Chapter 7
CONCLUSION

To quote Mahatma Gandhi, “It is not a mistake to commit a mistake without knowing it to be one; but it is a mistake not to correct the mistake knowing it to be one.” And the issue of access to GRs and resultant benefit sharing unveils a story of continuing and rather uncorrected mistake of facilitating misappropriation through IPRs. The demand for property rights over GRs and associated TK is a direct outcome of the exercise of monopolistic IPRs by the North over the GRs and associated TK of the South. This grab even affected the very existence of many farming communities of the developing world. Factors like the inability to carry on traditional farming, exorbitant prices of the high yielding commercial varieties and the taking away and use of GRs and associated TK leading to products of high market potential without getting compensated made the developing countries to demand property rights over their GRs and associated TK. They called the gene rush over GRs and associated TK without permission and without due returns as biopiracy and misappropriation. The developing countries devised the shield of property rights to defend the attack of patent monopoly since property rights are the best tools to fundamentally argue for legal regulation. The major thrust of this work is to assess the legal basis of the property claim over GRs and associated TK and to further assess the success of the different international initiatives which are based on this property right, in the battle for preventing misappropriation.

Legally regulating access proves to be a laborious task owing to the multiplicity of actors as well as issues involved in it. Since rampant international resource transfer could be traced from many centuries back, the
most difficult question relates to ascertaining the country from where a particular resource originate. Similar resources could be found out from different countries. People belonging to different countries may be having same or different knowledge over the uses of a particular GR. A GR native to a particular country may sometimes be obtainable from a gene bank. Within a particular country, a GR may be in possession of various people. Sometimes, there may not be identifiable holders for some GRs within a country. Often, the knowledge of different uses of a GR may be a matter of common knowledge to the people of a particular country. Over and above all, the nature of GRs adds to the complexity of issues as they can be easily appropriated even without anybody’s consent. Since the value of a GR lies in its parts, taking some leaves or a stem or a root would be sufficient to identify or isolate its properties. Mixing up of property rights with this complex scenario makes the affair more problematic. To be considered property in the strict legal sense, the subject matter should sufficiently outline the element of ownership over it in exclusion to others. Ownership and exclusivity are the underlying norm of property in the Western legal philosophy. Further, only the owner of the GR can provide legitimate access to it. The study reveals that the principle of permanent sovereignty which constitutes the basic premise of the CBD also constitutes the basis of property right of the State over the GRs. It helps to own the State the GRs found in its *in-situ* condition in exclusion to the rest of the world. The permanent sovereignty doctrine also allows the State to decide the issue of ownership internally whether to enjoy complete ownership of the GRs or share the ownership with its people or to vest it completely with the people. In the legislation of Sarawak, the ownership over the resources is vested completely with the State while most of the other States follow a principle of the resources being jointly held by the State as well as the people and the former acting in a supervisory role so as to protect the interest of the local people with substantially low bargaining power in the ABS process. From
the CBD as well as various implementing legislations, the study also elicits out the dual nature of GRs containing both tangible and intangible elements and also the need to treat them as inseparable. Considering TK over GRs as an intangible element, it forms an inseparable part of the GR and together with the State and the people who possess the tangible element in GR, the holders of these intangible element also have ownership rights over the GR. Considering the rights of such knowledge holders, it is concluded that if the State enjoys complete monopoly over the GRs and associated TK as in the case of Sarawak, it may result in the grant of access without the consent of the real holders of GRs and associated TK thereby leading ultimately to chances of State-aided misappropriation. Tracing the earlier understanding of property rights over GRs before the proclamation of sovereign rights over GRs divulges the general perception of an open access regime perpetuated through various "common" concepts like the common heritage of mankind, commons, common property, public domain etc. The study establishes that the philosophical understanding of these various common concepts surrounding GRs is basically incorrect and the commonness propaganda was aimed only at ensuring unhindered access to them. But after the conclusion of the CBD, it is undoubtedly established that the ownership over the GRs and associated TK is vested with the country of origin that possesses the resources in-situ.

