

RESEARCH COMPONENT II- NATIONAL LEGISLATION ON IPRs

I. THE PATENTS (AMENDMENT) ACT, 2005

Section 2 - This section does not include the definition of micro-organisms, but refers only to the 'Budapest Treaty' which does not provide for a definition of micro-organisms either.

Recommended that micro-organisms should be defined in extremely narrow terms, through a multi- stakeholder consultation process. This is because granting monopoly rights like patents on micro-organism always carries with it the risk of restricting accessibility to the resource base, due to the expansionary tendencies of the patent holder claiming ownership rights over all the usage of that resource and consequently the risk of a rights spill over.

Section 25- It allows third parties to represent to the controller for non-granting of patent. However, by the addition of the proviso that the person making such a representation shall not become a party to any proceeding under the Act, the clause prevents the active participation of the person making the representation.

Gene Campaign's view is that the participation of the person representing is vital not only for the establishment of the initial facts, but also to gauge the nature and scale of misappropriation, for the affected parties, as well as the circumstances involving the misappropriation and modes of redress. Thus, this provision of the Act, which necessarily translates into a disincentive for any person making the effort, needs amendment.

We also believe that it should be made mandatory for the National Biodiversity Authority, constituted under the Biological Diversity Act, to represent to the patent controller in cases where the invention claimed was anticipated, having regard to the knowledge available within any local or indigenous community in India, where NBA has such information. This is imperative since NBA being the specialised body meant for the express purpose of protection of biodiversity and indigenous knowledge, has both the constitutional mandate and the expertise to play an active role.

Section 26- It states that any person interested after the grant of patent (within one year) may give notice of opposition to the controller. Herein the *locus standi* for filing of opposition is limited to 'any person interested'; the implication is to restrict the filing of opposition only to those persons who have been commercially affected by the grant of the patent.

This would unduly limit the *locus standi* and would *de facto* nullify the effect of the stated grounds of opposition, which would logically entail the involvement of actors who may not be interested in the commercial aspect of the patent. Thus 'interested persons' should also include any persons acting pro bono.

The Act provides a limit of **one year for post-grant opposition**.

This time period is insufficient, because the existing IK may not be noticed within a year of grant of patent, especially given the relative newness of the patent system in India. The time period should be extended to at least three years, with the added flexibility that any notice of opposition after the expiry of three years would be acceptable on the condition that the applicant satisfies the authority that he had sufficient cause for not making the application within the prescribed time period.

Section 54 deals with any ‘invention’ that has been modified or improved.

It is important to realise that this may become a mechanism by way of which indigenous knowledge may be used to undertake improvements or changes to the initial ‘invention’. It is therefore, necessary, to include an express exclusion of the usage of indigenous knowledge to contribute to the improvement or modification of the ‘invention’.

Section 19 specifies the powers of the controller in cases of potential infringement. In this case the basis of a potential infringement is “that the patent applied for cannot be performed without substantial risk for infringement of a claim of any other patent”.

Herein the risk of potential infringement should be expanded to also include substantial risk of infringement of any indigenous knowledge.

Section 83- states the general principles applicable to the working of patent inventions.

The mere inclusion of such a general clause is not sufficient to protect larger social objectives and goals, especially that of protection of indigenous knowledge. This could be done in two steps. Firstly, it should be expressly stated that the violation of any listed principles should be a ground for revocation or compulsory licensing. This would make the provision enforceable and thus inherently enabling. Secondly, the phrase ‘public health’ should be extended to include the right to access biological resources and health remedies sourced from therein. And, therefore, if the grant of a patent right over certain resources (micro-organisms being patentable) circumscribes this right of local or indigenous communities, it should be interpreted to mean violation of public health needs.

II. THE BIOLOGICAL DIVERSITY ACT, 2002

(i) Section 2 (f) defines the phrase ‘fair and equitable benefit sharing’ as something that will be determined by the National Biodiversity Authority.

The determination of fair and equitable benefit sharing is a matter in which local persons and beneficiaries must have a strong say. This actually amounts to a transgression of the rights of the local and indigenous communities, who being the actual beneficiaries of the benefits arising out of the use of their knowledge, would have no role in this process of determining equitable benefit sharing.

(ii) Section 37 of the Act declares that the power of declaring a Biodiversity Heritage Site lies with the state government. This provision threatens the local and indigenous communities who live in forest areas where we find the maximum bio-diversity. The Act fails to recognize communities as a critical component of this diversity, and thus

specifies that when the state so wishes it may declare an area as "heritage site" and remove all communities from there. This is an anti-people clause. The heritage sites should be designated only after consultation and moreover, consent of the affected communities. (The Tribal Rights Bill has tried to some extent to address such issues and take corrective steps).

