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Intellectual property rights and the Third World

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Issues of generation, protection and exploitation of intellectual property (IP) are assuming increasing importance. The new IP regimes will have wide ranging socio-economic, technological and political impact. As per the obligations under the Trade-related Aspects of Intellectual Property Systems (TRIPS), all the members of World Trade Organization (WTO) are supposed to implement national systems of intellectual property rights following an agreed set of minimum standards. However, there is an increasing feeling that harmonization is demanded from those that are not equal, either economically or institutionally. The major concerns of the Third World about such harmonization and the new challenge it faces in diverse areas of intellectual property protection are discussed and some suggestions about the way ahead are made.

The discussion includes the need for a fair play in technology transfer, creation of 'favourable economics' of essential medicines from the point of view of the Third World, protection of traditional knowledge, etc. The creation of Traditional Knowledge Digital Library (an essentially Indian initiative) and linking it to the International Patent Classification System (IPC) through a Traditional Knowledge Resource Classification System is an important conceptual step forward. The possible models for material transfer and benefit sharing when products are created based on community knowledge are also discussed.

Other discussions include the challenge of bridging the divide between the Third World and other developed nations, with special emphasis on intellectual property information sharing, capacity building with creation of appropriate physical and intellectual infrastructure and awareness building. It is argued that the Third World should negotiate a new 'TRIPS plus' which means 'TRIPS plus equity and ethics'.

IPR and Third World concerns

The twenty first century will be the century of knowledge, indeed the century of mind. Innovation is the key for the production as well as processing of knowledge. A nation's ability to convert knowledge into wealth and social good through the process of innovation will determine its future. In this context, issues of generation, valuation, protection and exploitation of intellectual property (IP) are going to become critically important all around the world. Exponential growth of scientific knowledge, increasing demands for new forms of intellectual property protection as well as access to IP related information, increasing dominance of the new knowledge economy over the old 'brick and mortar' economy, complexities linked to IP in traditional knowledge, community knowledge and animate objects, will pose a challenge in setting the new 21st century IP agenda. Intellectual property will no longer be seen as a distinct or self-contained domain, but rather as an important and effective policy instrument that would be relevant to a wide range of socioeconomic, technological and political concerns. The development of skills and competence to manage IPR and leverage its influence will need increasing focus; in particular, in the Third World.

An ideal regime of intellectual property rights strikes a balance between private incentives for innovators and the public interest of maximizing access to the fruits of innovation. This balance is reflected in article 27 of the 1948 Universal Declaration of Human Rights, which recognizes both that 'Everyone has the right to the protection of the moral and material interest resulting from any scientific, literacy or artistic production of which he is the author' and that 'Everyone has the right... to share in scientific advancement and its benefits'. The burning question seems to be balancing the interest of the inventor and that of the society in an optimum way.

Intellectual property rights are being harmonized worldwide. As per the obligation under the Trade-related Aspects of Intellectual Property Systems (TRIPS) agreement, developing countries are now implementing national systems of intellectual property rights following an agreed set of minimum standards, such as twenty years of patent protection; the least developed countries have an extra 11 years to do so. One of the Third World concerns is that while a fully harmonized system of IPR is being advocated, today's ad-

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vanced economies had refused to grant patents throughout the 19th and early 20th centuries. They formalized the enforced intellectual property rights gradually as they shifted from being net users of intellectual property to being net producers. Indeed, France, Germany and Switzerland, who are leading developed countries today completed, what is now standard protection, only in the 1960s and 1970s.

Further, there is a feeling that without good advice on creating national legislation that makes the most of what TRIPS allows, and under pressure to introduce legislation beyond that required by TRIPS, many countries have legislated themselves into a disadvantageous position. The TRIPS agreement entered into force in most developing countries in January 2000; the least developed countries have until 2006. With implementation still under way and industries still adjusting, little empirical evidence is available on the effects of the legislative change.

The battle today is between those that are not equal, economically and institutionally. TRIPS, like other World Trade Organization agreements, is an agreement on a legal framework. Its implications will be decided by resolving disputes. That makes case law and the power of the parties involved of great importance. The third world has a clear disadvantage here.

In the developing world, the impact of TRIPS will vary according to each country's economic and technological development. Middle-income countries like Brazil and Malaysia are likely to benefit from the spur to local innovation. Countries like India and China, which are endowed with a large intellectual infrastructure, can gain in the long term by stronger IPR protection. However, least developed countries, where formal innovation is minimal, are likely to face higher costs without the offsetting benefits.

TRIPS has important provisions for a fair play in technology transfer from which the developing world should benefit. Article 7 of the TRIPS Agreement states 'the protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations'. Furthermore, Article 8.2 states 'appropriate measures, provided they are consistent with the provisions of the Agreement, may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the International transfer of technology'.

Facilitating the access of the Third World countries to technologies required by them constitutes one of the key elements in accelerating the pace of their economic and social development. Such access is generally the result of licenses and technology transfer agreements. The fact of the matter is that the prospective technology seekers in developing countries face serious difficulties in their commercial dealings with technology holders in the developed countries. These difficulties arise for a variety of reasons. Some arise from the imperfections of the market for technology. Some are attributed to the relative lack of experience and skill of enterprises and institutions in developing countries in concluding adequate legal arrangements for the acquisition of technology. Some arise due to government practices, both legislative and administrative, in both developed and developing countries, which influence the implementation of national policies and procedures designed to encourage the flow of technology to, and its acquisition by, developing countries.

There are concrete examples to show that technology transfers to the Third World have not taken place when they were needed most. The 1990 Montreal Protocol on Substances that Deplete the Ozone Layer ran into conflicts over commitments to ensure fair and favourable access for developing countries to chlorofluorocarbon (CFC) substitutes protected by intellectual property rights. The 1992 Convention on Biological Diversity aims to ensure fair and equitable use of genetic resources partly through technology cooperation, but its technological provisions have received little attention. The 1994 TRIPS agreement calls for technology transfer to the least developed countries, yet that provision has scarcely been translated into action.

