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NO MONOPOLY ON GENES

*Gene politics is high on the international agenda, with serious implications for health, trade, and the environment. Three Swedish Ministers - **Thomas Bodström**, Minister of Justice, **Kjell Larsson**, Minister for the Environment, and **Leif Pagrotsky**, Minister for Trade - jointly wrote the following article which was published by Dagens Nyheter, Sweden's national newspaper on 10 December, 2000. In this article, which is an unofficial translation from the original entitled "Patent på gener måste förbjudas," the Ministers argue that no one should be allowed to monopolise the building blocks of life and that the right to claim patents on genetic material must be strictly limited. Sweden currently holds the Presidency of the European Union (January-June 2001).*

The development of gene technology is moving faster and faster and we are all faced with difficult ethical dilemmas. Our knowledge about the building blocks of life itself has evolved so far that science is about to give us answers to why we are susceptible to serious diseases, and how we can in the near future, cure those affected. This is indeed a welcome development whose benefits must be shared by society as a whole.

This new knowledge has however also a downside that carries with it a frightening dimension. Commercial forces believe they have the right to claim ownership of the discoveries of the inner building blocks of life. Such an attitude is totally unacceptable to us. It is absolutely vital that this information is freely accessible to society as a whole.

We must clearly set the ethical framework for society. For us, it is essential to guarantee a pluralistic view by providing public financial support to research. But it is equally important that other factors do not limit the independence of science. **This is why the right to claim patents on genetic material must be strictly limited.** It would not only be illogical from a research and development perspective to create a system that limits the use of genetic information and knowledge, it would also be ethically questionable.

President Bill Clinton and Prime Minister Tony Blair this spring issued a joint statement where they underlined the importance

of making the knowledge on the human genome freely available, in order not to hamper the development of new significant innovations in the pharmaceutical and food sectors. We fully endorse this view.

Furthermore, we believe that no one should be allowed to patent genes, plants and animals in their natural state. **Neither genes nor organisms identified with the help of new methods can be considered as inventions.** These are nothing but discoveries. Not until a new discovery is applied in an industrial process or other commercial application, could a patent be considered. This is in line with existing Swedish legislation and also established through the EC-directive on legal protection of biotechnological inventions adopted in 1998.

No one shall be allowed to monopolise the building blocks of life.

Research on genes and their functions is one of the most rapidly expanding scientific disciplines in the world. Today, the genetic make-up of a number of species has been mapped at research institutions around the world. Examples are the fruit fly, **rice** and now also the human genome. Sweden is at the forefront in genomic research and recently an additional 800 million SEK was allocated to Swedish Universities in

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support of this research. Knowledge of our and other organisms' genes and their functions is of the utmost importance. It does not only increase our understanding of evolution and the internal biological systems of humans and other organisms. It also makes it possible to develop better and more efficient treatments for several currently incurable or severe diseases, in particular hereditary diseases. Increased knowledge about genes and their functions will, of course, also provide benefits in the health and food sectors.

In view of our fundamental opinion, it is most welcome that several major companies have clearly distanced themselves from a development that limits access to genetic information purely for profit reasons. One example is the Human Genome Project that, in part, is financed by the British Medical Company GlaxoWellcome, where all information is made available for research and development of new pharmaceuticals.

When the Convention on Biological Diversity (CBD) was adopted in 1992, a paradigm shift took place as regards the right of access to the genetic resources of the world. The Convention recognises the authority of every country to determine access to its genetic resources. One of the main reasons for the Convention to emphasise the sovereign right of every country to its genetic resources was to give developing countries the possibility to share the benefits arising from the commercial use of genetic resources that often arise in developed countries.

Bearing in mind that most developed countries are poor in genetic diversity but rich in technical and financial resources and most developing countries are rich in genetic diversity but poor in resources, the concept of sovereignty

is correct. Multinational companies should not be allowed to collect genetic resources from developing countries and exploit them commercially without sharing the benefits with the countries of origin.

But the fact that countries now possess the exclusive right to their genetic resources could also have undesired repercussions regarding the use of genetic resources in research and development.

Let us give a concrete example: the fungal disease *Phytophthora infestans* is a threat to the cultivation of potatoes in Sweden. To fight *Phytophthora* without increasing the use of chemicals, new varieties with effective resistance to *Phytophthora* are needed. Such resistant varieties, and thus genes, could only be found in the country of origin for potatoes - Peru.

Peru is about to adopt legislation that more or less makes access to its genetic resources impossible without undergoing an extensive consent procedure. This will render development of, for example, new *Phytophthora* resistant potato varieties, difficult. In other words, regardless of whether it is a multinational company or individual countries that restrict access to genes and genetic information, it can cause very concrete effects for people.

Sweden is active in the international arena to find models and systems to achieve the objective of fair and equitable sharing of benefits arising from the use of genetic resources. The term 'benefits' to us means more than money. It also encompasses capacity building and transfer of technology and knowledge.

At the moment intensive negotiations are under way in the FAO on how free access to genetic resources for food and agriculture

can be secured for research and development, whilst the benefits from commercial use of these resources shall be shared fairly with the stakeholders.

Patenting, access to genetic resources for food and agriculture as well as genetically modified organisms (GMOs) are intimately linked and will without doubt affect many of the already complex and difficult international processes in coming years.

