

Patenting of human genetic material v. bioethics: revisiting the case of John Moore v. Regents of the University of California

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Abstract

Moore v. Regents of the University of California was one of the first cases internationally that dealt with the patenting of human genetic material. The case is closely related to the development of medicine and of biotechnology applied to medicine. These developments require the utilisation of human body parts, both for experiments and for transplant, and present certain major medico-legal problems. However, the case did not produce conclusive decisions on the various key legal issues that it raised involved in biomedical research and the patenting of human genetic material. This article re-examines the case from an Indian and an international perspective.

After a brief introduction in Part I, Part II of the article describes existing laws in various countries with respect to the patenting of human genetic material. Part III discusses legal regimes applicable in the context of biological materials. Part IV elaborates on the importance of the doctrine of informed consent in the context of biomedical research on human subjects. Part V discusses the significance of bioethics in research and the patenting of biotechnology, according to international law. Part VI concludes the article with an assertion of the urgent need for legislation in this area.

I. Introduction

In *Moore v. Regents of the University of California* (1) (hereinafter referred as the Moore case), John Moore, a resident of Seattle, USA, was treated for hairy-cell leukaemia by David W. Golde at the University of California-Los Angeles (UCLA) Medical Center. Moore was advised to undergo surgery to remove his spleen. At that point in time, apart from regular consent forms for the surgery and other related procedures, he was also asked for permission to contribute to medical research, which he explicitly refused. Following the surgery, despite his refusal, portions of Moore's excised spleen were used by Golde and his research colleagues to develop a cell line from his T-lymphocytes. UCLA applied for, and was granted, a patent on the cell line, which listed Golde and a colleague, Shirley Quan, as inventors. Neither Golde nor anyone else at UCLA informed Moore before surgery, after surgery, or during the three follow-up visits suggested by Golde, during which additional blood and other biological specimens were obtained, that UCLA intended to use Moore's biological material for research or commercial purposes. When Moore learned of the use of his cell lines without his permission, he sued the defendants under various causes of action. Two of these were: breach of fiduciary duty and "conversion" – the use of property of another for

commercial benefit, without the owner's authority (2). His case was decided in 1990.

The case, from the legal perspective, has two important aspects. The first one refers to the authorisation that should have been obtained from Moore, and the second one is the susceptibility of patenting body parts. The California Supreme Court of Justice which rendered a decision partly in favour of Moore based its decision on three basic principles (3):

- An adult in full use of his faculties has the right to decide whether or not to submit to a medical treatment, based on his "right to have control over his own body".
- The patient's consent shall be informed.
- The physician has the obligation to give all the necessary information for the patient's decision.

The California Supreme Court ruled that Moore's consent was not obtained, and the doctors were in breach of their fiduciary duty. However, the court rejected Moore's argument that his cells were unique and therefore he had a right over them. They stated that the lymphokines used by the defendants were of the same basic molecular structure in all human beings. It is difficult to accept such an argument, in science or in fact, because it was precisely the uniqueness of the cell line derived from John Moore that purportedly made it so valuable. It is evident that the case is closely related to the development of medicine and biotechnology applied to medicine, which requires human body parts both for research and for transplant, resulting in certain major medico-legal problems (4). The Moore decision reflects an unwillingness to recognise the infringement of human dignity that results from intentional fraud. No judgement was made on the consequences of, or the problems caused by, the absence of informed consent. The decisions given by the court did not concern the legal regime that governs informed consent in biomedical research. These decisions will become increasingly important as biomedical research advances in the 21st century. This is a judgement by a United States court and is not binding in other jurisdictions like India. However, the case has serious implications regarding the patenting of human genetic material. Such patenting is beginning to be accepted in the US and is a matter which could arise in any other country. Thus, it is essential to revisit the Moore case in order to analyse those issues which were not sufficiently dealt with by the California Supreme Court and also to explore the case from the point of view of Indian law.

II. Legal overview: patenting human genetic material

Patents are said to serve the goal of fostering the development of innovation (5), promoting the growth of knowledge by providing innovators an incentive to risk their time and the costs of research and development (6). However, this view is a matter of controversy; some scholars question the notion that patents necessarily lead to innovation and that they are an incentive to research.

