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Why Biotech Patents are Patently Absurd—Scientific Briefing on TRIPS and Related Issues[†]

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The author discusses TRIPS Agreement and gives reasons for revoking and banning patenting of life forms and living processes. He further discusses about the ways of classifying patents and proprietary databases on life forms and living processes. Also covered are patents based on plagiarism and biopiracy, discoveries, transgenic processes and organisms, nuclear-transplant cloning and other *in vitro* reproductive techniques, stem cells isolation and culture techniques, GM constructs and vectors. He further analyses TRIPS and EU system and discusses about positive aspects of EU Directive, which strongly excludes plant and animal varieties from patenting category.

TRIPS, or Trade-Related Intellectual Property Rights, is an agreement between member states of the World Trade Organization (WTO) that seeks to enforce US style patent laws around the world. This agreement covers everything from pharmaceuticals to information technology software and human gene sequences, and is emerging as a major issue dividing North and South.

Signatories to TRIPS must have passed national legislation to become 'TRIPS compliant' by 2000, although the poorest countries have until 2006. But since the dramatic breakdown of the WTO negotiations in Seattle at the end of 1999, there has been a stalemate. Developing countries are demanding a review of existing TRIPS Agreement at the same time the rich industrialized countries are clamouring for a new round to introduce extra issues into the WTO, such as the multilateral agreement on investment (MAI), which is strongly opposed by developing countries.

The TRIPS Agreement is controversial in at least two areas. First, it threatens the right of poor countries to manufacture or to import cheap generic versions of patented drugs. This is particularly devastating and immoral at a time when the AIDS epidemic and other diseases are

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killing millions every year because people in poor countries cannot afford the exorbitant prices the pharmaceutical giants are charging for the patented drugs, and making record profits at the same time

The other major controversy is that the existing TRIPS Agreement forces all countries to accept a medley of new biotech patents covering genes, cell lines, organisms and living persuaded into accepting these 'patents on life' before anyone understood the scientific and ethical implications.

The patenting of life forms and living processes is covered under Article 27.3(b) of TRIPS. A scientific briefing explains why such patents should not be included in TRIPS[1]. The present paper is an update of that briefing, showing why those patents should be revoked and banned altogether.

Glossary of Terms

Antibiotic resistance marker genes are genes coding for antibiotic resistance used in genetic modification. They allow the cells that have taken up the foreign GM construct to be selected with antibiotics, and frequently remain in the genetically modified organism and transgenic line created.

A *cell line* is a supposedly genetically uniform population of cells derived from one individual cell, or it could be a clone (theoretically genetically identical descendants) of one original cell. The genetic identity of all the cells is a fiction, as the genetic material is subject to many 'fluid genome' processes that constantly make cells genetically different from one another, and especially in culture. Both plant and animal cells are subject to large variations known collectively as somaclonal variations.

A *clone* is an identical copy of a cell or an organism.

A *DNA sequence* refers to the sequence of bases in a stretch of DNA. DNA is a linear molecule consisting of units strung together. There are 4 different units, each identified by the specific base contained. There are 4 different bases, which are simply represented by the alphabets, A, T, C and G. An example of a DNA sequence is as follows: ATTTCCGCTACGCGTTA... An *RNA sequence* is similar, except that U replaces the alphabet T.

An *"essentially biological process"* is scientifically suspect. Does it mean a process that occurs naturally or which is carried out by organisms? Similarly, a *"non-biological process"* is difficult to define, as all processes in biotechnology, by definition, are biological. A weak case may be made on the ground that it is one that does not occur naturally, or which is not normally carried out by organisms.

A *gene* is a stretch of genetic material (DNA or RNA) with a defined function in the organism or cell. It usually codes for a protein. There are many genes within a genome. For example, the human genome is now found to contain about 30,000 genes, while the rice genome has about 50,000.

Gene expression refers to the synthesis of the gene-product or protein encoded by the gene.

A *genetically modified organism* (GMO) is one which has foreign DNA inserted into its genome by means of genetic modification in the laboratory.

Genetic modification or *transgenesis* is the process whereby a genetically modified organism is made in the laboratory. This involves making artificial or modified genetic material (GM constructs), which is inserted into the genomes of cells or embryos. The cell or embryo is regenerated to an organism, out of which a GM line or transgenic line is derived.

