Of Patents & Pirates
Patents on life: the final assault on the commons
July 2000
http://www.grain.org/publications/reports/pirates.htm

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"I never imagined people would patent plants and animals. It's fundamentally immoral, contrary to the Guaymi view of nature and our place in it. To patent human material to take human DNA and patent its products That violates the integrity of life itself, and our deepest sense of morality."
President of the Guaymi General Congress, on learning of the patenting of a Guaymi woman's genes

r Imagine that a medicinal plant your family and community have cultivated and used for as long as anyone can remember has been taken and patented by a multinational corporation.
r Imagine you are a medical researcher trying to find a cure for breast cancer, but you are blocked from using the genetic materials you need for your research because they have been patented.
r Imagine during a medical procedure that blood samples and scrapings are taken from your cheek without your consent, and from these, a research institute patents your cell lines.
r Imagine that you are a farmer who can no longer save your seed to re-sow next harvest, but must purchase it anew from the company each year because they have

patented it.

PATENTING LIFE EXPLAINED

A patent is a legal claim over an idea for an invention that gives the holder exclusive rights to profit from it for a set number of years. Permission for public use of the invention is granted by paying the patent holder licence or royalty fees. To be granted a patent, an applicant must be able to prove:

r Novelty: it must be a new idea, not known or used by anyone before.
r Use: the patent application must explain what the invention is to be used for and why.
r Inventiveness: it must involve an inventive step that is 'non-obvious'.

The patent system was originally designed over 500 years ago to reward industrial inventors, protect their inventions from theft, and stimulate innovation. Perhaps a fair idea, but not abuse-proof. Patent laws have frequently been manipulated to become instruments of monopolists and their investors rather than as incentives to creativity. This has been particularly apparent over recent decades.

Since 1980 the system has been gradually extended to patenting existing or genetically 'improved' life forms. This has largely been due to a) the rapid development of genetic engineering, and b) the surge of interest in the commercial use of genetic resources and wild species. As the patent laws require a product to be a new discovery and involve a degree of inventiveness, companies or individuals get round this by extracting and/or manipulating the chemical or genetic material of interest. This makes the organism different from its original form, allowing companies to claim ownership and intellectual property rights (IPRs). 'Products' that have been patented include micro-organisms, staple crop species, genetically modified organisms, cloned animals and human genes. This has raised serious concerns over the ethical, economic and political consequences surrounding a key question: should private individuals and multinational corporations own the fundamental biological components of life?

Power Games

The business of IPRs has led to a huge increase in the exploration of biodiversity for commercially valuable genetic and biochemical resources, known as 'bioprospecting'. In the highly competitive life science industry, collecting patents has become a valuable defensive tool, sometimes resulting in a company's investment value being determined solely by its intellectual property. Using patents on life forms as defence methods to fend off competitive threats to investors is doing more harm than good. Pharmaceutical companies are playing a controversial game of double standards. On the grounds of patent infringement, they are preventing countries of the South from producing or acquiring cheaper generic drugs to combat public healthcare crises such as AIDS, while stealing medicinal plants and the associated knowledge on them from indigenous people and profiting from the royalties received though their patents. Moreover, prolonged protection of IPRs is stifling and impeding innovation as shown in the case where the company that has patented breast cancer genes is making researchers pay royalties for using those genes in investigative studies. By ensuring market control, and thus helping to guarantee fast profits for investors, patents fund

technology developments that purchasers have no say in. In some cases, this technology destroys the original effectiveness of life forms rather than improving them. For the first time in history, farmers can legally be prevented not only from saving and regrowing patented seed but also from 'owning' the offspring of patented farm animals, leased by the patent owner much like computer software. Obviously, patents are giving private companies unprecedented control of the world's germplasm, human genetic profiles, and more.

The political and economical power wielded by patents on life forms means that countries all over the world, and particularly the biodiversity rich countries of the South, are coming under intense pressure to adopt US-style intellectual property rights laws through the 'harmonization' of world trade rules. This comes under the Trade Related Intellectual Property Rights (TRIPS) agreement of the World Trade Organisation, and would force all 135 member countries to acknowledge patents on life forms. In the middle of these power struggles and patent wars, the rights to benefits for the primary custodians of biodiversity and its knowledge, that is, indigenous peoples, get sidelined. Compensation is little if non-existent and their access to their collective heritage becomes limited or in some cases illegal. Ultimately, what these patents ensure are market monopolies and guaranteed profits from food, drugs, and technology sales for a handful of individuals and not the source communities.

## The Consequences of Biopiracy

The consequences, especially for developing countries, are immense. Farmers face having to buy new seed and pay royalties each harvest. Technologies such as the 'terminator' and 'traitor' seeds, genetically engineered to prevent the seed from reproducing itself naturally, carry enormous risks not only for communities but biodiversity itself. As patented seed is usually 10 to 30% more expensive than non-patented seed, this will cripple the food industry and governments. Furthermore, other less lucrative but important agricultural research gets marginalized. Commercialisation of biodiversity can also cause prices of the material to escalate, and exacerbate the scarcity of wild resources. Overall, a dangerous dependency is evolving that is open to exploitation, food insecurity, genetic erosion and an undermining of sustainable livelihood systems.