The tool designed by the CBD to regulate access to GRs and associated TK is bilateral contract stipulating PIC and MAT. It is aimed to ensure that consent of the custodians is taken before accessing the resources and that a fair share of the benefits is paid back to them along with specification of other terms such as purpose of access, duration of access, quantity of GR needed for research etc. But the CBD is silent in respect of implementing the obligations to be created on PIC and MAT by the State Parties. Even though the Bonn Guidelines provide detailed guidance in this
regard, due to their non-binding nature, the States have no compulsion to legislate in that line. This produced considerable ambiguity and uncertainty for CPs while implementing the legislation. Moreover, though the CBD system elaborated through Bonn was basically intended for regulating the grant of patents for inventions involving GRs and TK taken without PIC and benefit sharing, there are no provisions in both the documents to this effect. Thus, the CBD system expanded through Bonn proved to be a failure in preventing misappropriation and facilitating benefit sharing and consequently, the international community was compelled to conclude the Nagoya Protocol on ABS.

The Nagoya Protocol, to some extent clarified the issues relating to the coverage of subject matter and the ownership over it by specifically including GRs and TK within the scope of the system. It has also succeeded to indirectly include ‘derivatives’ of the GRs within the scope of the subject matter. But since the scope of the protocol as well as many other provisions do not expressly provide for the inclusion of derivatives, there is scope for differing interpretations on this. Nagoya clearly recognises the ownership rights of the State and the communities over the GRs and associated TK as contemplated by Article 8 (j) of the CBD. It even goes beyond the CBD, insisting for PIC from and MAT with the communities when they have established rights over the GRs as well as the TK. Still, it creates a gap in the system since PIC for TK is mandated only from the communities and that too in limited cases where they have established their right over such TK. So, the TK widely spread in the country without identifiable owners are kept out of the ABS system of the Protocol. This reduces the scope of benefit sharing under the Protocol, especially in cases where the GR is susceptible to access out of the country of origin. In such cases, there is no benefit sharing obligation for the use of the TK, thus amounting to misappropriation. The major highlight of the Nagoya protocol was the imposition of obligations
upon the user countries to ensure that the use of the resources within their jurisdiction is in compliance with the domestic requirements of the providing countries. But the reality is that the user obligations as contained in Nagoya are weak, without bringing any deterrent effect. The ambiguity regarding the designated check points and absence of sanctions for fraudulent or non-disclosure at such check points render the user country measures meaningless. On the other hand, Nagoya is imposing more obligations on the providing countries than what is contemplated by the CBD. The requirement of fair access procedures without any standard for determining the same has left the 'fairness' to be determined by the user countries based on which they can decide whether to enforce the obligations of the user domestically. Finally, Nagoya keeps complete silence with respect to the IP aspects of ABS and the vacuum perceived in the CBD continues here as well. Efforts during the negotiation to bring patent office as a designated check point in the user countries miserably failed thereby leaving no scope for enforcing the obligations of PIC and benefit sharing at the instance of patenting. In light of the above discussion, the following amendments are suggested in the Nagoya Protocol:

- Article 3 on scope of the Protocol should be amended to expressly include derivatives within the provision. This would make clear that for access to derivatives, PIC is needed from the State and/or the communities.

- It should also be made clear in the Protocol that the PGRs covered by the ITPGRFA also come within the purview of the Protocol when they are used beyond the purposes of the Treaty.

- Article 5 (benefit sharing clause) should be amended by adding a new paragraph to the effect that in the case of TK widely spread in the country of origin without identifiable owners, there should be PIC and benefit sharing with the State. Here PIC is not mandated from
people/communities taking into account of the difficulty in identifying the owner. Patent office should be made a mandatory check point under the Protocol.

- Check points including the patent office should be furnished with information relating to the country of origin as opposed to the present mandate regarding source. This disclosure of the country of origin should be made a mandatory requirement.

- The check points should also be furnished with details relating to the TK associated with GR accessed by the user.

- There should be sanctions for fraudulent or non-disclosure of the required information at the designated check points. Such sanctions should range from injunction preventing further use of the resources in the domestic jurisdiction of the user country and such sanctions should depend on the nature of the check points. At the patent office, the mandatory check point, the sanction should be non-processing of the application till the required information is provided. If at a later stage, the information furnished found to be fraudulent, the patent granted should be revoked.

- Finally, the Protocol should be amended to include a provision to the effect that if the requirements of PIC and MAT are not complied, there should be civil, criminal or administrative sanctions and including revocation of IPRs granted.