A. Human genetic material is patentable

The fact, however, is that human genetic material has been granted a patent in numerous cases. In *Diamond v. Chakrabarty* (7), the United States Supreme Court held that a genetically engineered bacterium was patentable as a "new and useful ... manufacture, or composition of matter", thereby opening the floodgates for gene patenting in the US. A patent claim on human genetic material, DNA, was made for the first time in *Amgen v. Chugai* in 1991 (8). Similar claims were made in *Re Bell* (9), and in *Re Deuel* (10). These reiterated the stand that human genetic material was patentable.

In the *Relaxin* case, for the first time in Europe (11) the European Patent Office issued a decision on whether or not a gene coding was patentable. This was for a hormone, Relaxin. The patent was granted. The Patent Office held that patenting of human genes did not go against ethics, as patenting genes was not tantamount to patenting a human being. Following the *Relaxin* suit, in *Biogen v. Medeva* (12) a patent application was made for human genetic material and subsequently granted. It is now a settled matter of law in the US and recently in the European Union (EU) that human genetic material is patentable. Many other countries support this but have not incorporated express provisions in their domestic statutes. However, there are also countries which staunchly oppose the patenting of human genetic material.

In the *Moore* case, for the first time in the history of patent law, a patent was claimed on a human cell line (1). A cell line, in tissue culture, is defined as the cells growing in the first or later subculture from a primary culture, or a clone of cultured cells derived from an identified parental cell type (13). The distinction between primary cells (cells taken directly from the body) and cell lines is that while primary cells typically reproduce a few times and then die, one can sometimes continue to use cells for an extended period of time by developing them into a cell line, a culture capable of reproducing indefinitely (13). In the case of *Moore*, a patent was obtained for a cell line using cells taken from *Moore's* body.

The court in this case held that the patented cell line and the products derived from it could not be *Moore's* property. The court stated that this was so because the patented cell line is both factually and legally distinct from the cells taken from *Moore's* body. Since then, there have been numerous instances where cell lines have been patented across the world (14, 15).

B. Product of nature v. product of man

It is this inventive effort that patent law rewards, and not the discovery of naturally occurring raw materials. Intangible intellectual property in the body, such as a gene patent or a cell line, receives much more protection than do physical body parts. The "inventor" or "discoverer" of intellectual property in the body is granted broad protection, unlike the individuals who are seen as supplying the "raw materials" such as the blood, tissue, and other body parts necessary to conduct such research.

In the case of *Diamond v. Chakrabarty* (8), the court held that *Chakrabarty's* invention, a genetically engineered bacterium, was not a product of nature but a product of man; the human role involved in the invention differentiated it from a product of nature. The court stated that the starting point of the invention was a product of nature, but the inventor had added his ingenuity in engineering the bacterium to possess the capacity to eat up oil spills. Therefore, the court held, the invention was a non-natural, human-made product, a result of human ingenuity and labour. The court explicitly held that "anything under the sun that is made by man" is patentable.

Even the EU directive on legal protection of biotechnical inventions, 1998 (16), and Article 3 of the European Patent Convention, 1973 (17), declare that biological material produced or isolated and purified by means of some technical process is patentable. As biological materials are not available in isolated and purified form in nature, it is argued that the isolation and purification involved is an inventive step (18).

Similarly, the decision of the court in *Moore's* case clearly indicates that under US law a cell line is an invention and therefore a non-natural, human-made product, different from *John Moore's* cells, which are a product of nature. The cells were a product of nature until human intervention, whereupon they turned into a product of man and developed new abilities to grow in different media. This is the direction in which US and EU laws have been developing, though it is not explicitly accepted in other parts of the world.

It is essential to note that the court in the *Moore* case did not acknowledge the fact that the cells used for making the cell line were *Moore's* property, and *Moore* alone had the right to determine and direct the use of his cells. Using his cells for research without his consent raises issues relating to property and privacy, which are addressed in the next section.

III. The right to property v. the right to privacy

It has always been a moot question whether the law applicable in the context of biological materials is the "Law of Property" or "The Law of Privacy". Conversion is a common law tort related to the law of property. As defined in the case of *Fouldes v. Willoughby* (19), conversion is a voluntary act of taking with the intent of exercising over the chattel (in legal terms a moveable possession including intangible and transferable possessions such as a lease) an ownership that is inconsistent with the real owner's right of possession.