A *genome* is the totality of all the genetic material (deoxyribonucleic acid or DNA) in an organism, which is organiZed in a precise, though by no means fixed or constant way. In the case of viruses, most of them will have ribonucleic acid or RNA as the genetic material.

Horizontal gene transfer is the direct transfer of genetic material to unrelated species, for example, from plants to bacteria.

A *microorganism* is an organism that can be seen only under a microscope, usually, an ordinary light microscope. It includes bacteria, cytoplasm, yeasts, single-celled algae and protozoa. Multicellular organisms are normally not included, nor fungi apart from yeasts. Viruses are also not automatically included, as many scientists do not classify them as organisms. However, all organisms including human beings begin life as microscopic germ cells and fertilized eggs, so in practice, all reproductive processes can be interpreted as microscopic, and hence patentable.

A *"microbiological process"* is presumably one that is carried out by microorganisms. But as a microorganism is ill defined, so too, is a microbiological process.

Nuclear transplant cloning is a process whereby the nucleus containing the genome of an adult cell is transferred into an egg from which the nucleus was previously removed. The egg with the transplant nucleus is then stimulated to divide and develop into an organism. The organism is supposed to be identical in genetic makeup to the individual from which the cell was taken.

A *promoter* is a piece of genetic material that acts as a gene switch, so that a gene can become expressed in the cell.

Stem cells are cells that have the potential to become many different cell types.

A *vector* is a carrier or transmitter, of genes or of disease. Artificial vectors are made in genetic engineering for multiplying and transferring genes into genomes.

A *virus* is a parasite consisting of genetic material wrapped in a protein coat. It depends on infecting and entering a cell to multiply copies of itself.

Range of ‘Patents on Life’

There are numerous patents and proprietary databases under TRIPS Article 27.3(b), and the range is growing all the time. All of them should be

revoked and banned for one or more of the following reasons:

— involving acts of plagiarism and biopiracy
— technology unreliable and hazardous
— all depend on biological processes, therefore little or no invention
— discovery, not invention
— knowledge, not invention
— unethical in threatening livelihood
— violation of basic human rights and dignity
— contrary to public order or morality
— lack of scientific basis
— obstructs diagnosis and treatment
— stifles scientific/medical research and innovation

Nearly 400 scientists from all over the world are calling for a ban on all such patents, as well as a moratorium on releases of GMOs on grounds of safety[2].

There are many ways to classify patents and proprietary databases on life forms and living processes. The classification has been done on the basis of how they fail to satisfy the accepted criteria for patent awards. Some of the categories would overlap:

— Patents based on plagiarism and biopiracy.
— Patents based on discoveries or knowledge, which also violate basic human rights and dignity: These include patents on cell lines, genomes and genes of natural organisms, natural microorganisms, and proprietary information and databases owned by companies.
— Patents on transgenic processes that cannot be said to be inventions because they are unreliable, uncontrollable and unpredictable as well as being inherently hazardous. These properties also extend to the transgenic organisms and lines produced.
— Patents on nuclear transplant cloning and other reproductive technologies and on the cloned animals and lines produced, which also do not qualify as inventions and violate public order and morality, or are contrary to animal welfare.
— Patents on stem cell isolation and culture techniques and the stem cells and cell lines produced which are parts of natural organisms and should not be patentable. Many also violate public order or morality.
— Patents on artificial vectors and other GM constructs and methods for producing them which depend on recombining natural genetic material but the functions of which depend on living organisms. GM constructs and artificial vectors are inherently hazardous.

Patents Based on Plagiarism and Biopiracy

These include patents on extracts, formulas, and genes of plants that have been developed and used for millennia by indigenous communities for medicinal and other purposes. Examples are patents

on extracts of the neem plant from India (at least one of which has been challenged and revoked), patents on extracts of the bibiru and cunani from the Wapixana Indians in North Brazil., and patents taken out by the Japanese cosmetic company Shideido on several traditional formulas of Indonesian herbs and spices including the anti-ageing agents made from Sambiloto (*Andrographis panicurata*) and Kenukus (*Piper cubeba*), and hair tonic from Japanese chili.

