Chapter 6

Patents on Life forms- Legal Implications

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Man is the finest creation of God. He has proved his supremacy over all living organisms but has not been satisfied with what he has achieved so far. Of course, it is his quest only which has helped him to prove his supremacy. After conquering all living creatures; man now has started challenging nature and its very creator i.e. God. The advancement in medical science has posed a serious threat to the supremacy of God. In challenging the supremacy of God man has struck on the two most fundamental functions/powers of God i.e. birth and death. Though man has not yet conquered death, medical science is able to put the death of a person a few steps behind. Mythology says that God lives in man's heart and when God leaves, the heart stops functioning and a person dies. But with artificial hearts and heart implantation techniques this myth no longer exists.

But in the case of birth, man is successful to a great extent in controlling birth not only by preventing it through abortion and contraceptive methods but also by making it happen even in cases where it is not physiologically possible, by in-vitro fertilization and other techniques. Till date man was trying to improvise his life, which is a creation of God, but now has taken a giant leap forward to create this life itself! To understand human evolution a mega genome project was carried out which

has just concluded successfully. It was a Herculean task but man could do it. Cloning is the first step towards creation of life. **Man has started playing God!!!**

6.1 Genetic Modification – Playing God

The patenting of life raises a whole range of issues - not only technical and legal but also ethical, moral, social and religious. Scientific advances in genetic manipulation have been so rapid and startling that their consequences have generated wide ranging apprehensions. It is almost as if man has acquired the capacity to 'play God' through his knowledge and control over life at the cellular level. The cloning of cells has not stopped at the sheep Dolly but has traveled from sheep to mice, calves, pigs, ox, cat, and has finally reached human beings with the cloning of a female human and named 'Eve'. Outlandish ideas that belonged to the realm of science fiction thrillers or Hollywood movies have turned into a hardcore reality and this reality is certainly horrifying. The possibility of having a genetically engineered clone left people in a whirlwind of intrigue and fear even as it seemed too futuristic an idea to actually happen in their lifetime. Not any more. Welcome to a strange new world where 'mini ME' is not just a figment of Austin Power's imagination. The idea of extending patenting rights to such genetic technology and making it a monopoly of a handful of people, receiving a royalty for every such human birth will end all social values. The patent holder will then decide whom he wants to sculpt – Osama Bin Laden or Mother Teresa!

By far the biggest public concern recently has come with new developments in the life sciences such as cloning and genetically modified organisms. Some of the ethical issues have been exaggerated, but the following deserve serious reflection:

(a) the potential to misuse genetic information about individuals
(b) the question of who owns genes and genetic code
(c) the implications of patenting knowledge that traditionally has been shared
(d) the acceptability of cloning human beings for reproductive or other purposes
(e) the acceptability of transferring genes from one animal species to another
(f) the safety of genetically-modified organisms, both in terms of the environment and the consumer, including reduced biodiversity.

Genetic engineering techniques are currently being used to produce a wide range of new products, which the biotechnology industry believes will benefit all citizens. Most research involves plants and animals although some effort is now being put on genetically engineered microbes, such as nitrogen fixing bacteria, frost suppressive bacteria, and some microbial soil amendments.

Genetically Modified Organisms

A genetically modified organism (GMO) is an organism whose genetic material has been altered using techniques in genetics

generally known as recombinant DNA (rDNA) technology. rDNA technology is the ability to combine DNA molecules from different sources into the one molecule in a test tube. Thus, the abilities or the phenotype of the organism, or the proteins it produces, can be modified through the modification of its genes.

The term generally does not cover organisms whose genetic makeup has been altered by conventional cross breeding or by "mutagenesis" breeding as these methods predate the discovery of the recombinant DNA techniques.

A GMO can thus be defined as an organism, with the exception of human beings, in which "the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination". Genetic Modified Organisms according to the Gentechnikgesetz (Genetic Technique Law) in Germany are organisms whose genetical material were modified in a way which is not found in nature under natural conditions of crossbreed or natural recombination. The genetic Modified Organism must be a biological unit which is able to multiply itself or to transmit genetic material.

A US definition of GMO - The term "Genetically Modified Organisms" refers to plants and animals containing genes transferred from other species to produce certain characteristics, such as resistance to certain pests and herbicides.

Genetically Modified Animals

Like bacteria and plants, animals can be genetically modified by viral infection. The genome of an animal embryo can be modified by the addition of synthetic chromosomes, targeted removal of certain genes, or addition of genes. The embryo can then be implanted into a mother to develop. However, the genetic modification occurs only in those cells that become infected, and in most cases these cells are eventually eliminated by the immune system. In some cases it is possible to use the gene-transferring ability of viruses for gene therapy, i.e. to correct diseases caused by a defective gene by supplying a normal copy of the gene.

Genetically Modified Microbes and Viruses

GM microbes are being developed in several fields, including:

- Medicine - in the production of therapeutic medicines and novel GM vaccines and gene therapy
- Bioremediation - the use of microbes to clean up pollution

Following is a sample of the rationales promoted by the industry for experimenting with agriculturally-related genetically engineered products.

Genetic Engineering and Plants

* Herbicide tolerant plants won't die when sprayed with broad-spectrum herbicides, thereby allowing the herbicide to be used more.

* Insect and disease resistant plants contain toxins and other factors produced by other organisms, including bacteria, scorpions and other venomous organisms. The toxins enable the plant to resist pests.
* Delayed ripening allows food to be shipped farther. For example, genetic engineering allows the regulation of ripening in the trademarked FLAVR SAVR tomato[1].
* Environmental tolerance enables plants to become more drought resistant, freeze tolerant, and so on. This allows the geographic range of crops such as corn and soyabeans to expand, potentially intensifying monoculture cropping and transforming local economies.
* "New commercial products" such as "pharm" plants that produce pharmaceuticals or modifications to canola and soy oils to enhance their use as industrial chemical inputs for the production of frivolous specialty soaps and cosmetics.

