

S



U

T

H

B

U

L

L

E

T

I

N

*This issue of the South Bulletin is the third in the series on Traditional Knowledge and Intellectual Property, focusing on the theme of Traditional Medicine (TM).*

### TRADITIONAL MEDICINE - FIGURING IN THE CALCULUS

For the first time, on 16<sup>th</sup> May, 2002, the World Health Organization (WHO) chalked out a global strategy on Traditional Medicine. But on the very first page of its strategy paper, the WHO makes a distinction between traditional medicine - TM - the term used when referring to Africa, Latin America, South-East Asia and the Western Pacific and CAM - complementary and alternative medicine - when referring to Europe, North America and Australia. So much of the traditional knowledge of ancient civilisations has to do with health and well-being that even today up to 80 per cent of the people in the developing world rely on traditional systems of medicine. Unlike modern medicine which targets the disease, traditional medicine (TM) is known to be holistic - increasing the body's ability to fight in addition to targeting the disease.

The fact that it has taken the WHO such a long time to come up with its first-ever strategy on TM strategy despite the fact that the masses in developing countries depend on it for survival, is noteworthy. Even this strategy is a working document that aims to assist countries to: develop national policies on the evaluation and regulation; create a stronger evidence base on the safety, efficacy and quality of the TM/CAM products and practices; ensure availability and affordability of TM/CAM, including essential herbal medicines; and promote therapeutically sound use of TM/CAM by providers and consumers. The WHO has made it known that in the next four years it will give priority to only the first two of the above four objectives.

But more than sheer recognition, the fact that TM has begun to figure in the international calculus at this juncture can

lend itself to other interpretations as well. Much of the economics of health, as it is currently defined, is predicated on almost total dependence on allopathic or the modern medicine system. It is with this system in mind that the number of doctors, hospital beds and the distribution system - all the relevant statistics are churned out. Even the WHO's Commission on Macroeconomics and Health appears to have made all its calculations of the nearly \$25 billion in health grants needed from rich donor countries to be able to save about 8 million preventable deaths a year - keeping the modern, largely western system of medicine in mind. But the colossal burden of preventable deaths calls for a speedier and more concerted response, otherwise it is "death on the watch of our world leaders" as Jeffrey Sachs puts it. In providing such a response, the best of both the worlds - traditional and modern - need to be properly blended.

But that blending is not going to be easy at all. WHO estimates the global market for traditional therapies stands at \$ 60 billion a year and is steadily growing. It also estimates that about 25 per cent of modern medicines are descended from plants first used traditionally. Indeed, the science of modern medicine has not emerged out of the blue. To a considerable extent, it has built on the knowledge known to man in some corner of the globe and continues to do so. If patents must reward the pharmaceutical research companies, some form of intellectual property must also decently compensate the custodians of traditional knowledge.

#### INSIDE PAGES

|  |    |
|--|----|
| Ayurveda - Gaining People's Confidence.....                        | 2  |
| Traditional Medicine - Accessible to the Masses.....               | 3  |
| China's Patent Protection of Traditional Medicine.....             | 6  |
| TK Digital Library : Another Tool For Biopiracy?.....              | 8  |
| Health Crises Need \$25 Billion Annual Grants - Jeffrey Sachs..... | 10 |
| Patents Cover Karawila Cure For HIV.....                           | 15 |
| TK in WIPO - A Long Way To Go.....                                 | 17 |

## AYURVEDA - GAINING PEOPLE'S CONFIDENCE

*Ayurveda is not a practice or a therapy but a well-developed scientific medical system, according to India's former health Minister Dr. C. P. Thakur. In Geneva recently during the World Health Assembly, Dr. Thakur, also a medical doctor by profession, shared India's experience of health care through the traditional Indian systems of medicine. "What makes them stand apart is their holistic approach to health and use of plant based raw materials little known for any adverse effects," he said. "The unbroken practice for centuries, wider public acceptance and no instance of drugs having been withdrawn on grounds of irrationality and adverse effect are great strengths of these systems." In addition to the treatment of common ailments, medical care of chronic, lifestyle-related diseases and refractory diseases have efficacious interventions in these systems, which have developed their own unique principles, concepts, and philosophy. Following are extracts from Dr. Thakur's presentation.*

"India, the land of ancient knowledge and wisdom is well known for its contribution to the spread of knowledge and also in improving the quality of life through ancient systems of medicine, like Ayurveda, Yoga and meditation.

In 1976, World Health Assembly took stock of the potential role that traditional medicine, today known as complementary or alternate medicine, can play in the extension of health services, particularly to the remote rural and tribal areas. A resolution was passed in the World Health Assembly of 1977, urging National governments of different countries to give adequate assistance to the utilisation of their traditional systems of medicine with appropriate "regulations", I feel proud to say that India has been using Ayurveda, Unani, Siddha, Yoga, Naturopathy and Homeopathy as part of the health network of the country for centuries. Ayurveda, Unani and Siddha - the main Indian systems of Medicine enshrine promotive, preventive and curative principles of health care which have contributed significantly in meeting the health care needs of the people. These systems have developed their own unique principles, concepts, and philosophy. However, what makes them stand apart is their holistic approach to health and use of plant based raw materials little known for any adverse effects. They do not only address the disease but the person as a

whole. The unbroken practice for centuries, wider public acceptance and no instance of drugs having been withdrawn on grounds of irrationality and adverse effect are great strengths of these systems. In addition to the treatment of common ailments, medical care of chronic, lifestyle-related diseases and refractory diseases have efficacious interventions in our systems.

The Government of India has vast infrastructure in terms of education, research, drug testing and standardisation, production of quality raw material and drugs. You have just been given a brief account of how Ayurveda is poised for growth and propagation and international acceptance and collaboration.

Today, the world over, traditional or commonly called complementary and alternative medicine is gaining ground. People are relying upon these gentler and less costly remedies. This is very encouraging. The people have the right to choose medical care. When the world is moving towards these systems and therapies for health care, the Indian systems of Medicine particularly Ayurveda must have its legitimate place and recognition in the world community. Ayurveda is not a practice or a therapy but a well developed scientific medical system.

I would like to share with you the recognition and interest shown in Ayurveda in other countries, We have a MoU with the Government of Russian Federation for education and research. Gujarat Ayurved University has signed MoUs with a number of institutions in other countries. Hungary has recognised Ayurveda and is proposing to start Ayurveda teaching. South Africa has also decided to start undergraduate and post-graduate teaching in Ayurveda. Medical Schools in USA are proposing to introduce sensitisation and orientation course in Ayurveda for their students. These are examples of growing relevance and acceptance of Ayurveda overseas.

The world community is now progressively realising the need for proper documentation of traditional knowledge, to recognise and protect the knowledge that belongs to the people and also to use it for the benefit of mankind. What has already been documented and is available in the public domain must be brought to the knowledge of the world community. India has taken an initiative to present its knowledge in the form of TKDL, which would be easily accessible, and retrievable in, English, French, German, Spanish and Hindi. This initiative has been commended by WIPO.

It is high time to look at the various aspects of Ayurveda and

equivalent Systems of medicine having holistic concepts and to revalidate their principles, remedies and practices. The modern scientists must take up the initiative to explore and unearth the truth behind their efficacy and put it in universally acceptable scientific language. The dire need is to break the invisible wall between modern medicine and non-conventional systems of medicine, particularly coded and organised ones and it is

more so in this millennium wherein changing pattern of environment, lifestyle, stress and strains of life would bring about extremely different scenario of individual and societal health.

In India, it is our accepted policy to integrate and converge medical care systems. A beginning has been made. Elsewhere, fundamental issues related to integration and convergence of different medical

systems are being raised on the future orientation of health systems. These issues mainly pertain to equity of access to health care and quality of care; the search for a new model that could integrate these factors; should begin now. And if the medical profession is required to be involved in health policy making and to be respected by society, it must adopt strengths and potentials of traditional and complementary systems of medicine."

## TRADITIONAL MEDICINE - ACCESSIBLE TO THE MASSES

*For centuries now, the bulk of humanity has relied on traditional systems of medicine. Even now, up to 80 per cent of the people in the developing world rely on traditional medicine (TM) for primary health care. The transition to independence for many countries across the world's continents also signalled some relief for traditional medical practitioners who used to get labelled as "witch doctors." Access to western medicine is recent and still limited in the developing world. Yet, in international circles, TM is still struggling to find its legitimate place. According to Dr. Ebrahim Samba, WHO's Regional Director for Africa, the resistance to TM can be accounted for in parts by forces of competition, a lack of understanding and a complex. For Dr. Samba, who looks after 46 countries, the biggest "evidence" for TM is that generations of people have survived using it. Following are extracts of a recent interview Dr. Samba gave to the South Bulletin.*

**Someshwar Singh**

**SB:** How would you describe the present state of TM in Africa?

**Dr. Samba:** I have been a doctor since 1958. And I started practice in Africa in 1961. And now I am regional director for Africa. I can tell you over 80 per cent of people in Africa use TM. In the colonial days, Western medicine was concentrated very largely in the capitals. As you go away from the city centres, into the rural areas, there was greater reliance on TM. So TM is African, has been there long before western medicine came. And many Western-oriented people like you and I use it after going to the western doctors. During the colonial days, some traditional practitioners were actually imprisoned because they were styled as "witch doctors."