(iii) Rule 22(6) of the Biodiversity Rules 2004 clearly states that the main function of the BMC is to prepare Peoples' Biodiversity Registers in consultation with the local people. The Register is expected to contain comprehensive information on availability and knowledge of local biological resources.

The PBR appears to be a one-way extractive flow out of information, which is likely to be controlled, in a centralized database where it then becomes easy for the State to negotiate/enter into agreements with private parties. There is no clarity on how this documented material could genuinely help people and communities or include their consent when evaluating access by third parties to information.

(iv) Section 3 and Section 7 differentiate between Indian and non-Indian citizens and companies. This is unjustified, given that Indian corporations are not any more responsible towards the environment or towards local communities. Also Indian Companies are often local fronts for foreign enterprises.

It needs to be ensured that Indian companies alone do not have automatic rights to commercialization. The only differentiated category can be the local community itself. Commercial interests both Indian and foreign must be treated on par with respect to access and benefit sharing when it comes to bioresources and IK.

(v) Rule 14(4) of the Biological Diversity Rules 2004 provides for the NBA to grant approval for access to biological resources and associated knowledge subject to such terms and conditions as it may deem fit to impose. This raises the question whether these terms and conditions incorporate the needs and ethos of the community associated with the particular knowledge.

A provision to ensure NBA consultation with a representative body of local communities is needed as a corrective.

(vi) Rule 14(6) lays down some clauses, which have to be included into the agreement of access. This list of clauses ignores the livelihood concerns of the community. Though it does state that the applicant has to adhere to the limit set by the authority regarding the quantity and quality of the biological resources, this limit clearly excludes the livelihood requirements of the local communities. This should be clearly stated.

(vii) The presence of various governmental agencies is likely to create a conflict of interest unless some clear and common mandate and understanding is developed. Further, conflicts in functioning are likely to arise with the presence of the elected local body – Panchayats and the other institutions such as Forest Management Committees, Eco-development Committees, Water users Associations and the Biodiversity Management Committees. Exact roles and jurisdiction needs to be specified.

(viii) Conflict likely between Various Legislation

Initially, the Biological Diversity Act was designed as an umbrella Act to make good the defects of the earlier colonial Forest Act and override it, and as a herald of a new age, it would have overridden many of the earlier acts such as the Forest Act designed in the colonial era. As passed, however, it only has the status of a complementary Act and will have to be operated side by side with a whole range of other Acts.

(ix) Under section 6 of the Act, a person must obtain the prior approval of the NBA before he applies for Intellectual Property Right in or outside India for any invention based on any research or information on a biological resource obtained from India. In case of a Patent, the permission from the NBA can be obtained after the acceptance of the Patent but before sealing of the Patent by the concerned Patent Authority. However, this provision does not apply to an application made securing any right under any law relating to protection of plant varieties.

The Biodiversity Act surrenders ground on IPR of bioresources that has been claimed by other legislation related to the subject matter. The PPVFR and the Patent Act have separately proscribed the application of patent protection to biological materials like plants and animals and their parts and products based on IK. By not qualifying the nature of the IPR, the Act may have tacitly accepted that IPR may include patents. This is distinctly out of tune with the prevailing ethos of not granting patents on biological material (except microorganisms) and IK.

(x) On occurrence of an instance of biopiracy, the NBA is empowered by the Act to take necessary action to oppose the grant of IPR in any country outside India on behalf of the Government of India [Section 18(4)]. In the absence of a globally agreed single forum wherein such cases can be challenged, the NBA may have to only engage in fire-fighting at different patent/ trade mark offices overseas.

Also, it has been realized that to check biopiracy, national action alone is not sufficient. The onus must also be shared by the users of this knowledge all over the world so as to ensure compliance of the consent requirement for using the knowledge and equitable sharing of benefits as visualized in the CBD.

III. THE PROTECTION OF PLANT VARIETIES AND FARMERS' RIGHTS ACT, 2001

The following clauses need to be amended in order for the Act to be effective:

Benefit Sharing

Despite its good intentions of protecting the interests of the farming community; the Act is likely to create problems in implementation because the description of the National Gene Fund is confused and poorly drafted.