Genetic engineering and animals

* Essential nutrients may no longer be required in animal feed if animals are engineered to no longer need these nutrients.
* Faster development may result from engineering animals that eat more or digest more efficiently so that they can grow larger and/or be slaughtered earlier. However, growing fast creates problems for the animal; some of these animals may be more prone to disease and stress.
* Environmental tolerance is a factor being engineered in certain animals that currently cannot tolerate cold or heat or wetness

[1] *Trademark no 74559147 to Colgene Inc which is abandoned on 10 1 2000*

or dryness. The animals would be able to withstand these environmental extremes so that they can be produced in now inhospitable areas – possibly leading to their escape and ability to out-compete wild species.

* "Quality modification" in animals that are engineered to produce characteristics humans find good to eat. The most well-known example is the genetically engineered lean but crippled pigs.
* "New commercial products" may "include "pharm" animals, similar to the concept of "pharm" plants. Examples would be cows or goats from which pharmaceuticals can be extracted from the milk.
* Bio-insecticides use genetically engineered viruses and bacteria to kill insects. Whether these microbes can escape and infect other organisms is not yet known.
* Artificial hormones stimulate faster growth, greater milk production, and so on. However, they also cause greater incidence of the disease mastitis, requiring the use of antibiotics which flow through the milk for human consumption.

Genetically engineered organisms (GEOs) are living, with the ability to reproduce. Once in the environment they will not be able to be recalled or collected. They present ecological threats that will magnify, not decay over time. The organisms will not respect national borders, and growing international travel and trade increases the chance of movement of organisms from one country to another.

WTO has forced countries to introduce laws that allow life forms and living organisms to be patented. In Europe it was implemented through the Biotechnology Directive. Shri S.P Shukla, India's GATT negotiator, during the Uruguay Round, gave the history of India's leadership in blocking TRIPs up to 1988. Subsequently India's leadership was eroded through US manipulation and Third World unity broken which led to the imposition of unjust and undemocratic WTO/ TRIPS agreement.[2]

Though it seems like science fiction in the minds of most people, genetic engineering is a current reality and is common practice in laboratories around the world. "With genetic engineering technology today, it is possible to manipulate the 'blueprints' of living organisms...to isolate, splice, insert, rearrange, recombine and mass-reproduce genes."

Scientists are capable of reprogramming the genetic codes of living things to suit societal or economic purposes. Transgenic experiments mix plant genome with that of animals, human genome with that of plants or animals.

6.2 Commodifying life

No one has a right to own a life form or to commodify parts of the human body for profits. The ethical and legal issues raised by genetic engineering technology are numerous and unanswered. This area of biotechnology remains virtually unregulated.

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[2] *International conference on "Biodiversity, Indigenous Knowledge and Intellectual Property Rights", organised by Navdanya*

Patent law is the primary vehicle which enables scientists to secure exclusive rights to the commercial benefits of their genetic research. Patent laws grant a limited property right to the patent holder, and exclude others from using the patented item for a specific period of time, usually for a 17-20 year period. Patents are usually granted for newly created inventions, as a means of recognizing the scientist's "Intellectual Property Rights."

There has been a disturbing trend in patent law that extends patent protection to life forms since 1980 when the U.S. Supreme Court ruled that the creation of an oil-eating microbe is patentable. Since then, the U.S. Patent and Trademark Office (PTO) has granted numerous patents for newly created micro-organisms, living animals, and for human tissues and genes, breaking long-standing policy that animate life forms were not patentable.

Do we as a species have the right to claim ownership over other species; does any one individual human being have the right to claim private monopolistic ownership over entire other species? However inventive scientists are in engineering a new strain of bacteria or a new variety of plant or animal, the essential elements with which they are working - the building blocks of life, and life itself - are not created by them. Increasingly we are beginning to accept the notion of equal rights for all living beings; IPRs take us back to the age of 'might is right'. IPRs on living beings are the ultimate manifestation of arrogance.

6.3 Human Genetic Engineering

Serious ethical issues arise even more starkly in the case of attempts to patent human genetic material or information. Human genetic engineering deals with the controlled modification of the human genome.

Human genetic engineering means changing the genes in a living human cell. If a person had a lung disease caused by defective genes in the lung cells, he might be cured if there was a way to fix those genes.

Scientists change the genes in living cells by putting the desired "new" gene into a little virus-like organism which is allowed to get into your cells and which inserts the new gene into the cell along with the "old" genes.

The first clinical trial of human gene therapy began in 1990, but (as of 2006) gene therapy is still experimental. Other forms of human genetic engineering are still theoretical.

These attempts have not stopped at only patenting genetic material like cells, but have led men to play God, creating clones of animals like sheep, mice, etc., and going on to clone human beings. This has opened up a Pandora's Box.

Although the argument for intellectual property protection is often couched in terms of increasing incentive to research, in

many ways the motivations and the pressures are much more commercial and trade oriented; patents are being used to protect investment. This is reflected in the very strong pressures being exerted, by the US and others, in bilateral and multilateral trade negotiations for international harmonization of intellectual property protection. Patent protection on living organisms is definitely included.

Patent legislation was not designed for living organisms. The limits are being set by the Courts using laws written before the invention of genetic engineering techniques. The resulting decisions are inconsistent and the implications of patents on living things are not known. It is clear, however, that there are serious technical and ethical issues that need to be addressed. The repercussions for developing countries may be even more serious than developed countries.

The Indian Patent Act of 1970 did not earlier permit the granting of patents on life forms and related technologies. These and other substances in the areas of agriculture, horticulture, and curing or enhancing human animal or plant life were not patentable "on the grounds of law, morality, and health". In the case of food, medicine, drugs, and chemicals, only process patents were allowed, since it is believed that the grant of product patents will inhibit the discovery of more efficient and economical processes for the manufacture of the same product. Experts have hailed these aspects of the Act as amongst the most socially progressive in the world.

Unfortunately, these provisions became a casualty of the internationalization of IPR regimes, which is taking place under the UPOV and the General Agreement on Tariffs and Trade (GATT). In many cultures, as in India, and according to patent laws, life cannot be patented because it cannot be owned and it is not manufactured. But GATT will force the giving up of these moral values, as well as economic priorities and sovereignty of nations; and the TRIPs accord pushes countries into making all living organisms the property of a handful of corporations. On first reading, it appears that the TRIPS article is about the exclusion of plants and animals from patentability. However, this phrase also exists in the US patent laws. The existence of this phrase has however not prevented the US from allowing patents for life forms.