The transfer and dissemination needs of the developing countries have to be seen from the point of view of the capacity of those in need of accessing the technologies, particularly where the cost of technology may be prohibitive due to economies of scale and other reasons. In such cases, in order to implement the related provisions of the TRIPS Agreement, commercially viable mechanisms will have to be found.

Traditional knowledge protection and promotion

Let us revisit the process of innovation. Normally when we consider innovation, we refer to only formal systems of innovation, namely that done in universities, industrial R&D laboratories, etc. Often not recognized is the technology innovation that takes place in an informal system of innovation, be it by artisans, farmers, tribes or other grassroot innovators. Indeed many societies in the Third World have nurtured and refined systems of knowledge of their own, relating to such diverse domains as geology, ecology, botany, agriculture, physiology and health. These informal innovators have, therefore, generated such a rich store of traditional knowledge.

One of the concerns of the developing world is that the process of globalization is threatening the appropriation of elements of the collective knowledge of societies into proprietary knowledge for the commercial profit of a few. An urgent action is needed to protect these knowledge systems through national policies and international understanding linked to IPR, while providing its development and proper use for the benefit of its holders. We need a particular focus on community knowledge and community innovation. To encourage communities, it is necessary to scout, support, spawn and scale up the green grass root innovation. Linking innovation, enterprise and investment is particularly important. New models and new thinking on IP will have to be envisioned to accomplish this.

The local communities or individuals do not have the knowledge or the means to safeguard their property in a system, which has its origin in very different cultural values and attitudes. The communities have a storehouse of knowledge about their flora and fauna – their habits, their habitats, their seasonal behaviour and the like – and it is only logical and in consonance with natural justice that they are given a greater say as a matter of right in all matters regarding the study, extraction and commercialization of the biodiversity. A policy that does not obstruct the advancement of knowledge, and provides for valid and sustainable use and adequate intellectual property protection with just benefit sharing is what we need.

The issues of the economics of community knowledge are truly complex. While it is true that many indigenous cultures appear to develop and transmit knowledge from generation to generation within a system, individuals in local or indigenous communities can distinguish themselves as informal creators or innovators, separate from the community. Furthermore, some indigenous or traditional societies are reported to recognize various types of intellectual property rights over knowledge, which may be held by individuals, families, lineages or communities. Discussion of IPRs and traditional knowledge should draw more on the diversity and creativity of indigenous approaches to IPR issues.

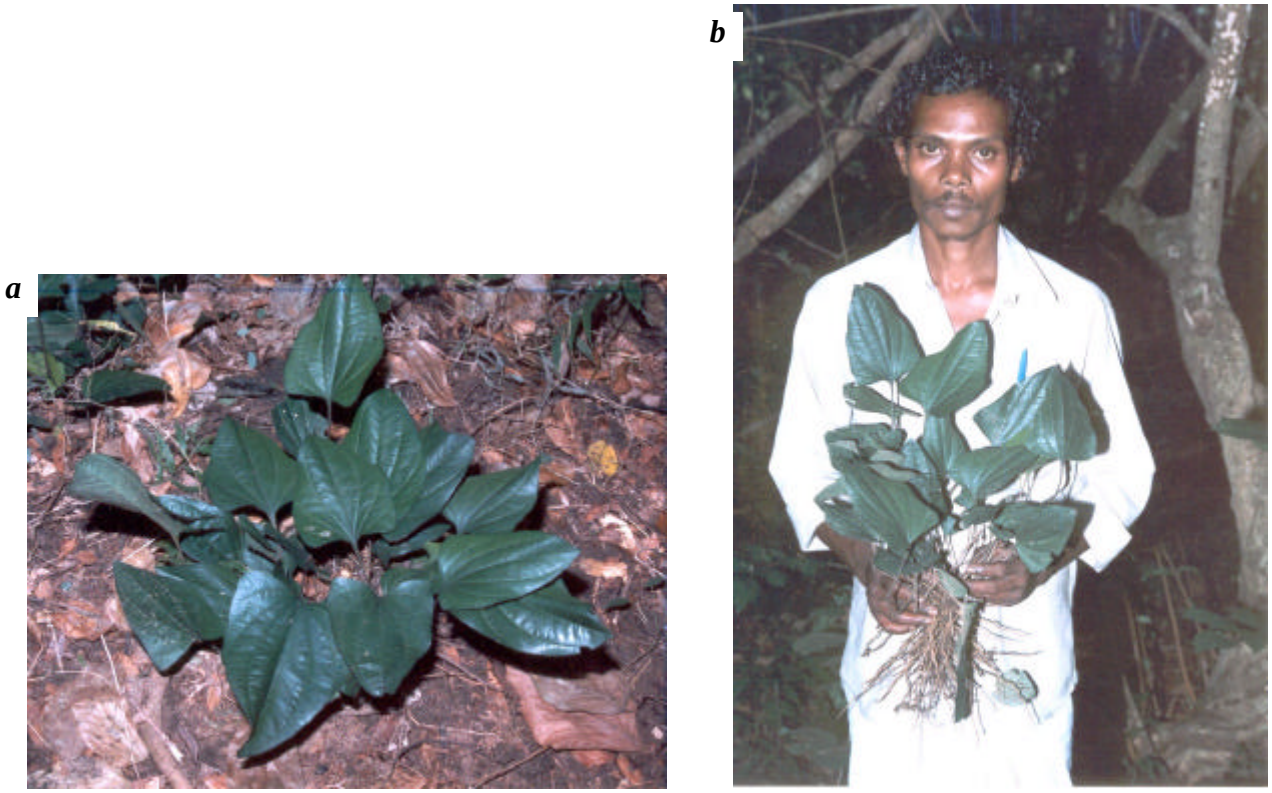
The existing IPR systems are oriented around the concept of private ownership and individual innovation. They are at odds with indigenous cultures, which emphasize collective creation and ownership of knowledge. There is a concern that IPR systems encourage the appropriation of traditional knowledge for commercial use, and that too without the fair sharing of benefits of the holders of this knowledge. They violate the indigenous cultural precepts by encouraging the commodification of such knowledge.