The recently adopted global Biosafety Protocol is a clear example of this. The Protocol underscores the need for clear rules on the handling of GMOs as well as the central role of the Precautionary Principle to safeguard the protection of the environment and human health. The Environment Ministers of the EU have proposed new legislation that clearly puts the responsibility for avoiding negative environmental and health effects on the producers of GMOs. The possibility for consumers to make informed choices is another key element that is secured in the proposal by requiring labelling of products containing GMOs.

Gene politics is high on the international agenda. The Governments of the world negotiate gene politics issues in a number of forums in addition to the CBD and the Biosafety Protocol, such as the WTO, The World Intellectual Property Organisation (WIPO), the WHO and the OECD.

We welcome an open and transparent discussion on these issues. The discussion must include the whole Gene Politics area and all its complex issues. The Government has, and will continue to hold, an open dialogue on these issues. It is necessary to hold such a dialogue and to survey all relevant rules, identifying the rules that need to be reviewed and where rules are lack-

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ing. This discussion is urgently needed to make it possible to develop a comprehensive Gene Politic.

Gene Politics spans most areas of society, e.g. health and consumer aspects, trade, environment, research, forestry, agriculture, development assis-

tance and intellectual property rights. This means that Gene Politics is not sufficiently integrated either at the national or international level. In December 1999, the Environment Minister invited representatives of various organisations and research institutions for a round table discussion on formulating a Swedish Gene Poli-

tic. These were the first steps of the intensified dialogue that the Government undertakes in order to develop a comprehensive Swedish Gene Politics with all stakeholders. For us, it is self-evident that such politics must be based on the view that no one should be allowed to monopolise genes.

PATENTS, TRIPS & PUBLIC HEALTH - I

The battle between public health and private profit has reached the courts. The South African government is in the docks, defending itself against 39 pharmaceutical companies. These companies have brought a patent rights challenge to a 1997 South African law seeking to deliver affordable AIDS drugs by using the core safeguard provisions allowed by the WTO agreement (compulsory licensing and parallel importing.) The court case, to be heard this month, has now been suspended. On 7 March, the World Health Organization (WHO) distanced itself from the case, saying "WHO wants to reiterate that it has as a general policy not to take position on litigation in Member States." Meanwhile, Médecins Sans Frontières launched a global signature campaign on 13 March to "drop the case" against the South African government. Oxfam's recent paper 'Patent Injustice: How World Trade Rules Threaten the Health of Poor People' makes a compelling case that current WTO rules sacrifice public health for private profit. The following is the first of a two-part series based on the Oxfam paper.

The WTO's Agreement on Trade Related Intellectual Property Rights (TRIPS) is a dream come true for trade lawyers, and a nightmare for the general public. Its complexity and possible differences in interpretation mean that its implications for human development and poverty reduction are difficult to decipher. Another problem is that TRIPS is arguably the most heavily politicised area of WTO negotiations. Implementation will be governed as much by power politics and corporate lobbying as by legal texts.

The TRIPS framework covers seven parts and 73 articles of the trade agreement adopted at the end of the Uruguay Round of world trade talks in 1994. The framework establishes minimum standards in the field of patent protection which are derived from legislation in industrialised countries. All member states have to comply with

these standards, where necessary by modifying their national legislation. In an important departure from previous conventions, pharmaceutical products are accorded full IP rights. In brief, the new regime:

*Creates a harmonised global system under which inventors are granted exclusive marketing rights for a minimum of 20 years for 'new and inventive' products. Enforcement of a country's compliance with TRIPS is ensured through the WTO dispute procedure, which places the burden of proof on the defendant. Countries failing to meet their obligations can be subjected to trade sanctions.

*Fully integrates sectors such as biotechnology and pharmaceuticals into the global regime. Prior to TRIPS, approximately 50 developing countries and several developed countries either excluded medicines from being patented, or

provided patents only for production processes rather than products.

*Gives developing countries until 2000, and Least Developed Countries (LDCs) until 2006, to bring their national legislation into line with WTO rules. Developing countries which did not have product patents have until 2005 to do the same. However, all countries are obliged to offer 'market exclusivity' (the equivalent of patent protection) to drugs for which patents were filed after 1995.

The TRIPS agreement explicitly acknowledges some of the tensions associated with patenting, including potential conflict between public and private interests. The preamble to the agreement states that IP rights should 'not themselves become barriers to legitimate trade'. Article 8 stipulates that,

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in framing national laws, members 'may ... adopt measures necessary to protect public health and nutrition, and to promote the public interest'.

However, this principle is then qualified with the remarkable requirement that measures be 'consistent with' the Agreement. Oxfam believes that TRIPS should be amended to include a clear statement that 'nothing in the Agreement shall prevent the adoption of measures to protect public health'.

From a health-policy perspective, governments have two important policy instruments which help them to balance the public interest with the claims of patent holders. The first is the ability to override a patent by authorising a compulsory licence for production of a drug. TRIPS lays down conditions about how and when this can be done.

The second is the right to engage in parallel importing, which means importing a patented drug from wherever it is sold cheapest, irrespective of the wishes of the patent-holder. Parallel importing is not covered by the TRIPS agreement, but the pharmaceutical TNCs and the US government are pressing for it to be banned in national patent legislation.

