Intellectual property rights on biological resources: Benefiting from biodiversity and people's knowledge

Ghate Utkarsh, Madhav Gadgil and P. R. Sheshagiri Rao

The Indian Patent Act is being amended, in part, because of our commitments under General Agreement on Trade and Tariff (GATT). Similar considerations have prompted us to formulate a Protected Plant Varieties Act. At the same time, a National Biological Diversity Act is also on the anvil in response to our commitments to the Convention on Biological Diversity (CBD). The CBD has advanced beyond the conventional intellectual property rights (IPR) regime to accept the sovereign rights of nations over their biodiversity resources, and the need thereof to share benefits of commercial applications of traditional knowledge of sustainable uses of biodiversity resources with local communities. It is important for India to benefit from these provisions and create a legislative framework that would be a model for other developing countries as well. Intellectual Property Rights (IPR) are now being extended to biological resources, beyond the conventional domain of mechanical and chemical innovations. On this new biological frontier, considerable pertinent knowledge and resources already exist in the public domain, and CBD has clearly accepted the need to respect and share its benefits with these public-domain resources. These considerations must be reflected in the Amended Patent Act. It is also vital that we ensure a proper harmonization of the provisions of the new Patent Act, Protected Plant Varieties Act, and the Biological Diversity Act. In this article we discuss measures for disclosure of country of origin, relevant public knowledge or agreements in the IPR applications under these acts.

KONRAD LORENZ, Nobel Laureate and one of the founders of the modern science of animal behaviour says that his philosophy of life has been to act creatively; neither to drift passively with the current, nor to break one's head against a brick wall[1]. We might, with profit, apply this philosophy to decide on how we should deal with the challenges being posed by the new compulsions of intellectual property rights (IPR) regimes. For, today, we seem to be engaged in pursuing the two courses rejected by Lorenz. Our political[2] and intellectual[3] leadership calls for rejecting most of the new provisions of the Trade Related Intellectual Property Rights accord (TRIPS) of the General Agreement on Trade and Tariff (GATT)[4]. Given the compulsions under which we operate, this is like breaking our heads against brick walls. So, in actuality, the Government meekly surrenders and we end up drifting with the current[5]. In fact, the few new provisions we make, such as the exclusion of innovations based on formulations in Indian medicinal systems, are more likely to harm rather than serve our interests. This is unfortunate, for the international Convention on Biological Diversity (CBD) has created space for us to creatively develop new approaches within the global framework that we are compelled to accept[6]. In this paper we have proposed various measures that should be adopted to take advantage of these possibilities, while developing the Indian framework for operationalizing a new IPR regime.

Trade-related intellectual property rights

IPRs are meant to assure rewards to innovators, and are claimed to have been an important driving force behind the rapid industrial growth in the developed world[7]. They primarily evolved to protect mechanical and chemical innovations for which identification of novelty, the inventive step and the innovator is relatively straightforward. The current IPR regimes fail to provide any rewards to the public-domain foundations, on which the innovations may be based. This becomes a particularly important concern when the IPR regime is extended to the biological domain too. For, in this domain, activities outside the purview of formal science as well as pub-

The authors are at the Centre for Ecological Sciences, Indian Institute of Science, Bangalore 560 012, India; Madhav Gadgil is also at the Jawaharlal Nehru Centre for Advanced Scientific Research, Jakkur, Bangalore 560 064, India.

lically funded research have generated extensive material and knowledge resources which could serve as the basis for further future protected innovations. Thus local cultivars of crops may provide genes with significant applications; as in the case of Pattambi varieties of rice that harboured a gene for resistance to the brown leaf hopper whose outbreak was causing extensive damage in southeast Asia[8]. Furthermore, many high-yielding varieties of crops have also been developed through large public investments in agricultural research institutions. Other applications, such as the use of neem oil as an insecticide, or turmeric powder as an antiseptic, are part of public-domain knowledge which could be built upon through small steps such as the process for increasing the shelf-life of azadirachtin, the molecule responsible for pesticidal properties of neem oil[7]. Thus, today the IPR regimes, as enshrined in TRIPS, provide for no sharing of benefits with this public-domain foundation, resulting in claims that have been termed 'biopiracy'[9].