The Nagoya protocol asserts that the ITPGRFA dealing with access to PGRs is a part of the CBD system. This necessitated an analysis of the MLS for benefit sharing under the ITPGRFA. The examination of the provisions of ITPGRFA brought out that even though benefit sharing under the Treaty is in a multilateral level as opposed to the bilateral contractual regime envisaged under the CBD, there is no deviation from the permanent
soverignty doctrine which forms the edifice of the notion of property under the CBD. It is evident that the ownership over the resources conferred by the CBD is being transferred to the MLS to provide easy access to PGRFA, owing to their widespread nature and their importance in ensuring the world’s food security. This in fact recognized the ownership of PGRFA and associated TK with the sovereign State even though it is widely spread for enjoying the benefits of MLS, a gap that was noticed in case of Nagoya Protocol. The Treaty system maintains an in-built mechanism for ABS through sMTA making it clear that the open access system no longer exists. The unique proposition of a third party beneficiary to initiate legal proceedings against violation of the terms of the sMTA is a great endeavour under the Treaty. While acknowledging the in-built ABS mechanism of the MLS, the study identified the gaps that still exist in the system which cut the roots of the benefit sharing objective. First, ITPGRFA makes a distinction between the materials of Annex I that are covered by the MLS and the material protected by IPR put voluntarily into the MLS by its owner leading to the interpretation that the owner of such material protected by IPR can charge more than what is contemplated by the MLS for access. This would affect the stability of the MLS that stands for access free of charge or at the minimal cost involved. Second, the obligation to share the benefits with the MLS is triggered only on the cumulative happening of three conditions that (i) there should be commercialization of the resultant product, (ii) incorporating the material availed from the MLS, and that (iii) such product should not be available without restriction. Many scholars interpret availability without restriction so as not to create a restriction on the availability of the resultant product for further research and breeding. This interpretation does not take into account of the fact that it still creates restrictions for the traditional farming communities for carrying out their traditional breeding and commercial farming including sale of the resulting harvest in light of the patents and plant breeders’ rights. Third, the provision
for voluntary contribution to the MLS when the products, derived out of the materials accessed from the MLS, are available without restriction is also problematic to the benefit sharing objective of the Treaty. It overlooks the fact that the materials are accessed from the MLS free of charge while the resultant product would be available at the payment of exorbitant prices. So it is concluded that the ITPGRFA is reducing the scope of benefit sharing available under the CBD where even the mere access itself would have triggered an obligation to share the benefits. Another ambiguity evident in the ITPGRFA is with respect to the restriction on acquisition of IPRs over the materials ‘in the form received from the MLS’ and their incorporation in the resultant product. It gives rise to the interpretation that if materials are isolated or purified from the MLS materials without change in the characteristics, they could be patented. There are chances that such materials could be incorporated in products and being commercialised. Since the availability of the MLS material is not restricted, there will be no obligation to share the benefits even though the breeder/owner of the product can derive substantial benefit out of the system. Thus, the study reveals that the ITPGRFA needs to be restructured to ensure benefit sharing in its fullest possible sense. So the study makes the following recommendations to fill the gaps in the ITPGRFA.

- The ITPGRFA should specify that all the materials covered by the MLS, including materials protected by the IP could be accessed free of charge or at the minimal cost involved.
- The obligation to share the benefits should be triggered at the instance of acquisition of IPRs over the resultant products and also upon commercialization.
- Availability without restriction should be redefined to mean availability under the MLS terms, i.e. free of cost or at the minimal
cost involved. Any restriction against this effect should attract benefit sharing obligation.

- The ITPGRFA should clarify that incorporation of the material in the form received from the MLS should also cover cases where the resultant product contains the isolated or purified versions of the MLS material without substantial change in characteristics. It is to be noted that this gap is theoretically addressed in Nagoya by adding derivatives within the scope of the protocol.