In the Moore case, the majority opinion decided that Golde's use of Moore's cells did not amount to "conversion". This decision was based largely on the proposition that a patient generally possesses no right to a body part that has already been removed from his body. The most challenging aspect of this case was the decision on whether or not Moore's cells and tissues could be considered "property," or "chattel" thereby allowing them to be converted. The court in this case addressed only the question of proprietary rights over the cell line developed by the doctors at the medical institute. It failed to deal with the infringement of the patient's right to privacy. In this section, I will discuss these rights in detail with reference to biological materials. I will also examine these rights from the perspective of Indian law.

A. The right to property

The definition of property is sufficiently broad to include "every species of real estate, real and personal, and everything which one person can own and transfer to another." Under existing law, a quasi-property right is recognised with regard to dead bodies and embryos (20-23). Even cell lines have been recognised as property (24). Therefore, by drawing an analogy from these cases, even extracted dead cells of John Moore can be considered to be his property.

Under existing law in the United States, John Moore has the right to control his body, exclude others from it, and dispose of it in any legal way. This right to dispose of property includes the right to direct the use of excised cells and tissue, while the right to exclude includes the right to refuse medical treatment (25, 26). A person of "sound mind and adult years" has the right to determine, in exercising control over his body, whether or not to submit to lawful medical treatment.

Further, in the United States, though the Uniform Anatomical Gift Act (27) applies only to anatomical gifts that take effect on or after the death of the donor, the general principle of "donor control" which the Act embodies is clearly not limited to that setting. In the transplantation context, for example, it is possible for a living donor to designate his organ to the specific donee. If a hospital, after removing an organ from such a donor, decided on its own to give the organ to a different donee, no one would deny that the hospital had violated the legal right of the donor by its unauthorised use of the donated organ.

The principle of "donor control" has also been recognised in India in the Transplantation of Human Organs Act, 1994 (28), which clearly states that "Any donor may, in such manner and subject to such conditions as may be prescribed, authorize the removal before his death of any human organ of his body for therapeutic purposes."

These particular laws, in the US and in India, clearly spell out some of the rights associated with property, one of them being the right to dispose of a tangible thing in every legal way. Other relevant privileges are the right to possess the thing, to use it and to exclude everyone else from it.

While these issues concerning human genetic material have not been interpreted in India, if such a matter comes up before an Indian court, the court may refer to the US case. The present state of the law in India and the US provides sufficient justification to establish that John Moore has a property interest in his blood cells, and the right to direct the use of excised cells and tissue before they were extracted.

B. The right to privacy

As stated above, the California Supreme Court did not deal with the law of privacy before delivering its judgement. The following paragraphs will exemplify how the law of privacy has been recognised in US and Indian jurisprudence, and how it can play a key role in matters concerning the patenting of human genetic material.

The conceptual framework of life is connected to natural law which stands for inherent values of life such as dignity, integrity, sustenance, survival and self-preservation. The Supreme Court of India has in *Francis Coralie v. Union Territory of Delhi* (29) held that the right to life enshrined under Article 21 of the Constitution of India means something more than survival or an animal existence. It includes the right to live with human dignity (30).

Patenting of biotechnology inventions is an incentive to the manipulation of living beings. The Constitution of India gives every living being a right to self dignity and integrity, and every living being has the right to preserve the intrinsic values of life which should not be disturbed or altered. Such alterations or manipulations strike not only at the dignity and integrity of the living beings concerned but also at the integrity and balance of nature (18). A patent is private property which can be owned, transferred or sold just as goods can be. It is suggested that patenting genetic materials of a person amounts to owning private property rights over life, making life a market commodity. Hence it is argued that patenting of genetic materials is nothing but commodification and marketing of life, which is a gross violation of the dignity of life.

The right to live with dignity includes the right to privacy. Genetic research may cause intrusion into three forms of individual privacy: bodily privacy in cases where the sample is taken from a person's body; genetic privacy, where predictive health and other information about the person is obtained from the sample; and behavioural privacy where genetic information is used to determine where a person has been and what he has done. Also, the right to publicity, or the right to control and profit from the commercial use of one's name, likeness and persona, is an intrinsic part of the fundamental right to privacy.