Compulsory licensing

Governments are permitted to allow the exploitation of a patent without the owner's consent, provided this is justified by the general public interest. Under Article 31, compulsory licences can be granted to third parties on public-health grounds. French law, for example, explicitly allows for compulsory licences 'if required in the interests of public health', notably when drugs 'are made available to the public in insufficient quantity or quality or at abnormally high prices'.

Compulsory licences can also be issued in response to national health emergencies. National legislation can provide special rules for compulsory licences granted to government agencies or contractors, notably by eliminating the patent holder's right to seek an injunction preventing the use of its patent (subject to adequate compensation). Compulsory licences can also be granted to restrain excessive prices.

The main limitation of a compulsory licence, in practice, is that a country needs to have a reasonably sophisticated pharmaceutical industry in order to produce the medicine concerned, and must be able to achieve economies of scale to bring the price down to affordable levels. The great majority of developing countries fail on both counts.

The solution might be to import from a generic manufacturer in a larger country but this is unlikely to be economically viable unless a compulsory licence has also been issued in the exporting country. Even if it has, TRIPS allows compulsory licensing only if it is 'predominantly' for domestic needs, so the exporting country may find itself accused of breaking the rules.

The TRIPS agreement is drafted in a manner that will further limit the scope for state action. Authorisation for compulsory licensing can only be granted if the proposed user has made efforts to obtain a licence from the patent holder on commercial terms, and if the patent holder is compensated. In addition, the scope and duration of compulsory licensing must be limited – and there are no clear criteria for determining the public-health grounds which may limit the rights of patent holders.

While in theory the TRIPS agreement provides scope for combating monopoly pricing through

national legislation, in practice this is likely to be easier in countries such as the USA, which has strong anti-trust laws and administrative capacity, than in developing countries. In each of these areas there is considerable potential for legal challenges from pharmaceutical companies, which are likely to prove most effective in countries which lack the capacity to meet them.

The use or threat of trade sanctions in support of corporate claims will further weaken the position of developing-country governments.

Parallel imports

Where a patented product is marketed at a lower cost in another country, governments can allow 'parallel imports' from that country in order to take advantage of the price differential – but only if this option is built into their national legislation. The pharmaceutical TNCs are lobbying hard for developing countries to prohibit parallel importing. Paradoxically for a WTO agreement, TRIPS allows this prohibition, which is a barrier to international trade, thereby revealing a clear bias towards TNC interests.

Parallel importing can be used to circumvent differential pricing by companies, and is widely used. In the UK, parallel imports from within the European Union account for about 12 per cent of all prescriptions, reflecting the high prices charged by drugs companies in Britain compared with other European countries. Parallel imports account for almost one-fifth of sales of Glaxo Wellcome (GW) products in the UK.

But from a public-health perspective there are serious limitations with parallel importing as a safeguard mechanism. One is the absence of information on market prices for pharmaceutical products.

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Another is that pharmaceutical companies may seek to establish uniform global prices at the highest possible level. Unless governments retain the right to import generic-equivalent products, the protection against monopoly pricing is likely to prove weak.

Early working

In order to ensure that low-cost generic supplies can come on-stream immediately after patent expiry, TRIPS allows governments to include in national legislation the right of generic companies to develop, test, and register (though not stockpile) products prior to patent expiry. This is known as 'early working'. Developing countries have been under pressure from the USA not to allow early working in their patent laws.

The US government and TNCs are also demanding protection for company data submitted to regulatory authorities on the testing and effectiveness of new drugs – a measure which will lead to further restriction of legitimate generic competition. The pharmaceutical TNCs claim that the data protection they seek is mandated by TRIPS, though this interpretation is contested by generic manufacturers.

Price controls

Governments retain the right to establish price controls, provided that they do not discriminate between foreign and local suppliers. However, price-control legislation is being fiercely resisted by drugs companies in both the developed and the developing world.

Regrettably, TRIPS weakens the bargaining position of developing-country governments when dealing with companies, by making compulsory licensing a difficult

last resort. Without the threat of compulsory licensing, a company is less likely to agree lower prices.

Implications for developing countries

As indicated above, under the new rules, governments will no longer be permitted to allow local companies to produce, market, and export low-cost copies of patented drugs. This has major implications at two levels.

First, in countries which have developed strong generic-drugs industries (which specialise in copying), there may be reduced self-reliance in pharmaceuticals, coupled with higher prices. Secondly, poor countries which lack strong generic industries will be prevented from importing from these sources.

One of the strongest generic-drugs industries is in India. Before 1970, the country was almost entirely dependent on imported drugs. Today, over 70 per cent of pharmaceuticals consumed in the country are locally produced. India has some 250 large pharmaceutical firms and 16,000 small producers.

Local market prices are far lower than international prices for equivalent products. Moreover, India has one of the lowest inflation rates for drugs prices. Leading Indian companies such as Cipla and Ranbaxy are also important exporters. This transition has been achieved partly as a result of a 1970 patent law, under which local companies were allowed to copy patented drugs, provided that they found a new process.

However, WTO rules commit India to full implementation of the new IP regime by 2005, and its patent law has already been reformed to give interim exclusive marketing rights for patents.

Egypt has also progressed rapidly towards self-reliance in pharmaceuticals.

Today, over 90 per cent of drugs consumed are locally produced. Exports have also grown rapidly. As in India, local drug prices are far cheaper than those for imported equivalents, partly as a result of strict price controls.