## De-arming the pirates

Some have suggested that patents should be taken out by the affected communities themselves in order to benefit from commercialisation. However, their knowledge is often collective, based on and dependent upon experiences and the free exchange of knowledge of biodiversity over generations. In contrast, intellectual property rights of any kind are, by definition, a limitation of this knowledge flow, a denial of its collective nature, and thus threaten the evolution of this kind of knowledge, its development, and its continued survival. Private ownership of that knowledge and its use as a traded commodity is an alien concept to the value systems of many.

Many people worldwide have joined a growing movement against patents on life. Citizen action in many countries has challenged, and sometimes successfully overturned unjust patents. In May 2000 a coalition of groups successfully overturned the patent held by US company WR Grace and the US Department on

Agriculture over the Indian neem tree, used by Indians down the centuries for its pesticidal, medicinal, and other properties. While over 80 patents on neem remain to be challenged, this case has set an important precedent. Rights to the cell lines of the Hagahai people, also held by the USDA have also been overturned, as was a patent taken out on any medical research undertaken using the human umbilical cord. Many countries in the South - trail-blazed by Africa - have resisted pressure from the World Trade Organisation to change their national laws to allow patents on life. The power of public pressure caused British Prime Minister Tony Blair and US President Bill Clinton to speak out against patents on human beings. Although their response was little more than a public relations exercise, it reflects how this pressure is building. People everywhere are articulating their collective rights to knowledge, and refusing to accept patents on life.

Intellectual property rights are not only transforming the global economy, they are fundamentally transforming the current basis for food security, healthcare provision, democratic rights, and perhaps human evolution itself. Some fundamental questions need to be asked about patenting. Can we abide by a patent system that is being grossly distorted to allow a few giant companies monopoly control over the world's genetic resources? Should farmers need a license to grow crops? Should body parts be patented? Should Western scientists get ownership rights over indigenous peoples' and rural communities' traditional knowledge, crops and medicines? Should these peoples' countries be forced to acknowledge such ownership? Are living beings no more than strings of DNA with potential industrial applications? We should also be questioning the promotion of genetics as an explanation for almost every aspect of human behaviour and health. This disregards and distracts attention from a whole range of social and environmental causes of disease which urgently need to be addressed.

The following seventeen case studies have been compiled to show the key landmark disputes and debates surrounding the business of the patenting of life forms and what their implications hold for future developments.

## PATENTS ON FOOD CROPS

Seventy percent of our food supply is based upon a vulnerably small number of staple crops <ETH> primarily wheat, maize, rice, and potato. Recognising that these are fundamental to food security, the European Patent Convention of 1975 ruled that no one could patent whole plant varieties, while US Congress implemented a Plant Patent System with similar rules. However, biotechnology corporations and researchers have been using a legal loophole to get around these measures by claiming ownership over "genes" and "plants" rather than whole varieties. In June 1999, the agricultural biotechnology lobby successfully persuaded the European Patent Office to unilaterally <ETH> and illegally <ETH> state that patents may be granted on transgenic plants. In January 2000 the US Court of Appeals decided that plant varieties were indeed patentable. But how can genes be new? How can an individual 'invent' a plant? What about the centuries of work of farmers and others who bred the desired traits in the first place? And most importantly: what does the granting of these patents mean for farmers and for local, national and global food security?

Bt gene

r Background: A naturally occurring soil bacterium, Bacillus thuringiensis (Bt), produces a protein fatal to many common insects that ingest it. Bt is an ecologically friendly biological pesticide that has been used by farmers since the 1940s. In the past decade several large agrochemical companies have invested in genetically engineering Bt into crops so that the plants produce their own insecticide. Bt crops include maize, soybean, cotton, rapeseed, potato, tobacco, rice, tomato, poplar, spruce, walnut and apple.

r Patents: Bt-maize, Bt-cotton and Bt-potato have all received commercial approval in the US. As of December 1999 there were at least 540 patents - and rising - granted or pending related to Bt worldwide. Continued mergers within the industry mean that today the technology is heavily concentrated in fewer and fewer hands, while companies are battling over who owns what. Belgium's Plant Genetic Systems (now owned by the corporate giant Aventis) has been granted a US patent for "all transgenic plants containing Bt". The US company Mycogen (now owned by Dow Agrosciences) was issued with a European patent that covers the insertion of "any insecticidal gene in any plant". Such broad patents confer huge market monopolies to the victor. In 1998, Monsanto won a patent case against Mycogen over the transplant of the gene from Bt into plants, while a jury invalidated a Novartis patent covering all Bt maize.

r Implications: Patents are a way to help recoup investments and ensure profits on GE technology. As a technology Bt crops carry many threats. Cornell University studies showed that pollen from Bt maize killed the monarch butterfly larvae that ingested it in the lab, whilst further up the food chain green lacewings that fed on European corn borers reared on Bt maize also died. Experiments at the University of Hawaii show that in one generation insects develop resistance to many forms of the toxin, rendering Bt useless as an implanted pest control strategy. This also renders the old Bt spray useless for organic farmers, since transgenic Bt crops will have destroyed its effectiveness. Despite this, patents on Bt genes and crops ensure that companies can make a quick profit from them, encouraging further development of this technology. The potential market is huge and dominated by a near monopoly of the life science giants. The legal wrangles over ownership of Bt technology in the US consume vast amounts of time and money amongst many of the leading agrochemical companies, who fight patent wars rather than developing more successful alternatives. Far from promoting innovation, patents on Bt create an artificial value for a technology likely to fail. In addition, patenting has not just pirated a known ecological insect control system, but looks set to render it ineffectual. The livelihoods of thousands of farmers and the consumer's right to choose are also at stake.