The issue of 'protection' of traditional knowledge needs to be looked at from two perspectives, the 'protection' may be granted to *exclude* the unauthorized use by third parties of the protected information. On the other hand, the 'protection' also means to *preserve* traditional knowledge from uses that may erode it or negatively affect the life or culture of the communities that have developed and applied it. Further, the protection also promotes self-respect and self-determination.

While recognizing the market-based nature of IPRs, other non-market-based rights could be useful in developing models for a right to protect traditional knowledge, innovations and practices. To date, debate on IPRs and biodiversity has focused on patents and plant breeders' rights. Provisions under undisclosed information or trade secrets could be invoked to protect traditional knowledge not available in the public domain. Geographical indications and trademarks, or *sui generis* analogies, could also be the alternative tools for indigenous and local communities seeking to gain economic benefits from their traditional knowledge. The potential value of geographical indications and trademarks is in protecting plants and germplasms that are specific and unique to geographical regions. They could protect and reward traditions while allowing innovation. They will emphasize the relationships between human cultures and their local land and environment. They are not freely transferable from one owner to another. They can be maintained as long as the collective tradition is maintained.

Giving legally recognized ownership of knowledge to communities through *sui generis* IPRs has several benefits. It will raise the profile of that knowledge and encourage respect for it both inside and outside the knowledge-holding communities. This will enthuse the younger members of such communities to contribute to the further development of that knowledge. Furthermore, prospects of economic returns for the use of that knowledge by others will act as a further incentive for the community members to respect their knowledge and continue to engage in practices in that knowledge. Prior protection will also provide disclosure, use and proliferation of such knowledge, which might have otherwise been eroded.

New experiments are beginning to emerge on benefit-sharing models for indigenous innovation. An experience in India is worth sharing. It relates to a medicine that is based on the active ingredient in a plant, *Trichopus zeylanicus*, found in the tropical forests of southwestern India and collected by the Kani tribal people. Scientists at the Tropical Botanic Garden and Research Institute (TBGRI) in Kerala learned of the plant, which is claimed to bolster the immune system and provide additional energy, while on an expedition with the Kani in 1987. These scientists isolated and tested the ingredient and incorporated it into a compound, which they christened 'Jeevani', the giver of life. The tonic is now being manufactured by a major Ayurvedic drug company in Kerala. In 1995, an agreement was struck to share the license fee and 2% of sales



Trichopus zeylanicus.

Box 1. The 'Jeevani' and the 'Kani' tribes.

The Kani tribals belong to a traditionally nomadic community, who now lead a primarily settled life in the forests of the Agasthyamalai hills of the Western Ghats (a mountain range along south-western India) in the Thiruvananthapuram district of Kerala. The Kanis, numbering around 16,000, live in several tribal hamlets, each consisting of 10 to 20 families dispersed in and around the forest areas of Thiruvananthapuram district. These Kanis do not constitute a cohesive unit, although they do share certain common characteristics and practices. Kanis are the traditional collectors of non-timber forest products from the forest. Living close to nature, the Kanis have acquired unique knowledge about the use of the resources, particularly the biological resources around them.

In December 1987, a team of scientists working on the All India Co-ordinated Research Project on Ethnobiology (AICRPE) led by P. Pushpangadan was trekking through the tropical forests of Agasthyar hills. They were surveying the 'Kani' tribal settlements and got exhausted after a while. This team was accompanied by a few 'Kani' tribesmen as guides, who surprisingly remained energetic and agile. They occasionally would munch some small blackish fruits. One of them offered a few of these fruits to the team pointing out that if they ate those, they could go on trekking without fatigue. And that is what happened to the AICRPE team, after they had followed their advice. It was later that the 'Kani' tribesmen introduced the 'magical' plant, which was subsequently identified as *Trichopus zeylanicus* ssp. *travancoricus.*

Detailed chemical and pharmacological investigations showed that the leaf of the plant contained various glycolipids and some other non-steroidal compounds with profound adaptogenic and immuno-enhancing properties. The fruits showed mainly anti-fatigue properties. The Tropical Botanical Garden Research Institute (TBGRI) was successful in developing a scientifically validated and standardized herbal drug, based on the tribal lead. The drug was named as 'Jeevani' and it was released for commercial production in 1995 in Arya Vaidya Pharmacy. While transferring the technology for production of the drug to the pharmaceutical firm, TBGRI agreed to share the license fee and royalty with the tribal community on a fifty–fifty basis.

The prime concern of the tribals in the beginning was to evolve a viable mechanism for receiving such funds. With the help of TBGRI, some government officials and NGOs, the tribals formed a registered trust. About 60% of the Kani families of Kerala are members of this trust. From February 1999, the amount due to them has been transferred to this Trust with an understanding that the interest accrued from this amount alone can be used for the welfare activities of the Kani tribe.

TBGRI has trained 25 tribal families to cultivate the plant around their dwellings in the forest. In the first year itself, each family earned about Rs 8,000 on sale of leaves from cultivation of *T. zeylanicus* in half-hectare area by each family. But unfortunately the forest department objected to the cultivation with the plea that the tribals may remove the plants from the natural population of this species in the forests and thereby make it endangered. It is understood that this problem has now been resolved and the Forest department has recently approved the cultivation of this plant. It is significant to note that while the issue of material transfer and benefit sharing was discussed and debated after Convention on Biological Diversity (CBD), India has already pioneered one of the first models.

of the product as royalty, that was receivable by TBGRI, will be shared on a fifty–fifty basis with the tribe. This marks perhaps the first time that for IP held by a tribe, a compensation in the form of cash benefits has gone directly to the source of the IP holders. We are still on the learning curve in this experiment (see Box 1) but we need to multiply such examples globally.