Local prices are on average one-fifth of those for imported Equivalents. Like India, Egypt achieved these outcomes under a flexible IP law, according to which patents expired after ten years – half of the period envisaged under the WTO regime. That law is now being reformed to ensure its compliance with WTO rules.

Other countries such as Brazil, Argentina, and Thailand have also developed strong local drugs industries under patent regimes which have placed a premium on improving access to essential drugs, rather than on the protection of monopoly rights.

In each case, major legislative reforms have now been undertaken to bring domestic legislation into line with WTO rules, often under extreme duress. The US in particular has consistently used the threat of trade sanctions to ensure compliance with the TRIPS regime.

In January 2001, the US government asked for a WTO dispute settlement panel to rule on aspects of Brazil's new patent legislation.

This is the first time a formal complaint has been made about a developing country's alleged non-compliance with TRIPS, and is a clear declaration by Washington that the gloves are coming off at the WTO.

GOLDEN RICE: THE SHINE IN QUESTION

*The promise of golden rice, rich in vitamin A, is being questioned by a number of NGOs who say there are other inexpensive and nutritious foods already available to tackle malnutrition among the poor. They contend that the introduction of golden rice is merely a marketing event by biotech companies. The following are extracts from an article that has just been published by the Barcelona-based **GRAIN** (Genetic Resources Action International), in collaboration with **BIOTHAI** (Thailand), **CEDAC** (Cambodia), **DRCSC** (India), **MASIPAG** (Philippines), **PAN-Indonesia** and **UBINIG** (Bangladesh). For the original article, see GRAIN's website: www.grain.org. The South Bulletin would welcome comments from its readers on the pros and cons of golden rice.*

Rice does not normally contain vitamin A or its precursor, beta-carotene. But a group of European scientists have spent the last decade trying to change this. By inserting two genes from daffodil and one gene from a bacterium, Dr. Ingo Potrykus of the Swiss Federal Institute of Technology and Dr. Peter Beyer of the University of Freiburg in Germany have managed to engineer a beta-carotene pathway into Taipei 309, a japonica rice variety. In August 1999, they unveiled the fruit of their research and named it "golden rice."

Shortly afterwards, they signed a deal with AstraZeneca, which agreed to waive technological fees to enable the development of the rice for "humanitarian" purposes. Monsanto was quick to jump on the humanitarian bandwagon by announcing royalty-free licenses for any of its technologies used to further the development of the rice. The small handful of transgenic rice grains produced in Potrykus' laboratory provided a much-needed public relations boost for the biotech industry at a time when genetic engineering is under siege in Europe, Japan, Brazil and other developing countries.

The biotech lobby is selling the idea that genetically engineered (GE) crops, starting with golden rice, will solve problems of malnutrition. The malnutrition agenda is drawing in support from every major agricultural biotech company, the Consultative Group on International Agricultural Research (CGIAR), the US Agency for International Development (USAID),

and its main funder, the Rockefeller Foundation. But at the end of the day, the main agenda for golden rice is not malnutrition but garnering greater support and acceptance for genetic engineering amongst the public, the scientific community and funding agencies. Given this reality, the promise of golden rice should be taken with a pinch of salt.

Golden rice has been met with excitement in every corner of the world. It has become a symbol of all the goodness biotechnology has to offer. Among other things, it is supposed to exemplify how genetic engineering can directly benefit consumers, which the first generation of genetically engineered crops has failed to do. It claims to provide a more sustainable, inexpensive and effective solution to vitamin A deficiency in poor, rice eating countries where drug-based supplementation and fortification have been ineffective. And in a climate where intellectual property rights (IPR) are the subject of controversy and uncertainty, it promises to provide the IPR-laden golden rice technology free of charge to subsistence farmers.

One of the major selling points of this golden rice technology is that the work has been done within the realm of public research using public funding. But the fact that golden rice has not been developed by and for the industry has come about not by design but default. Dr. Potrykus initially approached Nestle, the world's biggest food company, for funding but was rejected. In retrospect, Dr.

Potrykus describes this as "fortunate" because it kept the project open for public funding and the potential for free distribution. But it was more of an afterthought than a plan.

The Patent Tangle

Despite being the result of public research, golden rice is enmeshed in around seventy patents owned by some thirty-two companies and institutions, according to the US-based International Service for the Acquisition of Agri-biotech Applications (ISAAA). Because of the complexity of licensing arrangements, the inventors ceded their rights to Greenovation, a biotech spin-off company from the University of Freiburg, which then struck a deal with AstraZeneca (now Syngenta).

According to Dr. Potrykus, a veteran in dealing with multinational companies and an inventor of a number of patented technologies, forging an alliance with AstraZeneca seemed to be the only option available to gain "freedom-to-operate" and speed up the transfer of the technology to developing countries. Hence by a stroke of a pen, AstraZeneca was able to acquire exclusive commercial control over a technology that was developed with public funding and purportedly pursued for a humanitarian cause.

The AstraZeneca deal gives the corporation full commercial rights to the invention worldwide and "non-

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commercial” rights to the inventors for license-free use by national and international research institutes and resource-poor farmers in developing countries. A resource-poor farmer may sell the golden rice so long as s/he does not earn more than \$10,000 a year from it. Any other commercial use of the golden rice technology – using public or private germplasm – and any export from a producer country requires a license from Zeneca on commercial terms.