Biotech companies are aggressively scouring the globe 'bioprospecting' and accessing the biodiversity of the entire world. Diversa Corporation, one of the biggest players, is expanding its microbial genomic libraries to develop products for the pharmaceutical, agricultural, chemical and industrial markets. It already has access to Alaska, Costa Rica, Bermuda, Indonesia, Yellowstone National Park, and Russia, and the latest, South Africa[3], one of the world's most biologically diverse environments, and includes the famous Cape Floristic Region with 9,000 plant species, 70% of which are endemic.

The African agreement gives Diversa the right to discover genes and commercialize products provided by the Council of Scientific and Industrial Research (CSIR) currently undertaking nearly 10% of all research and development activities on the African Continent. In exchange, Diversa will support the ongoing bioprospecting activities of CSIR and pay royalties on any revenues that come from developed products. Diversa's strategic partners include The Dow Chemical Company, Novartis Seeds AG, Novartis Agribusiness Biotechnology Research, Inc., Aventis Animal Nutrition SA, Celanese Ltd, Invitrogen Corporation, and Danisco Cultor.

This class of patents has the potential to destroy biodiversity and livelihoods of indigenous communities. It could also undermine the entire healthcare system of a country. The Association of South East Asian Nations has just drafted a position paper supporting traditional knowledge and medicine[4]. It intends to promote traditional medicine for healthcare and at the same time protect the environment and avoid over-exploitation. In the review of Article 27.3(b) of TRIPS concerning biotechnology, it will maintain that plants and animals are not patentable and emphasize the prevention of biopiracy.

Patents Based on Discoveries

This comprises the broadest categories of patents already granted.

(a) Human cells and cell lines

Many are derived from blood collected from indigenous peoples under the Human Genome Diversity Project, without informed consent, and with coercion in some cases. A US company, Coriell Cell Repositories, lists Amazonian Indian blood cells in a DNA kit, which is openly advertised on the Internet.

A patent on umbilical cord cells was granted to the company, Biocyte, despite the fact that those cells have been used freely for transplant purposes previously.

The EU Patent Office have revoked this patent in June 1999, after a successful challenge by The European Campaign on Biotechnology Patents, a coalition of European NGOs.

Any cell line derived from a patient can be patented without informed consent, as in the famous case of John Moore in the United States, whose spleen cells were patented by his doctors.

(b) Human population DNA databases

Since the DNA database of the entire Icelandic population was sold by their Government to DeCode Genetics, a California-based company, other populations have been targetted. The Tongan population database has recently been sold to a private company, and the Swedish Government is negotiating with another company for the 'ethical' takeover of its population database. The UK government is planning to establish one of its own, and geneticists from Harvard University are cheating rural Chinese of their DNA[5]. These collections are purportedly used to discover genes involved in susceptibility to diseases. Apart from being entirely misplaced, such collections have the potential for gross violation of human dignity and rights to privacy[6]. It could compromise an individual's employment and health insurance as well as civil rights.

(c) Human gene sequences, gene fragments and single nucleotide variants of genes (SNPs)

The pace of human gene patenting has accelerated to frenzy as the human gene map was nearly completed. Applications for patents in the US went from an annual 1,50, 000 in the late 1980s to 275 000 in February 2001 when the 'complete' human genome map was announced. In October 2000, there were patent applications on 126 672 human gene sequences. By February 2001, there were 175 624, a 38% jump[7]. The US has granted patents for millions of SNPs (single nucleotide polymorphisms, variants of genes involving a single base change) and gene fragments for which functions are unknown before it tightened the patent laws in December 1999[8]. Since then, both the gene function and industrial application have to be specified. In practice, however, the 'function' is little more than a surmise based on similarity in sequence to other genes, and the industrial application simply a diagnostic test for predisposition to condition x, where x could be anything from cancer to criminality. The human genome is already covered with dozens of times more patents than there are genes, because multiple patents are being granted over the same stretch of DNA. Such patents are seriously distorting healthcare and stifling scientific research and innovation.

(d) Proprietary databases in 'bioinformatics' and 'genomics'

These databases have grown out of the application of information technology to sequencing of the human and other genomes. Private companies have been 'mining' the public databases (free access to all) for information to include in their own proprietary databases, which are

made available, at exorbitant fees to corporate subscribers hoping to identify targets for lucrative new drugs. This has now created an unprecedented knowledge monopoly.