B 1. Infringement of the right to bodily privacy

In the background of the Indian law, if the issue of privacy is raised in a case similar to that of Moore, an infringement of Article 21 of the Constitution of India can be argued. Article 21 of the Constitution of India states that "No person shall

be deprived of his life or liberty except according to the procedure established by law." The *Griswold v. Connecticut* (31) pronouncement of the United States Supreme Court, wherein the right to privacy was recognised as an extension of substantive fundamental rights embedded in the First, Third, Fourth and Fifth Amendments of the United States Constitution, was one of the judgements used to interpret Article 21 of the Indian Constitution in the privacy case of *Gobind v. State of MP* (32).

In India, the right to privacy flows from the right to life, and is therefore considered a fundamental right, as also held in *People's Union of Civil Liberties (PUCL) v. Union of India* (33), by the Supreme Court. Thus, the right to control one's body which is implicit in the right to privacy also includes the right to be free from unwarranted intrusion of body and mind.

In the US, this has been stated in *Schloendorff v. Society of New York Hospital* (34). The court in *Bouvia v. Superior Court* (35) also affirmed the proposition that "[e]very human being of adult years and sound mind has a right to determine what shall be done with his own body..." Thus, it is the patient who must have the ultimate power to control what becomes of his or her tissues and to hold otherwise would open the door to a massive invasion of human privacy in the name of medical progress. In *R v. Legere* (36), plucking a person's hair without his consent constituted a breach of his privacy and a violation of Sections 7 and 8 of the Canadian Charter of Rights and Freedoms. The courts have further extended the doctrine of privacy in *Venner v. State* (37) by holding that "[i]t is not unknown for a person to assert a continuing right of ownership, dominion or control, for good reason or for no reason, over such things as excrement, fluid waste, secretions, hair, fingernails, toenails, blood, and organs or other parts of the body..." Also, La Forest J observed in *R v. Dyment* (38) that "[t]he use of a person's body without his consent invades an area of personal privacy essential to the maintenance of his human dignity..." Lamer J places the right to bodily privacy on a higher pedestal by observing in *R v. Pohoretsky* (39) that "a violation of the sanctity of a person's body is much more serious than that of his office or even of his home."

The aforementioned Indian and US cases enumerate the development of privacy law in both India and the US, and its importance and influence on the issue of patenting of genetic material. Thus, if such a case is addressed in the Indian courts, the fraudulent taking of cell lines from the patient's body without adherence to the procedure established by law would amount to infringement upon his right to have control over his body and thereby would trample on his fundamental right to bodily privacy and dignity guaranteed under Article 21 of the Constitution of India.

B 2. Grave and imminent danger of infringement of genetic privacy

Another form of individual privacy which is important but which was not addressed in the Moore case is the concept of "genetic privacy", which has two dimensions: protection from

the intrusion of others and protection of one's own, hitherto unknown, secrets (40). The power and potential of genetics rest in the knowledge that it provides, thereby raising concerns about privacy and confidentiality in various situations.

In a similar case, the issue of genetic privacy comes up if the doctors or people involved in medical research, in the course of their practice, come across genetic materials of patients upon which they conduct tests or research without the patient's knowledge. The genetic material could expose the patient's medical history or bring out some confidential facts of his life, which the patient would not have wanted to be brought to light or made known, thereby violating his privacy.

B 3. Infringement of the right to publicity

The right to privacy is an evolving right (41) and also includes the right to publicity. The right to publicity finds its genesis in the right to privacy and is referred to as a "subset" of privacy rights. Roughly defined, it is the right to charge for (or bar entirely) the commercial exploitation of one's name, likeness, voice or "personality". By the broadest definition, the right to publicity is the right of every individual to control any commercial use of his or her name, image, likeness, or some other identifying aspect of his or her identity (42). Protecting the individual from the loss of commercial value resulting from the unauthorised appropriation of an individual's identity for commercial purposes is the principal purpose of the right to publicity.