The problem is that the phrase "plants and animals other than microorganisms" does not cover parts of animals and plants, nor does it include altered plants and animals and therefore allows the patenting of biological organisms. Also the worlds "other than microorganisms" prevent the exclusion of microorganisms from patentability and make patenting of microorganisms compulsory.

Since microorganisms are living organisms, making their patenting compulsory is the beginning of a journey down the slippery slope that leads to the patenting of all life. The best example of this slippery slope can be seen in the history of United States patent law where the granting of patents to

microorganisms signaled the taking of a first step to granting patents to so-called higher life forms. In 1971, General Electric and one of its employees Ananda Mohan Chakrabarty applied for US patent on a genetically engineered pseudomonas bacterium. Taking plasmids from three kinds of bacteria, he transplanted them into the fourth. As he explained, "I simply shuffled genes, changing bacteria that already existed".

The patent office rejected the application, on the basis that animate life forms were not patentable. The case was appealed in the Court of Customs and Patents Appeal Office and then in the Supreme Court where, nine years later, Chakrabarty was granted his patent on the ground that the microorganism was not a product of nature, but Chakrabarty's invention and therefore patentable. But as Andrew Kimbrell, a leading US lawyer recounts: "In coming to its precedent-shattering decision, the court seemed unaware that the inventor himself had characterized his microbes as simply 'shifting genes, not creating life'.[3]

On such slippery grounds the first patent on life was granted and despite exclusion of plants and animals in US Patent law, the US has since then rushed on to grant patents on all kinds of life forms.

All that genetic engineers really do is "shuffle genes around"; they do not create life. Therefore, literally speaking, no life forms

[3] *Shiva, Vandana (member of the UNEP expert panel on biodiversity)- 'Ecologists should worry about the Dunkel Draft'*

should be patentable. However, patent offices and courts have interpreted modification as creation. This allows the ownership of any altered biological material. The term "naturally occurring" does not prevent such patenting of life because the term does not cover altered biological material. It is in fact vacuous in preventing the patenting of biological organisms and materials.

6.4 The John Moore Case

In 1976, a leukemia patient, John Moore had surgery at the University of California to remove a cancerous spleen. The University was later granted a patent for a cell line called Mo, removed from the spleen, which could be used for producing valuable proteins. The long-term commercial value of the cell line has been estimated at over $1 billion. Permission had not been sought of John Moore for the use of his body parts. Moore demanded the return of the cells and control over his body parts. In 1984, he filed a lawsuit claiming that his blood cells were misappropriated while he was undergoing treatment for leukemia at the University of California, Los Angeles Medical Center. During his treatment, Moore's doctor developed a cell line which proved valuable in fighting bacteria and cancer. The UCLA Board of Regents filed a patent claim on this cell line and commercially developed valuable antibacterial and cancer-fighting pharmaceuticals. Moore claimed that he was entitled to share in profits derived from commercial uses of these cells and any other products resulting from research on any of his biological materials. In a significant 1990 California Supreme Court decision, the court established that a donor does not have a

"property right" in the tissues removed from his or her body.[4] The court further reasoned that to favor John Moore's claim would "...hinder research by restricting access to the necessary raw materials," thereby interfering with the progress of science.[5]

One of the most repugnant patents ever granted is for the Oncomouse. On April 12, 1988, the US Patent and Trademark Office (USPTO) issued the first patent on a living animal[6] to Harvard Professor Philip Leder for the creation of a transgenic mouse containing a variety of genes found in other species, including chickens and humans.

Mice do not usually have cancer, it is difficult to induce cancer. This causes problems for cancer researchers. Instead of recognizing that animals are flawed models, that is, if a mouse does not usually get cancer, then what validity are the results for a cure, genetic engineers have developed a mouse that is prone to cancer, the Oncomouse.

The licensing rights for the patent are held by Dupont Company, the transnational that financed the Harvard research responsible for creating the genetically engineered mouse. This means Dupont has patent ownership of any animal species – be it mice, rats, cats or chimpanzees, whose germlines are engineered to contain a variety of cancer-causing genes.

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[4] *Moore v Regents of the University of California et al , California Supreme Court (1985)*
[5] *Moore vs Regents of the University of California, 793 P 2d 479, 271 Cal Rptr 146 (1990)*
[6] *US Patent no 4736866 dt April 12, 1988 to Harvard College*

Putting questions of inventiveness aside, these trends have enabled scientists to hold patents for a wide variety of life forms, including almost 5% of the entire human genome. There is now a rush for control of the remaining 95% of the human genome.

6.5 The Human Genome Diversity (HGD) Project

In 1993, a bombshell was dropped amidst already heated debates on IPRs. It was revealed that the US Department of Commerce had sought a patent on human cell line of a woman from the Guyami Indian tribe of Panama, South America, developed from blood collected by scientists in 1990.[7] The cell line was shown to be resistant to a particular disease and could be potentially useful in research on Aids and cancer. The Guayami General Congress and the World Council of Indigenous People alerted to the patent claim by some NGOs, immediately raised an international furor stating that it was a moral affront for anyone to monopolise human genetic material. An enraged President of Guayami General Congress said, "Industrialized society has lost all sense of the proper place of human beings in the scheme of things to the point where it believes that it is right to own, control and fundamentally change life itself. We have lost all sense of our appropriate place in nature."

The patent claim was filed in 1993, under the name of U.S. Secretary of Commerce Ron Brown, on the cell line of a 26 year old Guayami woman from Panama. Patent Claim WO 9208784

[7] *Shand, H, 'a landmark year for biodiversity or biopiracy?' Biotechnology and Development Monitor, 17th December, 1993*

A1 was lodged for the Human T-Lymphotropic Virus Type 2, drawn from the "immortalized" DNA of the Guayami woman. Her cell line is of interest because some Guayami people carry a unique virus and whose antibodies may prove useful in AIDS and leukemia research. International protest and action by the Guayami General Congress and others led to the withdrawal of the patent claim in November 1993.[8]

The Guayami controversy alerted NGOs to several other similar applications pending in the US and Europe; it also shed new light on an international effort called Human Genome Organisation (HUGO), the most ambitious project ever to map the human genetic structure. Under its Human Genome Diversity (HGD) Project, sponsored by the United States National Institute of Health (NIH), scientists have begun an anthropological hunt for human tissue, hair and blood samples, from indigenous people of the world. The Human Genome Diversity (HGD) Project is taking blood and tissue samples from indigenous peoples of 722 communities throughout the world for genetic studies. This raises troubling questions regarding the definition of genetic materials as "property", the ownership of the genetic samples themselves, and who stands to profit from the commercialization of products derived from the samples. The HGD Project puts the raw resource, that is, the human genes of indigenous people, in the hands of anyone who wants to experiment with them. In doing so, the HGD Project is opening the doorway for widespread commercialization and potential misuse of the samples and data.