It is recommended that the Gene Fund should be the recipient of all revenues payable to the farming communities under various heads. This money should be collectively, rather than individually, accessed by farming communities. Exceptions could be made where individuals are clearly identified as breeders' of specific varieties. Farmers should have the right to decide how this money that they have earned will be spent. The

use of the money should not be restricted to conservation or for maintaining ex situ collections. The method for fixing and realising benefit sharing should be made simpler and easier to implement. One approach to fixing benefit sharing could be a system of lump-sum payments, based for example on (projected) volume of seed sale.

Protection against Bad Seed

In providing a liability clause in the section on Farmers Rights, the farmer in principle is protected against the supply of spurious and/ or poor quality seed leading to crop failures. At present there is too much left to the discretion of the Plant Variety Authority which will fix the compensation. This could lead to arbitrary decisions and should be amended. If it is proven that the breeder has made false claims and the farmer has suffered a crop failure, then compensation should be awarded amounting to at least twice the projected harvest value of the crop. Compensation should be large enough to be a deterrent. In addition, a jail term should be provided if the breeder repeats the offence.

Protection against innocent infringement

The legislation has attempted to address a concern voiced by several quarters, that when the new system of Plant Breeders Rights is imposed for the first time, there will probably be many cases of unknowing infringement of Breeders Rights. Section 43 specifies (somewhat fuzzily) that the farmer cannot be prosecuted for infringement of rights specified in the Act if he can prove in court that he was unaware of the existence of such a right. This well intended point is badly made and will have to be made more specific. Nothing is said about what would constitute a violation of Breeders' Right. This becomes especially critical since the Act would allow the farmer to sell generic seed of the variety protected by Breeders' Right. And what would constitute proof in a court of law that the farmer was unaware of the existence of such a right? In all likelihood this will boil down to a 'your word against mine' situation and be very difficult to prove.

Breeders' Rights

Breeders Rights over the varieties they have developed are more than adequately protected by the legislation. On registration, the Breeder has rights of commercialisation for the registered variety either in his/ her own person or through anyone he designates. These rights include the right to produce, sell, market, distribute, import or export a variety, in short, full control over formal marketing.

The strong protection granted to a plant breeder over his/ her variety is seen in the section dealing with infringement of Breeders Rights where punishment in the form of substantial fines and jail terms has been prescribed for those who infringe the rights of the registered breeder.

Violation of Breeders right can be construed at several levels. It applies to the variety itself as also to its packaging. Infringement will be established if the packaging is the same or even similar, such that the package could appear to be that of the Breeder. Legally, a similar looking package will be considered " Passing Off" and so actionable. Any one other than the Breeder naturally can not use the registered name or denomination. The use of the same or similar name in any way, by action or even suggestion, will constitute a violation and will be punishable. Penalties are prescribed

for applying false denomination and for selling varieties to which false denomination is applied.

The Breeders Rights have been strengthened to the extent that if there is mere suspicion of violation or infringement, the onus of proving innocence is placed on the alleged violator. In any prosecution for falsely using a denomination, the burden of proof is reversed and it is incumbent on the alleged violator to prove that the consent of the Breeder was obtained. This is excessive and needs to be toned down. The normal course in law is for the accuser to furnish proof for the accusation and so it must remain in this case too. The grounds constituting violation are laid out in such elaborate detail, listing the smallest acts that can be construed as infringement in a way that the hold of the Breeder over his variety is very strong indeed. Unless the alleged violator proves that he acted in innocence, without the intention to defraud, jail terms and penalties are stiff.

The Indian legislation in providing a well-defined breeder's right provides sufficient incentive for the seed industry to invest in this sector. At the same time, it is important to recognize that IPR protection does not necessarily deliver a successful product. If a variety decisively provides an advantage, it will be bought, if it does not, it will fool the farmers for a few seasons and then fail. It is also necessary to keep in mind that all IPR systems must strike a balance between the monopoly granted to the IPR holder, in this case the Plant Breeder, and the benefits to society, in this case the farmers and consumers. Since nobody concerned with public interest would want plant breeding to shift into just a few hands, it is important to maintain competition and vitality in the plant breeding sector. That is why freedom and rights for other researchers to use all genetic material, including IPR protected material, is important. An IPR system in a country should not grant such strong rights to breeders that farmers suffer and their livelihoods are threatened. On the other hand, the breeders' innovation should be rewarded so that they continue to breed useful varieties to benefit agricultural and food security.