The problem came to a head in February 2001, when Celera, the private company which raced the international consortium of the human genome sequencers to the finishing line, published their complete human genome map in *Science*. In a complete break with accepted tradition, Celera was allowed to retain control of access to the sequence described in the published paper, instead of having to deposit it in the public database GenBank/EMBL/DNA in Japan.

Celera stipulated it would only publish on the condition that the data are retained exclusively on its own website. Users are limited to downloading no more than one mega byte of data despite previously announcing it would "make the entire sequence available free of charge". Those seeking larger downloads have to submit a letter from their institution, promising not to redistribute the information. Scientists are outraged, for it will seriously obstruct efforts to make sense of the sequence data[9], and stifle any innovative research that can come out of it.

(e) Patents on genes of plants

The entire rice genome sequence was announced January 2001 by the European agribusiness giant Syngenta and US company, Myriad Genetics, which patented two-breast cancer genes[10.] The announcement triggered alarm from Action Aid, the hunger charity. There are already 229 patents on rice; the diet of the world's poorest will become the preserve of big business. Rice is grown in 100 countries but nine-tenths of the world's crop is produced in Asia, providing four-fifths of South-East Asia's calories. Rice has been domesticated by human beings for 5000 years.

Syngenta intends to sell data on the rice genome to seed businesses and other commercial groups, and to make the information to scientists "through research contracts". It would also provide information "without royalties or technology fees" to scientists helping subsistence farmers. The two companies said they would not patent the rice genome but they would patent particular uses of the genes as they were identified.

However, if human gene patenting is anything to go by, it would take no time at all to cover the rice genome dozens of times over with patents that will not only stifle independent research and innovation, but also seriously undermine farmers' rights to create new varieties or to preserve existing ones.

Hundreds of patents have already been granted on DNA sequences from plants taken from developing countries including such well-known plants as nutmeg, cinnamon, rubber, jojobe and cocoa, and the list is bound to grow as DNA sequencing is now routine.These patents will have adverse impacts on technology transfer and food security as they intensify corporate monopoly on food. They will also jeopardize the entire healthcare systems of third world

countries that are strongly dependent on indigenous medicine.

(f) Patents on genomes of pathogenic bacteria and viruses

These patents can, and are obstructing the prompt diagnosis and treatment of dangerous diseases such as meningitis and tuberculosis. Delay in diagnosis and treatment will result in unnecessary deaths. Dozens of bacterial and viral genomes have already been sequenced and patented, one of the most recent being the genome of *E. coli* 0157:H7[11], responsible annually for hundreds of thousands of cases of food poisoning in US, UK and other countries around the world.

(g) Patents on naturally existing microorganisms

Microorganisms are construed to be patentable. As microorganisms are the most abundant and essential part of natural biodiversity, this is potentially very serious. As mentioned earlier, companies like Diversa have been given licence to bioprospect in all parts of the world, and one of their main quests will be microorganisms. This class of patents could even infringe on natural processes that people all over the world have been using for thousands of years, as in baking, brewing, fermenting, and so on.

Patents on Transgenic Processes and Organisms

Transgenic processes are notorious imprecise. Transgenesis is not a technology at all. It is extremely hit or miss, with low rates of success and many abnormalities and other unintended, unexpected effects in both plants and animals, including toxins and allergens. Each transgenic line originates ultimately from a single cell that has taken up the GM construct. Its characteristics will depend on the form in which the GM construct is inserted and the precise location of the insert in the genome. The GM construct is often repeated, rearranged, and may have parts deleted or extra sequences originating from the vector used in transferring the GM construct. There may also be more than one site of insertion. The insertion invariably leads to genetic disturbances spreading far from the site. So, even if the transgenic lines are made with the same GM constructs, vectors and plant/animal cells, they will all end up being different from one another as well as from the non-genetically modified organism.