IPR and traditional medicine

Traditional Medicine (TM) plays a crucial role in healthcare and serves the health needs of a vast majority of people in developing countries. Access to 'modern' health care services and medicine may be limited in developing countries. TM becomes the only affordable treatment available to poor people and in remote communities.

World Health Organization (WHO) defines traditional medicine as *the sum total of all the knowledge and practices, whether explicable or not, used in diagnosis, prevention and elimination of physical, mental or social imbalance and relying exclusively on practical experience and observations handed down from generation to generation, whether verbally or in writing.* Health care providers worldwide including major pharmaceutical giants are turning to incorporate many of these into their mainstream activities. As traditional medicines are largely based on medicinal plants, indigenous to these countries, where the system has been in vogue for several centuries, the effort is on accessing them either directly or through the use of modern tools of breeding and cultivation, including tissue culture, cell culture and transgenic technology. IP issues linked to such endeavours remain unresolved.

The protection of TM under intellectual property rights (IPRs) raises two types of issues. First, to what extent it is feasible to protect, existing IPR system. Certain aspects of TM may be covered by patents or other IPRs. There have also been many proposals to develop *sui generis* systems of protection. Such proposals are based on the logic that if innovators in the 'formal' system of innovation receive a compensation through IPRs, holders of traditional knowledge should be similarly treated.

Box 2. Re-examination of US patents.

There is a general perception that the process of fighting an erroneous patent is long, arduous and very expensive. This is true as exemplified by the Eastman Kodak–Polaroid patent war, which was settled after several years for about a billion dollars. However, the process of re-examination of a US patent, a route that was adopted by CSIR to challenge the turmeric and the Basmati patent, is relatively straightforward. It cost CSIR approximately Rs 5 lakhs to win the turmeric case.

As per the provision of re-examination of granted US patents, any person may file a request for re-examination of a patent. Corporations and/or governmental entities are included within the scope of the term 'any person'. Even the patent owner can ask for a re-examination, which would be limited to an *ex-parte* consideration of prior patents or printed publications. It is also possible for the Commissioner to initiate re-examination at the Commissioner's own initiative under 37 CFR 1.520. Re-examination can be initiated by the Commissioner on a very limited basis such as where a general public policy question is at issue and there is no interest by 'any other person'.

The provisions for re-examination are as follows:

1. Anyone can request re-examination at any time during the period of enforceability of the patent.
2. A substantial new question of patentability must be presented for re-examination to be ordered.
3. Prior art considered during re-examination is limited to prior art patents or printed publications applied under the appropriate parts of 35 U.S.C. 102 and 103.
4. If ordered, the actual re-examination proceeding is *ex-parte* in nature.
5. Decision on the request must be made within three months from initial filing and remainder of proceedings must proceed with 'special dispatch'.
6. If ordered, a re-examination proceedings will be conducted to conclusion and issuance of certificate.
7. The scope of a claim cannot be enlarged by amendment.
8. All re-examination and patent files are open to the public.

After the filing of the re-examination request, the US PTO will decide within three months whether a 'substantial new question of patentability' has been raised by the request. If so, a decision ordering the re-examination to proceed will be issued. After the order to proceed is issued, there is a period of two months during which the patent owner can file a statement or amendment in response to the issues raised in the request. If the patent owner does this, the requester will have a period of two months to file a response. This response represents the last opportunity for the requester to participate in the re-examination. Ordinarily, the patent owner does not file any paper, so that the only opportunity for the requester to present his views is in the initial request papers. Thus, in the case of Turmeric or Basmati, if the full and comprehensive evidence was not presented by India, when the initial request was filed, there would have been no opportunity to file further evidence. After the deadline has passed for the patent owner to file a statement (or after any statement and response by the requester have been filed), the Examiner conducts the re-examination in a manner similar to a regular patent prosecution. The final re-examination certificate is then issued, as exemplified in the Turmeric case.

Box 3. Turmeric Patent: The chronology and lessons.

Two US-based Indians Suman K. Das and Hari Har P. Cohly were granted a US Patent 5,40,504 on 28 March 1995 on *Use of turmeric in wound healing.* The patent was assigned to University of Mississippi Medical Center, USA. This patent claimed the administration of an effective amount of turmeric through local and oral route to enhance the wound healing process, as a novel finding. Any patent, before it is granted, has to fulfil the basic requirements of novelty, non-obviousness and utility. Thus, if the claims have been covered by relevant published art, then the patent becomes invalid. CSIR could locate 32 references (some of them being more than one hundred years old and in Sanskrit, Urdu and Hindi), which showed that this finding was well known in India prior to filing of this patent. The formal request for re-examination of the patent was filed by CSIR at USPTO on 28 October 1996.

The first office action in the re-examination was issued by USPTO on 28 March 1997, which rejected all the six claims based on the references submitted by CSIR as being 'anticipated by the submitted references' and therefore considered invalid under 35 U.S.C. 102 and 103.

After receiving the first action, the University of Mississippi Medical Centre, to whom the turmeric patent was assigned, decided not to pursue the case and transferred the rights to the inventors, who, however, decided to file a response. The inventors argued that the powder and paste had different physical properties, i.e. bio-availability and absorbability, and therefore, one of ordinary skill in the art would not expect, with any reasonable degree of certainty, that a powdered material would be useful in the same application as a paste of the same material. The inventors, further, mentioned that oral administration was available only with honey and honey itself was considered to have wound healing properties.

In the second Office Action, the examiner rejected all the claims once again and made his action final. He made it clear that the paste and the powder forms were *equivalent* for healing wounds in view of the cited art.