Rights of Researchers

The Act has provisions for Researchers Rights which allows scientists and breeders to have free access to registered varieties for research. The registered variety can also be used for the purpose of creating other, new varieties. The Breeder cannot stop other breeders from using his/ her variety to breed new crop varieties except when the registered variety needs to be used repeatedly as a parental line. In such a case, authorization is required. It is however felt that the Indian law actually grants very restricted rights to researchers because of the acknowledgment of Essentially Derived Varieties, EDV, which is defined in detail in the 1991 UPOV Convention. According to the expansive definition of EDVs, it is felt that all kinds of research will become subject to the Breeders' authorization if a protected variety is used for research. In the Indian Act, the Breeders' authorization is needed for making EDVs. The processes for making EDV have been made so encompassing in UPOV (natural selection, mutant selection, somaclonal variants, backcrosses and transformation by genetic engineering) , that all known forms of creating new varieties would be covered. This would squeeze the researcher's space to the extent that for practically any kind of research on the protected variety, the authorization of the breeders would be needed, establishing their control on a lot of germplasm.

IV THE GEOGRAPHICAL INDICATIONS OF GOODS (REGISTRATION AND PROTECTION ACT, 1999

- (i) The weaknesses stem from the general characteristics of GIS, rather than from limitations of the Act.
- (ii) Section 22.2 of the Act provides the Central Government with the authority to give additional protection to certain goods or classes of goods, reserved for wines and spirits. This provision is ineffective without corresponding changes in the international scenario. India needs to successfully negotiate in the TRIPS Council, to broaden the scope of additional protection to other sectors of importance to it. It would be practical to base such absolute protection on a registration system specifying the geographical indications
- (iii) However, it is crucial for India to consider carefully the potential costs of extension. Increased protection, applied internationally, may adversely affect local enterprises which exploit geographical indications that may become protected by another party.
- (iv) The economic consequences of seeking and enforcing protection for geographical indications might be prohibitively high. Resources may need to be deployed to ensure that the required quality, reputation or other characteristics of the product covered by the geographical indication is maintained. Indian IK holders may not always be in a position to do so.
- (v) Registration under the Act is not enough; communities that own GIs must be alert to their misuse or abuse and prevent their genericide.

RESEARCH COMPONENT III- OTHER NATIONAL LEGISLATION WITH BEARING ON IK

I. THE INDIAN FOREST ACT, 1927

The combined effect of sections 6, 7, 8 and 9 is that if one fails to bring to the notice of the Forest Settlement Officer any right and corresponding claim over the specified area, his right shall extinguish. In other words, the burden of proving the right lies on the claimant unless such right is already in Government record. It is recommended that the procedure for proving the right of the claimant should be made more easy.

The Indian Forest Act anticipates 3 types of claims in forests proposed to be reserved. Firstly, a forest dweller might lay claim of ownership of land. Secondly, right to pasture and forest produce. And thirdly, right with respect to shifting cultivation. Notably, the Forest Settlement Officer has no power to confer any right on the forest dweller, which has not been satisfactorily established. But he is bound to express fully to the Government, his opinion and advice as to any practice which, though not satisfactorily proved to be an existing right, he may think is advisable to sanction as a right or a concession in the interest of the people. It is upto the Government then to decide whether such non-established rights or concessions may be granted in the interest of the people or not.

It is recommended that considering the fact that since community rights or customary rights are difficult to prove in the prevailing judicial system, the scope provided to the FSO should not be left to the whims of an officer.

From the point of view of protection of IK, the most important question that such a provision can pose is - what are the rights over the natural resources that the holders of IK possess. A community might have been relying on forest products for its livelihood for generations. But unless they have legally recognised rights over the forest they cannot assert them. Written records of the ancestors of tribal communities are not likely to exist, making claims to forest land contentious between tribal communities and non-tribal communities that have occupied land since generations.

Should any person currently using forest land or forest products be given rights over the forest? Should the granting of right be limited to communal rights of Schedule Tribes recognised under the Fifth and Sixth Schedule of the Constitution as distinct communities? Should rights be based on reference to historical documents? How feasible would that be for a community that is oblivious of the modern education and legal systems? The only practice that has been recognised by the Act is the practice of shifting cultivation, as a privilege or concession. But being a privilege and not a right, it is enjoyed at the pleasure of the state Government, which can prohibit such practice.

2. THE WILD LIFE (PROTECTION) ACT, 1972

Chapter IIIA of the Act, introduced by the 1991 amendment, with a view to protecting specified plants, clearly indicates that members of Scheduled Tribes can freely pick, collect or possess, in the district he resides, any specified plant or part or derivative thereof for his bona fide personal use. Thus, the introduction of this particular section creates a sanction for the activities of the Scheduled Tribes dependent upon forests. However if seen from the perspective of protection of IK, it gives rise to certain questions like:

- (i) Why it is only the Scheduled Tribes whose interaction with the forest land is kept in tact? There might be other people who are not Scheduled Tribes but dependant upon the forest.
- (ii) The holders of IK, for example a *vaid* in a village practicing herbal medicines, need not be a member of a Scheduled Tribe. It is essential that he is not prohibited from collecting and experimenting upon wild herbs, if his knowledge base is to be protected from extinction due to non use.
- (iii) Further, how to define 'personal use' in the context of a *vaid*, whose livelihood is to cure people from various diseases?