**SB:** Are they not called 'witch doctors' any more?

**Dr. Samba:** Since independence, nobody calls them witch doctors anymore. The use of TM is a fact of life. It is also widely used in China and India. We are trying to introduce it in our systems. I know there is resistance from the western-trained doctors.

**SB:** What is the resistance to TM basically about - competition?

**Dr. Samba:** Partly competition, partly a lack of understanding, and partly a complex. In 1978, at the Alma Ata Conference (in the Soviet Union), the people most against the use of TM in primary health care were the doctors themselves. Because they were saying you are allowing people who have never been to school. It is unfortunate that some of us look down on our own traditions. We want to be civilised. We want to be westernised. We want to wear suits

and people who wear traditional dresses are regarded as uncivilised bush-people. Many western-trained doctors say "we don't understand this." Well, the fact that you do not understand it does not mean that it is not good. I ask some of my western doctor friends - "How many of the medicines you prescribe every day do you really understand?" We have been using aspirin for over 100 years but it is only in the last 6 years that we have begun to understand how it actually works.

**SB:** Biopiracy is a big issue. The pharmaceutical industry relies heavily on herbal extracts. Do you think the pace of this biopiracy would slow down as TM becomes more acceptable in the West?

**Dr. Samba:** When I was a medical student nearly 40 years ago, practically 90 per cent of the medicines

were not synthetic. They were from plants, animals, herbs and so on. Now, we know that some pharmaceutical laboratories in the West come to Africa, see some traditional medicines - herbs, plants and animal products - bring them to the West, refine them and then patent them. This is recorded here in Switzerland. So, you call it biopiracy or whatever - stealing of intellectual property - it is going on and will continue to go on. But not all pharmaceutical companies do this. Some traditional practitioners to identify these herbs. They take these herbs to America, look at the active ingredients and molecules and split the profits between the pharmaceutical companies, the traditional practitioners and the government.

**SB:** Do you have similar arrangements for Africa?

**Dr. Samba:** It is being developed. In 1995, when I took over the regional office, I started pushing for TM. These are some of the elements that will be addressed - the legislation, the intellectual property rights, which is a concept that is new.

**SB:** How do you compare the Western system of medicine with that of TM in terms of access?

**Dr. Samba:** TM is ours. It is accessible. Western medicines are expensive. Anti-retrovirals, for instance, are very expensive and we cannot afford them. As I said, in the colonial days, before independence, every village had traditional practitioners. Even today, how many of the villages have access to Western-trained doctors, let alone medicines?

**SB:** So the WHO strategy on TM - how would you translate that into action?

**Dr. Samba:** First of all, we know that certain traditional medicines are effective against malaria. They bring down the *plasmodium falciparum* - they do not just symptomatically bring down the fever and the headache. We know that some traditional medicines are effective against HIV/AIDS. They bring down the viral load. They bring up the CD4 and CD8 (indications of the body's immunity). Now, (there are) similar cases for diabetes type 2, hypertension, anaemia and so on. We are supporting these local laboratories in Africa to make sure that these traditional medicines when delivered do not do harm to the other organs like liver, kidney and so on. How would they work, what are the doses, etc? There is so much in Indian and Chinese traditional medicine. When we come to evidence, what evidence do you need more than that we have survived because of TM. Our access to western medicine is very recent and limited.

**SB:** But what about longevity as an important factor in the choice between traditional and modern medicines?

**Dr. Samba:** I am a doctor of many years. There is more to longevity than just medicines. Your earning income, the food you eat, the clothes you wear, general education - these are far more important than just medicines. Medicines contribution to longevity is minimal.

**SB:** There is a lot of uncertainty with respect to acceptance of TM in the West on a large scale. This growing insistence on evidence. Who is going to prescribe what as the rules of the game? Is it the well-accepted standards and principles for allopathic medicine which should decide the fate of TM?

**Dr. Samba:** Well, why should they? Western standards are different from traditional standards. Why should the Western standard be our standard? Why should our standard be the western standard? They are different standards.

**SB:** So, who is going to lay down the rules?

**Dr. Samba:** Exactly, who is going to lay down the rules? This is one of the big questions. The intellectual arrogance of some of us who are trained in the West (assumes) we know everything and we should lay down the rules. No way. They are different rules. We should be humble. And I repeat, how many of the western things do we understand?

**SB:** But someone has to lay down the rules?

**Dr. Samba:** We set our rules. The traditionalists will lay down their rules and they are forming associations, clubs etc. They have different standards. It is in progress. It is evolving.

**SB:** So, you think the western standards should not judge TM and give it labels?

**Dr. Samba:** This is wrong. Can you imagine me coming to India and setting up my own standards. Or someone coming from New York and doing the same thing in New Delhi. This used to happen and this is neo-colonialism and not compatible with democracy.

**SB:** Do you have any collaboration with WIPO, which may also be looking into the intellectual property issues in the field of TM?

**Dr. Samba:** I am sure they will come to that. But remember, traditional medicine is different from

synthetic medicine. I am a scientist. You start from scratch, you synthesise, it is yours. Whereas in the case of traditional herbs or roots and so on, the plant belongs to the community. I can claim the knowledge but how can I claim the property of the plant itself. And these are the issues that we are struggling with. In other words, the standards are different. And it is wrong for any tradition to lay down the rules for another tradition. It is immoral.

**SB:** TM has acquired so many different names in the West - health food, complimentary or alternative medicine. Do you know of any more?

**Dr. Samba:** The thing is anything that is not from the West is not good enough. And, of course, they qualify it. For instance, in the colonial days, anyone labelled as "witch-doctor" would qualify to be arrested and put into jail. I have seen it. But now that Prince Charles is involved, it is called 'complimentary' medicine. It is more respectable.

**SB:** Like in parts of Asia, do you have a "run" on medicinal plants in Africa, whereby bulk exports with low-value added could easily lead to extinction of certain medicinal plant varieties?

**Dr. Samba:** We have and one of our practices is to get these plants and get organised botanical gardens to grow them. We are involved and encouraging governments and practitioners - like in China and India. We have to be careful. In the colonial exploitation, they came and took our diamonds, our wood, our animals and so on. But now that we are in charge, I hope we will protect our flora and fauna. The colonialists did not care about our flora and fauna. In India and China, centuries-old traditions

have been much better protected.

**SB:** In the Global Fund for Malaria, Tuberculosis and AIDS - do you see any role for TM or is going to be purely a reliance on allopathic medicines?

**Dr. Samba:** I hope as we have proof of certain medicines against AIDS and malaria - that some of the Global Fund is allocated to TM. I will strongly recommend to the countries availing of this Fund to allocate part of this to TM. Already, we have problems with malaria resistance. It may well be that active molecule in this TM is the same as active molecules in quinine and so on. So we are extending the research. But what we do know is that this TM in Mali, Ghana and Nigeria brings down the *plasmodium falciparum*, the commonest cause of malaria in Africa.

**SB:** This link between TM and AIDS, has it been scientifically observed?

**Dr. Samba:** Yes, at the regional Committee meeting in Oagadou, Burkina Faso, I went to see this clinic - a missionary clinic where the patients were left to die honourably and with dignity. And a traditional practitioner came along and said he had a medicine against the disease. The doctors said "Go ahead, we have nothing to lose. These people are going to die anyway." Responding to the traditional practitioners, the patients started gaining weight and some of them got sufficiently better to go back to their farms. The Clinic got in touch with CDC (Centre for Disease Control) in Atlanta, USA, who sent them the protocol along with laboratory equipment. They followed up and found the viral load coming down and the CD4 and CD8 going up. So I went back to the meeting and said to the Ministers, "Please go and see the patients at this clinic.

**SB:** Is there some personal experience you would like to recount?

**Dr. Samba:** I am 75 years old. I studied in Dublin and then some time in Liverpool, followed by Fellowships in Edinburgh (FRCS and FRCP). It is a rare combination. Very few people in the English speaking world that have a double fellowship.

**SB:** How do you see the future evolving in terms of the balance between traditional and modern systems of medicine? Can it evolve on a fair a just basis.

**Dr. Samba:** It will not evolve on a fair and just basis because the playing field is not even. The comparison really is between a Formula-1 Ferrari and a donkey-cart. But I hope it will evolve positively. After attending the world health assemblies since 1974, and every time we talk about traditional medicine - but we look down upon it. In Alma Ata in 1978, the use of traditional medicines and practices were singled out because they were accessible to the masses. That was and continues to be a strong point. Whereas the western medicines are available to only two to three or five per cent of the population.

**SB:** Why has it taken so many years for the WHO just to formulate a strategy on TM?

**Dr. Samba:** The gestation period has indeed been too long. I was in there in the drafting Committee in Alma Ata, where the WHO and UNICEF discussed primary health care and in the 8 elements identified TM. But since then we have talked about it. Even now, we pay lip-service. At the press conference (16 May, 2002), I said it was 'hypocrisy'. When you travel all the way from Africa to pass a resolution here, please do something to implement it.