One of the common problems noticed both in the Nagoya and ITPGRFA models of benefit sharing is the inability to achieve the objective of benefit sharing upon the acquisition of IPRs over the GRs and associated TK. The major reason behind this is the total vacuum in the TRIPS Agreement that lays down the minimum standard for protection of IPRs, to respect the CBD mandate regarding PIC and MAT. The main argument that there is conflicting relationship between the TRIPS and the CBD is the failure of TRIPS to appreciate the full-fledged property regime evolving out of the CBD. The analysis of the various provisions reflecting the interrelationship between CBD and TRIPS reveals that contract-based CBD system cannot act as a stand-alone solution to address the issue of misappropriation. It is evident that the absence of adequate provision in the TRIPS to create necessary link between CBD and TRIPS is the major reason for the facilitation of misappropriation through the TRIPS based IPR system. It is also made clear in the study that the TRIPS is the best platform to deal with the issue of misappropriation, considering the experience with the other international instruments in this regard, the reason being that unless a TRIPS level amendment is carried out, the IPRs has no obligation to respect the CBD mandates.
While addressing the interrelationship between the TRIPS and the CBD, one of the important suggestions at the TRIPS Council of the WTO to address the issue of misappropriation through IPRs was the proposal for inclusion of a disclosure requirement in the TRIPS Agreement. The tabled proposals on disclosure requirements could be classified into three types. The first proposal relates to a TRIPS level requirement requiring in the patent application a disclosure in relation to the source and country of origin of the GRs and/or associated TK used in the invention together with disclosure in relation to the evidence of compliance with PIC and MAT. If these three items are not disclosed or wrongfully disclosed with a fraudulent intention, the patent granted for such inventions are liable to be revoked. The second proposal also relates to a TRIPS level disclosure, but is confined to disclosing the source or country of origin of the genetic material used in the invention. It is to be followed as a formal requirement not affecting the validity of the patent granted. The third proposal relates to an amendment in the PCT level facilitating national legislations to incorporate a requirement mandating disclosure of the source of the GRs or TK used in the invention. This too is proposed as a formal requirement to be complied with, not affecting the validity of a patent granted. Analysis of these proposals reveals that out of the three, the triple disclosure requirement under the TRIPS stands out as they clearly establishes the link between the property right of the country of origin under the CBD revealed through PIC and MAT, and the patent system. But the recent negotiations going on in this regard dilute the triple disclosure requirements and stands only for disclosure of the source of the GRs and associated TK and keeps silence as to the inclusion of the PIC and benefit sharing requirement. This dilution results in negation of the property right of the country of origin and also delinks the ABS system with the TRIPS. Analysis of the arguments for and against the inclusion of triple disclosure requirements into the TRIPS, the study establishes that there is provision for bonafide exception to patentability criteria as
contained in Article 27 of the TRIPS, considering the complexities in certain product areas and that based on this reasoning inclusion of the triple disclosure requirement can go in tune with the TRIPS. The study makes the following recommendations in this regard.

- The best way to efficiently address the issue of misappropriation through patenting is the triple disclosure requirement under the TRIPS.
- All the three requirements must co-exist so as to effectively link the TRIPS system as well as the CBD.
- The legal form of inclusion of the requirements could be through amending Article 29 of the TRIPS.

Considering the initiatives undertaken by the WIPO to unearth the interrelationship between IPR and GRs, the possibility of creating any positive legal instrument owing to the wide difference of opinion in the Forum is doubtful. Adding to this, the absence of linkages between the efforts of the WIPO and TIPS Council makes the status of WIPO deliberations uncertain.

From an analysis of the work of different international organizations concerned with the issue of access, the present study reaches the conclusion that the TRIPS is the best platform to address the issue of misappropriation effectively than any other body. The first reason for this argument is that the nature of property contained in GRs and associated TK is similar to some of the TRIPS categories like GIs and that it has high trade potential too. Second, though the CBD is envisaging a regime of positive protection, due to lack of linkages with the TRIPS, the former system collapses particularly in case of use of GRs and associated TK for developing new products and process resulting in IPR protection. So, logically, the best solution is to
create a mechanism of protection for GRs and associated TK within the TRIPS system. The strong compliance and enforcement mechanism of the TRIPS Agreement is yet another attraction behind this argument for the enforcement mechanism of the CBD, as previously discussed, is weak in many respects.

Now the question, ‘in what form GRs and associated TK can be protected under the TRIPS’ comes to limelight. First, this study looks for solutions other than those previously discussed. It is an accepted fact that inventions, that are manifestations of the known and available uses of GRs taken without PIC or MAT, are granted patent protection due to the flexibilities in interpreting novelty. So, can a uniform standard on novelty solve the problem? Let us examine the situation where novelty is defined to mean ‘there should not be prior use or prior publication of the invention anywhere in the world’ wherein prior use is understood to cover, in the context of inventions involving GRs and associated TK, the knowledge over the use of a GRs either by individuals, ILCs or a common knowledge throughout any State. It may also provide that if the inventor has made contractual arrangements with the knowledge holder(s), there would be no bar to patentability. But a mere restructuring of novelty requirement could not exclusively address the misappropriation of GRs and associated TK. The problem with this solution is that it ensures benefit sharing only for the use of TK and GRs would not be covered. Yet another possibility is inclusion of a negative mandate in the TRIPS that ‘no IPRs could be obtained over materials found in or incorporated from nature’ But its implications are far reaching, sometimes negating incentives to many major industries like agriculture, pharmaceuticals, biotechnology etc. It also shuts down the commercial value of the GRS and associated TK. This makes it clear that slight modifications in the existing system, especially on the patentability
criteria of TRIPS cannot afford exhaustive protection to GRs and associated TK.