Subsequent to the second rejection, the inventors had an interview with the examiner and deleted claims 5–6 and also restricted the invention to a 'non-healing surgical wound' as supported by the two case histories mentioned in the patent stating that there was no disclosure or suggestion of using turmeric in surgically inflicted non-healing wounds and requested the examiner to allow the amended claims.

On 20 November 1997, the examiner rejected all the claims once again as being anticipated and obvious.

The re-examination certificate was issued on this case on 21 April 1998 bringing the re-examination proceedings to a close.

The following points are interesting to note:

1. The turmeric case was a landmark case in that this was the first time that a patent based on the traditional knowledge of a developing country was challenged successfully and USPTO revoked the patent. This eventually opened up the path to the creation of Traditional Knowledge Digital Library, Traditional Knowledge Resource Clarification, and finally inclusion of traditional knowledge in the International Patent Clarification System.
2. Amidst the loud protests against 'biopiracy' and 'theft' of India's biodiversity and traditional knowledge by foreign nationals, it is interesting to note here that the patentees were Indians (Das and Cohly), the re-examination in USPTO was done by an Indian (Kumar) and the re-examination was sought by an Indian institution (CSIR).

World Intellectual Property Organization (WIPO) has been sensitive to these concerns. At a conference held in October 1998, under the aegis of the WIPO an agenda for the future of IPR in the field of traditional medicines was prepared, which prioritized activities in this area, namely, development of standards for the availability, scope and use of IPRs on traditional medicine in Asian countries, systematic documentation of traditional medicine for protection purposes, regional and inter-regional information exchange and compilation of the requisite databases, etc. This agenda needs to be moved forward.

The codification of TM varies significantly. A distinction can be made, particularly in Asia, between the *codified* systems of 'traditional medicine' and *non-codified* medicinal knowledge, which includes 'folk', 'tribal' or 'indigenous' medicine. Thus, in India, folk traditions are handed over orally from generation to generation. The 'folk' medicine is based on traditional beliefs, norms and practices based on centuries old experiences of trials and errors, successes and failures at the household level. These are passed through oral tradition and may be called, 'people's health culture', home remedies or folk remedies. TM may be possessed by individuals. In some cases, for instance, healers use *rituals* as part of their traditional healing methods, which often allow them to monopolize their knowledge, despite disclosure of the phytochemical products or techniques used. The codified tradition consists of medical knowledge with sophisticated foundations expressed in thousands of manuscripts covering all branches of medicine. Examples are ayurveda, siddha, unani and the Tibetan tradition.

The grant of patents on non-original innovations (particularly those linked to traditional medicines), which are based on what is already a part of the traditional knowledge of the developing world have been causing a great concern to the developing world. It was CSIR that challenged the US patent No. 5,401,5041, which was granted for the wound healing properties of turmeric. The process of re-examination of a US patent is well laid out (see Box 2). In a landmark judgement, the US Patent Office revoked this patent in 1997, after ascertaining that there was no novelty; the findings by innovators having been known in India for centuries (see Box 3).

The Coordinating Body of Indigenous Organizations of the Amazon Basin (COICA), which represents more than 400 indigenous tribes in the Amazon region, along with others, protested about a wrong patent (US Plant Patent No. 5,751 issued on 1986) that was given on a plant species native to the Amazon rainforest, called *Banisteriopsis caapi* and its traditional medicinal uses through an indigenous product called 'Ayahusca' in 1999. On reexamination, USPTO revoked this patent on 3 November 1999. However, the inventor was able to convince the USPTO on 17 April 2001, the original claims were reconfirmed and the patent rights restored to the innovator (see Box 4).

These two cases were followed by yet another case of revocation in May 2000. The patent granted to W. R. Grace Company and US Department of Agriculture on Neem (EPO patent No. 436257) by European Patent Office was squashed again on the same grounds that its use was known in India. India filed a reexamination request for the patent on Basmati rice lines and grains (US Patent No. 5,663,484) granted by the USPTO, and Ricetec Company from Texas has decided to withdraw the specific claims challenged by India and also some additional claims (see Box 5).

There is a problem on the grant of such patents linked to the indigenous knowledge of the developing world that needs to be addressed jointly by the developing and the developed world. We need to understand that there is a distinction between the patents that are granted based on modern research and patents, which can be categorized as traditional knowledge-based patents. A recent study by an Indian expert group examined randomly selected 762 US patents, which were granted under A61K35/78 and other IPC classes, having a direct relationship with medicinal plants in terms of their full text. Out of these patents, 374 patents were found to be based on traditional knowledge not that all of them were wrong. The Governments in the Third World as well as members of public are rightly concerned about the grant of patents for non-original inventions in the traditional knowledge systems of the developing world. At international level there is significant level of support for opposing the grant of patents on non-original inventions. For example, more than a dozen organizations from around the world got together to oppose the EPO Neem patent and the entire process took five years. Such a process of opposition is, understandably expensive and time consuming.

Box 4. The case of Amazon Rainforest Plant Patent.

Many traditional healers and religious leaders from the indigenous tribes of the Amazon used to collect a plant named *Banisteriopsis caapi*, and process it to produce a ceremonial drink – 'ayahausca', also called 'yage'. They used ayahausca in religious and healing ceremonies. According to tradition, ayahausca was prepared and administered only under the guidance of traditional healers. A Plant Patent No. 5,751, issued to Loren Miller on 17 June 1986 by USPTO claimed rights over a supposed variety of *B. caapi,* which Miller dubbed 'Da Vine'.

The challenge to this patent was made by the Center for International Environment Law (CIEL), on behalf of the Coordinating Body of Indigenous Organizations of the Amazon Basin (COICA) and the Coalition for Amazonian Peoples and Their Environment (Amazon Coalition). COICA is a coordinating body of more than 400 tribes.