Soybean

r Background: First domesticated as a food crop in China, today soybean (Glycine max L.) is a multi-billion dollar commodity crop, particularly important for oil and animal feed. The USA has well over half of the global export market. Other top soybean producers are Brazil, China and Argentina. Whilst soya remains an important vegetable and protein crop for Asians, soybean is now used in a surprising range of industrial products - from the ink in daily newspapers to

the ketchup on fast-food outlet hamburgers. Patent rights over the world's soybean crop render to the holder enormous economic, social and political control over a basic item of the global economy.

r Patent: In 1994, biotechnology company Agracetus was awarded a patent, which effectively covered all transgenic soybeans. The biotechnology industry was stunned by the patent, which was challenged in the courts. The chemical giant Monsanto vehemently opposed the patent in November 1994 on the grounds that, "the alleged invention lacks an inventive step" and was "not ... novel". Later, Monsanto simply bought up the whole of Agracetus - including the patent - and quietly dropped its complaints.

r Implications: Species patents such as this one on soybean, and others on cotton and rice, show how broad speculative patents are being used to stake territorial claims with no relation to invention, as a means to block research and competition. These patents also affect the farmers, who must follow stringent rules when using transgenic soybeans in those countries where the patents are recognised. In purchasing Monsanto's patented "Roundup Ready Soybeans", US farmers may only use the company's own Roundup herbicide on the crop, may not save a single seed for the next season - as is traditionally done - and may not conduct any research using the soybean. By December 1999, Monsanto had cases against at least 475 farmers whom it suspected of saving and re-sowing its seeds.

Brazzein

r Background: Brazzein is a protein 500 times sweeter than sugar derived from a West African berry. Unlike other non-sugar sweeteners, brazzein is a natural substance and does not lose its sweet taste when heated, making it particularly valuable to the food industry. It came to the attention of industry after a US researcher observed people and animals eating the berries in West Africa.

r Patent: Researchers at the University of Wisconsin have been granted US patents 5,326,58, 5,346,998, 5,527,555, and 5,741,537, as well as European patent 684995 for a protein isolated from the berry of Pentadiplandra brazzeana, the genetic sequence coding for it and the transgenic organisms where it has been added. Subsequent work has focused on making transgenic organisms that produce brazzein in the laboratory, thereby eliminating the need for it to be collected or grown commercially in West Africa.

r Implications: The University of Wisconsin reports that corporate interest in brazzein is strong: the worldwide market for sweeteners is reported to be $100 billion a year. The university is quite clear that brazzein is "an invention of a UW-Madison researcher" and there are no plans for benefit-sharing with the West African people that actually discovered and nurtured the plant. Currently, Nektar Worldwide and ProdiGene, a spin-off of Pioneer Hi-Bred International, the world's largest seed company, have genetically engineered maize that produces large amounts of brazzein. They estimate that future demand will be met with one million tonnes of genetically engineered maize instead of any source from West Africa. This is a clear example of how the patent system completely disregards local knowledge and innovation of Southern peoples by permitting researchers to claim to have invented something they merely isolated and reproduced in a Northern laboratory. By allowing patents on these kinds of 'discoveries', the

patent system promotes what Third World countries rightly call biopiracy.

Quinoa

r Background: Quinoa (Chenopodium quinoa) is an important part of the diet of millions of people in the Andean countries of Latin America, especially for indigenous people. Since pre-Incan times, they have cultivated and developed varieties of quinoa suitable for the wide range of harsh conditions in the Andes. In recent years, quinoa has started to enter the US and European market for its high nutritional value - about twice the protein content of maize or rice. The value of Bolivia's export market is an estimated US$1 million per annum.

r Patent: In 1994, two researchers from the University of Colorado received US patent number 5,304,718, granting exclusive control of male sterile plants of the traditional Bolivian "Apelawa" quinoa variety and plants derived from its cytoplasm. This included some 36 traditional varieties cited in the patent application. The researchers admitted that they did nothing to create the male sterile variety, but that it was"just part of the native population of plants ... we just picked it up." They claimed they were the first to identify and use a reliable system of cytoplasmic male sterility in quinoa for the production of hybrids.

r Implications: The US patent had serious implications for Bolivian farmers. The logic of developing hybrid quinoa was to increase the crop's yield to make it suitable for commercial-scale cultivation in North America. Although the researchers promised to make the technology available to researchers in Chile and Bolivia, in corporate hands, the right for the patent owners to prevent Bolivian exports of quinoa to the US would almost certainly have been exercised. The displacement of Bolivia's export market would have undermined the livelihoods of the thousands of small farmers who grow quinoa. These concerns led the ANAPQUI, the Bolivian National Association of Quinoa Producers, together with a number of NGOs led by the Rural Advancement Foundation International, to fiercely oppose the patent. Due to the international pressure they generated, the University of Colorado had already abandoned the patent by May 1998.

