INTERNATIONAL INITIATIVES FOR REGULATING ACCESS TO GENETIC RESOURCES

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By

PRABHA S. NAIR

Under the guidance of

Prof. Dr. N. S. GOPALAKRISHNAN
(Director, IUCIPRS, CUSAT)

SCHOOL OF LEGAL STUDIES
COCHIN UNIVERSITY OF SCIENCE AND TECHNOLOGY
COCHIN-682 022

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Declaration

I declare that the thesis entitled ***"International Initiatives for Regulating Access to Genetic Resources"*** for the award of the degree of *Doctor of Philosophy* is the record of bonafide research carried out by me under the guidance and supervision of Prof. (Dr.) N. S. Gopalakrishnan, Director, Inter University Centre for Intellectual Property Rights Studies, School of Legal Studies, CUSAT. I further declare that this work has not previously formed the basis of the award of any degree, diploma, associate-ship or any other title or recognition.

Cochin — Prabha S. Nair

26/08/2011

Preface

Demand for property rights over biological diversity and its constituent elements is a continuing international debate from the past three decades. Contractual regulation of access to biological resources and associated traditional knowledge recognising the right to get compensated is the central theme of the debate. Though the Convention on Biological Diversity in 1992 legally materialised the notion of property in biological resources, the equitable sharing of benefits arising from their utilization remains a dream far from reality due to a number of outstanding issues to be resolved internationally. It was the complexity of the issues involved that attracted my attention while selecting this topic for my doctoral thesis. The timely interventions of my supervising guide Prof. Dr. N. S. Gopalakrishnan helped me a lot to correctly focus upon the intricacies involved in this area.

At this moment of the fruitful accomplishment of the targeted study, I would like to first place on record, my profound gratitude to Prof. Dr. N. S. Gopalakrishnan, my Supervising Guide, who was always there with me during all my frustrations, both academic and personal. His academic interventions sharpened my thoughts, understandings and attitudes towards the topic while his personal interventions were a major driving force for me to complete this task.

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ABBREVIATIONS

ABS	:	Access and Benefit Sharing
BR	:	Biological Resource
CBD	:	The Convention on Biological Diversity
CGIAR	:	Consultative Group on International Agricultural Research
CMS	:	Cytoplasmic Male Sterile varieties
COP	:	Conference of Parties
CPs	:	Contracting Parties
CTE	:	Committee on Trade and Environment
EC	:	European Commission
EU	:	European Union
FAO	:	Food and Agricultural Organisation
GATT	:	General Agreement on Trade &Tariff
GB	:	Governing Body
GIs	:	Geographical Indications
GRs	:	Genetic Resources
GURTs	:	Genetic Use Restriction Technologies
HGR	:	Human Genetic Resources
IARCs	:	International Agricultural Research Centre
IGC	:	Inter Governmental Committee
ILCs	:	Indigenous and Local Communities
ILCs	:	Indigenous and Local Communities

ING	:	Inter Regional Negotiating Group
IP	:	Intellectual Property
IPRS	:	Intellectual Property Rights
ITA	:	Information Transfer Agreement
ITPGRFA	:	International Treaty on Plant Genetic Resources for Food and Agriculture
IUPGRFA	:	International Undertaking on Plant Genetic Resources for Food and Agriculture
IWG	:	Inter-Sessional Working Group
LDCS	:	Least Developed Countries
MAT	:	Mutually Agreed Terms
MEA	:	Multilateral Environmental Agreements
MLS	:	Multi Lateral System
MOP	:	Meeting of Parties
MTA	:	Material Transfer Agreement
OAU	:	Organisation of African Unity
PBR	:	Plant Breeders Rights
PCT	:	Patent Cooperation Treaty
PGR	:	Plant Genetic Resource
PGRFA	:	Plant Genetic Resources for Food and Agriculture
PIC	:	Prior Informed Consent
PLT	:	Patent Law Treaty
R&D	:	Research and Development
sMTA	:	Standard Material Transfer Agreement

SPS	:	Sanitary and Phyto Sanitary Conditions
TBT	:	Technical Barriers to Trade
TK	:	Traditional Knowledge
TRIPS	:	Trade Related Aspects of Intellectual Property Rights
UPOV	:	International Convention for Protection of New Plant Varieties
US	:	United States
WHO	:	World Health Organisation
WIPO	:	World Intellectual Property Organisation
WTO	:	World Trade Organisation