It was argued that to obtain a plant patent, an applicant must show that the plant is a new variety; that it is distinct from existing forms; and that it is now found in an uncultivated state (35 U.S.C. §161). Such patents are authorized under a 1930 law designed to reward efforts of growers who develop new varieties of crops such as fruit trees or grapevines.

Although the patent claimed to have identified a variety of the species with new and distinctive physical features, particularly the colour of the flower. But according to Prof. William A. Anderson of the University of Michigan, a leading expert on the plant family to which *B. caapi* belonged, the features described as 'prior art' were already there in the records of major herbaria. Further, this plant grew naturally throughout the Amazon basin. By law, plant patents cannot be awarded to plants 'found in an uncultivated state'.

The USPTO rejected Miller's patent claim in an Office Action dated 3 November 1999. The rejection was made on the narrowest grounds possible, under the statutory bar of 35 U.S.C. §102(b). Section 102(b) prohibits, *inter alia*, the issuance of a patent when the invention was patented or described in a printed publication more than one year prior to the date of patent application.

The rejection notice noted that the accessioned specimen sheets from the Field Museum in Chicago contain specimens of *B. caapi* whose major defining feature is flower colour indistinguishable from that of Da Vine. These sheets were known and available in the United States more than one year prior to the filing of Miller's patent application.

By permitting §102(b)'s statutory bar to be met by these specimen sheets, the USPTO confirmed in its rejection that such sheets qualify as 'printed publications' for the purpose of determining a plant's patentability. This way the first time the USPTO had adopted this interpretation of prior art publications. However, the interpretation is a logical extension of earlier decisions that recognized as printed publications single copies of doctoral dissertations catalogued in university libraries, and single copies of grant proposals indexed and publicly available on file with the National Science Foundation.

The case finally took a different turn. The inventor convinced the USPTO about the novelty of his claim to the new variety and the USPTO reversed its decision given on 3 November 1999 in the re-examination certificate given by it on 17 April 2001 with a statement 'No amendments have been made to the patent. As a result of re-examination, it has been determined that the patentability of claim 1 is confirmed'.

Thus Turmeric and Basmati still continue to be the only successful battles on traditional knowledge with USPTO todate!

To mitigate this problem, the Indian Government has taken steps to create a Traditional Knowledge Digital Library (TKDL) on traditional medicinal plants and systems (see Box 6), which will also lead to a Traditional Knowledge Resource Classification (TKRC). Linking this to internationally accepted International Patent Classification (IPC) System will mean building the bridge between the knowledge contained in an old Sanskrit Shloka and the computer screen of a patent examiner in Washington! This will eliminate the problem of the grant of wrong patents since the Indian rights to that knowledge will be known to the examiner. In a further action, the examiner has decided to disallow seventeen of the twenty claims.

Eventually the creation of TKDL in the developing world would serve a bigger purpose in providing and enhancing its innovation capacity. It could integrate widely scattered and distributed references on the traditional knowledge systems of the developing world in a retrievable form. It could act as a bridge between the traditional and modern knowledge systems. Availability of this knowledge in a retrievable form in many languages will give a major impetus to modern research in the developing world, as it itself can then get involved in innovative research on adding further value to this traditional knowledge; an example being the development of an allopathic medicine based on a traditional plant-based therapeutic. Sustained efforts on the modernization of the traditional knowledge systems of the developing world will create higher awareness at national and international level and will establish a scientific approach, that will ensure higher acceptability of these systems by practitioners of modern systems and public at large.

IPR and essential medicines for the Third World

The consensus statement of Global Health Forum I, February 2000, said 'The move to globalize the protection of intellectual property is not politically sustainable without, at the same time, making the delivery of health technology more equitable'. On 23 April 2001 the United Nations Commission on Human Rights called on governments to ensure the accessibility of pharmaceuticals and medical treatments used to treat pandemics such as HIV/AIDS, as well as 'their affordability for

Box 5. Re-examination of US patent on Basmati.

Background: Rice Tec Inc. had applied for registration of a mark 'TEXMATI' before the UK Trade Mark Registry. It was successfully opposed by Agricultural and Processed Food Exports Authority (APEDA). One of the documents relied upon by Rice Tec as evidence in support of the registration of the said mark was the US Patent 5,663,484 (hereafter referred to as '484 patent) granted by US Patent Office to Rice Tec on 2 September 1997 and that is how this patent became an issue for contest.

This US utility patent '484, was in a unique way to claim a rice plant having characteristics similar to the traditional Indian Basmati Rice lines and with the geographical delimitation covering North, Central or South America or Caribbean Islands. The patent was granted to Rice Tec by the US Patent Office on 2 September 1997. The said patent covered 20 claims covering not only a novel rice plant but also various rice lines; resulting plants and grains, seed deposit claims, method for selecting a rice plant for breeding and propagation. Its claims 15–17 were for a rice grain having characteristics similar to those from Indian Basmati rice lines. The said claims 15–17 would have come in the way of Indian exports to US, if legally enforced. The grant of this patent created a stir in the public, government, business circles and academics.

In the wake of this controversy, the Government of India set up a Task Force under the Chairmanship of Secretary, Ministry of Industrial Development, to examine the possibilities of filing a re-examination request against the above-mentioned US Patent. The Task Force, in turn, set up a Technical Committee comprising primarily the ICAR and CSIR scientists to examine the Patent specification in detail and to collect necessary documentary evidence that may be required to file the re-examination request against the US Patent.

Evidence from the *IARI Bulletin* was used against claims 15–17. The evidence was backed up by the germplasm collection of Directorate of Rice Research, Hyderabad since 1978. The various grain characteristics were evaluated by CFTRI scientists and accordingly the claims 15–17 were attacked on the basis of the declarations submitted by CFTRI scientists on grain characteristics.