[8] *www Intellectual property rights and biodiversitybrbr htm*

While the HGD Project does not plan to do genetic engineering, no safeguards exist to prevent others from doing so with the genetic samples collected.

The HGD Project states that the research will help reconstruct the history of the world's populations, address questions about the history of human evolution and migration patterns, and identify the origins of existing populations.

This material will be stored at the American Type Culture Collection, Maryland. The attitude of the researchers is shown in the language of the project documents. Since blood does not survive long without cold storage, the project authorities remark that "one person can bleed 50 people and get to the airport in one day"! The 722 target groups, many of them in danger of extinction and some potentially from India like the Andaman and Nicobar tribals, are called " Isolates of Historic Interests ...because they represent groups that should be sampled before they disappear as integral units so that their role in human history can be preserved." Critics allege that there is no commitment on the part of the project authorities that such genetic material, or material derived from it, will not be put up for patenting.

6.6 Implications of the HGD Project

While the HGD Project is looking for answers about human evolution, indigenous peoples already possess strong beliefs and knowledge regarding their creation and histories.

The cosmologies of indigenous people are environmentally and culturally specific and are not congruent with popular Western theories, such as the Bering Strait migration theory or Darwin's theory of evolution. The assumptions posed by the HGD Project that the origins and/or migrations of indigenous populations can be 'discovered' and scientifically 'answered' is insulting to groups who already have strong cultural beliefs regarding their origins. Questions arise concerning the impact of the findings on indigenous communities. For example, will theories of migration be used to challenge aboriginal territorial claims or rights to land?

Medical and Military Science

The project will also gather information of potential or actual medical interest, possibly leading to medical applications. In terms of reciprocal benefits to donor groups, the HGD Project will offer token benefits such as providing medicines, or treating easily diagnosable medical problems.

If indigenous people were interested in genetic research for a genetic question specific to their group, they do not need the HGD Project to do this work. The technology and expertise is widely available to groups interested in genetic research.

Many in the indigenous communities are worried the research may identify genetic information that may be used against genetically distinct populations. The HGD Project raises the spectre of misuse of the genetic materials or data for racist

purposes, and even raises the possibility of genocide by biological warfare. While scientists disagree on the feasibility of such uses, it is difficult to predict what will be technologically possible in ten years, or twenty. Biological warfare has been used on indigenous peoples in the past, a reminder of the potential threat presented by such scientific projects.

These occurrences have awakened the world to the horrific implications of IPRs on life forms and biotechnologies and have increasingly brought demands for severe curbs on this runaway, out of control juggernaut. A major blow to the biotechnological industry came in March 1995, when the European Parliament rejected a proposed European Community Commission directive that would have made patenting of plants, animals and human genes possible throughout Europe.

IPRs on life forms have serious ethical, social, economic and ecological implications, which must be considered while deciding whether we, as a society, are willing to allow them. Biocyte has been granted patents in the US and Europe that give it rights to the blood cells extracted from the umbilical cords of new-born babies.

Endangered indigenous people are having their genes sampled and stored in gene banks against the day when their race becomes extinct. If they are lucky, they receive a token payment. UNESCO's international bio-ethics committee has endorsed the criticism raised by indigenous people.

6.7 Protection of the Indigenous Communities

Genetic manipulation raises serious ethical and moral concerns with regard to the sanctity of life. For indigenous peoples, any violation of the natural law and the natural order of life is abhorrently wrong. Scientists are genetically manipulating existing life forms, altering the course of natural evolution, and creating new life forms. Genes are living organisms which reproduce, migrate and mutate. The full impact of genetically manipulated life forms cannot possibly be anticipated.

Indigenous people must engage in community education and discussion about the full scope of this project and the potential dangers of genetic manipulation. It is imperative that indigenous communities become fully aware of the implications of this project, and learn whether any genetic sampling is being conducted or is proposed to take place in their areas.

Every effort should be made to alert indigenous communities worldwide of the work of the Human Genome Organization and the Human Genome Diversity Project. The communities must be free to reject the taking of their genetic materials by such projects or by free-lance scientists. Groups from which any genetic materials have already been taken may wish to ensure the return to their possession of these materials.

Indigenous communities need to stand together and call upon the Human Genome Diversity Project and the Human Genome Organization to halt collection efforts. These organizations must

work directly in consultation with indigenous people and organizations which reflect the diversity of the world's indigenous populations to develop appropriate domestic and international policies which protect the best interests of indigenous peoples.

Indigenous people must raise international awareness of these efforts and develop support among all people to prevent the further violation and assault of their human rights, further appropriation of their natural resources, and to protect the integrity of life.

6.8 Life as property

The concept of patenting a living organism strikes many as being somehow wrong. Western society has a long tradition of ownership of physical property. Indeed, everything on earth has at some time been considered eligible to be treated as property. Human beings were excepted, but only after a long and very painful period during which human beings too were subject to treatment as commodities.

But with the advent of the cloning technology and the patent granted to Gerona Corporation based at California for exclusive commercial rights to embryos created by cloning by British Patents Office, the day does not seem very far when human beings will once again begin to be treated as commodities to be owned, controlled and traded in. The US company has been awarded two British patents that appear to grant it commercial rights to human embryos created by cloning. The patent gives

Gerona Corporation exclusive rights to animal embryos prepared by transferring the nucleus of a donor cell into a suitable recipient cell. The precedent setting patents were issued on the cloning method that produced the now famous sheep, Dolly. These new patents have sparked off protests from groups concerned about the ethics of biotechnology patents especially those covering human genes or cells.