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Chapter 1

INTRODUCTION

The 20th century, earmarked as the era of biotechnology, has witnessed two major and divergent international controversies owing to the biotechnology boom coupled with the far-reaching impact of patent monopoly. First one relates to the issue of patenting of life and the social, legal, moral and ethical questions surrounding the same[1]. Second controversy relates to the proprietary claims over genetic resources (GRs) and associated traditional knowledge (TK)[2]. Both created unrest in the domain of Intellectual Property (IP) law since they aroused serious questions on the basic standards of patentability itself. These issues still remain unsettled and controversial as they represent the divided policy considerations and politico-economic interests of the North and the South. It is interesting to note that the second controversy mentioned above, i.e. the proprietary claims over biological materials, stands out from the issues of patentability over life forms since they operate on the basic premise that patent protection is permissible for life forms or at least for biotech inventions. This is exposed by the claim of its proponents that the holders of biological materials and associated TK have the right to get compensated

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[1] Rebecca Dresser, ñEthical and Legal Issues in Patenting New Animal Lifeò, 28 *Jurimetrics* 399 (1988); Ned Hettinger, ñPatenting Life: Biotechnology, Intellectual Property and Environmental Ethicsò, 22 *Boston College Environmental Affairs Law Review*, 267 (1995); Daniel J. Kevles, ñPatenting Life: A Historical Overview of Law, Interests and Ethicsò, prepared for the Legal Theory Workshop, Yale Law School, (2001); Hope Shand, ñNew Enclosures: Why Civil Society and Governments Need to Look Beyond Life Patentingò available at http://muse.jhu.edu ; Daniel J. Kelves, ñOf Mice and Money: The Story of the Worldôs First Animal Patentò, *Daedalus*, Vol. 131, No. 2 (Spring, 2002), pp. 78-88

[22] Fred Powledge, ñWho Owns Rice and Beans?ò, *BioScience*, Vol. 45, No. 7 (Jul. - Aug. 1995), pp. 440-444; Emily Marden, ñThe Neem Tree Patent: International Conflict over the Commodification of Lifeò, 22 *Boston College International and Comparative Law Review* 279 (1999); Stephen B. Brush, ñBioprospecting the Public Domainò, *Cultural Anthropology*, Vol. 14, No. 4 (Nov. 1999), pp. 535-555

when such resources are being used. So the logical understanding is that genetic/ biological resources and their associated TK can form part of a patented invention if such use is conditional to compensating the right holders of such resources. This positive assertion is posing more problematic issues than the basic questions of patentability. From the inventorôs side, it raises the questions ówho owns?ô and ówhat is owned?ô For the holders of biological materials and associated TK, the remarkable queries would relate to the purpose of research, nature and extent of the use of their entitlements, and the possible compensations. It is to be noted that prior to the patenting over biological materials, the demand for property rights over them was quite unheard. The domain of biodiversity was an open access regime from prehistoric times. The interception of IPRs (Intellectual Property Rights) with biotechnology has made such property claims evolve with an international magnitude. A survey of the international initiatives in the field of regulation of access to GRs shows how the open access regime over biological diversity responded to private enclosure through monopolistic IPRs and the present status of such responses.

1.1 Property in Biological Diversity: An Evolutionary Regime

The most widely transferred resources are plant genetic resources (PGRs) due to their medicinal value and as food supplements. There had been contributions from the farmers for their conservation and breeding. Lot of resources had been collected and conserved in *ex-situ* collection centres. Due to the technological developments strong proprietary rights like plant breeders right began to be created for the new varieties developed out of the GRs, thereby curtailing the scope of access to genetic resources and also affecting the food security and the same was promoted through international efforts like the International Union for the Protection of New Plant Varieties (UPOV). Thus the Food and Agricultural Organization (FAO) took over the concern of food security and adopted a non-binding International

Undertaking for Plant Genetic Resources for Food and Agriculture (IUPGRFA) in 1983. This was aimed at strengthening the rights of suppliers of the (GRs) and to act as a counterbalance to the increasing protection of technology resultant from the use of (GRs). It stood for free access to GRs and was based on the principle of common heritage. But the IUPGRFAôs efforts were not strong enough to offset the increasing IP protection over PGRs and the IUPGRFA had to make compromises on its open access regime by recognising the IP protection granted over the new and high yielding plant varieties developed by commercial breeders.

The claim for property protection to biological materials and the TK associated with them is of very recent origin, traceable from 1980s. The demand could be directly linked to the overwhelming patents granted to biotechnology inventions that made use of scientific and technological tools like recombinant DNA technology that facilitate genetic manipulation of biological materials to get the desired traits[3]. Inducing characteristics such as insect resistance or pest resistance to crops through genetic engineering is an example for this process. These technological advancements also augmented the demand for high yielding crops worldwide. Even, developing countries replaced their traditional varieties with high yielding crops, which paved the way for eventual species extinction. This increasing demand together with the possibility of stronger monopolistic protection of patents attracted the corporate giants to make huge investments in this field. The legal protection afforded to them was either through patents or through breedersô rights. The greatest negative impact was that in this private enclosure movement, many crops that ensured food security to the poor and the common man and the