Eventually, a request for re-examination of this patent was filed on 28 April 2000. Soon after filling the re-examination request, Rice Tec chose to withdraw claims 15 to 17 along with claim 4.

Although Rice Tec did withdraw these claims, the US Patent Office on its own judged that 'a substantial question of patentability has been raised in respect of the remaining claims'.

Based on the exhaustive office action, Rice Tec has now surrendered the claims 1 to 3, 5 to 7, 10, 14 and 18 to 20.

As such, the claims that Rice Tec now intends to protect are 8, 9, 11, 12 and 13. These claims pertain to specific rice lines and the progeny and the grains of the specific crosses. This means that as against the Indian attack on 3 claims, Rice Tec is withdrawing 15 claims.

In summary, Rice Tec having withdrawn claims 15–17, the threat of infringement by the export of Basmati grains to US has been averted. And now, with the surrender of all the other broad claims, even the alleged threat to the export of grains of insensitive rice lines from India has been averted. Further, USPTO has ordered that the title of the patent be changed from 'Basmati Rice Lines and Grains' to 'Rice Lines Bas867, RT1117 and RT1121'. In short, the objective for which India had filed the re-examination case has been fulfilled.

Box 6. Traditional Knowledge Digital Library.

Three issues relating to treating traditional knowledge 'on par' with industrial property systems, designing new International Patent Classification Systems to give due recognition to traditional knowledge, and creating a Traditional Knowledge Digital Library (TKDL) were taken up by this author with World Intellectual Property Organization (WIPO), when he was the Chairman of the Standing Committee on Information Technology (SCIT) in WIPO during 1998–99. This had found a generally favourable response from the member states.

A comprehensive initiative was spearheaded by the Department of Indian Systems of Medicine and Homeopathy (ISMH). It set up an inter-disciplinary task force, known as TKDL task force, by drawing experts from Central Council of Research of Ayurveda and Siddha, Banaras Hindu University, National Informatics Centre, Council of Scientific & Industrial Research and Controller General of Patents and Trade Marks.

The Task Force evolved a scientific classification approach known as Traditional Knowledge Resource Classification (TKRC), which would enable retrieval of information on traditional knowledge in a scientific and rational manner. The structure of TKRC would be similar to that commonly used for classifying modern innovations, which enable an easy linkage with the International Patent Classification (IPC). All the patent examiners around the world use IPC during patent examination.

Early this year, WIPO set up a Traditional Knowledge Task Force consisting of US, Japan, European Union, China and India. The Indian proposal on creating TKRC was presented to them. All members of the Task Force (significantly, including China, which has a rich traditional knowledge of its own) fully endorsed the Indian effort. The Task Force has already initiated its work and is likely to submit the draft report to WIPO by February 2002.

If this report is accepted, then what would be its effect? First, IPC has more than one hundred thousand sub-groups for retrieving information on modern scientific inventions. However, it has only one sub-group for retrieving information on medicinal plants. Indian TKRC has information on 5,000 sub-groups. Therefore, their inclusion in IPC will enhance the quality of patent examination substantially. Secondly, similar systems will be evolved by other countries and regions, such as China, Latin America, Indonesia, etc. which are rich in traditional knowledge. Traditional knowledge of the developing world will thus get a legitimacy. The burning issue of the grant of wrong patents based on the traditional knowledge of the Third World will also be resolved to a large extent, since the patent examiners will have access to the pertinent information in an appropriately classified form.

all', in accordance with international law and international agreements. The resolution also calls on governments 'to safeguard access to such preventive, curative or palliative pharmaceuticals or medical technologies from any limitations by third parties'. However, the recent landmark event on medicines HIV/AIDS in South Africa has raised new questions in this regard.

The adoption of the TRIPS Agreement has entailed significant changes for the protection of pharmaceutical products and processes. The Agreement not only made product patent protection binding to all Member countries (article 27.1); it also strengthened, *inter alia*, process patents (articles 28(b) and 34), narrowly defined the conditions for establishing exceptions to patent rights (article 30), and limited the possibility of applying especial modalities of compulsory licenses to pharmaceuticals (e.g. as provided for in Canada until 1993).

A key question is whether the TRIPS regime has led to an increase in the prices of patented medicines. Although many researchers argue that that there is no clear relationship between the patents and the prices of medicines, there is a strong evidence that average pharmaceutical product prices decline in the face of entry by generic substitutes. Competition is important to keep prices down.

There are a number of options available within TRIPS to ensure affordable access. Compulsory licensing, parallel imports and differential pricing between developed and developing countries have been suggested as instruments to improve access within the broad framework of TRIPS. But it is not clear as to the kind of legal instrument that could be used to enforce differential pricing and segment markets. It is also not clear as to whether TRIPS regime is compatible with national exhaustion or international exhaustion. There is an additional problem with differential pricing in those developing countries, which have capacity for producing generics. They will slap on anti-dumping duties because of the pressure from domestic industry. Under the differential pricing regime, one will have to decide as to how to organize competition based on negotiated prices. There is also a fear that if one segments markets in pharmaceuticals in this manner, these will have repurcussions in other sectors.

The full implementation and application of the TRIPS Agreement will entail welfare losses to varying extent depending on the economic status of individual countries. The question is about the extent of this loss and what should be done to mitigate the adverse consequences.

Bridging the divide

International agencies will have to make an effort to bridge the gap between the developed world and the Third World. Some laudable efforts are afoot in this direction. WIPO is setting up WIPONET to narrow the information access gap that exists between the developed countries and developing countries; improve the flow of information concerning intellectual property rights among WIPO member states, regional intellectual property offices and the International Bureau; to im-

prove access to and exchange of intellectual property information in terms of costs and access time; to improve intellectual property information dissemination; to consider the information needs and filing requirements of applicants and develop electronic services keeping in mind the need to provide benefits to applicants and intellectual property offices, and to other interested parties; to help guide the International Bureau to leverage information technologies and to improve the retrieval of intellectual property information through further development of international classifications of patents, trademarks and industrial designs as efficient search tools.