India, along with 129 other countries, is now a signatory to GATT – with TRIPS as one of its components – which has several provisions favouring developed countries over the developing ones[10]. TRIPS requires all member countries to provide for a strong 20-year-long patent protection to processes as well as to products based on both domestic and foreign innovations. Its Article 27 compels member countries to protect through patents innovations in all fields including food, health and other biotechnology-related fields. It also erodes the authority of the governments to demand compulsory licensing of essential goods, in the name of public interest, and to regulate their prices. Member countries may however exclude plants, animals, and essentially biological processes for reproduction from patenting. However, now it is mandatory to protect plant varieties through patents, or any other independent *sui generis* system, or combinations thereof that are effective. This requirement of efficacy would preclude farmers from saving, replanting, or selling for reproductive purposes their produce from the protected varieties. Within these limits, it is not mandatory for member nations to adopt the International Union for Protection of New Varieties (UPOV) system, which has no provisions to protect farmers' interests, or to reward them for development or maintenance of cultivars[9]. UPOV only provides for strong breeder's rights, suited to the developed countries, where functions of grain and seed production are divided between the farmer and breeder respectively[3]. Developing countries, like India, where more than half the seed supply is ensured by saving and exchanging of seeds[3], therefore require an innovative piece of legislation looking beyond UPOV.

Developing countries have been allotted a period of 10 years to reform their national IPR legislations to meet the aforesaid requirements. However, the developing countries must soon provide a mailbox facility to file applications for product patents, which will be scrutinized after 2005 AD. Till then, the developing countries must provide for Exclusive Marketing Rights (EMRs) to innovations, have obtained patent protection and marketing approval from any other GATT member nation. Developing counties, committed to these provisions, are finding it difficult to formulate legal and policy measures required to mitigate the serious implications of this requirement for the health and food sectors.

Product patents regime

It has been advocated that India must not allow patents on life forms and their derivatives[3]. No country has as yet adopted this stand, as it might conflict with the TRIPS provisions and invite multilateral sanctions. India was, in fact, taken to task by the World Trade Organization (WTO) for not providing the mailbox facility and EMRs[10]. In order to meet our obligations under TRIPS and to avoid possible sanctions, the Indian Parliament has amended the Indian Patent Act 1970, so as to grant EMRs in the field of agro-chemicals and pharmaceuticals[5]. EMRs would last for a period of 5 years, or till the patent application is approved or rejected after 2005 AD, whichever is shorter. When the amendments were tabled in Rajya Sabha during December 1998 session of the parliament, the pressure from opposition forced the government to agree to further modify them so as to exclude from the purview of EMRs any inventions based on formulations in Indian medicinal systems[11]. It is likely that such inventions may be excluded from product patents, even after the patent act gets amended further.

It is our contention that excluding the innovations based on the Indian system of medicine from the EMR regime may cause more harm than good: it would deprive Indian entrepreneurs and the Council for Scientific and Industrial Research (CSIR) of an opportunity of claiming IPRs; the developed countries may object to this restriction and continue to encourage IPR protection to such innovations domestically, putting Indian entrepreneurs at a disadvantage; and they may also refuse to share any benefits generated from such protected markets unless we too extend similar protection, as required by the 'national treatment' clause of the TRIPS.

In this context, there seems to be little reason to shy away from a system of product patents, with appropriate safeguards, so as to create space for approval of applications on the merit of each case. After all, the Indian government has amply demonstrated its commitment to TRIPS by drafting a Plant Variety Protection and Farmer's Rights (PVP) Act, ready for tabling in the parliament[11]. The earlier drafts of the PVP act proposed a 'Community gene fund' to recognize and reward farmers' contribution[12]. We are given to understand that the recent drafts have done away with such an arrangement in view of the proposed national biodiversity fund, under the draft

Biological Diversity Act. Thus, the term farmers' rights, included in the title, appears to be cosmetic and, in reality, the act merely provides for strong plant breeders' rights (PBR) at the cost of the farmer.