PATENTS ON ANIMALS

Patent laws have traditionally prohibited the patenting of animal breeds/races and inventions "contrary to morality". Patents on animals are already so controversial they have been excluded from requirements of the international community to comply with the World Trade Organisation's Trade Related Intellectual Property Rights rules. However, as with the prohibition against patenting plant varieties, scientists and companies have been finding legal loopholes to change the spirit and the letter of the law to obtain patents on animals. These moves have aroused moral outcries and strong objections to the way they reduce animals to the sum of their products or to industrial machines. Technological applications on animals are seen as moving us one step closer to those on humans. Others are concerned that patents will make it impossible for small and family farms to afford livestock raising, further consolidating corporate control. Many are also simply disturbed by the way that patents on animals mark the final stage in the total industrialisation of livestock

farming.

Oncomouse

r Background: The oncomouse or Harvard mouse was genetically transformed to be susceptible to cancer. Medical research facilities now have a ready-made test patient for experiments in cancer therapy, since all offspring of the oncomouse are predisposed to contract the disease.

r Patent: In 1987, the oncomouse became the first animal ever to be patented in the United States. The research had been done at Harvard University but it was a multinational corporation, DuPont, that was awarded European Patent 169672 on the mouse in 1992. Du Pont's European patent application attempted to gain control over all modified animals using the oncomouse technique, including their descendants. Significantly, the company also claimed patent protection on any anticancer product ever derived from the mice.

r Implications: The European patent on the oncomouse has been heavily challenged by public interest groups on the grounds that this patent was contrary to morality. The EPO authorities' initial reply was that they had no competence to interpret what is morally acceptable and what is not. They later accepted the challenge and ruled that any invention whose benefit to mankind outweighs the suffering of an animal is morally acceptable. Opponents to the patent found this unsatisfactory and the patent is still in limbo in Europe. However, this case opened the door to patents on animals.

Meat and Eggs

r Background: With their high saturated fat and cholesterol content, meat and animal products are identified with diet-linked health damage, and developed countries face a dramatic increase of obesity, cardio-vascular ailments and diet-related cancer. Unprocessed, low-cholesterol animal products hold promise for large markets.

r Patent: The Johns Hopkins Medicine University holds a patent (WO9833887) that covers animals (including avian, bovine, ovine, piscine, murine, and porcine species) genetically engineered to have increased muscle mass without related increase in fat content, and decreased cholesterol levels. Through its patent, the University not only claims ownership on the transgenic animals and the methods to obtain them, but also on their by-products, such as eggs, beef, milk, pork, lamb, chicken, and turkey meat.

r Implications: Patents on animals for animal husbandry could restrict farmers who wish to increase their herds or even replace numbers after livestock death or sales. Some biotechnology companies specialising in livestock have already claimed they expect to be able to forbid on-farm reproduction or to charge royalties on any baby from a transgenic, patented cow or sheep, which they consider farmers will be "leasing" rather than owning. However, it was farmers - and, later on, breeders - who developed livestock races and breeds in the first place. The concerns raised by patent WO9833887 go far beyond the farm gate, since ownership has been granted on the final products - eggs, milk and meat - of the transgenic animals. This turns farmers into 'renters' of livestock, and gives the patent holder unprecedented control over the end product food items.

Tracey

r Background: Tracey is a sheep which had human genes introduced into her mammary glands to produce the protein alpha-1-antitrypsin, a human blood-clotting agent. A company spokesperson described Tracey as one of Pharmaceutical Proteins Ltd's (PPL) "furry little factories walking around in fields". Tracey's transformation was considered successful enough by PPL to provide "a strong impetus to the further exploitation of transgenic sheep as bioreactors for the production of large amounts of pharmacologically active proteins". Some people call this "factory pharming".

r Patent: Tracey and her relatives are now the subject of US patent 5,476,995 and a multi-million pound contract between PPL and the German chemical giant Bayer. There are at least another 50 patents covering transgenic animals that produce human proteins.

r Implications: Tracey raises important questions on the radical alteration of the genetic makeup of animals to suit industrial-scale processes. Sheep naturally produce meat, milk and wool. They do not naturally produce human proteins. Turned into a four-legged pharmaceutical factory, Tracey is viewed no longer as an animal, but as a machine that is described as a human invention and patented, much like a typewriter or refrigerator.

Dolly

r Background: Dolly is the world's first cloned mammal, living proof that viable offspring can be developed from a single adult animal cell. News of this cloned sheep took the world by storm in February 1997. What shocked people were how Dolly brought the prospect of human cloning out of the realms of science fiction and into the realms of possibility. Since then, the public in developed countries has been reassured that human reproductive cloning will not be allowed, but has been encouraged to support cloning-based technologies to commercially develop human spare cells, tissues and organs.

r Patent: The Roslin Institute, responsible for the Dolly experiment, has applied for two world patents (WO 9707668 and WO 9707669) for the cloning technology used. The patents cover the use of the technology in all animals, which does not exclude human beings. At the time the Roslin Institute argued that it had no commercial interest in, nor moral tolerance of, human cloning. The Institute calimed that it specifically included humans so as to ensure that nobody else could lay claim to human cloning. But patents, once taken out, can always be bought. In January 2000 Roslin granted licensing rights to Geron, a US company that later bought the institute. Geron's business is about developing human clone cell implants to reverse degenerative diseases. Roslin's patent-protected technology will allow Geron to own the cloned human embryos that are to be the source of the cells for the implants, and nothing legally prevents Geron from claiming ownership on any foetus that might be developed from such embryos, up until birth.