According to a press release jointly issued by IRRI (International Rice Research Institute) in January 2001, six out of the 32 or so companies and institutions which own patents on certain technologies used to develop golden rice, had each licensed the technology free of charge. The companies are Syngenta Seeds, Syngenta, Bayer, Monsanto, Orynova, and Zeneca Mogen. Subject to further research, initially in the developing countries of Asia, as well as local regulatory clearances, golden rice will be made available free of charge for humanitarian uses in any developing nation.

However, the terms of the free license agreements are still unclear: they appear to cover research, but not release or commercialisation. This lack of clarity casts a huge question mark over how “free” the agreement really is and has huge implications for the accessibility, availability and affordability of golden rice to farmers around the world.

Instead of resolving the intellectual property issues around golden rice, the inventors have passed the buck to developing countries and public institutions to sort out the mess themselves.

A Reality-based Assessment

Malnutrition is said to be high in rice-eating populations. But these

nutritional problems are not caused directly by the consumption of rice. They reflect an overall impact of multiple causative factors similar to those of other developing countries where rice is not a major staple. Various deficiencies including zinc, vitamin C and D, folate, riboflavin, selenium and calcium occur in the context of poverty, environmental degradation, lack of public health systems and sanitation, lack of proper education and social disparity. Poverty and lack of purchasing power is identified as a major cause of malnutrition. These underlying issues that can never be addressed by golden rice.

The Green Revolution with its inherent bias towards monocultures of staple crops has led to unbalanced patterns of food production in many places. As the UN Food and Agriculture Organisation (FAO) has stated, variety is the key and should be the norm rather than the exception in farming systems. According to Dr. Samson Tsou of the Asian Vegetable Research and Development Center (AVRDC), countries with vegetable consumption of more than 200 grams of vegetables per day do not have vitamin A deficiency as a major problem. Although animal sources are expensive, inexpensive plant food sources are widely available. It only takes two tablespoonfuls of yellow sweet potatoes, half a cup of dark green leafy vegetables or two-thirds of a medium-sized mango in a day to meet the vitamin A requirement of a pre-school child. This way, not only is the vitamin A requirement being addressed, but a whole range of other micronutrients as well.

With what has been shown so far, 300 grams of golden rice can only provide at most 20 per cent of an adult’s daily vitamin A requirement. A child would have a lower requirement of 450 µg retinol as against 500-600 µg retinol for adults. But 300 g of rice a day is

way too much for a child. In the Philippines, pre-school children consume less than 150 grams of rice a day. In principle then golden rice will only supply a little over 10 per cent of the daily vitamin A needed by pre-school children. And children are the target population in this case.

Whether the beta-carotene contained in golden rice will be bioavailable is yet another question. Dietary fat is needed for it to be absorbed by the body. Unfortunately dietary fat is also limited in rice-eating countries and in fact is being looked at as one of possible “hidden” causes of vitamin A deficiency itself. There are also important interactions between different nutrients and minerals, which further warrants variety in food intake. Zinc deficiency, for example, may lead to an impairment of vitamin A metabolism. Disease control and hygiene, food selection and preparation will significantly influence absorption and utilisation of vitamin A (and iron).

Furthermore, there has been debate over the bioconversion of beta-carotene from green leafy vegetables into vitamin A. Some reports claim that the conversion rate is less than one-quarter of what has been assumed up to now. Should this be the case, the amount of vitamin A made available from golden rice would be almost negligible.

Despite statements being made that there is not a slightest risk of overdosage from golden rice and conceivable risk to consumer health and the environment, no testing has been conducted.

According to Dr. Mae Wan Ho, vitamin A poisoning has been known to result from excessive beta-carotene intake in food. Allergenicity has also been raised as a possible issue. Daffodil, which is the source of the genes for the

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beta-carotene rice, is responsible for an allergic reaction which manifests as “daffodil picker’s rash” in some people.

Clashing Perspectives

According to Gary Toenniessen of the Rockefeller Foundation, “The benefit of having the beta-carotene in the crop is that the delivery system is already there. The current generation of improved varieties is being grown in rural areas not be-

ing reached by supplements.” But we know too well that the Green Revolution did not reach marginal areas where many of the poor reside, so golden rice is not likely to go there either.

According to Dr. Gurdev Khush of IRRI, the golden rice trait will be inserted in commercially grown rice varieties (such as IR64) since these varieties provide 80 per cent of the rice in cities. Will it reach the rural poor? Or will it create a segmented market where golden rice captures

a premium due to its added “nutritive” claim? It may be that golden rice will develop as a “specialty crop” in the Philippine market according to one of the leading rice breeders in the Philippine Rice Research Institute.

Dr. Emorn Wasantwisut of the Institute of Nutrition at Mahidol University in Thailand goes as far as saying that it may initially start off as a “brand name” crop, in which case accessibility to the poor may be limited.

TRADITIONAL MEDICINE - AFFORDABLE AND POPULAR

In sharp contrast to the aggressive corporate monopolies being entrenched via the Trade-Related Intellectual Property Rights (TRIPS) agreement, and the consequent rise in prices of essential modern medicines (particularly those in the pipeline), the whole area of traditional medicine hardly receives the attention it deserves. For bulk of the people in the developing world, traditional medicines provide the main source of affordable health care. Yet, the intellectual property systems associated with cures based on traditional knowledge can, at best, be said to be in a nascent stage. The following article is based on a presentation by WHO's Dr. Xiaorui Zhang, to a recent UNCTAD meeting on “Systems and National Experiences for Protecting Traditional Knowledge, Innovations and Practices.”