[3] Susanne Droege and Birgit Soete, ñTrade Related Intellectual Property Rights, North South Trade and Biological Diversityò, 19 *Environmental and Resource Economics* (2001) pp.149-163

livelihood of many farming communities were also enclosed[4]. The staple food crops and key export crops of many developing countries went prey to this resource hunt venture[5]. In addition to the monopolisation over many major food crops, there were also efforts to make nature-based products by exploring the biological diversity for commercially valuable traits from biological and GRs[6]. This process is called bioprospecting which created a strong market for new nature based products ensuring high returns for the investment and the flourishing industries range from chemical, pharmaceutical, biomedical, biochemical, microbiological, cosmetic and so on. The greatest irony was that though the technology rich developed nations of the North were making investments and reaping the benefits, the biological diversity of the developing nations constituted the field of raw materials for them and that in this game, the providers of resources remained mere spectators. Adding to this, the North also began to use the TK associated with biological diversity to prospect the valuable traits of GRs[7]. Flavouring the resultant products with IPRs finally converted the developing countries the consumers of their own knowledge and of the technology of the North[8]. The developing countries realized that the reason behind this strange

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[4]Jagjit Kaur Plahe and Chris Nyland, ñThe WTO and Patenting of Life Forms: Policy Options for Developing Countriesò, Vol.24 No.1 *Third World Quarterly* pp.29-45 (2003) ; Also see Michael Woods, ñFood for Thought: the Biopiracy of Jasmine and Basmati Riceô, 13 *Albany Law Journal of Science & Technology* (2000) p. 123

[5] *Ibid.*; Also see Robert W. Herdt, ñEnclosing the Global Plant Genetic Commonsò, available at *http://ip.cals.cornell.edu/people/robertherdt/documents/EnclosingGloGenCommonsRevised.pdf*; Sabuj Kumar Chaudhury, ñGenetic Erosion of Agro Biodiversity in India and Intellectual Property Rights: Interplay and Some Key Issuesò, *Patentmatics*, 5(6)

[6] Andrew W. Torrance, ñBioprospecting and the Convention on Biological Diversityô, available at *http://leda.law.harvard.edu/leda/data/258/Torrance,_Andrew_00.pdf;* Aykut Coban, óCaught Between State-sovereign Rights and Property Rights: Regulating Biodiversityô, *Review of International Political Economy*, Vol. 11, No. 4, Global Regulation (2004), pp. 736-762; Roger A. Sedjo, ñProperty Rights, Genetic Resources and Biotechnological Changeò, *Journal of Law and Economics*, Vol. 35, No. 1 (Apr. 1992), pp. 199-213

[7] See Graham Dutfield, *Intellectual Property Rights, Trade and Biodiversity*, Earthscan Publications Ltd, London (2000), pp.65-67

[8] Paul Gepts, ñWho Owns Biodiversity and How Should the Owners be Compensated?ò, *Plant Physiology*, Vol. 134, (April 2004) pp. 1295ï1307; Cecilia Oh, ñIPRs and

phenomenon (the so-called õbiopiracyô or misappropriation) is the unregulated access to their GRs and associated TK. They found that their GRs treated as common heritage of mankind and their TK in the public domain under the Western legal philosophy ensured unhindered access. This realization together with the reported cases of more and more enclosures prompted them to devise a mechanism for regulation of access to GRs as well as the associated TK. The other factors that accorded momentum to the plan for regulation of access were considerations like species extinction, importance of contributions of farmers and local and indigenous communities in maintaining the sustenance of the biodiversity as well as the global ecosystem[9]. The easiest way of legal regulation of GRs and associated TK was to confer them the status of property that was precisely done by international community through the Convention on Biological Diversity (CBD) in 1992 by access regulation and the obligation to share the benefits arising out of utilization.

Even after the adoption of the CBD, misappropriation of genetic resources without any benefits to their custodians continued to persist and the developing nations started defending this through two different strategies. One strategy was to initiate steps for strengthening domestic Access and Benefit Sharing regimes for which they adopted a legally non-binding instrument, the Bonn Guidelines on Access to Genetic Resources and Equitable Sharing of Benefits Arising out of their Utilization in 2002, providing insight into the different measures in relation to the ABS process. The second strategy was the effort to create binding obligations in the TRIPS Agreement to respect the CBD goals of prior informed consent and mutually agreed terms. The non-binding nature of Bonn Guidelines never compelled

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Biological Resources: Implications for Developing Countriesò, JIPR Vol.8 (September 2003), pp.400-413