An important class of transgenic process patents are on the ‘Traitor Tech’ or ‘Genetic Use Restriction Technologies’ (GURT) which are based on the original ‘terminator technologies’ that engineer harvested seeds not to germinate, thus offering *de facto* protection of transgenic seeds[12]. A newer version makes seeds dependent on the application of a chemical for germination, or for expressing the desired transgenic trait. These patents are unethical as they serve no other purpose than to intensity corporate monopoly on seeds and on food production, and have been universally rejected by civil society around the world.

Large failure rates are typical in making transgenic animals and

abnormalities are frequent even among the successes. The GURT technologies are even worse. They depend on 'site-specific' splicing of genes that is supposed to be precise, but far from the case in practice.

Transgenesis in its current state-of-the-art certainly cannot be said to be an invention in the usual sense of the word. Most importantly, there is a raging debate on the inherent dangers of the process of creating transgenic organisms, which is why there is still a *de facto* moratorium in Europe, and many other countries are imposing moratorium or ban. Transgenic DNA has the potential to generate new viruses and bacteria that cause diseases, and may also cause cancer by integrating into mammalian cells. Another major worry is the spread of antibiotic resistance marker genes to pathogens, making bacterial infections untreatable. The British Medical Association issued a report in 1999 calling for an indefinite moratorium on transgenic crops, and further research on the possible health risks of GM foods, including new allergies, the spread of antibiotic resistance and the effects of transgenic DNA in animals and human beings.

The terminator or GURT technologies involve even greater risks, as they make use of genes that are inherently dangerous, one of the genes kills all cells in which it is expressed, and the other, can scramble genomes by breaking and joining the genetic material in inappropriate places. These genes can escape both by ordinary cross-pollination between related species as well as by horizontal gene transfer to unrelated species. The Institute of Science in Society have recently discovered that terminator crops have been field tested in Europe and the United States since the early 1990s, and several of them have been approved for commercial release in the US[12].

Both the US and EU are now granting patents on transgenic processes as well as the resulting transgenic organisms or GMOs. GMOs for which patents are granted include not only crops, but also livestock and fish. Livestock such as cows and sheep are genetically modified to serve as 'bioreactors' to produce pharmaceuticals and industrial chemicals in their milk, blood, urine and semen. Fish are genetically modified to grow faster and bigger. Millions of mice have been genetically modified to serve as models for human diseases, the first transgenic mice to be patented was the notorious 'oncomouse' genetically modified for increased susceptibility to cancer. Pigs 'humanized' to provide spare organs and tissues for transplant into human subjects have also been patented[13]. Recently, a transgenic rhesus monkey has been created, raising fears that transgenic human beings might be next in line[14].

Broad patents for transgenic processes have been awarded which include applications to all other species. This has led to disputes among different patent holders: those holding patents on the individual transgenic organisms, and others holding the patent on the transgenic process. Hundreds of millions of dollars are spent, unproductively, on litigations.

More seriously, the patents on GM seeds are preventing farmers from saving seeds for replanting unless they pay royalities to the companies. GM seeds intensify corporate monopoly which is already threatening the livelihood of small farmers all over the world. Patents on transgenic animals are encouraging transgenic practices that are contrary to animal welfare.

Patents on Nuclear-Transplant Cloning and Other *In Vitro* Reproductive Techniques, and Organisms Resulting from Those Techniques

The procedure that produced Dolly, the first cloned sheep, involved transferring the nucleus containing the genome of a cell from an adult organism to an egg with its original nucleus removed. This patent actually covered all species, including human beings. It brought PPL, the company owning the original process patent, into dispute with a Japanese company that used a similar procedure later to produce clones of mice.

The same cloning procedure is involved in so-called 'therapeutic' human cloning, the creation of human embryos in order to provide spare cells and tissues for transplant.

The cloning process is hardly a technology, as it also generates large numbers of failures and abnormalities even among the 'successes'[15]. There are high proportions of fetal and neonatal deaths, abnormalities in the placenta, the umbilical cord and severe immunological deficiencies in cloned monkeys. In sheep and cows, clones develop serious abnormalities in heart, lungs and other organs. Many die before birth, others succumb suddenly weeks or months after birth. In some cases, the surrogate mothers carrying the cloned fetuses are also affected. Three cows died while pregnant with clones, and autopsy revealed livers that were filled with fat, suggesting metabolic abnormalities induced by the clones. How can this be regarded as a patentable technology? It is both scientifically flawed and ethically unacceptable to create so much suffering.