Implications: As techniques are the same for human and animals, and some of them even merge human and other mammals' cells, the line between what is legal for humans and for animals is blurred. The rush to control such a lucrative market has lead to at least 20 patents on processes related to animal and human cloning. The ethical and moral debates surrounding life patenting have come

alive for millions of people. In addition to the well-publicised moral dilemmas about human and animal cloning, Dolly raises further questions. Widespread cloning of livestock will further exacerbate the serious problem of genetic erosion among domestic animals. Livestock breeds are already being lost at the rate of 5% each year thanks to selective breeding and artificial insemination, and cloning could make the situation much worse. This furthering of genetic erosion in the European livestock sector as promoted by the patent system and cloning will have a dramatic impact on the vulnerability to pests and diseases of the animals involved.

PATENTS ON MEDICINE

Medicines are often derived from or based on biochemical compounds found in nature, many of which originate from the biodiversity of the tropics and subtropics. This is as true for synthesised drugs as it is for natural medicine. Many indications of their application and effectiveness come from indigenous and local communities' rich medicinal knowledge of their environments. Western scientists are often accused of biopiracy when they appropriate not only the chemical cures derived from the rainforests but also the traditional knowledge of shamans and healers who have mastered the use of local materials for health problems. This is both physical and intellectual theft, since researchers then patent indigenous knowledge. Fundamentally, this goes against most indigenous value systems, which tend to harbour systems of collective management of biodiversity and the knowledge of that biodiversity.

Tepezcohuite

r Background: The 'skin tree', tepezcohuite (Mimosa tenuiflora) is a thorny tree with a wide distribution, but it is only in very localised areas of Chiapas, Mexico, that the species has healing properties. Toasted tepezcohuite bark has been used by the Maya since the 10th century to treat skin lesions. Still used in the region today, it is particularly effective at healing burns. In 1984, a terrible explosion of a gas factory in Mexico City left 500 people dead and 5 000 suffering from severe burns. This overstretched the medical capabilities of the city. They turned to tepezcohuite to treat the burns on the advice of Dr Leon Roque, who was raised in Chiapas and was familiar with its traditional use. Later, Roque brought tepezcohuite out of Chiapas to market it globally. Its anti-inflammatory, anti-bacterial, anaesthesic and epidermal regeneration properties earned it the nickname of "miracle plant", and it was classified as part of Mexico's national heritage.

r Patent: In 1986, Dr. Leon Roque posted a patent application in Mexico covering the powder obtained from the roasted bark of the tepezcohuite tree. In 1989 he was granted a US patent on the powder (US 4,883,663). In 1992, Jacques DuPoy de Guitaard and Julio Tellez Perez received a US patent (US 5,122,374) covering the active ingredient of the tepezcohuite bark and also a method of extracting and isolating it through solvents plus the use of these extracts in pharmaceutical compositions. Both patents have also been applied for in Europe.

r Implications: Dr. Leon Roque's patent on the powder from tepezcohuite describes the traditional usage, the only addition being that of a sterilising step. This effectively means that all the powder produced under traditional

methods is an infringement of his patent. Roque approached an industrialist, Jorge Santillan, who now claims to have been granted a monopoly on the production of tepezcohuite by the Mexican government. His company grows the tree in two states, and is seeking foreign cosmetic markets. Meanwhile, for the locals of Chiapas, prices have soared and wild resources have been depleted. The communities have not only suffered appropriation of their knowledge, but also appropriation of a part of the scarce territory where Mimosa tenuiflora is grown. Locals will have to compete for access to the tree with those commercialising it for the Mexican tepezcohuite market.

Hoodia

r Background: Hoodia and Tricocaulon are two very similar succulent plants indigenous to southern Africa. Known traditionally as Ghaap they have long been used by San and Khoi shepherds of the harsh arid environments of southern Africa to reduce hunger and thirst. The South African Army has also used the plant as an appetite-suppressant. CSIR, one of Africa's largest scientific and technological research institutions, and the UK Company Phytopharm have entered in an agreement to develop an appetite suppressant (dubbed "P57") derived from Hoodia. Obesity is one of the main public health problems in developed countries. With 35 to 65 million obese people in the US alone, the market potential for appetite suppressants is vast.

r Patent: The international patent application WO 9846243 claims monopoly use of the appetite suppressant agent of the extracts of Hoodia or Trichocaulon and its use in pharmaceutical appetite suppressants.

r Implications: The Hoodia-derived appetite suppressant promises large profits for all research institutions involved. The CSIR projects earn royalties of what they describe as "hundreds of millions of Rand per annum for the lifetime of the patent". Phytopharm has received US$35 million from Pfizer, which in turn expects to make US$ 3000 million annually out of the drug. While CSIR says it will invest the money it receives back into the organisation, no proportion of projected royalties has been earmarked for conservation, or for benefit sharing with holders of traditional knowledge about the plant. Cultivation is undertaken by commercial farmers, not by those who have traditionally nurtured the resource, or even by resource-poor farmers. This is in conflict with South African policy that requires bioprospecting to stimulate economic development among the most disadvantaged sections of the population. Questions about the actual mechanisms through which the commercialisation of the extracts of Hoodia will contribute to biodiversity conservation remain.