Scientists like Ian Wilmut and Ron James have declared themselves to be makers and creators of Dolly, whom they can "own" as "biotechnological" invention. When these techniques are applied to humans, the human "products" will also be treated as an invention and the "intellectual property" of scientists involved.

While Dolly has been bravely announced as creating a new world free of disease and scarcity, the idea of cloning is in reality a recipe for ecological devastation. The experiment has been welcomed as heralding techniques for the replication of animals with proven performance within "elite selection herds". This is the logic that has destroyed diversity and created monocultures vulnerable to stress and disease.

6.9 Enclosure of the Commons

During the highland clearances in Scotland, peasants were removed from the land to make way for sheep for the wool industry. When the commons were enclosed in England for

rearing sheep for wool, the peasants' cry was "enclosures make fat beasts and lean poor people".[9] "Sheep eat men" wrote Sir Thomas More. Everywhere people were reduced to starvation while sheep were fattened to produce wool for the textile industry.

The new world of Dolly is a second coming of the enclosure movement, except that this time it is for pharmaceuticals rather than wool that the sheep will be bred. This enclosure is also a deeper enclosure because it encloses life and knowledge through patents. Roslin Institute has "smuggled" embryo of a nearly extinct breed of cattle called Vechur from Kerala in India and is reportedly attempting to patent its genome. Patents on life in the hands of a few scientists and corporate labs imply an enclosure of the free, living biodiversity of the planet which supports life and livelihoods of millions. The enclosure of biodiversity will lead to even more massive dispossession than the enclosure of land. It will also create a deep ethical crisis for the human species.

6.10 Patenting Life

The patenting of microorganisms or patenting of biotechnical inventions raises a number of issues. The TRIPs Agreement of the WTO excludes 'plants and animals' from patentability, but makes it obligatory to provide patents for 'microorganism' and 'microbiological process'. The word microorganism is neither

[9] *Rifkin Jeremy in Biosphere politics*

defined in the TRIPs agreement nor does the agreement specify any parameters concerning the scope of the protection.

Ian Wilmut, a biologist has defended the two patents granted in Britain on the cloning technology used to make Dolly. He says, "There is reasonable concern about the idea of patenting process, but the commercial benefits of a patent bring the needed money to bring forward the research". There are also countless potential medical uses. If human genes are added to those of a pig, for example, humans in need of new organs may be able to receive them without the rejection that often plagues the process. In therapeutic cloning, embryos are created so that scientists can mine them for stem cells. These master cells of the body have been hailed as a potential medical breakthrough of the 21st century because of their ability, in theory, to replace damaged tissue. They could, one day, be used to patch up damaged heart muscle following heart attacks or to form new neurons in the brains of Parkinson's and Alzheimer's patients. For diabetics stem cells may be a source of new islet cells in the pancreas. Later, perhaps even whole organs might be grown, all free from the threat of tissue rejection. Though Dolly was the sheep that was first produced by the patented cloning method, the most important sheep in Edinburgh today is not Dolly, but Polly – cloned and genetically transformed, and whose milk contains a protein called AAT which could be useful in treating human lung diseases such as cystic fibrosis and emphysema. AAT is otherwise scarce and expensive.

However, Wilmut is against human cloning and has said, "cloning humans is a long way off, that should give people and their governments time to consider the ethical implications. I have never heard a good enough reason to copy a human."[10]

6.11 Equity problems related to patents on life

Patents on life generate ethical problems because of their impact on equity and on access to food and medicine especially in poor countries. Patents on life are based on the "return on investment" logic -- that investors get a return on their investment. However, this "right to return on investment" runs into conflict with the right to food and right to health guaranteed under the Constitution.

The equity dimensions of bioethics in the context of IPRs are also related to the fact that patents create a drain on economic systems. Corporations might reap rich harvests, but society grows poorer. An estimate indicates that the debt burden of Third World countries will increase ten fold with the expansion of IPRs to life.

The Indian scientific system is seeing in IPRs a fund raising mechanism. This was highlighted by Dr. Mashelkar, Director of Centre for Scientific and Industrial Research (CSIR). However,

[10] *Wilmut Ian and Campbell Keith, 'The second creation the age of biological control'*

"selling" knowledge in IPR arrangements creates a system of monopolies, which renders society systematically poorer and the public research system impoverished both because more revenues flow to finance royalties and because techniques, processes, equipment that were freely available as scientific instruments and materials have to be paid for.

Further, the ultimate impact of the patents on life logic is the total neglect of areas which are necessary for society but which do not offer enough profits for the global corporations and hence get no scientific attention.

These are subtle processes through which the nourishment to knowledge and science is denied, and through which islands of wealth and well endowed research systems exist in a sea of poverty and ignorance. It is in recognition of these ethical and social impacts that even the TRIPs agreement has clauses of exclusion that enable societies to have exclusions and safeguards for protecting public morality, environment and people's health.

Article 7 of the TRIPs agreement states,

> Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this agreement.

Article 27.2 states,

> Members may exclude from patentability inventions, the prevention within their territory of commercial exploitation of which is necessary to protect "Order Public" or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.

Each country needs to take its unique ecological, ethical and socio-economic systems into account to ensure that the implementation of TRIPs protects ethics, ecology and equity and does not become an instrument of unethical, anti-ecological and inequitable arrangements of our social and natural world.

6.12 Patenting from Ewe to Eve

According to the TRIPs agreement, naturally occurring microorganisms, including genes, gene sequences, cell lines, sub-cellular material howsoever derived or trivially modified, are excluded from patentability. But genetically modified microorganisms (GMOs) are allowed to be patented, if human intervention and value addition in their creation is substantial and the organisms involve a novel genetic make up. The prominent view is that these GMOs are patentable, because they are creations of humans and they cannot be regarded as 'pre-existing' matter.

In February 1997, scientists at Scotland's Roslin Institute unveiled the sheep, cloned from the cell of a six year old ewe by nuclear transfer process and after six years, Dr. Brigitte Boisselier, CEO of Clonaid announced the birth of Eve, a female clone, on December 26, 2002. Patenting of human cloning will raise a number of legal and ethical issues. Though scientists claim a number of advantages of cloning, the reality is something else.