Challenge of biopiracy

The emerging IPR regimes, as enshrined in the TRIPS, primarily protect innovations developed within the system of formal sciences. As a consequence, the scientists and the entrepreneurs, especially from the developed world, are protected; while there is no provision for acknowledging and sharing benefits with the foundations of resources or knowledge in the public domain. For example, take the case of neem oil, a well-known pesticide in many parts of rural India, whose active principle, azadirachtin, breaks down quickly. W.R. Grace & Co., a transnational corporation, invented a chemical treatment for stabilizing the azadirachtin, thereby increasing its shelf life and making it possible for it to be transported worldwide. This innovation was protected through a US patent (No. 5124349)[7]. Although the use of neem oil by the Indian farmers was mentioned in the patent application, there can be no provision for sharing the resultant huge commercial benefits from the sales of the insecticide with the Indian farmers under the present regime. Although the patent would not prevent the Indian farmers from using neem oil locally as a pesticide, as long as it was produced on the farm or purchased in crude form from neighbours or local market, any Indian entrepreneur would be prohibited from developing and marketing a similar commercial invention. The Indian entrepreneurs would therefore be compelled to pay royalty to the Grace Company and sell their product at the prices fixed by the company. Since neither the Indian farmers nor industry knew the process of stabilizing azadirachtin, it is therefore difficult to contest the claims of novelty and inventiveness of the patent.

In the case of Basmati rice, traditionally grown in India and Pakistan, a US Company, Rice Tec., has obtained a patent on similar rice grown in the US (Patent No. 5663484)[13]. The patent claims specify that the inventive steps lie in obtaining equivalent or superior quality of grain from crop grown in an entirely different country. Given the complexity of the case, Indians are still engaged for over a year in collecting evidence to contest it. In contrast, in one of the controversial cases, the US patent office granted a patent (No. 5401504), after initial reluctance, on use of turmeric in the powder form for wound healing, on the grounds that such usage was not known in the US[7]. However, CSIR could present published evidence in an appeal in the US court that such usage was known in India, and hence not novel. Consequently, the patent was revoked. This was an exceptionally easy case to argue. As exemplified by the neem and basmati cases, proofs of public-domain origin of knowledge or resources can be of little use in contesting and rejecting the patents. It is however possible to visualize using such evidences to claim a share of the subsequent commercial benefits, and channel these reward to promote public-domain knowledge and conservation of biodiversity resources, taking advantage of the opportunities created by the CBD.

Convention on Biological Diversity

CBD reflects, to a great measure, the worldwide concern to prevent unfair exploitation of the rich genetic wealth and traditional knowledge of the developing countries by the developed world[14]. Signed by 170 countries till date, including India, CBD came into force in 1993. The convention reaffirms sovereign rights of the member nations over their genetic resources. It requires all the nations to facilitate foreign access to their genetic resources; such access must be on the basis of prior-informed consent of the country of origin (article 15). The terms of agreement could include sharing of benefits, technology transfer, and preferential location of R&D units in the country of origin. It also requires member countries to obtain traditional knowledge of sustainable uses of biological resources with the approval of its holders, their involvement in its wider application and sharing with them the resulting benefits (article 8j). It requires nations to protect the traditional knowledge and customary practices relating to uses of biological resources (article 10c). Furthermore, it stipulates that IPR regimes should be supportive of and do not run counter to the CBD objectives of conservation, sustainable use and equitable sharing of benefits (article 16(5)). For example, countries providing genetic resources could seek technologies including those protected by IPRs, provided that adequate protection is ensured (article 16(3)).

Unfortunately, CBD does not provide any explicit rights, either to nations or people, regarding the vast store of genetic material or knowledge transferred abroad prior to 1993. Much of the public-domain repositories of germplasm and other pertinent information on it is today more readily available through repositories housed in the developed countries rather than in the developing countries of origin. For example, the most extensive and efficient source of information on traditional uses of Indian plants, like neem, is a database, NAPRALERT, housed at Chicago in the US[8]. This information is compiled through exhaustive search of literature, including Indian sources, often not available to most Indians. Moreover, Rice Tec. developed its Basmati lines from the strains obtained before the CBD[13] came into force. Hence, the question of prior-informed consent of India or Pakistan does not arise within the existing CBD framework. Despite such limitations, many of the provisions in CBD may be of great help in safeguarding the interests of the developing countries, provided that they enact supportive national legislation as well.