The twentieth century has witnessed a revolution in human health care. The dramatic decline in mortality, increase in life expectancy and the eradication of smallpox are all part of this success. Scientific innovation, leading to the development of new drugs and medicines, has played a major role.

However, despite these achievements, it is estimated that over one third of the world’s population lacks regular access to affordable drugs. For these people, modern medicine is never likely to be a realistic treatment option. In contrast, traditional medicine is widely available and affordable, even in remote areas, and generally accessible to most people.

In India, for example, 70 per cent of the population uses Indian medicine, as reported by the Indian government.

In Africa, the resolution on “Promoting the role of Traditional Medicine in Health Systems: A strategy for the African Region”, which was adopted by the 50th Regional Committee of Africa in August 2000, states that the African member states are aware of the fact that about 80 per cent of the population living in the African region depend on traditional medicine for their health care needs.

In the last decade, there has been a global upsurge in the use of traditional medicine and complementary and alternative medicine in both developed and developing countries. Various reasons have been proposed for this increase, including affordability, but also changing needs and beliefs.

For example, the percentage of the population which has used complementary and alternative medicine, at least once, are as

follows: Australia - 48 per cent, Canada - 50 per cent, USA - 42 per cent, Belgium - 40 per cent, France - 75 per cent and the United Kingdom - 90 per cent as stated in governmental and non-governmental reports.

The most widely used traditional medicine and complementary and alternative medicine therapies are herbal medicines and acupuncture. The world market for herbal medicines, including herbal products and raw materials, has reached US\$43,000 million as reported by the secretariat of the Convention on Biological Diversity (CBD). The annual world-wide growth rates for 91/92 was between 5-15 per cent. As a consequence, today traditional medicine and complementary and alternative medicine play an increasingly important role in health care and health sector reform globally.

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Protection Challenges

The efficacy of certain types of traditional medicine, such as acupuncture and herbal medicine, has been widely investigated and reports have been published.

Artemisia annua is one of the Chinese traditional medicines for the management of malaria since ancient times. Artemisinin and its derivatives have been developed recently by modern scientific research as one of the most valuable anti-malarial drugs of today, worldwide. St. John's Wort is another example for the treatment of mild to moderate depression. Such findings have stimulated research to discover new drugs from traditional medicines.

The new issues are concerned with how benefits are derived from the use of biodiversity and how associated traditional medicine are shared, and how to protect the intellectual property rights between holders of traditional knowledge to (those of) the modern technologies. The challenge is that the vast majority of plant genetic resources and other forms of biodiversity are found in - or originate from - developing countries. In most situations, knowledge of traditional medicine is at times appropriated, adapted and patented by scientists and industry, for the most part from developed countries, with little or no compensation to the custodians of this knowledge and without their prior informed consent. The protection of traditional knowledge, innovations and practices of indigenous and traditional medicine and equitable sharing of benefits have been receiving increasing attention on the international agenda in recent years.

Another issue is that with the widespread use of traditional medicine and the tremendous expansion of international herbal prod-

ucts markets, the great commercial profit from traditional medicines and plants have also brought serious problems of global biodiversity loss. Because pharmaceutical herbal production needs big quantities of raw materials of medicinal plants, many plants have been over collected and become endangered species. For example, some information mentioned in 1997 that African potato was good for AIDS. After two years, this particular specie has completely disappeared in the Democratic Republic of Congo.

Patent gaps

Currently, some 95 per cent of patents in the world are held in developed countries. At present, international patent law and most national conventional patent law protection requirements of novelty and inventive steps do not seem to be applicable to traditional knowledge and biodiversity.

For example, there is no act under patent law which could be used to protect the non-medication of traditional therapies, such as manual therapies and spiritual therapies. Because of the lack of database and the same medicinal plants growing and being used in various countries and continents, it is very difficult to identify the founder.

Pharmaceutical products can be protected by the existing conventional patent law. However, herbal medicines and herbal products are quite different from chemical drugs. They are very difficult to be protected by the existing patent law.

For example, there are only three key protectable subject matters in order to get patent for pharmaceutical products in the conventional patent law:

- . patent for discovering new chemical components
- . patent for know-how in producing the products
- . patent for the trademark

In addition to patent law, knowledge on herbal medicines could also be protected by keeping it a secret!

Firstly, the above-mentioned means are with little or no compensation to the custodians of this traditional knowledge and without their prior informed consent.

Secondly, herbal medicines have been defined by several WHO guidelines that they include crude plant materials such as leaves, flowers, fruit, seed, stems, wood, bark, roots, rhizomes or other plant parts, which may be entire, fragmented or powdered. The products, (to) which chemically-defined active substances have been added, including synthetic compounds and/or isolated constituents from herbal materials, are not considered to be herbal medicines. Therefore, it is impossible to get existing patent law protection for herbal medicines through the discovery of new chemical components.