Patents on Stem Cell Isolation and Culture Techniques and the Stem Cells and Cell Lines

These patents are the most recent to come on the scene. Stem cells can be isolated from embryos, fetuses, newborn and adults. Thus, the opportunity arises for patenting isolation procedures, culture techniques and the cells and cell lines established[16]. Biotech companies already own dozens of patents on these technologies and cells lines.

One of the most controversial aspects of stem cell research is 'therapeutic' human cloning. This involves using the nuclear transplant cloning to create a human embryo in order to provide embryonic stem cells for cell and tissue transplant, the embryo being 'sacrificed' in the process. In January 2001, the UK became the only country in Europe to approve of such procedure, which has been overwhelmingly rejected by all the other EU countries. In so doing, the UK has committed a grave moral and scientific error, as the scientific findings tumbling out of laboratories are

indicating that there is absolutely no need for such human cloning. The Institute of Science in Society is calling on the UK to reject therapeutic human cloning and to support research and development of adult stem cells, especially those that minimize intervention and costs.

'Human' clones have already been created by transferring the genetic material of a human cell into the empty eggs of cow and pig. An application for such human-pig hybrid patent has been rejected in Europe on grounds of being contrary to public order and morality[17].This entire class of patents should be vigorously rejected, as they will seriously distort healthcare as well as social ethics.

Patents on GM Constructs and Vectors

In addition to separate stretches of genes and control sequences such as promoters being patented, particular combinations have also been patented. These include GM constructs and artificial vectors of all kinds.A case could be made to support the patenting of these constructs, as indeed, many of them have never existed in billions of years of evolution. However, these could hardly qualify as inventions, as they all imitate naturally existing combinations. The methods for producing them and their functions are entirely dependent on the cells and organisms themselves. Furthermore, they are structurally unstable, and are inherently hazardous.

Many GM constructs are made from genetic material of bacteria, viruses and other genetic parasites that cause diseases and spread drug and antibiotic resistance genes. They are designed to cross species barriers and to invade genomes. Therefore they have increased potential for horizontal gene transfer and recombination, the processes responsible for generating new bacteria and viruses that cause diseases and to spread antibiotic resistance genes.

Analysis of Articles Related to Patents in TRIPS and EU Directives

Article 27.3(b) of TRIPS

Members may also exclude from patentability, (b) plants and animals other than microorganisms, and essentially biological processes for the production of plants and animals other than non-biological and microbiological processes. However, members shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof.The non-exclusion of "non-biological and microbiological processes" needs to be challenged as all biotech processes are biological and there is no sound reason to regard microbiological as anything but biological.

Articles 4 and 5 of the EU Directive

Article 4

1 Plant and animal varieties, and essentially biological processes for the production of plants or animals are not patentable.
2 Inventions, which concern plants or animals, shall be patentable if the technical feasibility of the invention is not confined to a particular plant or animal variety.

3 Paragraph 1(b) shall be without prejudice to the patentability of inventions which concern a microbiological or other technical process or a product obtained by means of such a process.

Article 5

1 The human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene, cannot constitute patentable inventions.

2 An element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element.

3 The industrial application of a sequenced or a partial sequence of a gene must be disclosed in the patent application.

"Essentially biological processes" could include transformation and transfusion, processes used in creating transgenic organisms.

The "technical feasibility of the invention is not confined to a particular plant or animal" could be challenged, as without performing the actual experiment, it cannot be assumed that what works for one species works for another. In fact, this is very often not the case. Besides, as argued in Chapters 6 and 7, neither transgenesis nor cloning qualifies as an invention, as each fails to work less than 99 times out of 100.

The description, "a microbiological or other technical process" needs to be challenged, as a microbiological process is not a technical process, and should not be pantentable.

Analysis

Both the TRIPS and EU Directive articles are designed to allow all categories of patents listed in Section 3. One positive aspect of the EU Directive is Article 6, which excludes from patenting, commercial exploitation contrary to ‘ordre public or morality’, such as human cloning, use of human embryos for industrial or commercial purposes, cloning human beings, and modifications of animals causing substantial suffering without substantial medical benefit. This has led to the pig-human hybrid patent being rejected for example, though many transgenic animal patents are still being approved.