Proposed Indian Biological Diversity Act

To give effect to the provisions of the CBD, Indian government has drafted a biological diversity legislation[15] to be tabled in the parliament for enactment. It was widely circulated and discussed by the Ministry of Environment and Forests, including with the authors. The legislation contains the following important clauses relating to IPRs and benefit-sharing:

(i) People's knowledge shall be registered at local, state and national levels and protected with the help of a *sui generis* system of IPRs (article 14). This provision presumably refers to information yet undisclosed. Besides, institutions of self-governance – from village-level upwards – have been entrusted with the responsibility of chronicling biodiversity resources, people's knowledge, and conservation efforts (article 11); presumably to define the extent of public-domain resources.

(ii) Any person applying for IPRs in India or abroad, relating to biological resources occurring in and/or accessed from India, must obtain prior permission of and abide by the benefit-sharing conditions imposed by the national authority (article 17).

(iii) The national authority, if necessary shall oppose worldwide the IPRs granted in relation to biological resources or knowledge derived from India (article 8iv).

(iv) No foreign agency can access biological resources occurring in India and related knowledge without the prior-informed consent of the national authority (article 15).

(v) In cases where a person or a group of persons exclusively contribute to the resource or knowledge, they shall directly share the royalty resulting from its subsequent commercialization. Otherwise, such share of benefits shall be deposited in a national biodiversity fund (article 16).

(vi) The national biodiversity fund would be primarily used to reward people for their conservation efforts and knowledge (article 21). Although the basis for making such awards is not specified in the act, the periodic documentation of resources, knowledge, and conservation practices by the village-level management councils, envisaged in article 11, may offer an accountable and transparent foundation.

These are indeed positive provisions. However, to operationalize these provisions, the proposed PVP Act and the amendments to Patent Act must play a supportive role. To enhance the complementarity among these three acts, we suggest below a series of measures.

Complementarity measures disclosing biological material and knowledge

Any benefit-sharing arrangements would critically depend on our ability to link the innovation to its biological origin and to prior knowledge of its uses. To do this effectively, it will be necessary that the patent, PVP act, and Biodiversity Acts enforce following disclosures and submissions in the specification section of the applications.

(i) *Biological source*: Specify the organism/s and products thereof used to produce the invention such as a drug, or the parental crop lines, or germplasm accessions used to breed a new variety.

(ii) *Country/ies of origin*: Specify the country/ies that harbour the biological source/s in natural or naturalized conditions. Several proposals suggest using some cutoff date in the history, such as 1500 AD, to determine prior natural geographical distribution of organisms[6].

(iii) *Accession details*: Specify country and agency (e.g. private farmer or village council, public sector or private sector gene bank, etc.) providing the organism or variety/ies used as source material/s.

(iv) *Material transfer agreement (MTA)*: Provide a certificate from the national authority of the country and, if necessary, the donor agency that provided the resource; specifying that access was granted on the basis of prior-informed consent and on mutually agreed terms. In case the country providing the resource does not require an MTA, then a sworn statement to that effect has to be provided.

(v) *Public-domain knowledge*: Provide relevant prior knowledge about uses of the biological materials; available through public sources such as patent documents, publications, other printed media, computerized databases and other electronic media, inscriptions and the village-level documents proposed under the draft Biological Diversity Legislation (article 11).

(vi) *Information transfer agreement (ITA)*: For knowledge not publicly available as above, mention the information transfer agreements with the private persons providing the undisclosed information. In fact, the proposed Biological Diversity Act mentions that the knowledge about biological resources occurring in India cannot be accessed by foreign agencies without the prior-informed consent of the national authority (article 15). Obviously, this provision seems to refer to transfer of undisclosed information. The law must additionally allow persons holding such information to become a party to the agreement. Such disclosures and proofs of prior-informed consent have been widely advocated in the IPR reforms suggested in recent literature[9,16,17].

Registering claims of knowledge

It is possible that some of the applications provide inadequate or misleading disclosures or agreements. For example, an entrepreneur may obtain information about medicinal usage of a plant from a villager without any prior agreement, and apply for IPRs on subsequent innovations. In such a case, when the patent claims are laid

farmer communities or to appropriate institutions of self-governance. Identifying all the beneficiaries would of course be an immense challenge, requiring innovative mechanisms. In case a folk variety does not seem to be distinct in terms of either its identity or ownership, the cultivators could be rewarded from the National Biodiversity Fund as a general incentive for continued conservation; not specifically linked to the cultivar. Implementing any kind of benefit-sharing would necessitate a decentralized programme of documenting agro-biodiversity at the village-level itself. This could be organized along the lines of the village-level documentation proposed in the Biological Diversity Act (article 10). The local-level characterization of the folk varieties will have to be validated by agricultural university scientists, including through use of advanced techniques, such as DNA fingerprinting. This information must also be linked to the databases of accessions held by the National Bureau of Plant Genetic Resources (NBPGR). As a matter of fact, NBPGR has recently initiated a countrywide drive to collect germplasm of folk varieties[21]. This programme must include provisions to enable us to distinguish folk varieties, their geographical distribution, and the custodian farming communities.