Thirdly, the major dosage of traditional herbal medicines are directly derived from their herbal preparations, which include powdered herbal materials, or extracts, tinctures and fatty oils of herbal materials. They also include preparations by steeping or heating herbal materials in alcoholic beverages and/or honey, or in other materials. The production process and major dosage forms of traditional herbal medicines is normally very simple. There is almost no know-how available to protect this by patent.

Fourthly, except for pharmaceutical companies and industries, other holders of traditional knowl-

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edge find it impossible to get protection for their product through trademark.

Fifthly, it is impossible to keep knowledge a secret because registration of herbal medicines have to be made if the products are to be sold in the market. Therefore, all of the components in the products have to give account to their national drug authorities.

Some countries, however, have been aware of the important role of intellectual property rights for traditional medicine. India, Kenya, and Madagascar, for example, have updated their legal system and national patent law in order to protect the knowledge of traditional medicine. We need to share national experiences.

Future Co-operation

The issues on the protection of traditional knowledge, innovations and practices of indigenous and local communities have been raised in recent years. The Expert Meeting initiated and organized by

UNCTAD was not only to repeat the issues again, but focus further on what systems can be used for protection of traditional medicine and the sustainable development of indigenous and local communities.

How can existing systems be strengthened? How can national policies and measures be supported at multilateral level? How can developing countries obtain greater benefits from the commercialization of traditional medicine-based products and what would be the role of certain intellectual property regimes?

Traditional medicine continues to play an important role in health care in both developed and developing countries in the 21st century. Biodiversity of natural resources, from which medicinal plants and herbal products are derived, have maintained their great potential with economic benefits.

WHO organized the *WHO Interregional Workshop on Intellectual Property Rights in the Context of Traditional Medicine* in Bangkok, Thailand from 6-8 December 2000

and discussed, in particular, solutions for the protection of knowledge of traditional medicine.

Conclusion

The intellectual property rights is one of the important means in protecting the benefits of traditional knowledge. It needs to be further developed and expanded. Patent law, however, is not the only means in protecting the benefits of traditional knowledge. Each government should develop its own means to protect the benefits of the knowledge of traditional medicine.

There is no doubt that these discussions will share ideas and information to facilitate our member states to develop their own practicable systems, means and regimes for the protection of intellectual property rights in order to achieve fair and equitable benefits in sharing traditional knowledge.

Traditional knowledge will greatly contribute to the development of economies and health care in the 21st century.

CUTTING GREENHOUSE GASES

Geneva, 5 March (South Development News)-- After confirming that climate change is for real and then outlining areas that will be impacted, the Intergovernmental Panel on Climate Change (IPCC) came out with its latest report that outlines effective policy and technology options that can help cope with a warmer world.

"The Third Assessment Report represents a remarkable consensus and a sound basis for international decision-making," said Professor G.O.P. Obasi, Secretary-General of the World Meteorological Organization (WMO), which

together with UNEP launched IPCC in 1988. Prof. Obasi called upon the world's governments to consider rapidly a legislative framework for effective implementation of the many available cost-effective solutions to the greenhouse emissions problem.

"This report moves us from a focus on the problem to a focus on the solution," observed Klaus Töpfer, UNEP Executive Director. "The good news is that there are cost-effective policies and technologies available for cutting emissions. The bad news is that there are many barriers to rolling these out.

We must figure out how to break down these barriers."

"I am convinced that the turnaround in global emissions can be achieved over time through cost-effective policies and 21st century technologies that will benefit economic growth and sustainable development," said Michael Zammit Cutajar, Executive Secretary of the UN Climate Change Convention. "Developed countries must take a convincing lead in demonstrating these opportunities. The Kyoto Protocol, on which negotiations will resume soon, seeks to start this movement."

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The choice of energy mix and associated investment will determine whether atmospheric concentrations of greenhouse gases can be stabilized, and if so at what level and cost. Currently, most such investment is directed towards discovering and developing more fossil resources, including both conventional and unconventional. According to the latest report, progress since 1995 on developing technologies that reduce greenhouse gas emissions has been faster than anticipated. Important advances have included the market introduction of efficient hybrid engine cars and wind turbines, the demonstration of underground carbon dioxide storage, the advance of fuel cell technology and the rapid elimination of industrial gases such as N₂O emissions from adipic acid production and perfluorocarbons from aluminum production.

While a change in energy supply will play a central role, hundreds of technologies and practices for end-use energy efficiency in buildings, transport and manufacturing industry account for more than half of the potential for global emissions reductions from 2010 to 2020.

Some studies also show that half of this potential can be realized through options that actually save money – known as “no regrets” options. However, governments will need to adopt more supportive policies if this potential is to be realized. The report also notes that the costs to industrialized countries of achieving their Kyoto Protocol targets without the benefit of an international emissions trading sys-

tem would be 0.2 – 2.0 per cent of projected GDP in 2010. With full emissions trading amongst these countries, the cost would decline to 0.1 – 1.1 per cent. If reduced air pollution and other ancillary benefits are included, as well as the removal of market imperfections and other factors, the costs can be reduced even further.

Earlier, on 3 March, UNEP released a new report “*Natural Selection: Evolving Choices for Renewable Energy Technology and Policy*” (<http://www.uneptie.org/energy/Publications/naturalselection.htm>) which notes that fossil fuels (the major cause of greenhouse gas emissions) provide three-quarters of the energy needed to drive a \$35 trillion world economy – a situation that is rapidly degrading earth’s natural systems.