## CHINA'S PATENT PROTECTION OF TRADITIONAL MEDICINE

*As one of the world's largest repository of traditional medicine system, China has taken steps in recent years to protect this branch of traditional knowledge by way of intellectual property through patents. The way that has been done holds relevance for many other countries around the world where traditional medicine needs to have a similar kind of protection. The following account of China's recent experience in this field was given recently by Zheng Yongfeng, representing the Patent Office of China's State Intellectual Property Organisation.*

From April 1, 1985 when the Chinese Patent Law became effective it has been amended twice. The first amendment was adopted on 4 September, 1992 and the second one was adopted on 25 August, 2000. The number of patent applications relating to Traditional Medicine in the recent past was more than 12,000 cases. Most of them were domestic applications. About 1400 cases relating to Traditional Medicine were filed every year. From 1992 when the Chinese Patent Law was first amended, the applications of the Chinese Patent Office domestic filings relating to traditional medicine occupied an absolute dominant position over foreign applications. So patent protection of traditional medicine is one of the important means for protecting traditional medicine in China.

### Forms of protection

Usually patent law protects products, methods and usage. Before January 1, 1993, products and usage were not protected, but methods of preparing drugs were patented. After the first amendment of Chinese Patent Law, pharmaceutical products, methods and usage can all be patented according to Chinese Patent Law. This also applies to Traditional Medicine.

#### Pharmaceutical Products

Pharmaceutical Products which can be patented in the field of traditional medicine include traditional medical composition, herbal preparation, extracts from herbal medicine or com-

position, treated herbal materials, health food with herbal medicine etc.

#### Methods

The methods which can be patented in the field of traditional medicine include method of preparing the pharmaceutical preparation, method of extracting special substances from natural medical materials, method of treating the material, and natural medicine.

#### Usage

If a known drug was found to have any new properties, the new properties can be protected by Chinese Patent Law. For example, the known Chinese drug Sweet Root is known to have the effect of regulating the function of different drugs in a composition. If it is found to have the effect of curing AIDS by a doctor, this new property can be protected by Chinese Patent Law.

According to article 25 of Chinese Patent Law, methods for diagnosis or treatment of diseases shall not be granted patent rights. So, if a patent application is for a new use of a known drug is filed, the drafting of claims and description of the application is very important for the patent examiner. If it is described as a method of treating diseases, patents may not be granted. However, if it is claimed as a method of use in preparing drugs for treating special diseases (which is a new

indication of known drug), the applicant can be granted a patent right.

#### Requirements for grant of patents

Three types of inventions-creations can be patented, i.e. inventions, utility models and designs according to Chinese Patent Law. Most of the applications relating to traditional medicine are inventions. According to Article 22 of Chinese Patent Law, any invention for which patent right may be granted must possess novelty, inventiveness and practical applicability.

Novelty means that, before the date of filing, no identical invention has been publicly disclosed in China or abroad. Nor has it been publicly used or made known to the public by any other means in China. It also means that no person has filed previously with the Patent Office an application which described an identical invention but published after the said date of filing.

Inventiveness means that, as compared with the technology existing before the date of filing the invention has prominent substantive features and represents a notable progress.

Practical applicability means that the invention or utility model can be made or used and can produce effective results.

Concerning traditional medicine, novelty means that, no information on identical compositions

of drugs or identical substances extracted from natural material medicine was published before the date of filing the application or no identical method or use was published before the date of filing the application, relating to the method or use separately. The inventiveness about the patent applications in the field of traditional medicine are described as follows:

## **Inventiveness**

### ***Pharmaceutical Products***

A patented medicine may be a medicine made of one or more than one active substances. If a medicine is composed of or prepared from several material drugs for example herbal medicine in certain ratio and the composition is newly created, or a medicine is composed of or prepared from one active not-known substance which may be a material drug for example a herbal medicine or one extract thereof and other ingredients, it possesses the patent inventiveness provided that data to prove its effectiveness are submitted .

If a medicine is composed of or prepared from several material drugs for example herbal medicine and the composition is changed based on a known composition by changing its constitution or the ratio thereof, it possesses the patent inventiveness provided that the applied medicine has new indications or less side-effect compared with the known drug, or it is more effective than the known drug.

### ***Method***

Any new method of preparing drugs, of extracting or separating active substances from natural material medicine which is used in the procedure of pharmaceutical production can be

regarded as possessing inventiveness if the method makes the drugs more effective, for example to increase production, to decrease cost, to increase the purity of the extract separated from material drugs, or to decrease side-effects.

### ***new use***

Any new indications of known medicine which were filed for patents are regarded as having inventiveness if the data to prove the existing new indications are provided.

Practical applicability concerning traditional medicine relates to two things: one is that the pharmaceutical products must have curative effect; another that the pharmaceutical products must be produced industrially or the methods must be applicable to industry.

Except for the above base requirements of the law, another important requirement for the applicants is that a detailed description of technology relating to inventions must be disclosed sufficiently, clearly and completely so as to enable a person skilled in the field of traditional medicine to carry it out. Usually this is not desired by the inventors, but it is required by the patent law of China.

## **Experience with TM Protection**

Chinese Patent Law has taken important steps to protect the intellectual property of traditional medicine since 1985. As said above, only less than 10 years was used to change the objects of protection by patent law from method of producing medicine implemented between 1985 and 1992 into medicinal products implemented from 1993. In China

a patentee can protect their patented medicine in an administrative way or by judicial way, and all administrative procedures must comply with judicial decisions, which is contained in the second amendment of Chinese Patent Law. When any infringement dispute arises, if the patent for invention is a process for the manufacture of a new medicine, any entity or individual manufacturing the identical product shall furnish proof of the process used in the manufacture of its or his product. This regulation decreased the burden of proof on the patentee which may be difficult to obtain for them for Traditional Medicine.

China has published the "Regulations for the Protection of Intellectual Property by Customs" according to which the products infringing patent rights would not pass the customs.

China also joined the PCT (Patent Cooperation Treaty) and the Chinese Patent Office became an International Reception Bureau as well as International Search and Primary Examining Bureau of WIPO (World Intellectual Property Office) for PCT applications in 1994 .So this makes it easy for Chinese people to apply for patents for traditional medicine directly in China.

On 23 March, 1999, China became a member state of the Union for the Protection of New Varieties of Plants (UPOV) and on 23 April, 1999, China implemented the "Regulations of the People's Republic of China on the Protection of New Varieties of Plants" by which a new herbal medicine could be protected if it was first found to have a curative effect.

However, there are still some problems in the Protection of Intellectual Property in the field of traditional medicine. First, because drugs are special products. It takes 2-5 years to do research and pass

through the procedure of production approval before they are commercialized. If the patent application was filed at the same time when research work had been completed, the exact period of protection time is 2-5 years less than 20 years protection period as compared with other products. In this case, different countries have different measures to compensate

the patentee. China has not developed any such measures for compensating the patentee. Second, inventors may not wish to disclose their technology before the patent applications are granted. But Chinese Patent Law does not permit this because it requires the publication of the documents of patent application 18 months after the date of filing. Third, it is usually difficult

for the patent applicants to describe the constitution of traditional medicine clearly because, in many instances, traditional medicine is a mixture of many unknown substances, so it is also difficult for the judge to determine whether an infringement has taken place between a previously patented drug and the patent application. These problems will be addressed in the future.

## TK DIGITAL LIBRARY : ANOTHER TOOL FOR BIOPIRACY?

*It has happened in the past. Any tinkering of an original medicinal remedy with a little cosmetic covering can be easily presented as a novel product that was not previously known. For every successful revocation of a patent, whether it is neem, turmeric or ayahuasca, there are at least a thousand others that simply go unnoticed. Of the 4,896 references on 90 medicinal plants in the United States Patent and Trademark Office (USPTO) database, 80 per cent of the references pertain to just seven medicinal plants of Indian origin. In other words, nearly 4,000 patents or patent applications are based on the medicinal properties of plants that were already known. Thus, 360 of the 762 patents on medicinal plants that were granted by USPTO could be easily categorised as 'traditional.' But it is not easy to wage a battle against the 'patent' force of intellectual property regime. Without an international 'safeguard' mechanism to guard against such apparent cases of biopiracy, countries could as well go slow with their build-up of TK digital libraries, argues **Devinder Sharma**, a New Delhi-based food and trade policy analyst, in the following article written recently. Otherwise, biopiracy will gather greater speed.*

There is excitement in the air. India's proposal of setting up a 'Traditional Knowledge Digital Library (TKDL)' has been selected for a pilot study in 170 countries. And even before the ink has dried, digital library is being hailed as the answer to the ever-growing threat of biopiracy of traditional knowledge and folklore.

The digital library of traditional knowledge will have some 35,000 *slokas* or verses drawn from the available literature on one the Indian systems of medicine, Ayurveda. It will in addition have 1,40,000 pages of information, which will be easy to retrieve. These CD-ROMS will be made available to each of the patent offices world wide with the hope and expectations that the patent applications will be matched with the details provided so as to ensure that a patent is not granted on something that was traditionally known.