- **The clones are unhealthy...**

  Harry Griffin, assistant director of the Roslin Institute that successfully cloned Dolly says: "It would be wholly irresponsible to clone a human being, given the present state of technology. The success rate with animal cloning is about 1-2% only. The risks are far too great for the woman and the child". Of the small number of animals cloned, most have severe abnormalities: malfunctioning livers, abnormal blood vessels, heart problems, under developed lungs, immune system deficiencies and hidden genetic defects. Dolly, the first cloned mammal, already has arthritis just five years after being born.

- **Skewed family relationships...**

  Is the clone an offspring or a sibling? If you take your own DNA and give birth to your own clone, the big anthropological question is: will your family comprise you and your daughter or you and your sister? Family identities and lineages would thus become ambiguous.

- **Clone farming begins...**

  With the patenting of human clones, they could be "farmed" to provide spare body parts for their donor. Human organs would then be treated as commercial commodities and would soon be found on the shelves of biological showrooms.

- **Bio-battles with another IPR...**

  So far, bio-battles have been between patents and biodiversity. With the emergence of human cloning, the battle has been taken to a new dimension of IPRs – copyrights. A hundred Amitabh Bacchans in the neighbourhood are unlikely to please Amitabh Bacchan. Which is why a new Californian company is trying to capitalize on DNA copyrighting. The DNA Copyright Institute (DCI) believes a lot of people are going to want to clone their heroes. For worried celebrities, DCI is offering to record their DNA fingerprint, check that it is unique and store it. The client will get copyright protection to prevent "actions such as DNA theft". The fee: $1500.

6.13 Devaluing life

One of the principal arguments against patents on life forms is that they devalue life. Patents, as a mechanism of social policy should reflect a society's ideals and traditional values. Yet patents on living organisms do no reflect the distinction that our society has traditionally made between living and non-living, between animals and machines. None of the arguments cited by

the advocators of patents on life seems to invalidate the concern that patents on living organisms reduce society's concept of life and serve to blur the distinction between the animate and the inanimate. The main concern of this argument is not with the patents per se but with the institutionalization of a reduced definition of life. This naturally leads to concerns that social barriers preventing maltreatment of other living organisms will be lowered and to related concerns that human life will be similarly devalued.

There are other arguments against granting patents on life forms based on metaphysical and theological grounds that reject the idea that humankind should tamper with God's creation. These include the notion that a species has a right to exist as a separate species and that the introduction of genes from another species contravenes this right; humankind is entrusted with the responsibility to preserve the integrity of life; humankind should not attempt to usurp the organic, natural, or God-given powers of reproduction and species' evolution; producing new life forms simply for the sake of profit is morally offensive; and it is inappropriate to grant a patent for an invention that involves transferring human genetic material to animals.

There is also the fairness issue that must be considered before deciding to grant patents on life forms. Every living organism is a product of millions of years of natural evolution and, in the case of most domesticated species, considerable human selection and human-induced change as well. Now, by generating a

relatively very small change in an organism, it is possible to gain legal control over the exploitation of the modified organism and all of its progeny (for 20 years or so). What was considered the common heritage of humankind becomes the private property of a few.

Ananda Chakrabarty did not create a new form of life; he merely intervened in the normal processes by which strains of bacteria exchange genetic information, to produce a new strain with an altered metabolic pattern. "His" bacterium lives and reproduces itself under the forces that guide all cellular life. We are incalculably far away from being able to create life *de novo.*

The fairness issue is particularly acute when patents are considered from the perspective of developing countries. Most of our domestic animals and almost all the major agricultural crops originated in the tropics and subtropics in areas that are now developing countries.

Intellectual property law is a product of Western society and Western ideals. Yet, within the Western cultural tradition, there are serious concerns raised by the concept of patenting life. The social and ethical implications of transferring patent policies, designed in the West, to completely different cultural and social environments must be greater by orders of magnitude, if not completely different in kind. Other societies have very different concepts of life and of ownership that may not correspond with those inherent in patent policy.

In the developing countries, small-scale farmers, aboriginal herbalists, and others develop an enormous range of useful innovations, many of them involving the use of biological materials. These innovations are not now protected by any intellectual property law, and so would be very vulnerable to being improperly appropriated by others in the wake of strengthened national intellectual property protection. The innovators themselves may not use the new laws to their advantage for a whole range of reasons: they many not be able to afford the costs of applying for (and certainly not of defending) a patent, they may be unaware of the market potential of their innovation and unwilling or unable to market it, they may even be unaware of the existence of patent right protection, they may be barred by language or geographical barriers from applying for coverage, they may be unaware of the implications, or they may simply not want to become involved in the market system.

The most important point is that patent laws that were not designed to deal with living organisms are being applied to living organisms without adequate reference to society. They are being used in ways that were not anticipated by the legislators, and the necessary public debate has not been undertaken. There is a series of profound ethical and moral questions raised by the spectre of patenting life forms that has not been answered. Indeed, in the light of the uniqueness of the issue, there has not been time even to formulate the questions adequately. Beyond the ethical issues, there is also a whole host of very important

questions relating to the direction and focus of research in the life sciences.

With or without GATT TRIPs, it appears quite likely that many developing countries are going to be coerced into adopting strengthened protection regimes. Intellectual property is being treated as a trade issue and not as a research issue. With the principal focus on trade-related issues, it is very unlikely that adequate consideration will be given to the needs or design of the resulting protection systems. Intellectual property protection for living organisms is likely to be included as part of the overall package, with serious ethical implications and with considerable potential to alter the research environment globally.

This trend to link intellectual property protection relating to living organisms to trade agreements, both bilateral and multilateral, is cause for serious concern. Every country should decide whether and to what extent they should adopt such protection on its own merit. The issue must be given adequate discussion and evaluation at the national level before any action is taken.

6.14 Human Genome and IPR

In 1953, two scientists, one from the United States and the other from Britain, Dr. J.D. Watson and Dr. F.H.C. Crick, published in 'Nature' magazine an essay that was to revolutionise our understandings of the basic forms of life. Not just human life,

but all forms of life.[11] They provided a model for understanding the process of the transfer of genetic information between generations of the same organism.