[9] Daniel M. Bodansky, ñInternational Law and the Protection of Biological Diversityò, 28 *Vanderbilt Journal of Transnational Law* (1995), 623

the nations to carry out the measures suggested and the second strategy too proved to be a failure due to lack of consensus on incorporation of new requirements into the TRIPS. Interestingly, we could see that both the strategies have found new avenues. The ABS process under the CBD has developed into the creation of a new protocol on benefit sharing and the issues related to IP and genetic resources and associated traditional knowledge are currently under the consideration of the WIPO. Similarly, with the adoption of the CBD, the open access regime of the IUPGRFA contrasted with it, which ultimately culminated into the adoption of the International treaty on Plant Genetic Resources fir Food and Agriculture in 2001. Thus the whole regime of access and benefit sharing is crowded with multiplicity of actors and multiplicity of instruments with varying objectives. The subsequent sections of the chapter line up the multiple instruments and briefly provide an overview of their objectives and the interesting issues arising out of them.

1.2 The CBD: Evaluation of the Legal Framework

The CBD provides the legal platform for regulation of access to biodiversity. Its main objectives are conservation of biological diversity, the sustainable use of its components and the fair and equitable sharing of the benefits arising out of their utilization[10]. The CBD operates on the principle that States have sovereign right to exploit their biological resources (BRs) pursuant to domestic environmental policies[11] and identifies conservation of biological diversity as the common concern of mankind[12]. Recognising the sovereign rights of States, the CBD vests the right to determine access to GRs with national governments and subject to national legislation[13]. The

[10] The Convention on Biological Diversity, 1992, Article 1
[11] *Id.* Article 3
[12] *Id.* Preamble
[13] *Id.* Article 15.1

mandate of the CBD is to facilitate access[14] subject to prior informed consent (PIC)[15] and mutually agreed terms (MAT)[16]. It calls for a positive State action to respect, preserve and maintain the knowledge, innovations and practices embodying traditional lifestyles of local and indigenous communities relevant to the conservation and sustainable use of biological diversity[17]. It also aims to promote the wider application of such knowledge, innovations and practices with the approval and involvement of their holders and facilitating them to have an equitable share of the benefits arising from the utilization of such knowledge bases[18]. The CBD also mandates to facilitate access to and transfer of technology including biotechnology, relevant to the conservation and sustainable use of biodiversity, under fair and most favourable terms to other Contracting Parties (CPs)[19]. As regards technology protected by patents and other IPRs, access and transfer shall be consistent with effective protection of IPRs[20]. It further mandates that CPs that are developing countries providing access to GRs shall be granted access to and transfer of technology, including technology protected by IPRs, upon MAT[21]. It also stipulates that patents and other IPRs should be supportive and do not run counter to the objectives of the CBD[22]. As regards the handling of biotechnology and distribution of its benefits, it is provided that there should be endeavours to promote active participation of developing countries which provide the GRs in biotechnological research[23]. Promotion of fair and equitable access to results and benefits of biotechnological research based on GRs to developing countries upon MAT

[14] *Id.* Article 15.2
[15] *Id.* Article 15.5
[16] *Id.* Article 15.4
[17] *Id.* Article 8 (j)
[18] *Ibid.*
[19] *Id.* Article 16.1 & 2
[20] *Id.* Article 16.2
[21] *Id.* Article 16.3
[22] *Id.*Article 16.5
[23] *Id.* Article 19.1

is yet another mandate in this regard[24]. Annexes and Protocols can form an integral part of the CBD system and are also liable to be amended including the provisions of the CBD[25].

A perusal of the provisions of the CBD does not give any clue to the property rights envisaged or its mechanism of access and benefit sharing (ABS). While acknowledging that biological diversity is a ócommon concernô of mankind rather than ócommon heritageô, the CBD vests the right to regulate access to (BRs) with the sovereign nations. This right emanates from the right of the nations to exploit their (BRs) stemming up from the permanent sovereignty over natural resources. This confers the GRs the status of property. Since it opens up GRs for exploitation, including by means of biotechnological research, and claims a share of the benefits of exploitation, the CBD aims to commoditise the GRs[26]. It acknowledges the role of IPRs in the ABS process and claims access to technology protected by IPRs as a *quid pro quo* for access to the resources. The CBD also calls for commoditisation of TK associated with biological diversity and acknowledges the need to compensate them in return. The concept of PIC is incorporated to materialise ownership and bilateral contracts serve as the tools of exploitation and benefit sharing. To regulate the process of ABS, the CBD tries to elicit out the subject matter of access by defining GRs, BRs, genetic material and biological diversity[27]. But, since the right to regulate access is vested with sovereign States, it is for the individual nations to draw the contours of the subject matter as well as the limits of permissible access. Anyway, by Decision II/11 of the Conference of Parties (COP), human GRs