On the face of it, the digital library seems to be a wonderful weapon against biopiracy. After all, public outcry and outrage against some of the better known cases of biopiracy or thefts of traditional knowledge - *neem, turmeric, brinjal, ayahuasca* and *quinoa* - could have been avoided if those who granted these patents knew that the medicinal or insecticidal properties of these plants were widely known among the traditional communities in the developing countries. In technical parlance, these patents were based on 'prior art'. It is however not as simple as that. In a world where profit and greed has become the new economic mantra, private companies will go to any extent to manipulate what is already known to project it as an invention or a novelty.

Any tinkering of the original medicinal remedy with a little cosmetic covering can be easily presented as a novel product that was

not previously known. It has happened in the past. For every successful revocation of a patent, whether it is neem, turmeric or ayahuasca, there are at least a thousand others that simply go unnoticed.

The TKDL Task Force itself was astounded to learn that of the 4,896 references on 90 medicinal plants in the United States Patent and Trademark Office (USPTO) database, 80 per cent of the references pertained to just seven medicinal plants of Indian origin. In other words, nearly 4,000 patents or patent applications are based on the medicinal properties of plants that were already known. The Task Force studied the patents and interestingly found that 360 of the 762 patents on medicinal plants that were granted by USPTO could be easily categorised as traditional.

Does it mean that once the digital library is in place, the USPTO

will strike down these faulty patents? The answer is no. Does it mean that the USPTO will ensure that in future no such patents are granted? The answer again is no. After all, what is available in the Ayurveda verses is not scientific decoded language of the medicinal properties of the native plants. What is presented before the patent offices, on the other hand, is mired in technical details and legal complexities that is difficult to easily decipher. There are patent applications pending before the USPTO, for instance, which run into 1,000 pages. It has already been said that a complete examination of this patent application alone will not be complete before the year 2035 !

Take the case of a patent granted on the ailment 'dry eyes'. In the Indian literature, 'dry eyes' control has been spelled out through the use of leaves of Kumari plant (aloe vera). The remedy is to take few leaves of aloe vera, wash these in clean water and then crush the leaves. Put some drops of the solution that is extracted from the leaves into the eyes and the 'dry eyes' problem is taken care of. In the patent application that has been granted by the USPTO, the only difference is that clean water has been replaced with chlorinated water. And of course, there is enough technical jargon like temperature etc. to make it look as if it is a novel product.

The proposed digital library will therefore be only helping the companies to easily scout for the commercial uses of the medicinal and therapeutic properties from the database. A minor tinkering or value-addition will qualify it for the grant of a patent. And then, how will the infringement be checked, is something that has been very easily left to interpretation. Even in a country where patent and theft of intellectual property rights has become an emotive issue, it has been rather difficult to fight the piracy of

traditionally known products like basmati rice. The Ministry of Commerce has, in fact, issued a circular saying that it has no money to take the basmati battle any further. If the government has no money and the political will to challenge and fight the patent on basmati rice, which is a culturally and politically sensitive issue, it is futile to expect any meaningful challenges to any more cases of biopiracy.

To challenge and fight the patent infringements is simply prohibitive. In the case of basmati rice, the challenge came only from India while the scented rice is also grown in neighbouring Pakistan. Despite first making claims that it too will join the battle against basmati rice, Pakistan chickened out when the cost of the legal battle was worked out to something around US \$ 3,00,000. Not only the developing countries, even the rich industrialised countries find it difficult to fight the legal patent battles in the US Courts. A British company BTG, for instance, had a filed a case for patent infringement over the use of hover crafts in use by the Pentagon. BTG won and the Pentagon was forced to fork out US \$ six million in penalties. But the lesser known fact is that the company had spent a whopping US \$ 2 million towards lawyers' fees.

Even adequate protection and safeguards, as spelt out under the National Biodiversity Act, and in the Patent (Second Amendment) Bill 1999, does not guarantee that such patents will not be drawn abroad. In India, the grounds for rejection of the patent application as well as revocation of the patent include non-disclosure or wrongful disclosure of the source of origin of biological resource or knowledge in the patent application, and anticipation of knowledge, oral or otherwise. It has also been made necessary for patent applicants to disclose the source of origin of the biological material.

Other provisions include anticipation of invention by available local knowledge, including oral knowledge, as one of the grounds for opposition as also for revocation of patents, if granted.

In the absence of any global safeguards, the digital library will become a much wanted source of information on bio-prospecting for the private companies. If such digital libraries are constructed all over the world, the private companies will surely laugh their way to the banks. And if you are wondering as to why the World Intellectual Property Organisation (WIPO) and the UNCTAD is showing so much of interest in creating the database for traditional knowledge, the answer is obvious. Both these organisations are desperately pushing in for a system that legalises the monopoly control over what was traditionally known.

Documentation of traditional knowledge has therefore to be seen in the national interest before any move to make the community knowledge accessible globally. To say that such initiatives will come with benefit sharing is to duck the real and sensitive issues linked to its theft and misappropriation.

Perhaps this can best be done by stopping the documentation process and the subsequent creation of the digital database. Heavens are not going to fall if documentation of traditional knowledge and putting it in the form of a digital library is stalled till an effective safeguard mechanism is prepared. The only other plausible approach is to do what the Chinese have done. Between 1992 and 2000, China revised its patents laws twice to ensure that it could draw intellectual property control over its unique system of medicine. China has drawn a total of 12,000 patents on the its medicine system and therefore does not have to worry about constructing a digital library.

## HEALTH CRISES NEED \$25 BILLION ANNUAL GRANTS - JEFFREY SACHS

*Twenty-five million people are dead already by the AIDS killer virus and 65 million stand affected. "This is death on the watch of the world's leaders right now." It was not one of the voices of public rage that swept the UN-AIDS Conference in Barcelona last week but the studied observation of the Harvard economist Professor Jeffrey D. Sachs who was the main invited speaker at the recent World Health Assembly meeting in Geneva. "Time is lives right now," he said, "We are just going to face a tragedy of profound proportions that will shame our generation if we do not do more." At a press conference before addressing the Assembly, Prof. Sachs talked about the main findings of the WHO's Commission on Macroeconomics And Health, which he chaired, and what the rich countries, international organisations and the pharmaceutical industry should be doing. Despite a grim picture of progress, he strikes an optimistic note. But strangely, the Commission saw more evidence of TM as being 'dangerous' and 'expensive.' Following are excerpts from Prof. Sach's introductory remarks at the press conference and his responses to questions.*

### Key Findings of the Report

"The conclusions are clear, striking and important. Basically, there are three conclusions. Health is at the centre of the development challenge, not only because health is the outcome we want from economic development but because health is one of the essential inputs into economic development. When poor countries are besieged by diseases, they also cannot achieve economic progress. So health has to be at the very core of a global strategy to fight poverty. Investing in health is investing in poverty alleviation as well as in the direct improvement of human well-being. Second conclusion was: to undertake this struggle in the poorest countries, means the fight against AIDS, TB and malaria and a relatively small number of other major killer diseases - we need to focus and conquer conditions that are claiming millions of lives unnecessarily in the sense that these are conditions or diseases which can be prevented and when not prevented, can be treated. Yet we found that millions of people die every year because of preventable or treatable diseases because they are simply too poor to gain access to the life-saving health interventions. The third conclusion of the study was that to finance the investments in health which are at the core of the investments in development, the rich countries have to be partners

of the poor because there is no way these countries on their own, no matter how they try or organise themselves, will be able to finance this effort without the rich countries doing vastly more than they have before.

We found on the one hand, that the amount that is needed, sounds rather large - around \$25 billion per year. Precisely, we said by the year 2007, the rich countries should be giving in grants \$27 billion for health. It sounds like a large number. Indeed, it is, compared to the current levels of aid. But fortunately, the rich countries are so vastly rich now - \$25 trillion a year in income - that to finance the life-saving interventions would require a mere one penny of every \$10 in income in rich countries. That would make a pool of resources each year of around \$25 billion which, according to the studies of the Commission, would save around 8 million lives every year. That is the real choice before the world. It is the best investment available in the world. It is so good that we are actually going to make it. Not everybody knows that yet. But they are learning. We have for the first time in a generation, the rich countries beginning to increase their donor assistance again. We have for the first time, a new global fund to fight AIDS, TB and malaria, which the WHO and many of the rich countries have played an instrumental role in and which, for

the first time in 21 years of the AIDS pandemic, is now going to finance access to treatment as well as prevention programmes in the poorest countries. We are still nowhere near where we need to be but the tide is turned and the Commission report is going to have its day. It is such a powerful need that I am quite optimistic that we are going to get there."

**Q:** How do you get the rich countries to be good partners? And, any message for the World Bank and IMF on their structural adjustment conditionalities and the WTO as they all affect resources for development?

**Prof. Sachs:** I have messages for all of them and tried to deliver them in the report. To the IMF, I would say the core task of the IMF for the poor countries is to help shape a macro-economic framework to achieve development goals, not merely to stop inflation or to balance a budget. The test for the IMF is not whether prices are stable and people are dying. The test for the IMF is whether countries are meeting the development goals that the world community has called for. The answer overwhelmingly right now is no, they are not meeting those goals. And for the past generation have not been meeting those goals. We have to do things differently in the next 15 years to meet those goals. That is what the report is saying - we need a lot

more donor assistance which needs to be core part of the strategy on macro-economic framework. And we need to challenge conditionalities on both sides - donor and recipients - that the bottom line is meeting goals that the world community has established: reducing infant mortality by two-thirds; maternal mortality by three-fourths; curbing the pandemics of AIDS, TB and malaria; and reducing hunger by at least half. This has not been on track for the poorest countries. This is the only standard in my view that can be legitimate in international environment where the whole world has stated its intentions to meet these goals. So the international institutions all have to shape their programmes around these development objectives. I met the Managing Director of the IMF recently and he is committed to shaping the IMF programmes in this way. I will try and do my bit, at the technical level, to see that is the case. There are needed changes in procedures to have the IMF play that constructive role which it can play.