Broader public scrutiny

Safeguarding the interests of nations or people who conserve biodiversity and associated knowledge, requires tailoring IPR regimes to strike a balance between the protection and public accountability. The evaluation of the IPR claims is becoming an increasingly complex affair demanding greater sophistication and specialization. The quantum of information available globally is also sky-rocketing, posing difficulties in its compilation and screening. Patent authorities therefore find it difficult to adequately scrutinize new applications, especially the ones making claims of novelty. To step up the pace of granting patents, without sacrificing social justice, it would be desirable to make the patent scrutiny a more broad-based process. For example, specialists such as *Ayurvedic* and folk healers, private and public plant breeders, farmers, etc. must be effectively involved in evaluating the IPR applications[22]. Such openness would also serve democratic interests by eliciting participation of various stakeholders to create a 'win–win' kind of situation. Today, the only opportunity for such diverse sectoral interests to evaluate the IPR claims is when these are made public for inviting opposition. Instead, it may be more appropriate to institute a multidisciplinary appraisal of the IPR applications from the outset itself.

Benefit-sharing tribunal

The purpose of these various suggestions is to suitably reform the IPR regime so that folk knowledge and resources too have a share in the commercial benefits; since, traditionally, the IPR legislation is only meant to protect the ability of an entrepreneur to monopolize the market and corner the benefits. Hence, IPR laws cannot on their own provide for sharing of the commercial benefits with the public-domain foundation of knowledge and resources underlying the innovation. That function is being entrusted to the national authority being constituted under the proposed Biological Diversity Legislation. It is therefore necessary for the patent office or the PVP authorities to evolve mechanisms to share their information with and provide appropriate advice to the national biodiversity authority to promote equitable sharing of accruing benefits. This collaboration is necessary to effectively discharge, at a minimum the following functions:

(i) To identify the nature and extent of public-domain knowledge collated through registration of claims on the one hand, and village-level documentation of knowledge and conservation efforts on the other. These activities are proposed under the Biological Diversity Legislation. It would be preferable to compile such information as networked computerized databases.
(ii) To adequately employ the material and information transfer agreements issued by the biodiversity authority.
(iii) To convey information relating to the grant of the IPRs to the biodiversity authority, so that it can levy appropriate benefit-sharing fees, and other conditions such as technology transfer, local R and D installation, etc.

A multi-disciplinary tribunal to achieve harmony between the objectives of the Patent Act, PVP Act, and the Biological Diversity Act might best serve these interests. The national biodiversity authority is empowered to constitute any such committee to execute specific functions (article 8).

People's biodiversity registers

The village-level documentation of crop cultivars, locally used medicinal herbs, wild foods, and other biodiversity resources; and of their use, and conservation and management practices envisaged in the legal framework might take the form of people's biodiversity registers (PBR) for which we now have gained some practical experience[23]. These PBR, may also serve another important function, namely, that of promoting sustainable management of biodiversity resources. This would be greatly facilitated by suitable amendments in the Panchayat Raj Act so as to empower local communities to manage local biodiversity resources, to regulate harvests, and to charge appropriate collection fees along the lines of the provisions of the extension of the Panchayat Raj Act to Scheduled Areas Amendments of 1996 (ref. 24). Such collection charges are already a common practice in several other tropical countries[14]. Such empowerment of panchayats would

strengthen the ongoing programmes of joint forest management; with PBR serving as an appropriate information base for planning and monitoring purposes[25].