It was precisely the unique properties of his genetic "programs" – the fact that his virus-infected cells overproduced lymphokines – that made John Moore's tissue and bodily fluids valuable for medical research. Therefore, although a patient may not retain any legal interest in a body part after its removal when he has properly consented to its removal and use for scientific purposes, it is clear from the above arguments that before a body part is removed, it is the patient, rather than his doctor or hospital, who possesses the right to determine the use to which the body part will be put after removal.

However, if the case was such that Dr Golde and his research assistant, Dr Shirley Quan, had informed John Moore, prior to removal of his spleen, of the possible uses to which his body part could be put, and if Moore had authorised one particular use, then, in my opinion it is possible that the defendants would be held liable for conversion if they had disregarded Moore's decision and used the body part in an unauthorised manner for their own economic benefit, or if they intentionally withheld material information that they were under an obligation to disclose to him.

IV. The doctrine of informed consent

A violation of the fundamental right to privacy usually occurs when the procedure of informed consent has not been observed. The doctrine of informed consent is that the donor of any genetic material used for genetic or genomic research, or for any therapeutic purpose, must give consent to

the procedure after being fully apprised of all relevant facts regarding the method of collection of the information and the end use of such data. The doctrine of informed consent was developed in research settings in express response to revelations of abuses of human subjects by researchers. The deliberations that followed these revelations led to the construction of the informed consent doctrine and to the institutionalisation of bioethics as an area of practice (43).

The ethical principles laid down in the Nuremberg Code (44) were developed following the trial of Nazi doctors and researchers who had conducted horrific experiments on human subjects during the Second World War. These principles articulated concepts such as consent to participate in medical research and the avoidance of harm to human research subjects.

The Nuremberg Code was followed by a number of guidelines, codes and regulations to ensure the protection of human volunteers in medical research; among these the most important documents are the Declaration of Helsinki, 1964 (45), Ethical Principles and Guidelines for the Protection of Human Subjects of Research, 1979 (the Belmont Report) (46), the Council for International Organizations of Medical Science (CIOMS) International Ethical Guidelines for Biomedical Research Involving Human Subjects (47) and the International Declaration on Human Genetic Data (48).

In India the concept of informed consent was recognised in The Ethical Guidelines for Biomedical Research on Human Subjects issued by the Indian Council for Medical Research (ICMR) in 2000 and revised in 2006(49), followed by the Good Clinical Practices Guidelines prepared by the Central Drugs Standard Control Organisation (50). In 2005, Schedule Y of the Drugs and Cosmetics Rules, 1954 (51), was amended to include, inter alia informed consent of volunteers.

According to the principles set out in the ICMR guidelines and the GCP guidelines, "respect for persons" implies that the person should be recruited into research voluntarily only if he comprehends the (adequate) information provided to him by the investigator.

An important principle concerning informed consent for research that is expressed in international as well as Indian guidelines is that volunteers should be allowed to withdraw from the study at any stage, even if it means terminating the study.

A. Judicial decisions explaining the informed consent doctrine

A plethora of judicial material supports the rigorous application of the principle of informed consent, particularly to cases where blood and tissue samples are collected for the purpose of conduction of genetic research upon them, irrespective of the element of risk (52-54). In this section, I discuss Indian and US case laws which have analysed this doctrine.

The binding nature of the doctrine of informed consent entails more than a formal acquiescence; it requires that consent is

granted pursuant to complete knowledge of the purpose for which consent has been undertaken. Thus, the use of a patient's genetic material for a purpose wholly unconceived of by the patient, without availing of his fresh consent for this use, is a reprehensible violation of the principle of informed consent (48). More particularly, the principle of informed consent is antithetical to the use of any coercion in the collection of blood and tissue samples; the term coercion includes within its ambit the provision of any incentives to the donor of blood and tissue samples, particularly when the donor belongs to a marginalised, economically, socially, geographically or otherwise backward community, and particularly indigenous communities in developing nations (55).