Now for the rich countries - I do not know if my job is really to be a nuisance because I am going to keep saying that this cannot be done without help from the rich countries. Without more donor resources, millions of people are going to die every year. This is death on the watch of the world's leaders right now. There are ways to stop these deaths but they require resources and skill and neutral commitment and partnership. They can't just be wished away. All of the good rhetoric in the world will not curb the AIDS pandemic. We need good anti-retrovirals, prevention programmes and comprehensive efforts and that costs money. That is the message. For a long time it was tried without resources and now we have reached 65 million people affected by the killer virus. Twenty-five million are already

dead. The pandemic is reaching the highly populous centres of Asia. It is too devastating to ignore any longer. The opportunities - technologically, organisationally and politically - are finally at hand to do something about it. Even in the United States Senate now we are seeing responses that we have not seen before. But we need to keep showing the evidence, keep calling honestly for what will be needed. We are just going to face a tragedy of profound proportions that will shame our generation if we do not do more.

**Q:** Is the Global Fund going to be the main way this money is going to be channelled?

**Prof. Sachs:** I think the rich countries cannot yet gauge what they are really going to do. We have turned the corner but once they turn the corner, they are going to see ahead farther than they have before. I was quite optimistic that the Bush Administration would increase aid at a time when people least expected it. President Bush, for the first time in 20 years, called for an increase in foreign assistance and quite a substantial, meaningful increase - by \$5 billion per year relative to base line in this plan. I would say to the President and the Congress "We have to do more and I'll bet that we will do more just as I bet we do this step because for a country that earns \$10 trillion a year can afford to do more and a country that aspires to lead a world coalition for freedom and against terrorism, we are going to have to do more and we will. Others (Canada and Europe) are evincing clear evidence now, reversing a generation long decline in development assistance and showing readiness to do more. But again, when you turn the corner, you see the road ahead more clearly. We are going to go farther than we think right now because the benefits of doing so are going

to be vast for the rich countries as well as for the poor countries.

On the Global Fund, we recommended in the Commission that it be the channel for a little less than a third of the total - we said \$8 billion a year, that is a correct number and I stand by it. (UN) Secretary General Kofi Annan estimated \$8-10 billion year. We looked hard at these numbers - harder than anyone else before or up to this point and \$8 billion seems to be what is needed through the Fund. That leaves a lot of room for a lot of other programmes but it means scaling up what the Fund is doing by about tenfold compared to what is probably going to happen.

**Q:** Could you breakdown the total of \$8 billion for the Global Fund and say what is should be used for ?

**Prof. Sachs:** First, the Global Fund is to fight AIDS, TB and malaria. Those are the three critical conditions but the report stresses that the fight against disease in the impoverished countries is broader than that. It is to improve basic health care access, to fight against diarrhoeal disease, respiratory infection, maternal deaths in child birth, nutritional deficiencies, vaccine-preventable diseases and so forth. The Global Fund has its specific challenges. AIDS is certainly the most dramatic and compelling challenge of any sort the world faces in modern history and it could well become the greatest pandemic in all human history if we do not change what we have been doing - which is not enough. But the Fund is only part of the story. We need a range of strategies. The Fund is designed to elicit proposals from the countries themselves to fight these three diseases, to judge those proposals on scientific merit, to monitor epidemiologically - and financially for that matter - what is happening with the diseases, to implement and to evaluate the implementation,

even to audit financially the process. So this is a marvellous new tool that enables donors to get the job done much better than if the 22 donor countries tried to do this simply on their own. This is the best friend of the donor countries that want to fight these diseases and we are only at the beginning. It has been set up with remarkable speed, not relative to the age of the epidemic - because a shockingly and dismayingly long time was taken to start this scaling up - but from the time that Secretary General Kofi Annan launched this proposal in Abuja, Nigeria, in April 2001 till now, this is a lot of progress for a complicated international process. I would urge that WHO be given more tasks and ways to lead on this to achieve the scaling up as fast as possible because time is not just money, convenience and doing something better - time is lives right now. Every day we are losing thousands of lives unnecessarily. Every month and year, we are losing millions of lives.

**Q:** Could you specify where exactly the money from the Fund should go - to treatment or prevention?

**Prof. Sachs:** Everyone of these diseases should be both prevented and treated. Prevention and treatment is the right public health strategy, whether it is malaria, TB or AIDS. We have life saving and life extending interventions in all three of them. We also have the technology to prevent the spread of these infections. In the case of AIDS, we recommend spending roughly one-third for prevention, one-third for treatment of opportunistic infection and one-third for anti-retroviral therapy. For malaria, we recommend prevention through insecticide-impregnated bednets as well as treatment through better case management and accessibility of new combination drugs and other improved case management approaches. And TB, we could not

more strongly endorse the WHO long-standing strategy of directly observed therapy (DOTs) short courses, the most effective intervention to cure TB and also through surveillance and DOTs to prevent the transmission of TB within crowded urban slums and other environments in which the disease is transmitted. The biggest cost is AIDS right now but malaria definitely needs a couple of billion dollars a year. TB needs a scaling up of around a billion dollars per year to extend DOTs. AIDS, of that \$8 billion, would be about \$5 billion divided roughly in the ways that I said but with an amount that will grow overtime until this pandemic is decisively turned.

**Q:** How can the WHO get more involved with the Fund? Is there a political problem there?

**Prof. Sachs:** Let me give you an absolutely strong and straightforward assessment. I come from a country where a lot of people roll their eyes at the UN in general and at the specialised UN agencies. I cannot tell you how utterly impressed I am with the professionalism and the capacity of the WHO and the readiness to take on these challenges if given the opportunity. But I know politically among many of the major countries there was a sense "We need to keep this out of the UN system" or "we do not want this tied down in regular UN bureaucracy" and so forth. My assessment is that delayed things, because the specialised agencies are uniquely qualified in their respective spheres to help the world achieve its shared goals. In the area of disease control, WHO is an absolutely essential institution for the world, one that we should be cherishing and building up at every opportunity. Ironically, as the report itself discussed, these specialised agencies had their budget frozen at the time when the AIDS pandemic and the resurgence of

malaria and TB have put incredible, unprecedented challenges before us. It does not make sense for the rich countries that aspire to help solve these problems to try to do so with one hand tied behind their backs. By that I mean to do so without empowering the very institutions that could play such an essential role in achieving success. Where could the WHO, and I would add by the way - UNICEF, World Bank other specialised institutions - where could they play a role in doing this? The Global Fund has just announced grants for a number of countries. I would hope that the WHO and other UN agencies that are on the ground in every one of those countries - is given the chance to help put those new programmes into place, to help setting epidemiological baselines so that we could actually know what the disease levels are right now and can measure the progress or regress, can help at the technical assistance side with the necessary training and organisation. For countries that have never used these medicines before, WHO issued wonderful guidelines on anti-retroviral therapies last month because the expertise is in-house. But I have just come back from Africa - from visits to three countries where I know that there is no training on the use of these drugs because they have not been available at any scale up until now because countries have been too impoverished to use them.

Again, I would speak as a North American to my own countrymen, if we understand these institutions which we helped to create, they are critical for us to help meet our own goals.

**Q:** Is privatisation the correct answer for health systems?

**Prof. Sachs:** Public health has its name in part because you need public institutions in order to help manage the challenges of health.

The private sector can never by itself manage disease control, the research and development necessary for technologies to fight disease, the surveillance of infections and epidemics and the provision of health services for the poor who cannot afford the market price. So there is a very powerful role for the public sector in public health. In my view, it is an irreducibly central role. Now, the private sector can also play a role in delivering health services, in drug development and help challenge the public sector when it gets lazy and monopolistic in provision. A mixed system in which there are both public and private providers of health can be a stimulus for new approaches, more competition and more alternatives. So our report emphasises the central and irreducible role of the public sector. It cannot be privatised away. But also leaves open room for the private sector at many points of delivery. We need both.

**Q:** What is going to be the role of pharmaceutical industry in relation to this Fund, as there is little to nothing of this industry in the third world?

**Prof. Sachs:** We recommend that the pharmaceutical industry, especially the patent holders on many of the essential drugs to fight AIDS and the other diseases should provide those drugs to the Global Fund or to donors or to the poor countries at the cost of production rather than at a margin protected by their patents. In other words, we say the companies should agree to provide their drugs at the lowest commercially viable price - the price which covers their cost but no more. Within rich countries, their intellectual property rights should be respected. They should earn good market returns on their R&D so that they get the incentives to develop new drugs. But for the poorest countries, they should provide the drugs at cost. We

strongly recommend differential pricing as the approach. We also say that when a generics producer - a non-patent holder can provide these drugs at lower cost, they should have the right to bid because the public health needs should take precedence for the poorest countries. This is the spirit of Doha and we believe that within the international trading system, this approach can and should be implemented. We believe the pharmaceutical industry can play a constructive role in this and believe that they will play such a role. I should add that on the basis of my discussions with almost all the major pharmaceutical companies - they are prepared to play that constructive role. But they cannot do that without the Fund operating at a proper scale and with proper funding.