[24] *Id.* Article 19.2
[25] *Id.* Articles 28, 29 & 30
[26] Valerie Boisvert and Armelle Caron, ñThe Convention on Biological Diversity: An Ambivalent Attempt to Reconcile Communal Rights and Private Propertyò, Paper presented at the *Conference on Constituting the Commons: Crafting Sustainable Commons in the New Millennium*, The Eighth Biennial Conference of the International Association for the Study of Common Property at Bloomington, Indiana, USA during May 31-June 4, 2000
[27] *Supra* n.10, Article 2

are excluded from the ABS framework of the CBD. Again, the State Parties have the freedom to decide whether or not to include TK associated with the GRs within the scope of access. ôWho can provide accessô and ôwhat can be the pertinent subject of accessô are the most important questions emerging out of the access regime created by the CBD. This needs clear examination in the context of the uncertainties existing in the implementation of the obligations under CBD.

Coming to the benefit sharing mechanism of the CBD, the only traceable elements are the bilateral contracts to be entered into between the persons seeking access and the country providing access. Though it talks about PIC, the CBD is silent as to from whom PIC is to be obtained. The most interesting part is the absence of provisions in the CBD mandating PIC and MAT as the obligation to be fulfilled while taking IPRs over GRs and associated TK. Other legal vacuums relate to the benefits to be shared, with whom, and the mechanism to share. All these areas provide the CPs enough flexibility to design legislations responding to and reflecting their national, economic and social priorities. To provide proper insight in relation to the ABS process, the CBD has adopted the Bonn Guidelines as an instrument facilitating implementation.

1.3 The Bonn Guidelines on Access to Genetic Resources and Equitable Sharing of Benefits Arising out of their Utilization, 2002

For the purpose of operationalization of the provisions of the CBD, the COP of the CBD had adopted the Bonn Guidelines at its sixth meeting[28]. The Guidelines are intended to help the Member States while establishing legislative, administrative or policy measures on ABS and also during contractual negotiations for the ABS process. The non-binding Guidelines

[28] COP Decision VI/24

are voluntary in nature[29], and are intended to assist the Parties in developing an overall ABS strategy and to identify the steps involved in the process of obtaining access to GRs and sharing the benefits[30]. It provides that competent national authorities should be established for regulating the grant of access and sharing of benefits with responsibility towards the negotiating process, securing of PIC and MAT, monitoring and evaluation of ABS agreements, enforcing ABS agreements, processing and approval of applications, ensuring stakeholder participation in different steps in the ABS process etc[31]. The Guidelines also provide that the CPs have the duty to ensure that the decisions regarding access be informed to relevant indigenous and local communities and relevant stakeholders and also the responsibility to enhance the capacity of local and indigenous communities to represent their interests fully at the negotiation[32]. It requires the users of the GRs to seek informed consent prior to exercising access; respect the values, customs, traditions and customary practices of local and indigenous communities; respond to requests for information from indigenous and local communities; stick on to the terms and conditions of the PIC and MAT; endeavour to carry out the use of GRs in and with the participation of the providing country; and to ensure the fair and equitable sharing of benefits including technology transfer to providing countries in accordance with the MAT established with the stakeholders[33]. It identifies stakeholder participation as the key to ensure adequate development and implementation of ABS agreements[34]. Participation means consulting the relevant stakeholders and taking into account their views in each step including determination of access, negotiation and implementation of MAT, sharing of

[29] The Bonn Guidelines on Access to GRs and Equitable Sharing of Benefits Arising out of their Utilization, 2002, para. 7
[30] *Id.* para. 12
[31] *Id.*para. 14
[32] *Id.*para. 16
[33] *Id.*para. 16(b)
[34] *Id.*para. 17

benefits and in the development of national strategies, policies or regimes on ABS[35].

The Guidelines lay down that the basic principles of a PIC system are legal certainty and clarity, transparency, minimal cost, and consent of the relevant competent national authority and indigenous and local communities or the relevant stakeholders as the case may be[36]. The chief elements of a PIC system involve competent national authorities, timing and deadlines, specification of use, procedures for obtaining PIC, mechanisms for consultation of stakeholders and the process/ procedure followed by the competent national authority for the grant of access[37]. The Guidelines reiterate that respecting established rights of local and indigenous people, securing PIC from them and their approval and involvement in accordance with their traditional practices and domestic policies is essential[38]. The Guidelines also reiterate that the State while granting PIC can insist for clarity as to the benefits that could be claimed including the benefit arising out of the utilization of derivatives and products arising out of the utilization of the GRs and associated TK. As regards MAT, the basic requirements are legal certainty and clarity, minimization of transaction cost, creation of user and provider obligations, development of model agreements and creation of suitable contractual arrangement for different uses and different resources, setting out reasonable time span for negotiation process and specification of terms in a written agreement[39]. The guiding parameters for contractual arrangements are consideration of the concerns of relevant stakeholders, indigenous and local communities, ensuring the continued customary use of

[35] *Id.*para. 18
[36] *Id.*para. 26
[37] *Id.*para. 27
[38] *Id.* para 31
[39] *Id.* para 42

GRs and related knowledge, possibility of joint ownership of IPRs according to the degree of contribution etc[40].

