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Patents: Some issues and implications

by Jagath Gunawardena

To many people, a patent means a kind of protection given to new inventions in industrial and technological fields. Indeed, till recent times, patents were available only for inventions and remains so even at present in many countries including Sri Lanka. However in some, notable in the United States of America and to a great extent in the European Union countries, patents are given to living organisms and their parts and human parts. Such patents are referred to as Life Patents and are not limited to animals, plants and microbes but include human and animal tissues and cells and extend further to cover DNA and RNA molecules, their parts, genes and even to the sequences in these molecules. The allowing of life patents have brought about a situation where some living animals, plants, microbes and their parts as well as some human body parts have become private properties owned by individuals and companies.

All new products and new processess are not given patent protection as every country has excluded certain inventions from being covered by patents. In many countries including Sri Lanka, animals, plants, methods of diagnosing and treating diseases are not-patentable, so are new discoveries. But, in U.S.A., patents can be taken for both inventions and discoveries. This had made it possible to patent things derived from plants and animals that have been in existance for thousands of years but newly "discovered" by those who intend to get them patented. In the U.S.A., patents are available for new, asexually propagated plant varieties under the Plant Patent Act of 1930. The opening of floodgates to get utility patents for plants, animals their parts and parts of human beings came in subsequent to the decision of the U.S. Supreme Court decision in the much quoted Diamond vs Chakravarthy case in 1980. The directive on patents by the European Union allows certain animals, plants and parts to be patented in the European Patent Office (EPO).

All new varieties of animals and many of the plant varieties that are the subject of utility patents are those created by genetic-engineering. That is, by the introduction of one or more alien genes to a plant or an animal. Those who patent these living beings claim that new animals or plants which have introduced alien genes are "inventions" and that their intellectual ability had gone into the "creation" of them. What the technology had really done is to add one or more genes to an already existing variety which had added or altered one or more functions or traits in the organism. Their creative effort, if successful, could be seen in the altered being, since it can be easily compared with the unaltered beings of the same variety. Since the process of inserting new genes into particular beings so that they are able to express the desired trait had been due to the creative effort of scientists, it is clear that it is an inventive process of theirs. If they ask for a patent to cover such processes, it is a way of seeking a just reward for all their efforts. But, what we increasingly see is that once such inventive processes are patented, they cover all the beings created as well as any others that may be created as well.

The first patent for human parts was for a cell line from the spleen of a person named John Moore, who is still alive and well. This patent, obtained in 1984, by the University of California (U.S. 4,438,032). It covers the T-lymnoblast cell line obtained from his spleen, the proteins produced by them and the DNA and RNA molecules that expresses these proteins. This is so wide to cover any organism made by genetic-engineering to produce these proteins. The patent for the cell line was obtained without the consent of Moore but it prevented him from even donating part of cells to another institute to produce these proteins that are able to destroy certain types of cancers.

For example, the first patent for a living animal was granted to the Harvard University in 1987 (U.S. 4,736,865) by the U.S. Patent and Trademarks Office. It was thereafter patented (EP 169672) in the EPO. This animal, a transgenic mouse is often referred to as the Oncomause Greaning cancer-mouse or the Harvard mouse. In this, they have introduced a cancer-causing gene to a mouse, making it susceptible to cancer. This mouse was seen as a great help to scientists doing research on various types of cancers to study them and to try various cures and therapies, and to develop cell lines. In the patent, they explain five methods of introducing a cancer-gene and the preferred mathod. If the scope was limited to these processes, it could have been justifiable from all angles, since it is their creative ability that resulted in finding out the process and anyone using it should reward the inventers for their effort. But, the claims of the patent is so broad that the popularly quoted "oncomouse patent" is a misnomer. The patent really covers all mammals, except human-beings that contain any gene able to cause cancer or make them susceptible to cancer, and any call line extracted from any such mammal. It is an example how those inventing a process lay claim to all products that have been subjected to the process.

This same trend is evident in some patents on transgenic plant varieties. In 1994, a patent on transgenic Soya beans (EP 301749) was given by the European Patent Office (EPO) to the biotechnology firm Agracetus which covers any Soya Plant with a foreign gene. This patent, in effect covers any variety of transgenic Soya, or in effect block and prevent all research by others from making transgenic Soya. It is a patent bent clearly on creating a monopoly on a particular crop, and not to protect or safeguard an invention, and are an abuse of the law. This particular patent was challenged by the Monsanto Company, which later bought Agracetus and dropped the action. Ironically, the same Monsonto Company has a patent covering all transgenic Cotton Varieties (US 5,159,135 and EP 270355), which has been challenged by several companies and even by the U.S. Government. In addition, Monsonts has got patents (US 5,188,958 and EP 270615) that covers any plant variety belonging to the genes Brassica (Cabbages, Cauliflower, Broccoli), genetically engineered using the Agrobacterium Method.

Utility patents are not confined to transgenic crop varieties as the infamous patent (US 5,663,484) for Basmathi Rice lines and grains show. Basmathi is a name used for a line of rice varieties traditionally grown in India and Pakistan. The patent covers not only these rice lines but the desirable lines for breeding, new lines that are semi-dwarf, high-yeilding and grains" similar or superior to those of good quality Basmathi rice grains produced in India and Pakistan". The patent for the Apalewa variety of Quinoa (Chenopodium quinoa), given to two research. Scientists (U.S. 5,304,718) who found it growing among the plants cultivated in Bolivia covers any hybrid made using this variety as a patent and all traditional varieties that have 'cytoplasmic male sterility" as a characteristic. Patents such as these, in addition for creating monopolies, strifling research, restriction of imports are classic examples of how the genetic wealth of developing countries are robbed and misappropriated by companies in the developed countries.