**Q:** With regard to proposals for the Global Health Research Fund to help build capabilities in developing countries, what about its funding and governance?

**Prof. Sachs:** If you look at achievements of the pharmaceutical industry in providing drugs in the last 30 years, the National Institute of Health in the United States has been fundamental in providing the science that has gone into the new drugs. NIH is one of the great achievements in the United States and in biomedical science. Certainly, my own vision of Global Health Research Fund is that it is the NIH for the world - so it would be a WIH rather than an NIH. It would operate on the same principles, which would be peer review and scientific excellence but it would be directed at the challenges facing the poorest peoples in the world, which are not the same health challenges facing the richer people. That is the major theme of why we need a Global Fund because NIH does not do enough research on diseases facing the poorest people in tropical

locations. Those are not naturally the central concern of an American institution. The same could be said of the European and many other institutions. And the institutions in the poorer countries that are concerned about that do not have the money to do it. So the idea is to have research funding at a large scale for basic and applied sciences for the diseases of the poorest of the poor. The money really has to come from the taxpayers, by and large. Private industry is not fundamentally charitable institution. Even the proposal that private industry provide its drugs at cost is not calling for charity. It says do not lose money on the poorest countries - just do not make money on the poorest countries because if you raise prices they will not be able to buy the drugs from you anyway. So I do not view private industry as the way to finance global public goods. We can view them as partners in public-private partnerships where the private industry contributes on the basis of its expertise. But somehow, in the long term or the short term has its cost covered or its returns on investment covered. I think we should distinguish - we do not say to the pharmaceutical industry "you fund the NIH" - we say that to the taxpayers. To the pharmaceutical industry, we say "Go make profits by developing new drugs that people want in our country. It just does not work for the poorest people in the world because there is no market for those drugs. We believe that if you had the basic science funded and you had a market for drugs for people through increased funding through the Global Fund to fight AIDS, TB, and malaria - through increased donor purchases for other diseases, through increased purchases of vaccine through GAVI (the Global Alliance for Vaccines and Immunisation), we would both create the market incentive for the private sector and the basic science on which they could draw upon to achieve the

same kind of throughput on the R&D that we get in the United States for diseases that concern us. It therefore means both creating market demand - in this case through donor funding - and scientific capacity by and large through public sector funding through an international effort.

**Q:** Does the Commission recognise the role of traditional medicine on which the 70 to 80 per cent of the people in developing countries depend on and what is the WHO doing to promote TM?

**Prof. Sachs:** The Commission actually heard a lot of evidence that a lot of traditional medicine is not only without scientific basis but extraordinarily costly to households and damaging of their well-being and health. That is not a blanket statement. It is a warning. The warning that I would give is that because something is called TM, it is neither politically correct nor incorrect, necessarily valid nor invalid. It should face the same kind of scrutiny as any other kind of interventions. There are some traditional medicines that become the breakthrough for the whole world. Where did quinine come from, if not from the cinchona bark that was a traditional Peruvian anti-pyretic. What is probably the most important anti-malarial for the next generation from artemisinin based compounds, a traditional Chinese remedy. I also know in trips through Africa in last three years that some of the traditional remedies for AIDS are useless - they may speed death and suffering. They come under 'traditional' rubric but they have nothing to do with controlling the HIV virus nor the opportunistic infection that it causes. So I would appeal, and I know that many places around the world are doing this now, to accelerate the research on the traditional approaches. We are going to find wonderful things - new

anti-malarials in herbal treatments. I have heard recently of investigations of new herbs in the Sahel which may be promising. I would also urge us to have the same empirical standards that we would apply for any new drug coming. So, we have to keep an open mind. We heard plenty of evidence of a lot of damage done in a lot of places in the name of traditional approaches.

**Q:** Is the pharmaceutical industry laying down pre-conditions for discounted drug supply?

**Prof. Sachs:** Their focus is where they make their money. They are ready to participate and have already made drugs available at much lower cost. I believe that the cost can be reduced further. They can be much more pro-active in making the supply lines of these drugs reliable. They can be more pro-active in licensing their technologies to producers of these drugs in low-income countries and I think they are going to be prepared to do so because it is not as if they are making money in these poor countries. It is more a matter of neglect than profits or losses. These are not just markets for them. So I do not think it is so much pre-conditions. I think it is a matter of organisation and extent of attention. I long believe that we need a scaled intervention to fight these diseases - that is scaled enough to demand participation of all the stakeholders and to be able to monitor effectively what they are doing. But we are not quite there yet. With the Global Fund releasing money for treatment for the first time, well there is going to be a lot of eyes watching what the pharmaceutical industries are tendering their drugs for. I am going to be watching because I have been told a lot of things about their willingness to provide the drugs at cost and am going to be monitoring

every one of these transactions that I can. I hope a lot of other people do too. This system has not started going adequately as yet. The drug companies have for the last couple of years expressed their willingness to provide the discounts and they have in many cases. But we also know that there have been some serious glitches in supply reliability. And what the drug companies discovered, and which did not surprise me for a moment but did surprise some of them, is that just because you discount prices it does not mean the poorest countries can take you up on anything. The fact is that whether the drugs are at \$350 per person or \$10,000 per person, it is too much for the poorest countries and the only way this is going to work is through a combination of efforts. That is the point. You need the drug discounts, the Global Fund buying those drugs at their lowest prices, WHO with its expertise on the ground, and you need political commitment within these countries to set up systems so that these drugs are not diverted in the black market so that supply chains are effective. Whenever you have four or five things to get done, everyone can say "Well, I do not have to do my part because the others are not in place." We have been operating at that kind of a breakdown for quite a long time. We are finally reaching a stage when all of those components are falling into place. In at least a relevant number of countries, we are going to have programmes with WHO on the ground, commitments of the companies and donors, finally supplying money to help provide the anti-retrovirals. The thing now is to see that all of these commitments that have been made are really put into operation. Let me stress that they will be.

## PATENTS COVER KARAWILA CURE FOR HIV

*It tastes so bitter children normally avoid it. Known as bitter melon in China, karawila in Sri Lanka and karela in India, bitter gourd has been grown and eaten in China and South-East Asia for centuries. It is known to be an anti-infection and anti-tumour agent. The age-old remedy has now been patented as "Plant protein useful for treating tumours and HIV infections" in USA (US 5,484,889), the European Union (EP 552257) and in Japan (JP 6501689). This story of the bitter gourd is told in the following article written by Jagath Gunawardena. It appeared in a Sri Lankan publication - The Island - on 26 June 2002. The article traces how the current rush for patents has led to the illogical predicament of "owning viruses" and how medical research itself may be hurt. The author also believes that patents covering the 'MAP-30' protein, derived from bitter gourd, are another example of biopiracy and the victims are China and the other Asian countries.*

The development of effective cures and preventives against life threatening diseases has been predominant concern of medical researches and scientists. These have been always done in the name of public interest or for the sake of humanity. In the past a successful new drug would invariably bring in profits and recognition for those who were behind it, but their motivation was to serve the people and not personal enrichment. This has changed during recent times and the emphasis is now on profits. This change has come about due to the greater involvement of the private corporate sector in medicinal research.

It is now common to see that many of the new discoveries becoming the private properties of individuals and firms with the help of intellectual property laws that grant patents over them. This is not confined to new drugs and their manufacturing processes, but has extended to therapeutic methods and even disease-causing (pathogenic) organisms. These have brought about a large number of hitherto unknown and unimagined problems, stifled a lot of research, delayed critically important research, increased the prices of drugs and diagnostic kits. The end result is that thousands of people have been denied the opportunity to live a healthy life.

Among the large number of viruses that cause diseases in

human beings are those that belong to a sub-family known as retroviruses. The most notorious in this group is those that are known as Human Immunodeficiency Viruses (HIV) that causes the condition known as Acute Immune Deficiency Syndrome (AIDS). These viruses attack and destroy the immune system, making people vulnerable to other diseases. There are lots of scientists working on this disease who are investigating everything from the different forms of HIV to finding cures or arresting the progress of the disease and its prevention. These efforts draw in a lot of attention and appreciation from all concerned people throughout the world who wishes to see this disease eliminated.

There are, at the same time, a number of subtle manoeuvres that are taking place which go against the public interest. These are done by those who want to cash in on the disease and are mostly hidden from the public eye. There are different variations of the HIV and there are efforts to identify these in order to develop more specific and effective cures. At the same time, some groups are in the process of identifying these in order to lay exclusive ownership over these strains.

The *Institut Pasteur* (Pasteur Institute) of France got recognition as the first research body to identify the HIV and received a lot of

appreciation for the efforts. They were taking steps to own these virus strains by patenting them.