Benefit sharing agreements also form part of MAT and the benefits could be monetary and/or non-monetary and short-term, medium-term or long-term. Monetary benefits could include access fees/fee per sample, up-front payments, milestone payments, payment of royalties, license fee in case of commercialization, special fee to be paid to trust funds supporting conservation and sustainable use of biodiversity, salaries and preferential terms as mutually agreed, research funding, joint ventures and joint ownership of IPRs[41]. Non-monetary benefits could be sharing of research and development results; collaboration, contribution and cooperation in scientific research and development programmes; participation in product development; collaboration, contribution and cooperation in education and training; admittance to ex-situ facilities of GRs and to data bases; transfer of technology under fair and most favourable terms including concessional and preferential terms; strengthening capacity for technology transfer to developing countries and countries with economies in transition; institutional capacity building; training related to GRs; access to scientific information relevant to conservation and sustainable use of biodiversity; contributions to local economy; research directed towards priority needs such as health and food security; food and livelihood security benefits; social recognition and joint ownership of IPRs[42]. Benefits are to be shared fairly and equitably with all those who are identified as having contributed to resource management and scientific or commercial process. The benefits should be aimed at promoting conservation and sustainable use of biodiversity[43]. Mechanisms for benefit sharing may vary depending upon the type of benefits, the

[40] *Id.* para 43
[41] *Id.* Appendix II
[42] *Ibid.*
[43] *Id.* para 48

specific conditions of the country and the stakeholders involved[44]. Such mechanisms should include full cooperation in scientific research and technology development and those that derive from commercial products including trust funds, joint ventures and licenses with preferential terms[45].

The Bonn Guidelines make it clear that the spirit of the CBD lies in public participation in all stages of ABS. It acknowledges the different practices followed in CPs and the problems that may arise during identification and ensuring participation of stakeholders, especially the local and indigenous communities. Through this participation, the CBD as well as the Bonn Guidelines envision an ideal scenario where the communities and the common people can argue for their cause as per their needs and this would strengthen them socially as well as economically. This would serve as a tool to bring these usually downtrodden and sidelined groups towards the forefront of the society. It is inferred that the CBD agenda expressed through the Bonn Guidelines places before us the need to design highly decentralised system to make its dreams come true. The ultimate object of the CBD as depicted in the Bonn Guidelines is the overall development of the people who are actively engaged in the conservation, preservation and maintenance of biological diversity through their constant and continuous interactions entwined to their traditional and customary practices and life styles. In another way, the CBD aims to operationalize its conservation ethic by providing incentives to the custodians of biological diversity. This implies that though the CBD recognises ownership of States over their natural resources, it provides ample scope for the recognition of the rights of the custodians of biological diversity and associated TK and to properly reward them for their contributions. The same principle is reflected even in the indicative list of possible benefits that could be claimed viz., social recognition, food and livelihood security benefits, contribution to local

[44] *Id.* para 49
[45] *Id.* para 50

economy, joint ownership of IPR and facilitation of the abilities of the local and indigenous communities to conserve and sustainably use their GRs. No doubt, enacting a piece of legislation conceiving this real spirit of CBD could serve as an instrument of social change.

Compared to the CBD, the positive attitude towards acquisition of IPRs over biological materials is more visible in the Bonn Guidelines thereby promoting the commoditisation of GRs as well as the related TK. Calling for stakeholder participation, the Guidelines propose a regime where the people including the local and indigenous communities can claim ownership rights over the resources as well as the TK associated. So, theoretically, the Bonn Guidelines expand the ownership regime by permitting the communities to take part in ABS. But due to its non-binding nature, the countries are still free to legislate on this aspect whereby they can determine complete state ownership or joint ownership with communities. Similarly, the same option continues in relation to the inclusion of TK within the access domain as well as to enjoy the benefits out of its utilization. The gap in the CBD created by not linking access obligations of PIC and MAT with the IPR is identified here as well. The leeway allowed by the CBD and the Bonn on different aspects of ABS permits adaptation of the mandates tailor made to the domestic conditions of the CPs. Neither the CBD nor the Bonn Guidelines gives a proper account of the nature of ownership over the GRs or the TK associated with it. The widely exchanged nature of the GRs within a country can anticipate the possibility of getting associated with the State and with the people and these instruments provide no insight to appreciate ownership in such situations. To claim ownership over something, there should be the element of exclusivity in enjoying the rights over it which makes it a property. This requires an effective appreciation of the idea of property in GRs and associated TK as conceived by the CBD, elaborated through Bonn and implemented by the different CPs.