Turmeric

r Background: To many people from India turmeric, Curcuma longa, is a magic cure-all. The orange root is native to the subcontinent and for thousands of years has been used to treat sprains, inflammatory conditions and wound healing. Turmeric is a key component of ayurdevic medicine.

r Patent: In 1995, two US scientists from the University of Mississippi were granted US patent 5,401,504 on the use of turmeric for healing wounds, claiming this to be novel. In their application, they acknowledged that "turmeric has long been used in India as a traditional medicine for treatment of various

sprains and inflammatory conditions". However, they claimed that there was no research on the use of turmeric as a healing agent for external wounds. The Indian government challenged the patent as blatant theft, and provided endless research papers predating the patent proving that turmeric has long been used in India to heal wounds. In the face of this overwhelming evidence, the US Patent and Trademark office rejected all 6 patent claims.
r Implications: The US patent would have prevented Indian companies from marketing turmeric for wound healing in the US. If the US government is successful in pushing stronger patent regimes in other countries including India, this patent would have actually made the commercialisation of turmeric in India illegal. India has been vocal on these issues in international fora, such as the World Trade Organisation. The Indian government opposed the patent on principle, and is increasingly concerned about biopiracy of other natural resources by foreign companies. Local communities are already victims of reduced access to this traditional resource due to greatly increased market prices. The patent claims remain rejected.

Ayahuasca
Background: The indigenous peoples of the Amazon basin grow ayahuasca (Banisteriopsis cappil) for medicinal use and religious ceremonies. It is central to the culture of many groups in the region. According to their cosmology, this is a sacred plant that has bestowed upon them their knowledge about nature, cures for many illnesses, and hallucinations that "show past and future".
Patent: US citizen Loren Miller claimed to have 'discovered' a new Banisteropsis variety in a home garden in Ecuador, and in 1986 the Plant Medicine Corporation was granted US patent PP 05751 on it. The patent granted exclusive rights to sell and develop new varieties of the plant. The company undertook the development of psychiatric and cardio-vascular medicines derived from Ayahuasca. Miller's intention was to set up a laboratory in the Equatorial Amazon. The Co-ordinating Body of Indigenous Organisations of the Amazon Basin (COICA) challenged the patent on the grounds of lack of novelty, since the variety Miller patented had been domesticated by their people for hundreds of years. In May 1997, the COICA's fifth congress agreed to launch a public awareness campaign. They declared Miller an enemy of Amazonian indigenous peoples, prohibiting him from entering their territories and warning Miller that they could not guarantee his physical safety in the event of entering those territories. In November 1999, COICA's legal challenge resulted in the cancellation of the patent.
Implications: Under the rules of the Convention on Biological Diversity, to which Ecuador is a party, every nation has sovereignty over its own biological resources and the right to legislate access to them. Therefore, unless Miller can prove he obtained the plants with official authorisation, his patent contravenes Ecuadorian law. It would also contravene the right of communities to exercise control over their own resources, to be previously informed of the goals and extent of the extractions, and to grant their previous informed consent. The fact that Ayahuasca is sacred means that the attempt to patent it was particularly offensive to the indigenous peoples affected, who viewed it as

a profound cultural attack.

PATENTS ON PEOPLE

Once you accept the patenting of life - micro-organisms, plants, animals - there is no way of keeping the door closed to the patenting of human genes, cells, organs and indeed other parts of the human body. Some recent patent claims have attempted to stake ownership over human cells, of one man's spleen in one case, and of the cells of all babies' umbilical cords in another. The idea of human genes being classed in law as 'invention' has triggered a huge ethical debate. Our patent laws are powerful tools to regulate control over technology and markets. Should they be used, unchallenged, to direct the future course of humanity? Can scientists and the companies hiring them have intellectual property rights over people, or over 'inventions' they cannot even describe? Are people just strings of DNA which have an industrial application? The patenting of human life - genes, sequences, constructs, cell lines, even body parts and ways of programming our children's traits - is the most controversial aspect of life patenting, and one of the most important debates of our time.

John Moore's Spleen

r Background: In 1976, a US citizen by the name of John Moore underwent surgery at the University of California. He was suffering from a rare form of leukaemia and the doctors had to remove his cancerous spleen. Despite the fact that he signed a pre-operative consent form which stated that his spleen would be destroyed after removal, his doctor cultured some tissues and cells from it which produced a special protein. Moore knew nothing about this until his attorney informed him that his doctor had received a patent on a cell line taken from his body. Later, Moore heard that the doctor concerned had referred to him as his "gold mine".

r Patent: Moore's doctor obtained US patent 4,438,032 for the cell line - dubbed "Mo" - removed from Moore's spleen, claiming it produced valuable pharmaceutical compounds for use in cancer therapy. The long-term commercial value of the cell line was estimated at more than US$ 3 billion. The Swiss pharmaceutical company Sandoz bought up exclusive rights for the commercial exploitation of the patent for an alleged US$15 million. Moore felt violated, and demanded the return of the cells and control over his body parts. However, the California Supreme Court decided that he was not entitled to any rights to his own cells after they had been removed from his body.

r Implications: This patent is unique since it is the first taken out on human genes where the unknowing 'donor' of the 'invention' was not only alive but able to discuss how it felt to be patented. In Moore's words, "Ultimately, everyone was protected and rewarded: the researcher, the physician, the entrepreneur, even Science. But I knew nothing. What was I? The dehumanisation of having one's cells conveyed to places and for purposes that one does not know of can be very, very painfull".Some accuse Moore of hindering useful research on cancer by claiming rights over his own cells, but forget that he might very well have wished to donate his cells to medicine if anyone had bothered to ask. Current trends in patent system development are unacceptable once they validate, encourage and legalise the speculative greed, immorality, and injustice of

corporate appropriation of human parts, as John Moore's case proves. The patent has expired.