This article was not, of course, the first step on the path of genetics. Even in primitive societies farmers knew the benefits of mating particular domestic animals or cross-breeding particular crops. In 1866 the Austrian botanist and monk Grigor Mendel described the basic laws of heredity based on his experiments with cross-breeding of pea plants. Though his findings were published in a local journal, they were at first ignored. Early this century biologists experimented with the fruit fly to reveal that some genetically determined traits were linked to the particular sex of the fly. These experiments suggested that inherited traits could reside on chromosomes, tiny threads within the nucleus of cells that appeared to be constantly dividing.

The early, primitive discoveries came together and were explained by Watson and Crick. They proposed that the basic determinates of living matter were to be found in DNA, in a structure described as the double helix. DNA was the molecule which carried the genetic code that would unlock the truth known instinctively by farmers and described in a primitive but accurate way by Mendel. From that moment to this, the search has been undertaken to explore the DNA and to unlock its remaining secrets.

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[11] *Watson, J D and Crick F H C, "A structure for Deoxy-Ribose Nucleic Acid" 171 Nature 737 (1953)*

The coincidental development of information technology, which in a large part had grown out of defence operations and miniaturization required for the space race (in their turn propelled by nuclear rivalry) presented the technology which would help scientists to perform the analysis necessary to understand the control mechanisms residing in the DNA. In 1990 a group of scientists decided that they should co-operate in sequencing the entire human genome. The genome represents the complete set of genes and chromosomes of the organism. The aim of this project, which became known as the Human Genome Project, was to construct a 'high-resolution genetic, physical and transcript map' of the human being with, ultimately, a complete sequence of the genome.

6.15 Human Genome Project

- The Human Genome Project is run by the Human Genome Organisation (HUGO) and is a major international collaboration which involves the mapping and DNA sequencing of the human genome of a male (in order to include the sequence of the Y chromosome). Mapping and DNA sequencing are carried out by chemical analytical processes. Since the project was initiated in 1990, the technology used for the analysis has advanced to become more rapid and automated. The project has been completed in 2003.
- The project was initiated by academic scientists with the intention of making the entire sequence available to all

academic and non-academic scientists, free of charge. Since the advent of the internet, it has been decided that this would be the best medium for maximum accessibility. Academic Scientists working on the project make the DNA sequences they discover publicly available within 24 hours. The information provided by the DNA sequence is expected to be an invaluable medical resource for the future if the riddles of many intractable diseases are to be solved.

- The object was to determine the location of the estimated 100,000 human genes. The purpose was to provide "the source book for biomedical science in the 21st century which would be of immense benefit to the field of medicine. The object is to understand and eventually treat many of the more than 4,000 genetic diseases that afflict humankind, as well as the many multi-factorial diseases in which genetic predisposition plays an important role.[12]

Project goals were to -

- identify all the approximately 20,000-25,000 genes in human DNA,
- determine the sequences of the 3 billion chemical base pairs that make up human DNA,
- store this information in databases,
- improve tools for data analysis,
- transfer related technologies to the private sector, and
- address the ethical, legal, and social issues (ELSI) that may arise from the project.

[12] *Human genome project information*

Although the completion of the Human Genome Project was in April 2003 and sequencing of the human chromosomes is essentially "finished," the exact number of genes encoded by the genome is still unknown. October 2004 findings from The International Human Genome Sequencing Consortium, led in the United States by the National Human Genome Research Institute (NHGRI) and the Department of Energy (DOE), have reduced the estimated number of human genes from an earlier estimate of 35,000 to only 20,000-25,000. Consortium researchers have confirmed the existence of 19,599 protein-coding genes in the human genome and identified another 2,188 DNA segments that are predicted to be protein-coding genes.

Scientists are now discovering the genes which trigger various genetic diseases which, in turn constitute a large part of the inherited causes of the suffering of humanity. For example, the genes, which express Huntington's disease, a serious affliction have been identified on the human genome. Their discovery permits the conduct of extremely accurate tests, which can now identify those people who carry and many transmit this genetic condition. That knowledge would theoretically in combination with pre-natal tests and abortion, permit the future elimination of carriers of Huntington's. Is this desirable? Can it be distinguished from the abortion of a foetus with Down syndrome? Where does this process of medical elimination of the results of 'defective' genes begin and end? Is there a less life-destructive means of using the genetic information to delay the onset or diminish the symptoms of Huntington's disease whilst respecting the life of a person born with those genes or others like it? The

UNESCO Declaration states that "No one shall be subjected to discrimination based on genetic characteristics that is intended to infringe or has the effect of infringing human rights, fundamental freedoms and human dignity." *(Article 6 of UNESCO Declaration)*

6.16 Universal Declaration on the Human Genome and Human Rights, 1997

The Universal Declaration on the Human Genome and Human Rights was adopted unanimously and by acclamation at UNESCO's 29th General Conference on 11 November 1997. The following year, the United Nations General Assembly endorsed the declaration.

The objective behind the Declaration was to prepare an international instrument for the protection of the human genome. The Declaration emphasizes on human dignity while dealing with the genome project.

This is the first universal instrument in the field of biology. It strikes a balance between safeguarding respect for human rights and fundamental freedoms and the need to ensure freedom of research. The adoption of this Declaration by the states is a starting point of international awareness on ethical and legal issues of the human genome. It is now up to the States, through the measures they decide to adopt, to put the Declaration into practice and thus ensure its continued existence.

The Declaration is without prejudice to the international instruments which could have a bearing on the applications of genetics in the field of intellectual property. The Declaration recognizes that research on the human genome and the resulting applications open up vast prospects for progress in improving the health of individuals and of humankind as a whole, emphasizing that such research should fully respect human dignity, freedom and human rights, as well as the prohibition of all forms of discrimination based on genetic characteristics.

Article 11 of the Declaration says that practices which are contrary to human dignity, such as reproductive cloning of human beings, shall not be permitted. States and competent international organizations are invited to co-operate in identifying such practices and in taking, at national or international level, the measures necessary to ensure that the principles set out in this Declaration are respected. This does not put any restrictions on cloning.