The EU Directive article 4.1b appears to strongly exclude plant and animal varieties, but article 4.3 makes clear that transgenic plants and animals are patentable, as they are produced by "microbiological or other technical process". But this point should be challenged, as transformation and transfusion used in making transgenic plants and animals, are biological processes. It is important to recognize that the patentability refers, not to the process, but to the product of the process. That is because in many cases, the process is standard, such as base

sequencing, or is covered by another patent, such as cloning.

Similarly, the EU Directive Article 5.1 appears to exclude the human body, cells and genes from patents. But this is nullified by 5.2, where the copying process or the amplification process that enables the copy of the gene, or the partial sequence of the gene, or the cell of the organism to be patented. This should be strongly challenged as the distinction between the putative original gene and cell in the body and the copy is a legal fiction. The very identification of the gene or cell involves processes of copying or amplification, so that it is actually the copies that are identified.

The EU Directive also explicitly extends the patentability of a process, say cloning, or technology such as the transgenic technology to all plant or animal varieties. So, in the case of nuclear transplant, the patent is protected for all other animals (though EU Directive Article 6 excludes human beings). In the case of the technology of using bt-toxin to protect plants, that is also extended to all plant varieties. This point should be strongly challenged for reasons given above, what works in one species may not work in another.

The EU Directive is being challenged as illegal by a number of European countries, the latest being Germany[18].

General Critique on the Patentability of Genes or Nucleic Acid (DNA or RNA) Sequence

The patentability of genes and other nucleic acid sequences is justified on the ground that they have been subject to a microbiological or nonbiological process, i.e., gene sequencing, which is itself a standard process patentable and patented under existing patent laws for invention. So, the actual patented entity is the nucleic acid sequence itself and its putative function.

However, the DNA or RNA sequence is subject to change by mutation, deletion, insertion and rearrangement. Does it mean that, for example, if the sequence patented is, ATCCAGGAACCTA, then variously mutated sequences such as AACCAGGAACCTA (single base substitution), ATAGGAACCTA (deletion of two bases), ATCCATCGGAACCTA (insertion of two bases), AGACCTGAACCTA (inversion of 5 bases) are no longer covered? The confusion is multiplied when single nucleotide polymorphisms (SNPs) are ruled to be independently patentable by the US Patent Office. Thus, the patent for the gene and the patent for the gene variant will legally clash.

The same arguments of mutability of entire genomes raise the question as to which genome is being patented. If the patent is on one DNA base sequence, does it cover genomes differing in DNA base sequence? For a DNA sequence of 1000 bases, the possible number of variants is 4^{1000}.

The "industrial application" stated in the EU Directive Article 5.1 involves the functional side of the gene sequence, and presumably qualifies it as an invention. It is important to realize, however, that the nucleic acid molecule by itself can do

nothing. It can only have a function in a living cell or an organism. However, its function depends on which kind of cell it is in, where in the genome it is inserted (not under the control of the human genetic engineer), in what kind of genome and in which environment. In other words, its function is uncertain and unpredictable. For example, the acetyl-CoA carboxylase gene, which confers herbicide resistance in monocots, is claimed primarily for regulating oil content in a patent. Under some circumstances, again beyond the control of the genetic engineer, the gene is silenced, so it has no function whatsoever. Thus, the patentability based on function is equally unscientific.

The patenting of genomes raises the question of the function of the genomes. Again, the isolated genome can do nothing by itself, while its "function" in the organism cannot be considered separately from the totality of the organism.

Conclusion

All biotech patents should be rejected on the following grounds:

— All those, which involve biological processes not under the direct control of the scientist cannot be regarded as inventions, but expropriations from life.

— The hit or miss technologies associated with many of the ‘inventions’ are inherently hazardous to health and biodiversity.

— There is no scientific basis to support the patenting of genes, genomes, cells and microorganisms, which are discoveries at best.

— Many patents are unethical; they destroy livelihoods, contravene basic human rights, create unnecessary suffering in animals or are otherwise contrary to public order and morality.

— Many patents involve acts of plagiarism of indigenous knowledge and biopiracy of plants (and animals) bred and used by local communities for millenia.

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