African HIV carriers
r Background: The HIV virus, which causes AIDS, is thought to have originated in Africa. Blood, saliva and other cells taken from prostitutes in Kenya, villagers in the West African Savannah, and other HIV carriers are being 'harvested' for DNA samples by Western researchers trying to find a source of immunity which could lead to a vaccine or some other means to stop the epidemic.
r Patents: In 1991, the Paris-based Institut Pasteur, which claims it first discovered the HIV virus, was granted US patent number 5,019,510 covering a mutant of HIV virus-1. This is alleged to be a useful source of antigens for vaccines and for detecting antibodies to the retrovirus. This strain of HIV-1 was isolated from a Gabonese "donor" in 1986.
r Implications: This case is just one of several HIV-related patents on human cell lines taken from African carriers. It is not clear whether they granted consent before becoming donors, much less whether they agreed to become the subject of patents once their cells were cultured by research institutes in the US and Europe. However, the greatest injustice arising from these patents is that Africans are very unlikely to benefit from the research. AIDS research is the most lucrative sector of the pharmaceutical industry. Profit margins on current therapies tip the 70% mark, before distribution. While over half of the 22 million HIV carriers today live in Africa, the current cost of triple-drug therapy is 30 times the average annual income on the continent. Patents are increasing the prices on drugs, which already form a US$ 2.3 billion market in the industrialised countries. The pharmaceutical industry has actively lobbied to keep AIDS therapies beyond the reach of most Africans. The South African government, in an attempt to be able to afford to alleviate the suffering caused by the AIDS epidemic in that country, encouraged local companies to produce and distribute cheap generic AIDS drugs. Between 1997 and 1999, major pharmaceutical companies persuaded the US government to threaten South Africa with commercial sanctions because their patents were being broken. It was only the stand taken by the South African government, backed by the strong US AIDS activist lobby, that managed to embarrass the US government into backing down, though companies are still defending their patents. The USA continues to block the World Health Organization from developing medicines based on healthcare patents the US government owns, even for those drugs identified by the WHO essential list as crucial for solving global healthcare crises. This is one of the clearest cases that demonstrate how patents on major medical research exclude the majority of the world's population from access to progress made in healthcare.

Human Genome
r Background: 1990 saw the launch of the Human Genome Project, a public initiative to map and sequence all the genes in an 'average' human body. This attempt to obtain the complete "human blueprint" will give unprecedented insights into the genetic mechanisms of disease. The potentially huge markets for diagnostic kits and pharmaceuticals meant the private sector were not far behind. In 1992, the company Human Genome Sciences was set up, in the hope of

cashing in on human gene sequences. Thus began an accelerating race to map the human genome. On the one hand are public research institutions from 18 countries, which are committed to publishing gene sequences in internet-accessible databases as soon as they decipher them. Racing against them are over a dozen genomic start-ups and their corporate clients, the giants of the pharmaceutical sector. The latter capitalise on the information published by the public sector and the sequences they decipher themselves, through patent applications and sophisticated, exorbitantly priced genomic databases. One of those companies, Celera Genomics, has leapt to the front of the race. Its claim that it could sequence the whole genome in less time than the public sector and at a fraction of the cost has led to soaring stock prices.

r Patent: The human genome is made of perhaps more than 140 000 genes. Some of these can be traced to a number of diseases, and some of those diseases make up for considerable markets - be it for diagnostic kits or for therapies. The US has allowed patents on gene sequences since the 1980s. As far as patent offices are concerned, the patenting of parts of genes - the most immediate result of sequencing efforts - has not been allowed. Companies have not been deterred by these limitations. By the end of 1999, Human Genome Sciences had filed patents for over 6 450 full-length human gene sequences, Incyte had filed patents covering an estimated 50 000 individual human genes, and Celera had filed for "preliminary patents" on over 6 500 partial human gene sequences.

r Implications: A large and growing section of the scientific community is seriously alarmed by the constraints that patents on genes are already putting on their research. In 1998, the president of the US National Academy of Sciences, expressed concern that patents were being used in ways that "create obstacles to conquering human diseases". Patents on genes are being used to carve out huge market monopolies. For example, in early 2000, US company Myriad Genetics, based on two patents covering a breast cancer gene each, tried to stop 15 publicly funded British laboratories performing genetic tests for breast cancer at half the price Myriad asked for. If the pending patents on human gene sequences are granted, and there is little indication currently to suggest that they will not, the implications for medical research and healthcare provision for ordinary people is tremendous. Negotiations between the Human Genome Project and Celera Genomics on possible future collaboration collapsed in February 2000, after Celera made clear its intention "to establish a complete monopoly position on the human genome for a period of at least five years". Dr John Sulston of the Human Genome Project drew attention to the danger of politicians being persuaded to reduce public funding for genome studies in the belief that it can be left to private companies. In March 2000, US President Bill Clinton and UK Prime Minister Tony Blair, responding to growing public concern, gave a call to maintain the human genome under the public domain. Biotech stock plummeted. Only weeks later Bill Clinton reassured industry and their investors, privately promising them that he had no intention of suggesting any change in U.S. policy on patents. In the light of this, it is difficult to believe that the participation of Celera's President, Craigh Venter, at the Clinton-Blair pompous announcement of the compilation of a "working draft" of the human genome, was little more than lip-service.