1.4 The Nagoya Protocol on Access and Benefit Sharing, 2010

The limitations of Bonn Guidelines in achieving the objectives of ABS have led to the most recent international initiative concerning the issue of ABS, the Nagoya Protocol. It is particularly aimed at operationalising the benefit sharing objective of the CBD. It is quite astonishing that even after 18 years of CBDôs adoption, there is a need of another instrument to carry out the most cherished benefit sharing objective of the CBD. This clearly depicts the gaps in the ABS process contemplated in the CBD and Bonn Guidelines. This raises the primary question whether Nagoya is able to achieve fair and equitable benefit sharing as envisioned by the CBD. Whether the Nagoya system is in tune with the philosophy of property established by the CBD is yet another concern in this regard. As the specific benefit sharing instrument of the CBD, the importance of Nagoya is that it should spell out the boundary of property right in the GRs and associated TK. It should also stipulate when the benefit sharing obligation begins and how. The Nagoyaôs contribution in preventing misappropriation through IPRs also requires special emphasis. In short, since Nagoya is the benefit sharing mechanism of the CBD, a thorough analysis of the system is warranted.

1.5 The International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA)

After the adoption of the CBD which proclaimed sovereign rights over GRs, the IUPGRFA which operated on the principle of common heritage stood in conflict with the CBD. So there arose a need for harmonization of the CBD with the IUPGRFA. Though CBD generally regulates access to genetic resources, access to *ex situ* collections and farmersô rights were not addressed by the Convention, and Resolution 3 of the Nairobi Conference for the Adoption of the Agreed Text on the CBD

recommended for the establishment of a global system for the *in situ*, on farm and *ex situ* conservation and sustainable use of PGRs for food and sustainable agriculture to be operated by the FAO. Subsequently, through a series of negotiations, the ITPGRFA was adopted in 2001 providing for farmersô rights, access to PGRFA and a multilateral system for sharing the benefits arising from their utilization. Under the ITPGRFA, the access is solely for the utilization and conservation for research, breeding and training for food and agriculture. Access is free of charge and no IPR could be claimed limiting subsequent access in the form received at the time of access.

Coming to the ITPGRFA, though it is based on the basic principle of permanent sovereignty over the resources, it envisages a multilateral system of benefit sharing as opposed to the bilateral contractual system of the CBD. So how the two instruments operate harmoniously is a fundamental question to be addressed. Yet another basic question is that if access is free, how it differs from its predecessor, the IUPGRFA? It also necessitates an enquiry regarding the possibility of any difference in the concept of property as conceived by the CBD as well as the ITPGRFA. Another interesting channel of discussion is the benefit sharing mechanism of the ITPGRFA which has already become functional from 2006 even before an international imperative for a similar mechanism under the CBD. Since the ITPGRFA insists that no IPRs can be taken over materials in the form received from its multilateral system (MLS), would it run contrary to the positive approach of the CBD towards IPRs is yet another concern to be addressed in this regard. Yet another outstanding issue is how far the ITPGRFA has succeeded in achieving the benefit sharing end through the regulation of access.

1.6 TRIPS Council Deliberations

In addition to the above mentioned international instruments specifically involved in the process of access regulation and benefit sharing, the TRIPS Council of the WTO (World Trade Organization) is another active player in the field. It is addressing the interrelationship between the GRs, associated TK and IPRs. The TRIPS regime, as it stands now, does not recognize the GRs and associated TK as a private property the use of which necessitates consent and due returns. So, at present there is no internationally binding obligation under the IP laws for the researchers to obtain consent from the resource holders and to give them a due share of the commercial returns. As long as appropriate changes are not made in the patent system in an international plane in the TRIPS level, the issue of misappropriation will continue to exist. Therefore negotiations are going on to implement new requirements in the TRIPS Agreement in relation to disclosure of the source and country of origin of the GRs used in the invention, evidence of PIC and benefit sharing. Altogether, all the above circumstances constitute unrest in the international level in the context of access.

Coming to the ongoing TRIPS Council negotiations in respect of the new disclosure requirements, the disclosure of source and country of origin of the GRs used is proclaimed as a basic tool in identifying the country of origin, which has the proprietary rights over the resources. So source will be the actual place from where the resources were taken, the country of origin will be the country where the resource actually originated. But due to the practical difficulty in tracing the country of origin, there is a push in the international level to limit it to the disclosure of the source country. If this position is accepted, it will go against the total philosophy of the CBD, which recognizes the rights of the country of origin. This issue and the adequacy of the proposed tools in curbing down the question of misappropriation are areas requiring special address.