The first ever patent issued to cover a strain of HIV was granted in 1991 and it went to the *Institut Pasteur*. This patent, US5,019,510 covers a strain identified as a variation or mutant of the HIV-1 virus. Since then, others have joined the race and ten years later, we find more than a dozen patents covering different variations of the virus. The claiming of exclusive or monopoly ownership of a disease-causing organism, and moreover for one that causes a lot of suffering and even death seems an irrational idea to many. It seems illogical how such things can be deemed as properties, which means something valuable.

For those who seek to gain profits from everything that has to do with these viruses, they have now become "their viruses" by virtue of these patents. These patents makes it mandatory to seek and obtain permission from the assignees to conduct all research. This research does not only mean those which are done in order to find cures but include all others such as developing of identifying methods, detection, making and use of all antibodies and testing of new drugs.

The other, comparatively better known, are those patents that cover new drugs and treatment methods. These patents have considerably increased the price of drugs. Another bad effect of these patents is that the profit motive prevents the development of drugs which are high in curative potential but give only modest profits. The other adverse effect of patenting is that research is not given to the public through other sources, especially if the patented cure is widely available and can be used in other ways which are quite simple, and easy to make and administer. The best example for the latter is the patent titled "Plant protein useful for treating tumours and HIV infections." Patents have been issued for this in USA (US 5,484,889), the European Union (EP 552257) and in Japan (JP 6501689).

The plant protein covered by this patent has been obtained from karawila or bitter gourd (bitter melon in some countries). The patent lists eight inventors, the principal inventor being Sylvia Lee-Huang. The patent is assigned to the US Government, the New York University and American Biosciences. This patent has only one claim, which covers a purified protein known as MAP-30, extracted from the fruit and seed of Bitter Melon (*Mormodica charantia*) and the amino acid sequence of this protein. A perusal of the patent document reveals it extends to cover the process of identifying and purification of the MAP-30 protein, the DNA sequence that encodes it and all cells modified with the addition of this DNA sequence that can then produce this protein. It also covers treatment methods of HIV, either using the

protein alone or in combination with other drugs. In addition it covers the treatment of tumours using MAP-30.

The document provides ways of obtaining MAP-30 protein in larger quantities with the help of genetic engineering. It gives examples of various promoters that can enhance the production and how to incorporate these new (recombined) genes to plants other than karawila to get a better yield of the protein. Another is to insert this gene to micro-organisms.

The best way, according to it, is to produce it by using insects. The method that is recommended is to first modify a virus that infects insects by the addition of the MAP-30 protein gene and then infect the insect or cultures of insect cells so that this gene is inserted to the genetic make-up of insect cells. The desired protein can be produced by using either the insects or by the use of insect cell cultures. The best results have been obtained by using larvae (caterpillars) of insects and insects modified with this gene would produce MAP-30 up to 20 per cent to 50 per cent of the total protein production.

The bitter gourd is found in many Asian countries where it is used both as a vegetable and as a medicine. In Sri Lanka, it is used to treat skin ailments and diabetes. It has been used in China since ancient times to treat infections and tumours. They have been eating the ripe fruit with the seeds to treat these illnesses. The effectiveness of these ancient medicinal plants in treating virus diseases had been subjected to a lot of research by Chinese

scientists. Among them has been Lee-Huang, who subsequently went to the USA and then started patenting the work she was involved in when in China. Lee-Huang herself had admitted in an interview to Bio-world Today (Age old folk remedies resurface as recombinant anti-HIV, anti-tumour therapeutics by Davil N. Leff 23.10.1996) that bitter melon had been widely eaten in China and had been used in China and South-East Asia for centuries as an anti-infection and anti-tumour agent. Therefore, these patents that cover the MAP-30 protein are another example of biopiracy and the victims are China and the other Asian countries.

It is sad to note that this simple, safe and effective remedy is kept hidden from the large numbers of HIV-infected people who would have derived benefits from it. The reason for this is profits. The National Institute of Health (NIH) of USA has been trying to get an industrial venture to get this patented product to be produced commercially.

It is the monopoly provided by the patents that has made it possible for them to keep others from making this protein. However, it does not prevent others from using this remedy without infringing the patent. The best way for a country like Sri Lanka where the karawila is widely grown is to advise patients to eat the ripe fruit, together with the seeds. The MAP-30 protein is found in the largest quantities in mature seeds and ripe fruits. Another is to make extracts and have them widely available to the needy. In this instance, we do not have to wait for a drug, but creating awareness would go a long way to help the needy.

## TK IN WIPO - A LONG WAY TO GO

*The search for a just reward in terms of intellectual property for the custodians of traditional knowledge systems and practices does not appear to be moving on a fast track. The third session of the Intergovernmental Committee (IGC) on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore was held in the World Intellectual Property Organization (WIPO) 13-21 June, 2002. The state of play in these talks - an area where developing countries have high stakes - was summarised by Mr. Francis Gurry, WIPO's Assistant Director General in the course of a press briefing on 25 June 2002. Following are excerpts from Mr. Gurry's briefing and responses to questions posed for the South Bulletin. The fourth session of the Committee will be held on 9-17 December, 2002.*

**Someshwar Singh**

"The bottom line is that there is an important international recognition of the importance of traditional knowledge and TK systems, and the importance of finding means of preserving the knowledge systems.

What I have to talk about today is a fairly abstract area. As you know, the IGC, which has a rather large terms of reference and they are looking at, in principle, two distinct but related questions.

### Genetic Resources

The first of those questions relates to access to genetic resources and benefit sharing - obviously a very important question - with biotechnology having such a high profile economically and technologically at the moment because genetic resources, if you like, are the oilfield and access to them is access to the oil of the biotechnology economy.

The Convention on Biological Diversity (CBD) establishes certain principles. The first of those is that each country is sovereign over its own genetic resources. The second is that a party external to the country may have access to the country's genetic resources only with prior informed consent of that country. Now the question arises from the intellectual property point of view - what if someone has access to a genetic resource and develops an

invention based on that, modifying in some way the genetic resources or form in some other way a part of an invention.

We are doing two things in respect of that. The first is that we have set up a prototype data base of contractual practices and contractual clauses relating to access to genetic resources and clauses which concern the exploitation of any intellectual property that may be developed on the basis of those genetic resources. So, (*it is*) ways in which you might share some of the profits from any invention you develop on the basis of the genetic resources with the custodian of the genetic resources in the countries concerned.

So, it is a non-legislative, practical measure - endorsed by all the member states unanimously across the spectrum as a good idea. It is a practical tool which will provide assistance in particular to developing countries. We think it is a very useful product. Now obviously, we have a fair way to go in its further development. We have the basic data structures in place and we will now be sending out, with the approval of our member states, a questionnaire to universities, companies, administrations and so on, asking them to provide us samples of contracts that correspond to this particular area so that we can enter the details

in the data base for our guidance and eventually, best practices in this area.

The other major thing we are doing in that area is that we have been asked by the last Conference of Parties to the CBD (April 2002) to undertake a study on the relationship between prior informed consent, genetic resources and patent system. To go to the crux of the matter, the issue is the following: We have a patent application that uses genetic resources, or the invention is based in some way on genetic resources. Should the patent applicant be required to disclose the origin of those genetic resources as part of the patent procedure? That is the first question. Secondly, if they do or are required to do so, what will be the consequence of non-compliance? They do have very different views amongst the member states.

If you look at the European Community Directive on Biotechnology, for example, in one of the recitals of its Preamble, it says, "it is a desirable thing that applicants should cite the origin, the source of the genetic resource that is used in the patent application. But they do not attach any consequence to non-compliance. Certain other countries but a limited number, particularly those rich in biodiversity (like the countries of the Andean Community - Ecuador,

Peru, Bolivia, Venezuela and Colombia), would like to see as a consequence of the non-compliance, the invalidity of the patent. But this is by no means a generalised view. Our mandate is to do a study on these questions - in the course of the next 12 months.

### Protection of TK

The second question which is related but distinct is the protection of TK. Why is it related? Because historically, the first appearance of TK in an international instrument was in the CBD. A certain class of TK is associated with genetic resources - for example, relating to the use of plants in traditional medicine - but that is not the whole universe of TK, there are others like cultural expressions. What we have done in this Committee is to examine two principal questions. One relates to the "defensive" protection of TK. That is making sure that an outside party does not obtain an intellectual property right over TK that belongs to someone else. Examples are the patents that were taken on *neem*, *turmeric* etc. when they are already known and part of prior knowledge. What we have done there is to establish a portal through which you can have access to a number of data bases that have been prepared by other states on disclosed or known TK. One such data base is on CTM (Chinese Traditional Medicine). Another one is on Ayurvedic medicine in India. This puts into a more systematic presentation and makes more widely available known or disclosed TK. These are measures that have been endorsed uniformly by the member states.

The other area is the "offensive" protection of TK - how traditional or indigenous peoples might acquire their own intellectual property rights that they can assert over TK. There, we are making progress but are a

long way from having any answers. We have done a lot of work but have been told to do further work on the question of definition of what TK is, how do you distinguish it as deserving protection. There are also certain conceptual difficulties in applying the largely Western-inspired knowledge of intellectual property system to TK systems. They are, in effect, two completely different knowledge systems. TK systems are governed frequently by traditional protocols about who may have access to the information, who may use it, who may use a particular design. There may be a whole series of customary protocols which govern the knowledge. The knowledge is generally collectively held. It does not have a known starting date. It is a living body of knowledge. So how do you apply our system which is rather author-centric or individualised system in the West to the TK system. These are the questions we are continuing to investigate and we are a long way from having any solutions on them but work is in progress.