6.17 The Human Genome and the Patent Boom Challenge

One of the key issues of genetic research concerns the desirability of permitting the patenting of human genes or their sequences as the basis for future therapeutic applications. The current explosion in the number and variety of applications for patents on the human genome is giving rise to an increasingly strident controversy. Will the rapid growth of intellectual property protection impede research holding the promise of

dramatic breakthroughs in the fight against HIV/AIDS, cystic fibrosis, muscular dystrophy and diabetes, among other diseases and health conditions? Will the cost of licensing fees for new therapies confine their use to the rich alone? Is there a contradiction between the TRIPS Agreement (The Agreement on Trade-Related Aspects of Intellectual Property Rights) negotiated in the World Trade Organization (WTO) and internationally protected economic, social and cultural rights?

Unless the rise in patents in relation to the human genome is soon curtailed, the cost of future therapies and genetic tests will become prohibitive for most human beings and nations. Thus a remarkable opportunity for humanity to act in a way defensive of the entire human species will be lost.

The great progress made in pharmaceutical development between 1920 and 1970 - penicillin and other antibiotics and vaccines - took place at a time when there was little demand for intellectual property protection. Things began to change thereafter as most recently illustrated in the case of HIV therapeutic drugs. Although essential to the right to life and health of millions, patents have, with few exceptions, reduced access to such drugs to the wealthier countries. This led to a public outcry, development of generic drugs, abandonment of court action taken to enforce property rights in South Africa and widespread public protest.

At conferences on the genome, strong views are expressed by participants from developing countries. They urge that the human genome is the common heritage of humanity. It belongs to the human species as a whole and not to private corporations engaged in research, however potentially beneficial such research may prove to be. There is also a lack of effective and fair benefit-sharing and technology transfers to developing countries from which genetic material are commonly taken, the reduction of communities' control (especially indigenous communities) over their own genetic and natural resources and cultural values, and restrictions on access to patented pharmaceuticals and the implications for the enjoyment of the right to health.

The 20-year duration of patent protection as a universal rule is excessive as regards genomic sequences that compose the human genome thread and the rapid advance of knowledge about them. Patents already granted and applied for will add greatly, and for many years, to national health budgets. For developing countries as well as for the poor in developed countries, the costs of licensing fees may mean that beneficial therapies or useful tests will effectively remain out of reach for a long time to come.

The growing tendency, witnessed of late, to seek and secure the widest possible patent rights over sequences of the human genome of uncertain future utility is likely to have large consequences downstream as the significance of a particular

gene - or of that gene in interaction with others or with environmental factors - comes to be known.

Once a genetic sequence has been "invented", the patent claims generally extend to cover most related genetic materials and most possible uses of those genetic materials. This means that most useful genetic diversity and almost every conceivable use is claimed, leaving very little room for further innovators. These broad claims are a problem because most of the valuable genetic resource is its useful diversity tied up in the subtle differences in genetic materials. Broad claims undervalue this resource. The broad patents also give a huge share of genetic materials to one patent holder, and in some cases give "ownership" of a technology or a field. This has consequences for follow-on innovation and competition.

Another source of concern is that the continuous decline in public funding for general research and the consequent increased proportion of research funded by the private sector may be skewing priorities towards areas offering a potential for maximum financial rewards as opposed to those that reflect the greatest human needs.

Ultimately there is a conflict or tension between ethical principles - those that uphold the right to protection of the creative inventions of the human mind and those that uphold the right to life, the right to health protection and promotion and the

solidarity of the entire human family. In the context of intellectual property law it is necessary to resolve this conflict in a just way. The present intellectual property law, municipal, regional and international, falls short of doing this.

Progress in genetic research continues to accelerate, opening up fresh possibilities of previously undreamed-of applications and posing new ethical problems. Examples include the ground rules relating to the setting up and management of genetic data banks which are now proliferating, questions concerning the observance of human rights and fundamental freedoms raised by the use made of such data, the fact that such data are increasingly employed for non-medical purposes, and related issues.

6.18 Patentability of the Human Genome

The crucial question is whether human DNA is patentable. The advocators of DNA patenting argue that patenting gives a company or an individual temporary custody but not ownership. There is also a debate on what can be patented -

- Gene fragments and sequences, or
- Knowledge of what a gene does in the body (process of discovery is treated like a medical invention).

UK and USA patent laws on this issue differ. Broadly speaking, DNA per se, is not patentable in the UK, but functional methods or products arising from it, are. However,

in the USA, it is possible to patent "raw" DNA. The US patent office routinely grants patents on genes, the only country in the world to do so. This allows the holder to charge a fee if anyone uses them for a commercial purpose. It is the US law that is causing the current problems in the human genome project.

If we allowed the patenting of sequences, it would be akin to patenting the alphabet and asking people to pay a royalty when they speak.

As an extra wrinkle, patent laws have historically required that an invention be non-trivial, non-obvious and demonstrable (invention in-hand). It should not be allowed to tie up all future uses (e.g., a patent for a lawnmower is specific, it can't be used to patent any means possible for cutting grass). Another question is whether mutations can be patented. For example, if someone patented the hundreds of mutations linked to breast cancer, they could tie up "downstream rights." They could own the rights to all medical diagnostic tests (licensing fees) that rely on such mutated genes as markers of cancer induction.
This would lead to *filing mania* – much like treating the human genome as a futures market.

Human beings are moral creatures. They are also gregarious. They group themselves in societies, ultimately international society. The genetic revolution will be overwhelmingly for the

benefit of humanity. It will provide the universal textbook for medical science in the next century. It is happening, and it is happening quickly.

Important ethical and legal challenges are presented. They not only affect wealthy nations in the forefront of genomic research, like the US, they also concern countries like India. Indeed, they concern every nation on earth and the people of every nation. They require us to consider our obligations to ensure that the global response is effective and that the benefits of the Human Genome Project flow to the people of all developing countries. The genomic revolution is about malaria and river blindness- not just about wrinkle prevention. Unless humanity realizes this, talk of genome as an attribute of the common property of humanity will be empty. Such exciting developments deserve to be shared with all people. Countries have a responsibility to promote, both nationally and internationally, a regime that is equitable, respectful of the dignity of the individual and mindful that the individual is always much more than a collection of his or her genes.