Based on the documented efforts of conservation or contribution of knowledge, village councils may be rewarded[6] from the National Biodiversity Fund. These incentives could take various forms, such as allotment of a venture capital fund for conducting experiments to implement the innovations; like commercialization of local health practices, establishing of small-scale enterprises to commercialize the biodiversity resources – for example, setting up of a forest produce-processing unit, or to initiate biodiversity-friendly development measures like manufacturing of a smokeless stove[6]. A part of the fund could also be assigned to organize knowledge networks whereby local healers or traditional farmers across the villages can exchange and validate views, get felicitated or rewarded. Such taluka-level or district-level networks may also undertake promotion of such enterprises as cultivation of medicinal plants or establishing of their processing units. Such units are often non-viable at a small-scale, owing to limited resource catchments, high fluctuations in supply and demand, and limited expertise. Therefore, cooperative arrangements and sharing of information between these district-level and taluka-level networks can greatly facilitate infrastructural capacity building for managing biodiversity sustainably.

Translating IPRs into economic benefits requires suitable market opportunities and good information on them. But, in the present scenario, the medicinal plant collector or traditional farmer has no information on the premium markets of Europe, or even for that matter of Mumbai. The meagre income the villagers today earn from their biodiversity resources, only promotes unsustainable harvests of medicinal plants or replacement of landraces with high-yielding varieties, a practice which is accelerated due to subsidies for modern seeds, chemical fertilizers and pesticides. Therefore, for encouraging biodiversity-friendly practices, information on local and global markets must be collated and fed back to the villagers for making informed choices, and consequently assert themselves in having a say about procurement prices.

The people's biodiversity register programme would suit well the mandate of the National Bioresources Board (NBB), proposed to be constituted under the Department of Science and Technology, according to the union budget 1999–2000 (ref. 20). Since formal launching of this programme at the level of the government would take its own time; in the meantime, NGOs all over the country have on their own, initiated such moves. For example, the Indian Institute of Science coordinated a countrywide effort with the support of World Wide Fund of Nature-India (WWF-I) during 1996–1998, which led to the compilation of PBRs 50-village clusters from 7 states, representing various socioeconomic and ecological zones[23]. Several other NGOs have also initiated preparation of such registers in their own areas, with their own flavour. Such NGOs represent a diverse spectrum including the Foundation for Revitalization of Local Health Traditions, Bangalore; Kalpavriksh, Pune; Navdhanya, Dehradun; M.S. Swaminathan Research Foundation, Chennai; Kerala Shastra Sahitya Parishad, Cochin; Vruksha Laksha Andolana, Sirsi; Nagarika Seva Trust, Mangalore; and Deccan Development Society, Hyderabad.

International follow-up

Our national efforts on IPR need to be complemented by similar international efforts by promoting supportive international policies and legislative frameworks. The measures suggested here are not inconsistent with the TRIPS provisions and hence will not invite any penalties. On the other hand, these provisions would place India in a leading position amongst developing countries in fighting the inequities within GATT. Today, most of the other countries in the world are increasingly providing strong IPR protection in all fields of technology, as recommended by GATT. Even China, which is not a WTO member, provides for strong IPR protection[26]. It is therefore necessary that we accept the general IPR framework, but with due safeguards to protect and promote customary uses and traditional knowledge of biodiversity through equitable sharing of benefits. No major developing country has so far amended its IPR legislation towards this end, and India could lead the way. It may be noted in this context that the Kenyan Industrial Law, 1989, has provided for granting of petty patents on folk medicinal formulations[27]. However, it does not enforce acknowledgement and rewarding of public-domain knowledge, as these became important concerns after the CBD came into force in 1993.

India must therefore lobby with other developing countries, in fora such as G-77, for similar changes in IPR legislation worldwide which include the developed nations as well. Most importantly, these amendments must be incorporated into the TRIPS itself, when article 27 is reviewed during 1999 and the entire TRIPS comes up for review in 2000 (ref. 9). As a matter of fact, India had proposed amendments to TRIPS relating to disclosure of biological material and its country of origin during the WTO negotiations in 1996 (ref. 28). However, these suggestions were not backed by other countries and were eventually turned down. India must now renew its efforts in collaboration with other developing countries, with emphasis on rewarding public-domain knowledge. World Intellectual Property Organization (WIPO) of the United Nations has initiated round-table discussions to institute mechanisms to protect folk knowledge[29]. The database treaty, negotiated under the WIPO, raises new concerns and challenges. It provides discretionary rights to the creators of the databases[30]. In the context of databases of peoples' knowledge, such as trade secrets of Eucador[14] or