It is to be noted that many scholars have suggested different solutions to address the issue of misappropriation through various mechanisms. Global bio-collecting society as proposed by Peter Drahos\(^1\), traditional resource right proposed by Posey and Dutfield\(^2\) and community IPRs\(^3\) suggested by the Crucible Group are to name a few. All these systems stand for one or other form of a registration system to be maintained nationally or internationally. Some talk about indigenous groups filing complaints before the national patent offices and international IPR agencies and getting the patents revoked. None of them clarify how a country of origin can enforce its rights and get a patent revoked when the invention is based on a GR taken way without complying with the domestic ABS requirements (in cases where TK is not associated). Such proposals understand neither the spirit of the CBD, nor the ground realities relating to the ILCs, the real custodians of biological diversity and associated TK. For the communities, the notion of property as we understand today is quite strange. Their life is based on the principle of collective sharing. Private enclosure and accumulation of wealth is not common to indigenous communities. On the contrary, it is the western understanding of property. Commoditization of knowledge or GRs never formed part of any indigenous culture. Whether it is knowledge or resources, they served the collective interests of everyone in the community. So, it is very difficult to put boundaries for a private right in this collective accumulated knowledge. It is not because of the difficulty in identifying a single owner, even the community as a whole can act as a single owner as evident in the case of GIs. The problem is that they do not know how the

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\(^3\) *Id.* p.97
private property regime works for them. So a system where the communities have to go and register their right for proper enforcement is not a feasible solution. What they need is a right which is always there for them, just like sweet water or the shadow of a tree. Whenever they need it, they will come to it and when not in need, both will not bother. This works suitable for enforcing the rights of the country of origin. For this purpose, the best way is to link the patent system with the rights of the communities as well as the country of origin on the GRs and the associated TK, the linkages of which are established by the triple disclosure requirement under the TRIPS or through some new provisions in the TRIPS. This study reaches the conclusion that the disclosure requirement in relation to the source and country of origin of the GRs and associated TK together with the evidence of PIC and MAT is one possible solution to address the issue of misappropriation and to ensure sharing of benefits. The best possible way to include the same would be to amend Article 29 of the TRIPS, for the requirements stand as information material to patentability rather than constituting criteria for the grant.

Another possible solution to prevent misappropriation of GRs and associated TK and to ensure benefit sharing out of their utilization is to incorporate them as a category for protection under the TRIPS by adding a new chapter. This suggestion takes justification from two major inferences drawn in this study. The first inference is in relation to the nature of property in GRs. It is revealed from the study that GRs and associated TK constitute resources of value, the prime feature to recognise property rights in terms of economics and law. The value of GR may be actual or potential and the actual value is the TK associated with it. Considering the value part, the associated TK and the unexplored potential value are inseparable with the tangible GR since the absence of one makes the other meaningless. All GRs will be having some value, the known uses constituting the actual value and
the unknown features leading to potential value. When held by the country of origin or the communities within the country of origin, the legal relationship of property rights through ownership and exclusivity is created over GRs. These are the attributes of private property under the western notion of property rights. The second inference is that the collective ownership of communities over IP is traceable from the TRIPS that advocates for private property based on individual ownership. Unlike the classical forms of IPRs like patents, copyright, trademark etc featured by individual ownership, the TRIPS recognises collective ownership system through the inclusion of Geographical Indications as a protectable category within its scope.

Thus, the value along with the elements of ownership and exclusivity render the GRs a strong candidate for protection under the TRIPS umbrella and as suggested, the GRs include the TK associated with it. The fact revealed from the study that IPRs create the major block in prevention of misappropriation and sharing of benefits calls for consideration and recognition of the prevailing form of this property under the TRIPS framework. A chapter which identifies the subject matter of GRs and associated TK, the scope of protection and the beneficiaries of protection will go a long way in checking the unabated issue of misappropriation. The coherence of this property with the present system of TRIPS needs further in-depth analysis. Though the jurisprudential analysis of property rights under TRIPS is beyond the scope of the present study, it is expected that an analysis in that line could sufficiently explore the possibilities of carving out a new standard of protection to GRs in the TRIPS.