**SB:** What you call "offensive" protection of TK - are you referring to the *sui generis* system?

**Mr. Gurry:** That is right. We are talking about the *sui generis* systems. There is a genuine and highly concerned constituency. African countries are extremely supportive of this, in particular in the area of folklore - TK cultural expression. They are very much in support of the establishment of a *sui generis* system. But they are not alone. Most of the Latin American countries and many of the Asian countries are in the same category. The ones that are the least enamoured of the notion are the OECD countries. So, while there is a genuine constituency, how to satisfy (them), that is a very difficult question.

**SB:** There are fears expressed that compilation of data bases may actually increase biopiracy by facilitating access to TK?

**Mr. Gurry:** I think it is a very legitimate concern. It is a concern from two points of view. The first is that in our enthusiasm to ensure that unauthorised parties do not acquire rights over TK, we have to be careful that we do not destroy the capacity of the custodians of TK to get their own protection. So if we were, for example, to disclose in a data base information that is already secret, we would be destroying the novelty of that information and the possibility of traditional owners of acquiring perhaps their own rights over it. That is something we are always conscious about and always say databases of disclosed TK.

The second is that we are making it more accessible throughout the world and it does mean that it opens up the possibility of everyone to be more familiar with these areas. If you look at the databases, you will see that in the Chinese Traditional Medicine (CTM), for instance, they give the Chinese name, the Western name and the common names. So it does make it much more sensible. We do not think it is a bad thing. We do not think it is different from the treatment of any other knowledge - traditional or otherwise. One of the objectives of the intellectual property system is to get the knowledge out there so that people can use it. We do that by creating a period of exclusivity over the use of the knowledge and thereafter, it is in the public domain.

One of the main goals is to have this information more accessible so that people do not get patents. For example, items of knowledge which have already been disclosed. The Indian database, for example, have demonstrated that if that had

been available to patent examiners, the patents on turmeric and neem would never have been granted because they would have had an indication before them that they were not novel.

**SB:** But are patent offices really aware of the universal novelty?

**Mr. Gurry:** That is one of the challenges - how to ensure knowledge of what is universally disclosed. Here we are doing assisting in making more known or more accessible an area of knowledge that has not been sufficiently publicised previously or known only in limited circles. For example, if you look at the Ayurvedic database, they are taking original Sanskrit text and translating them into various languages. The fact that it was in Sanskrit before does not mean that it is not a prior art. It was.

**SB:** Will WIPO take initiatives to make Patent offices in the West

more aware of what is available in the TK database?

**Mr. Gurry:** That is a very good question. Now, having established the tool, what we have to do is integrate it more into the normal patent practices of offices. That involves two things - establishing a classification for TK (If you look at international patent classification, the way they classify all the inventions in the world so as to be able to look them up). Then, the documentation that they refer to in the classification. Part of the documentation will be the databases (including through the portal), plus we have done inventories of TK in Reviews and Journals.

**SB:** The CBD has already accepted PIC. What exactly is the WIPO doing with having a debate on this issue?

**Mr. Gurry:** What we have been asked (by the CBD) to look at is

investigate relationship between the patent system and access to genetic resources and PIC. Should it be a requirement for a patent applicant to cite the source of any genetic resource that might form the basis of the invention. And if there is such a requirement, what would be the consequences of non-compliance? What would be the consequences of the disclosure of genetic resource that was not acquired with PIC? That is the mandate we have to look at. So it is a complementary study to the CBD.

**SB:** Is it just the facet of non-compliance?

**Mr. Gurry:** Not just the facet, the whole relationship - access to genetic resources, patent system and PIC.

**SB:** So the concept of PIC is not being reopened?

**Mr. Gurry:** Not at all.

## NEWS

### PATENT INFRINGEMENT

New York, 20 June (DNS) — Pfizer Inc., the world's biggest drugmaker, has filed a lawsuit against Dr. Reddy's Lab over its plan to market a generic version of Pfizer's hypertension treatment Norvasc, according to the Press Trust of India.

Pfizer notified Dr. Reddy's that it had filed a patent-infringement suit in federal court in New Jersey, according to a statement by Dr. Reddy's.

The company said earlier this month that it may begin selling a version of the blood-pressure medicine as early as next year.

Norvasc had 2001 worldwide sales of about 3.6 billion dollar, Pfizer said. Pfizer spokeswoman Mariann Caprino confirmed that Pfizer filed the suit.

### GREENPEACE FOR CLEAN ENERGY

Istanbul, 4 July (DNS) — Activists in inflatable boats from the Greenpeace ship MV Esperanza boarded the 274 m long 160,000 tonnes oil tanker 'Crude Dio' prior to its entrance to the Bosphorus Strait, according to Greenpeace.

Three climbers hung a banner showing a 'dinosaur oil industry destroying wind mills' with a

message that read "STOP OIL INDUSTRY. CLEAN ENERGY NOW!"

Greenpeace demands that oil giants stop their investments in the new oil fields at the Caspian region, threatening the Bosphorus and the world's climate and invest in safe and clean renewables instead.

"What Greenpeace is doing now is what the governments should have done since they signed the Climate Convention at Rio 10 years ago and what they should do at the Earth Summit in Johannesburg in August - stop the dinosaur oil industry. Even with the end of oil in sight in a couple of decades, they still resist positive change, by using

*continued on page 20*

## News

### Cow Urine Patented For Medicinal Use

New Delhi, July 3 (DNS) — A US patent has been granted to Indian scientists on the use of cow urine distillate as bio-enhancer, Minister Of Science And Technology Murli Manohar Joshi announced, the Press Trust of India reported.

“A combination of Indian traditional wisdom and modern science has led to a unique US patent No 6,410,059 that was granted to Indian scientists on June 25, 2002,” an excited Joshi said at a special function in New Delhi.

The patent has been granted for a pharmaceutical composition containing an antibiotic and cow urine distillate in an amount effective to enhance the anti-microbial effects of antibiotic and antifungal agents.

The invention relates to an absolutely novel use of cow urine as activity enhancer and availability facilitator for bioactive molecules including anti-infective and anti-cancer agents.

“The present invention has direct implication in drastically reducing the dosage of antibiotics, drugs and anti-cancer agent while increasing the efficiency of absorption of bio-active molecules, thereby reducing the cost of treatment and also the side-effects due to toxicity,” Joshi said.

The use of cow urine is known for a long time in India. Go-mutra

(cow's urine) has been described as a substance with innumerate therapeutic values in Sushrita Samhita and Ashtanga Sangraha.

### Headway Claimed in HIV research

New Delhi, 8 July, (DNS) — A breakthrough of sorts is promised in the treatment of AIDS after researchers at the National Chemical Laboratory, Pune, successfully isolated the first biologically derived molecule that inhibits HIV-1 protease, which is ultimately responsible for the dreaded disease, the United News of India reported.

An official report said scientists at the NCL, Pune, achieved this significant headway in a bid to combat HIV/AIDS.

The isolation of this molecule would help inhibiting the HIV-1 protease, the enzyme which is responsible for multiplication of the AIDS-causing Human Immuno-deficiency Virus.

Since HIV requires HIV-1 protease to multiply, this enzyme is an excellent target for developing drugs against the AIDS virus, the report said.

The molecule isolated at the NCL, according to the report, has an amino acid sequence that shows an exciting new class of inhibitors with important implications for the treatment of AIDS.

According to the report, research so far in this field has indicated that the drug that inhibits HIV-1 protease, in combination with another group of drugs called reverse trans-sceiptase inhibitors, dramatically reduced the levels of HIV in blood.

The NCL, the report adds, is poised to come out with much more positive results in the future in the battle against HIV/AIDS.

### GREENPEACE: CLEAN ENERGY

*continued from page 19*

the power of money and politics to block the safe and clean energy path,” said Melda Keskin,

### Greenpeace energy campaigner.

“Oil industry giants like ExxonMobil, BP, Shell, Chevron Texaco and TotalFinaElf are continuing to ignore the local and global ecological threats to the Bosphorus and the climate. At the same time, with support from the international financial institutions like the World Bank and from governmental Export Credit Agencies billions of dollars are being invested in new oil fields in the Caspian region,” said Keskin.

Greenpeace claims the fossil fuel industry either blocks climate saving efforts and renewables' developments worldwide, or uses relatively small renewables investments as a green mask to cover their multi-billion dollar unsustainable oil business,



AN INTERGOVERNMENTAL INSTITUTION  
OF THE DEVELOPING COUNTRIES

Articles from the **SOUTH BULLETIN** can be reproduced provided that the source is acknowledged.  
The Bulletin can also be accessed from the South Centre website.

PO Box 228, 1211 Geneva 19,  
Switzerland  
Tel. (+4122) 791 80 50  
Fax. (+4122) 798 85 31  
E-mail: south@southcentre.org  
Web page: www.southcentre.org

### SOUTH BULLETIN

Senior Editor: Someshwar Singh