The Supreme Court of India has recently, in *Samira Kohli v. Dr Prabha Manchanda and Anr* (56), formulated the law on informed consent in the following words:

We therefore hold that in Medical Law, where a surgeon is consulted by a patient, and consent of the patient is taken for diagnostic procedure/surgery, such consent cannot be considered as authorisation or permission to perform therapeutic surgery either conservative or radical (except in life threatening or emergent situations). Similarly where the consent by the patient is for a particular operative surgery, it cannot be treated as consent for an unauthorized additional procedure involving removal of an organ, only on the ground that such removal is beneficial to the patient or is likely to prevent some danger developing in future, where there is no imminent danger to the life or health of the patient.

In the US, in *Kaimowitz v. Department of Mental Health* (57), on the issue of consent, the Michigan Court discussed the Nuremberg Code and declared: "To be legally adequate, a subject's informed consent must be competent, knowing and voluntary." The court based its pronouncements on the need to protect the "inviolability of the individual" which, it said, was "one of society's most fundamental values." The court therefore concluded: "Consent is not an idle or symbolic act; it is a fundamental requirement for the protection of the individual's integrity."

Some individuals object on religious, ethical, or other personal grounds to particular medical procedures, even when those procedures carry an appreciable possibility for improving their own health (58, 59). Hence, the mere fact that collection of blood and tissue samples is a standard medical procedure, or can be necessary in a procedure that has medical benefits, is no ground for evading the doctrine of informed consent.

In light of the aforesaid judicial decisions, it can be concluded that, if the issue were brought to Indian courts, under Indian law, the fraudulent taking of cell lines from the body of a patient without adherence to the procedure of informed consent established by law would infringe upon his right to have control over his body, and would thereby violate his fundamental right to privacy that is guaranteed under Article 21 of the Constitution of India.

B. Informed consent and international law

Having examined judicial decisions recognising the doctrine of informed consent in the previous section, it is necessary to look at how international bodies have incorporated this doctrine in international treaties and conventions. The doctrine of informed consent is firmly ingrained in the corpus of customary international law. Article 7 of the International Covenant on Civil and Political Rights (ICCPR) (60), to which India is a signatory, prohibits medical and scientific experimentation on persons without their free consent. Further, free consent refers to consent obtained without the intervention of any element of coercion, undue influence, fraud, misrepresentation, or mistake (61, 62). Keeping in mind the doctrine of informed consent emphasised in the Nuremberg trials, and its significance in international customary law, Golde and Quan were under a duty to inform Moore, from whom genetic data were collected, that his genetic data were liable to be used for different purposes.

A number of international legal documents which came into effect after the inception of the ICCPR also state that consent must be not only free, but it must also be informed, expressed and given prior to the action for which it is sought (48, 63).

Article 16 of the International Declaration on Human Genetic Data (48) refers to a change of purpose, and states that if the original consent is incompatible with the different purpose for which genetic data are to be used, then prior, free, expressed and informed consent must once again be obtained from the person before the use of the genetic data for a different purpose.

Further, Article 17 of the ICCPR (60) states that no person shall be subjected to an arbitrary or unlawful interference with his privacy.

In the John Moore case, not only did the doctors disregard a specific directive from the patient with regard to the future use of his body part, before the spleen was removed, but they also intentionally withheld material information that they were under an obligation to disclose to him and that was necessary for his exercise of control over that body part. Therefore, the act of using the genetic material of the patient for a purpose incompatible with the original consent, as in the Moore's case, should be considered an arbitrary and unlawful interference with his privacy and confidentiality. Although a patient may not retain any legal interest in a body part after its removal when he has properly consented to its removal and use for scientific purposes, it is clear that when a body part is being removed, it is the patient, rather than his doctor or hospital, who possesses the right to determine the use to which the body part will be put after removal.

V. Bioethics and international law

The case of Moore and many decisions which followed it have recognised and acknowledged that patenting of human genetic material raises several ethical concerns. This has had serious ramifications leading to the development and growth of international law in this field.

In 1993, a patent on human cell lines was claimed before the patent office of the United States (64). The cell line was developed from the blood of a woman from the Guarani Indian tribe of Panama, South America. The cell line was expected to be useful in research on AIDS and cancer. The patent was claimed by the US government. However, several non-governmental organisations and the tribal communities in Panama objected and questioned the ethics of patenting a cell line. They argued that it amounted to commodifying life. Yielding to vehement opposition and international criticism, the US government withdrew the patent application.

