum was held between 17-19 of February 2006. The agenda was on “ethical issues in biomedical research including using human genetic material, human tissues. Experimenting with human body for bio-medical research and clinical trials was also in the agenda of the forum. The committee evaluates ethics involved in research in life sciences and biotechnology. The committee intends to:

1. Promote reflection on the ethical and legal issues raised by research in life sciences
2. Encourage awareness and to make recommendations on bio-ethics.
3. Co-operate with International governmental and non-governmental organizations as well as national and regional bioethics committees concerning bioethics.

The findings and recommendations of the forum may be considered for addressing various ethical issues raised by the research in biotechnology and life sciences. We have already sacrificed ethics to certain extent in allowing manipulation of microorganisms, plants and animals. When it comes to the manipulation of human being and human

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1145 See: www.gfbronline.com
embryos society does not accept the developments quickly as expected by the biotechnology industry. Besides it is not that easy and comfortable to scarifies and restructure the log lasting ethics in the society. There should be some limit to everything; on the same lines there should be an ethical fix to the developments in biotechnology. The research in biotechnology should not cross the line of control ethics. However ethical line of control should not undermine the potential benefits of biotechnology in the interest of the society. The United States of America is moving toward proposing a convention on research in biotechnology in the light of profound ethical objections to the developments in the field. It is a positive move and lets hope that in the future time we may find a solution to these ethical questions raised by the innovative developments in the field of biotechnology.

1146 The forum met for the first time in 1999 in Bethesda, second meeting was held in Bang Kong in 2000, third in Cape town, in February 2002, fourth in Brasilia in October 2002, fifth in Paris in April, 2002 the sixth in Blantyre, Malawai in March, 2005 and for the seventh between 17-19 February 2006.