The demand for energy has increased steadily in recent years, growing on average by roughly 2 percent per year in the 1990s. But, says the new UNEP report, the energy systems developed so far to meet this demand are clearly unsustainable, as they lead directly or indirectly to health damaging levels of air pollution, acidification of ecosystems, land and water contamination, loss of biodiversity, and global warming.

On the issue of health, the report says that much of the air pollution that kills an estimated 500,000 people each year comes from burning fossil fuels in power stations, industrial furnaces, and motor vehicles. Air pollution also causes an estimated four to five million new cases of chronic bron-

chitis, as well as millions of cases of other serious illnesses.

Renewable energy is abundant, clean, and inexhaustible, says the report. It is also the most cost-effective energy source for a variety of applications, meeting between 15 and 20 per cent of total world energy demand and 24 per cent of the world’s total electricity supply. Renewable energy in the form of traditional biomass fuels, such as wood and crop residues, represents about 14 per cent of the world’s total energy consumption – a larger share than coal.

However, the contribution of newer renewable energy technologies is increasing rapidly, in spite of new competition from deregulated energy markets. From a small base in the 1970s, biomass, geothermal, solar, small-scale hydropower, and wind technologies have grown proportionally faster than any other electricity supply technology.

The wind energy industry, for example, has grown in just two decades from a producer of small machines to a modern, multi-billion dollar industry supplying bulk, grid-connected power. At the beginning of the 21st century, 14,000 megawatts of wind turbines generate clean electricity in more than 30 countries. The evolution of the wind energy industry has far exceeded even the most optimistic predictions in 1990. Consequently, the cost of wind-generated electricity has dropped seven-fold, which makes windpower competitive with most fossil fuel technologies.

RECENT PUBLICATIONS

SOUTH CENTRE: Two Working Papers, on **Farmers’ Rights and Services** have been added to the series on T.R.A.D.E. (Trade-Related Agenda, Development and

Equity.) Working Paper no. 8 - *Options for the Implementation of Farmers’ Rights at the National Level* has been written by Carlos M. Correa. Working Paper no. 9,

on GATS 2000 Negotiations - *Options for Developing Countries*, has been prepared by Mina Mashayekhi.

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These publications respond to the needs of developing country negotiators in the WTO for concise and timely analytical inputs on selected key issues under negotiation in the world trade body.

These working papers contain brief analyses of chosen topics from the perspective of developing countries rather than exhaustive treaties on each and every aspect of the issue.

UNCTAD: *Measures of the Transnationalization of Economic Activity* analyses the growing transnationalisation of the world economy.

MWALIMU NYERERE MEMORIAL WEBSITE

The South Centre is proud to launch the Mwalimu Nyerere Memorial Site in honour of its founding and late Chairman, Mwalimu Julius K. Nyerere. The purpose of this special section within the South Centre website is to give access to all those interested, including researchers, to some of the most significant speeches, statements and writings of Mwalimu Nyerere, in tandem with the work and objectives of the South Centre.

The site also contains tributes to Mwalimu, papers or articles on his role, his speeches and a photo gallery. This site will be gradually expanded.

Comments, suggestions and contributions are welcome. The site will be active on 17 March and can be accessed at <http://www.southcentre.org/mwalimu>

NEW COCOA & JUTE AGREEMENTS

Geneva, 2 March (SDN) – Cocoa producers, all from developing countries, and consumers, mainly in the industrialised countries, agreed on a new Cocoa Agreement, under the aegis of UNCTAD, that will guide the London-based International Cocoa Organization (ICCO) through 2008.

The hallmark of the agreement, which could not be struck last November, is the formal entry of the private sector as an active partner, goals of sustainable development, and the regulation of the market through reliance on “morals” and “good faith” and not on “interventionist mechanisms” such as production quotas, buffer stocks and other price support measures.

Conference President Ransford A. Smith (Jamaica) said the agreement “did not contain everything that everyone wanted”, and struck “a delicate balance”. But successful implementation would be the impor-

tant test, he added. Particularly noteworthy was its emphasis on the role of the private sector in supporting a sustainable cocoa economy and in encouraging the promotion of cocoa consumption. Provisions on the use of cocoa substitutes and on marketing, monitoring and transparency were important as well, he added.

Producer spokesman Lambert N’Guessan (Côte d’Ivoire) said his group was satisfied with the agreement, but concerned as to how the “moral commitment” it contained would be translated into action. He said a partnership was needed, focusing on the transfer of technology, so that consumer countries can help the producers improve the quality of their cocoa and through value-added.

Although most cocoa is produced by small farmers, the market is largely controlled by a handful of multinational firms, which in some countries buy up a major part of the

crop and thus keep prices artificially low.

During the talks, Mr. N’Guessan had accused the multinationals in consumer countries of “financial bulimia” - trying to establish new cocoa plantations in an effort to keep supply steady and “make superprofits.” Cocoa prices have for long been depressed, though now showing signs of recovery due mainly to production shortfalls due to pests and diseases and bad weather.

Geneva, 13 March (SDN) – An International Jute Study Group has been established under the auspices of UNCTAD. Like in the case of cocoa, a distinguishing feature of this Group is the involvement of the private sector, which is expected to finance the jute modernization needs. About 11 million small farmers in developing countries grow jute, a natural and biodegradable fibre.



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