In 1991, the National Institutes of Health in the US sought patent protection for a cell line developed from the DNA of a person belonging to the Hagahai indigenous group in Papua New Guinea (65). The application was later withdrawn following public criticism as no consent was obtained from the Hagahai donor.

It can be argued that patenting and owning human beings and genetic materials of human beings without their consent amounts to holding them in slavery. Slavery infringes upon the dignity of the human beings, which is guaranteed under different international covenants and declarations (60, 66, 67). Research in biotechnology should always be in consonance with the ethical standards of society. Research in the fields of biology and medicine should not prevail over the respect for human rights and human dignity.

With the coming into being of the Agreement on Trade-Related Aspects Of Intellectual Property Rights (68), it is universally accepted that ethics, morality, and public order form restrictions to the patentability of inventions. The United Nations Universal Convention on Human Genome and Human Rights, 1997 (63), says that research on the human genome shall respect the ethical standards of society. No research in the fields of biology and medicine should prevail over respect for human rights and human dignity.

The European Patents Convention (17) states that inventions which are against public order and morality shall not be patented.

The Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the application of Biology and Medicine (69) intends to protect human dignity in respect of human beings being made the subject of research in biomedical sciences. According to the convention, research on human beings, tissues, organs or the human genome shall be undertaken only after the person concerned has been informed of the possible risks associated and has given informed consent. Using the human body and its parts for financial gain is prohibited under the convention.

The Indian Council on Medical Research has issued ethical guidelines in human genetics (49). The guidelines are intended to guarantee human rights and dignity with regard to genetic research in which human beings, human tissues, cells and genetic materials are used. They state that research on human

subjects shall be done only after voluntary and informed consent is taken in which the subject has been explained all the possible risks associated with participation in the research.

VI. Conclusion

Life form patenting is allowed in the United States and the European Union and many other countries support the notion that human genetic material is patentable. However, there are also countries which oppose the patenting of human genetic material. There are discrepancies and ambiguities as regards the legal principles to be applied when disputes concerning this issue come before the Indian courts, and changes in the law may be necessary to effectively address these issues.

Further, the need for uniform and universally recognised ethical guidelines for research on human subjects has acquired a new urgency with the emergence of critical issues in the areas of biogenetic research involving human subjects.

In order to fulfil its obligations under the Declaration on Human Genome and Human Rights, 1997 (63), the US government set up the National Bioethics Advisory Commission, whose primary job is to report on the ethics involved in research in biology and medicine, especially research on the human genome and on human cloning. Similarly, the European Union has streamlined ethical standards and incorporated these into the patent law.

In India, existing legislation does not sufficiently address the ethical implications of different biotechnology inventions. There is no specific legislation regulating biomedical research on human subjects. The guidelines issued by the ICMR (49), which are in consonance with international ethical guidelines for biomedical research involving human subjects, issued by CIOMS in 1993(47) and the principles of the World Medical Association's Declaration of Helsinki, first issued in 1964 (45) and revised a number of times since then, hold good in the absence of any definite legislation.

The Biomedical Research Human Subjects Promotion and Regulation Bill, drafted by the ICMR, was cleared by the Union Law Ministry in January 2006 but has not been placed before Parliament. The Bill is better equipped to deal with the complexities emerging out of the field of biomedical research. Once the bill gets the cabinet nod, it will become mandatory for all medical institutions conducting human research, and the ethics committees in these institutions, to be registered with a central agency.

John Moore v. Regents of the University of California (1) and subsequent cases illustrate the manner in which patenting of human genetic material and bioethics are inextricably intertwined in medical law. This overview of the existing laws pertaining to patenting of human genetic material in different countries has dealt with various legal approaches that could be taken in such matters and important doctrines such as informed consent which plays a crucial role in conducting research involving human beings. Detailed legislation in this respect is called for.

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Acknowledgement: The author would like to thank Mr Karan Singh Tyagi for his guidance and invaluable suggestions on the paper.

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Editors: Sandhya Srinivasan, George Thomas

Published by: Forum for Medical Ethics Society and Centre for Studies in Ethics and Rights, Mumbai. December 2007. 288 pages. Rs 200

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