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Another controversal patent related to human parts is the one obtained to cover the calls found in the umbilical cords of newborn babies. This patent (U.S. 5,004,681 and EP 343217) by Biocyte Company (now part of Avicord) has given them a monopoly over the extraction, freezing and thawing of cells without them dying, the use of these cells (Stem cells and progenitor cells) in any therapies and the products made in connection to them or from using them. They can justifiably claim a patent to the method (process) to freeze, store and then thaw the cells without losing their viability as an innovation but have instead laid claim to the cells themselves. These cells have been used by doctors in transplantation operations to restore immunity and to

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treat various diseases. The claims will stifle these operations and are also against the Code of Ethics of the International Society of Transplantation which state that human body parts should not be made commercial and organ and cell donations should be free.

A related development the patenting of genetic material including genes and their sequences. A gene is really a stretch of genetic material (or DNA molecule) with a particular function within the organism or cell. Till recent times, genes were transferred between related organisms when they interbreed. Biotechnology has it possible to take out a gene from one organism and insert it into a totally unrelated organism to function as desired. This had made genes that express desirable characteristics and products into valuable properties much sought after by biotech firms in U.S.A. and Europe. This had made research institutes to patent important genes, their sequences or genetic codes and any new techniques to insert them into organisms. So that it is expressed as intended, and had gone as far as to even claim all transgenic beings having these genes.

The project known as Human Genome Sciences (HGS) has detained patents (US 5,597,709 and EP 741578) for a human gene that can produce a human growth harmone. They have registered the patent at the World Intellectual Property Office (WIPO) under the number WO 9520398 and intends to obtain patents in other countries as well. The patent for the protein and dated from Bitter Gourd or Karawila (US 5,484,889 and EP 552257) covers not only the protein that can be used to treat tumors and HIV-infections but extends to the amino acid sequence, the DNA sequence encoding the protein and any method of transferring this gene into any other organism in which it can be expressed to give the protein. The organisms include insects and the caterpillars (larvae of butterflies and moths) are said to be the most productive because they can produce this protein upto 20% — 50% of their body weight.

The patenting of genetic codes goes beyond all logic of patenting inventions or discoveries. The sequence in a gene, DNA or RNA molecule is only the arrangement of the four different compounds, known as nucleic acids. Scientists are now able to "decode" or "read" these and is not an invention. It could be shown as a discovery, if it can be proved to be unique or distinct. Since the genetic codes of the majority of living beings is not known at all, it is possible that the some sequence may be found in another, unrelated organism. The application of a patent to the genetic codes after being "read" by a scientist is not different from a person going to a library, reading a publication or some pages of it and then requesting that it be patented under the person's name. Illogical as it is several groups decoding genetic codes have been filing applications in their thousands. For instance, the Human Genome Sciences had filed over a million applications for partial human gene sequences without even knowing where, when and how they are expressed in a human being.

Many developing countries do not provide for the patenting of life forms and discoveries. Some officials dismiss the implications of life patents as a problem of developed countries, which is of no concern to us. This problem need to be analysed, not confining to the provisions of the Code of Intellectual Property Act, but considering the importance of our biodiversity, laws in other countries, international conventions with special reference to the provisions of the Convention on Biological Diversity (CBD) and the Trade Related aspects of Intellectual Property Rights Agreement (TRIPS). According to Article 27(3)(b) of TRIPS, every country has the option of either patenting animals and plants, but made it mandatory that member countries should either provide patents for plants or a unique (Sui-Generic) law to provide protection to plants or a combination of both. The other is that countries must provide lows to patent micro-organisms.

In protecting new plant varieties under a unique law, the requirements of novelty, uniformity and stability are quite similar to that needed for a patent. This becomes clear because some countries allow both the registration and obtaining utility patents for plant varieties. The only positive features in such an act is that we could provide for the protection of traditional varieties, developed by farmers and farmers rights. The patenting of micro-organisms is life patenting itself with far more problems in effective implementation. It is for these reasons that some countries have opposed any patents on life forms and even asked that living beings and parts be dropped from TRIPS, or the abolition of Article 27(3)(b). It is encouraging to see that the focal point in biological diversity conservation in Sri Lanka, the Ministry of Forests and Environment has taken up the position that Sri Lanka should ask for the disallowing of life patents and to ensure that the proposed Sui generic system to protect plant varieties should protect the knowledge and rights of farmers and be in accordance with the use and conservation of biological resources.

This position is praiseworthy when one considers the manouverings that went on before the Seattle Round of the World Trade Organisation (WTO) under which TRIPS is administered Bio-tech companies in U.S.A. and EU wanted to amend Article 27(3)(b) of TRIPS to make life patenting mandatory. But, public interest groups in those countries opposed life patenting, their arguments ranging from religious grounds, morality, practical difficulties to bio-piracy. If life patenting becomes mandatory, it is countries rich in bio-diversity such as Sri Lanka that would be the loser. The scuttling of the Seattle Round of the WTO prevented the reviewing of TRIPS. But it is all too possible that the corporate lobbies of these countries, backed by their governments would make a strong case to amend the TRIPS to make life patenting a mandatory requirement and the developing, biodiversity rich countries need to take a stronger stand to take out all life patenting articles out of the TRIPS at the next review.

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