Human Genetic Diversity

r Background: After over a year of national controversy, the Icelandic government approved the Act on a Health Sector Database in January 2000. This granted DeCODE Genetics of Delaware, USA, founded by an Icelandic researcher, a 12-year monopoly on the commercial exploitation of a centralised database of non-personally-identifiable health data. The health sector database is unique in that it links genomic data to peoples' actual health records. Iceland is the perfect location for this project. Not only has the island remained relatively isolated for some centuries, but Icelanders have systematically collected their health records since 1915, and tracing back ancestors to the first settlers is a national past time. Long before it was sure of the license, DeCODE had already signed a US$200 million contract with Swiss pharmaceutical giant Hoffmann la Roche for gene identification work involving Icelandic populations. In exchange, DeCODE is to supply Icelanders with any drugs developed through the database for free.

r Patent: Genetic differences in susceptibility to disease and responses to medicines have been linked to small variations in genes, known as SNPs. Isolated populations such as the people from Tristan Da Cunha, the Guaymi, the Solomon islanders and Icelanders present higher frequencies of these variations. The Guaymi people of Panama and residents of the Solomon Islands have found their cell lines becoming the subject of patents owned by the US government. When people found out that agreeing to give blood samples meant becoming subject to a patent claim without their informed consent, they naturally protested. In some cases, local communities' objections, with the support of NGOs, have led to withdrawal of these patent applications. However, the practice of patenting particular cells of special human populations for the benefit of a particular researcher or company, continues as before and is increasing as the mining of the human genome proceeds.

In December 1999, the US Patent and Trademark Office ruled that when SNPs can be related to a genetic condition, they are patentable. The door to prospecting and commercialisation of human genetic diversity has been flung open.

r Implications: A very serious issue with the Iceland database is that personal health records are being used in a commercial venture without peoples' consent. Icelanders must actively opt out of the database, otherwise they are included by default. For Mannvernd, a coalition of Icelandic scientists, doctors and other concerned citizens, the Act clearly infringes on human rights, personal privacy, provides no ethical nor scientific controls over possible application for information, and also endangers freedom of scientific investigation. By mid March 2000, more than 17 000 Icelanders had opted out of the database. Unfortunately, profits are taking predominance over human rights. In spite of the furious debate in Iceland, the Health Sector Database is now a model for other countries. Gemini intends to establish a similar contract with Newfoundland and Labrador in Canada, and Britain's Medical Research Council has just outlined a similar database, starting with 500 000 volunteers. Genetically and culturally distinct groups in the South are extremely exposed to inclusion of their genomic and cultural information in databases in the US without their consent. This means that any pharmaceutical company that wants that database could buy up exclusive rights through sheer dollar power. Unless strong

political action is taken now, huge profit expectations coupled with new 'bioinformatics' technologies, will render the very concept of previous informed consent a relic of the past.

Human umbilical cords
r Background: The special properties of umbilical cord blood cells are widely known in medical circles. Blood cells from the umbilical cords of new-born babies are of interest in traditional transplant medicine and in gene-therapy. These cells are especially significant in blood and marrow transplantation research.
r Patent: US-based Biocyte Corporation, later bought by Avicord, was granted European patent EP 343 217 on the blood cells of the umbilical cord of foetuses and the newborn. The patent holder's novel 'invention' amounted to isolating and deep-freezing the cells. The patent gave Biocyte/Avicord monopoly control over the extraction and use of the cells and over any therapies developed in connection with them. This meant Biocyte could refuse access to and use of these blood cells and all therapeutic products derived from them to anyone unwilling or unable to pay their fees. Furthermore, receiving consent of the subjects from whom the cells are taken is obviously impossible.
Implications: The patent was challenged by European public interest groups on the grounds that the European Patent Convention prohibits the patents of therapeutic and diagnostic processes. Opponents also claimed that there was simply no inventive step involved, and besides, it was an offence against morality and public order. Eurocord, an alliance of transplant doctors, also challenged the patent. The International Society of Transplantation states that "no part of the human body can be commercialised and that organ or cell donations should be free and anonymous". Eurocord holds that "We deplore any attempt to patent a non-pharmacological method of treating patients with haematological diseases and recommend that clinicians and scientists disassociate themselves from patents of this type, be they already granted or only in application form". In June 1999, the European Patent Office reversed its decision, ruling that the "invention" was a statement of already existing practices and therefore did not represent anything new. Consequently, the patent was revoked. Biocyte is currently appealing the decision.

GRAIN (Genetic Resources Action International) is a small international NGO that promotes the sustainable management and use of agricultural biodiversity based on peoples' control over genetic resources and local knowledge, with a special emphasis on developing countries. Patents on life fundamentally undermine people's control over their resources and livelihoods, and pirate the collective knowledge systems of local communities in many parts of the world.

Sources include several RAFI CommuniquZˇs of the Rural Advancement Foundation International, the original patents, GRAIN's newsletter Seedling, and materials from "Global 2000" and the "No Patents on Life Coalition". GRAIN gratefully acknowledges the contribution of Janet Bell, Hope Shand of RAFI, Rachel Wynberg

of Biowatch, and Silvia Rodr'guez of CAMBIOS. We would appreciate feedback and comments. This is third revised edition, published August 2000, of the briefing originally entitled "Patents, Pirates, and Perverted promises". Spanish and French versions are available.

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