Inadequate preparedness of many national IP offices in most of the developing countries is a serious concern. The problem areas pertain to manual and paper-based operations, static manpower resources, rapid increase in the number of applications filed in recent years leading to inordinate delays in granting IPRs, non-uniformity in the examination, poor quality of search resulting in fresh objections even after the first examination report, inadequate search facilities and tools and lack of digital data & networks. Most seriously, IT has not yet been inducted in the IP administration in most cases. The question of capacity of the Third World IP Offices to handle complex IP issues is a serious one. In the year 2000, the World Intellectual Property Organization received 30 patent applications, which were over 1,000 pages long, with several reaching 140,000 pages. It is clear that the patent offices in the developing countries may not even have a capacity to handle this.

The Third World faces several other challenges. Weak physical infrastructure in terms of inadequate IP offices, as explained above, is just one aspect; but inadequate intellectual infrastructure, poor public awareness and lack of government policies that are not in tune with the times are some other hurdles. Many R&D institutions and industrial firms in the developing world have so far focussed on imitative research or reverse engineering, and have depended heavily on borrowed technology and, therefore, not created productive national IP portfolio. Apart from manpower planning for IPR protection setting up of patent training institutes and specialized courses, a judicious management of patent information is the need of the hour. This will require well-structured functioning of information creating centres, information documenters and retrievers, information users and information technology experts.

Internet can play a key role in the protection and promotion of traditional knowledge of the communities (while bringing in added economic value to these communities). An example is the recent experiment in India of the design of an e-commerce portal for Indian craftsmen and artisans, which will link individual craftsmen directly to designers and markets. It will be possible through this portal for a garment buyer in any part of the world to approach any craftsman directly, select a pattern, a weave and a fabric and place his order with him. This will mean not only a multiple increase in the craftsman's income but also his direct interaction with the market. This will unleash the creative skills to meet the demands of his market, and further enhance the innovation capacity. New challenges in IP protection will emerge as internet becomes a major facilitator in commercialization of traditional knowledge.

Finally

The industrial property systems were set up centuries ago for inanimate objects and that too in formal systems of innovation. The time has come to revisit them. The emerging challenge is to look at the systems that will deal with animate objects (such as plants and animals) and with informal systems innovation (such as those by grass root innovators like farmers, artisans, tribes, fishermen and so on). The standard intellectual property systems will certainly not suit such innovators and their innovations. We, therefore, need innovation in the intellectual property system itself! The issue of whether TRIPS should fundamentally belong to WTO is under discussion. Other issues such as the desirability of uniformity of patent term, need for new reforms to exclude certain sectors from TRIPS, lowering the minimum standards, differential treatment depending the state of economy of a developing country, etc. are also under discussion.

Finally, it is important is to recognize that the principal objective of the GATT/WTO system is to promote free trade. This can be done if competitive opportunities are provided across the nations on a non-discriminatory basis. The TRIPS provisions should be interpreted. In other words, the emphasis should be on promotion of competition, and not its restriction. The TRIPS provisions have to be interpreted in this context alone, and especially with an aim of laying down the foundation of a fair trade system. It is hoped that the Third World concerns enumerated in this paper will be addressed by a dialogue to create a new 'TRIPS plus', getting a new meaning of 'TRIPS plus equity and ethics'.

Glossary

Convention on Biodiversity (CBD): The convention was opened at the United Nations Conference on Environment and Development in Rio de Janeiro in June 1992. It came into force at the end of 1993 and has now been ratified by the overwhelming majority of countries, for whom it is now a legally binding commitment to conserve biological diversity, to sustainably use its components and to share equitably the benefits arising from the use of genetic resources.

Compulsory licensing: If the reasonable requirements of the public with respect to the patented invention have not been satisfied or if the patented invention is not available to the public at a reasonable price, then a prayer for the grant of a compulsory license to work the patented invention can be made. This is done at any time after the expiry of a three years period from the date of the grant of a patent.

General Agreement on Tariffs and Trade (GATT): GATT, the organization which was established in 1947 as the organization overseeing the multilateral trade system has been replaced by WTO with effect from 1 January 1995.

International Patent Classification (IPC): IPC subdivides the whole gamut of technology into different subgroups and is used by the national patent offices throughout the world in classifying the subject matter contained in patent documents. Each patent document bears one or more IPC codes assigned to it by the respective Patent Office.

Parallel Import: Parallel imports involve the import and resale in a country, without the consent of the patent holder, of a patented product which was put on the market of the exporting country by the title holder or in another legitimate manner.

Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS 1994): This Agreement constitutes Annex IC of the Marrakesh Agreement Establishing the World Trade Organization, which was concluded on 15 April 1994, and entered into force on 1 January 1995. The TRIPS Agreement binds all Members of the WTO.

Traditional Knowledge Digital Library (TKDL): An Indian initiative, presently aims at documenting and classifying according to IPC, knowledge from traditional systems such as Ayurveda, Unani and Siddha.

Traditional Knowledge Resource Classification (TKRC): TKRC is the classification evolved to enable retrieval of information on traditional knowledge in a scientific manner so that it can be readily linked to IPC.

World Intellectual Property Organization (WIPO): WIPO is an international organization dedicated to promoting the use and protection of works of human intellect and is one of the sixteen specialized agencies of the United Nations System of organization. Presently, 177 nations are its members.

WIPONET: WIPONET is a global Intellectual Property network set up by WIPO enabling the integration of IP information resources, processes and systems of world wide Intellectual Property communities, particularly IP offices of the member states.

World Trade Organization (WTO): WTO is the only global international organization dealing with the rules of trade between nations. WTO come into being on 1 January 1995. As one of the youngest international organizations, it is a successor to GATT.