The above questions need to be adequately addressed if this provision is to benefit the IK holders.

Section 36C of the Act introduces the concept of 'Community Reserves', under which the State Government may, where the community or an individual has volunteered to conserve wild life and its habitat, declare any private or community land not comprised within a National Park, Sanctuary or a Conservation Reserve, as a Community Reserve, for protecting fauna, flora and traditional or cultural conservation values and practices. This is a welcome step towards legal recognition of people's efforts at conservation. However, as per the definition provided for Community Reserve, it is confined only to private or community land. There may be communities traditionally involved in

conservation, though the land concerned might belong to the Government. In such cases, those communities will not be able to derive benefits from this new provision, nor extend the benefits to the biodiversity they are conserving. Further, there is no definition of community land.

Community land needs to be clearly defined so that this provision could be effectively used to recognize the rights of the people.

Section 36A the Act which provides for constitution of "Conservation Reserves", states that for such constitution, the nature of the land should be such that it is adjacent to national park or sanctuary and link one protected area with another. The objective is to protect landscapes, seascapes, flora and fauna and their habitats. Notably, the Act requires consultation with local communities in declaration of Conservation Reserve. Also, in the Management Committee for the Conservation Forest, there is provision for including member from the Village Panchayat and NGOs. Though it is a positive step, yet actual representation from the village community can not be said to be ensured. While on one hand the management committee is only an advisory committee, on the other, representation is sought through elected members from the Panchayat. The success of the *Panchayati* system is itself under a great deal of debate and there has been opinion that elected members often do not represent all sections of society, particularly the disprivileged.

The same concern also applies to the Community Reserve Management Committees, formed under the Act. It also consists of members nominated by the Village Panchayat and where there is no such Panchayat, nominated by the *Gramsabha*.

These provisions need to be reframed in such a manner that there is comprehensive representation from all sections of the society, particularly the disadvantaged, women and others.

THE DRAFT SCHEDULED TRIBES (RECOGNITION OF FOREST RIGHTS) BILL, 2005

(i) The Bill entrusts the Gram Sabha with a lot of responsibility, without going into the question whether all Gram Sabhas are willing to take on all the responsibilities and have the capacity to do so. In reality, many Gram Sabhas may not have the inclination or the capacity to deal with such daunting tasks as dealing with forest offences on their own. They may need or ask for a systematic support to handle the responsibilities that they have been entrusted with. The Bill doesn't provide for any such institutional or other kind of support; perhaps this can be built into the Rules.

(ii) During settlements of rights, the bill vests authority in the Gram Sabha to initiate action for determining and recording the forest rights that may be vested. This should be done in well-attended open meetings to ensure transparency and accountability and to protect the non-literate from the tyranny of paper work and bureaucratic procedures.

However, Gram Sabhas need not always be democratic.

(iii)The Bill treats wildlife and forest offences quite casually, by imposing an fine insignificant of Rs 1000 , which is inconsistent with fines for same offences under Wildlife Protection Act and other existing Acts. Penalties need to be more stringent and on the higher side to serve as effective deterrent.

(iv)The Bill will be applied in areas and subjects which are also under the Indian Forest Act, Forest Conservation Act and Wild Life Protection Act, which have elaborate provisions to deal with forest and wildlife related offences. There is no suggestion in the Bill about dealing with these offences in any coordinate manner.

The Bill needs to clearly specify the roles and responsibilities of the Gram Sabha and the forest department and the relationship between this Bill and other relevant Acts. Clear institutional mechanisms need to be worked out to deal with the offences, with appropriate checks and balances.

(v)The Bill presumes that all adivasi cultures and societies aid conservation goals.

Gene Campaign feels that it would be incorrect and dangerous to make such presumptions. It suggests that if the rights of adivasis over forest land are to be recognised, it must be done with the explicit understanding that they too, like other communities, can adversely impact wildlife and incorporate appropriate safeguards .

(vi) The Bill does not define terms like “sustainable use” of resources, or “community forest resource”.

Gene Campaign recommends that such terms need to be precisely defined as otherwise, these remain subject to diverse interpretations, and would be most difficult to implement.