1.7 Outline of the Thesis

In light of the various international instruments and international agencies that are actively engaged in resolving the issue of ABS, the present work tries to find an answer to the larger question how far the above agencies have succeeded in regulating access and make sure of benefit sharing. In this process, the work comprehensively analyses the work of different agencies involved in the process. It tries to find out the major obstacles that stand in the way of fulfilment of the benefit sharing objective and proposes the ways and means to tackle them. The study first traces the legal foundations of the concept of property in GRs and associated TK in Chapter 2. For this, it starts with analysis of the nature of property and the questions related to ownership in GRs as contained in the CBD as well as in various State legislations. It further examines the notion of property before and after the enactment of the CBD and establishes that the CBD contains strong private property jurisprudence.

Based on the theoretical foundation of private property right, Chapter 3 analyses the benefit sharing mechanism of the CBD, i.e. the Nagoya Protocol. It searches for a theoretical convergence of the notion of property as reflected in the two instruments and successfully establishes the same. It makes an appraisal of the Nagoya regime to find out how far it has gone beyond the CBD in ensuring the task of benefit sharing and the impediments in its way.

Realizing that the ITPGRFA forms part of the CBD system, Chapter 4 analyses the benefit sharing structure of ITPGRFA as revealed through its multilateral system. This gives the work the benefit of comparing two different benefit sharing models operating on the same philosophy of property. This chapter tries to find out whether there is conceptual coherence in the notion of property when the benefit sharing model changes. It also

compares the merits and demerits of both the systems and tries to locate the hurdles in achieving benefit sharing.

Aware of the legal impediments caused by IPRs in the process of ABS, Chapter 5 tries to explore the linkages between IPRs and GRs and associated TK and assesses why contract-based CBD system fails before the monopoly rights under TRIPS. Chapter 6 analyses the different solutions suggested by the international community at the TRIPS Council as well as the WIPO (World Intellectual property Organisation) and examines their effectiveness. Chapter 7 concludes that considering the inability of the present IP system to understand the grass root realities of the indigenous communities as well as the varying situations of the country of origin, the best possible way to recognise the CBD goals in the TRIPS could be better achieved through linking the two instruments by means of the triple disclosure requirement in Article 29 as suggested by the Disclosure Group during the TRIPS Council deliberations. It also recommends that considering the nature of property in GR, a new section/chapter in the TRIPS dealing with GRs would be another workable solution.

Chapter 2

PROPERTY IN GENETIC RESOURCES: A CONCEPTUAL ANALYSIS

The CBD assumes prime status in the regulation of access to GRs. It primarily talks about contractual regulation of access to GRs/BRs of the Member States[1]. This presupposes a clear understanding of the subject matter of access. So, one has to have a proper vision in respect of the nature and content of GRs and the extent of access that can be provided. This presumably involves an analysis of the definition of the term GRs as conceived by various international instruments and national laws in this regard followed by the extent of access permitted by them. One of the basic principles of Contract law is ñ*nemo dat quod non habet"* which means, no one can confer a better title than what one actually has[2]. This raises a primary question for our consideration regarding the ownership of GRs for only the country/person who is the owner of the GRs can make a legitimate transfer. These two analyses followed by the enquiry to trace exclusiveness would sufficiently outline the nature and content of the concept of property involved in GRs.

2.1 Nature of GRs and the Scope and Extent of Access - The CBD Standpoint

The CBD envisions regulation of access to GRs as a tool to achieve its goals viz., conservation of biological diversity, sustainable use of its components and fair and equitable sharing of benefits arising out of the commercial utilization of GRs[3]. Unlike its predecessor, the IUPGRFA that

[1] The Convention on Biological Diversity, 1992, Article 15 and Preamble
[2] *Black's Law Dictionary* (6th ed.) defines it as ôhe who hath not cannot giveö
[3] *Supra* n.1, Article 1

advocates for free access to PGRs[4] , the CBD proposes a regime that could regulate any type of access to GRs. Since the CBD gives enough flexibility to the Member States to devise access laws appropriate for their needs, its framework mandates a clear understanding with respect to the scope and extent of access. For this purpose, the current section of this Chapter will look into the definition of GRs as provided by the CBD and conceived by the international community.

The CBD defines GRs as ógenetic material of actual or potential valueô wherein genetic material is in turn defined as óany material of plant, animal, microbial or other origin containing functional units of heredityõ[5]. Genetic material and GRs may sound to refer to purified forms. But CBD permits access to raw resources by including BRs within its access framework. BRs are defined to include ñGRs, organisms or parts thereof, populations or any other biotic component of ecosystems with actual or potential use or value for humanity[6]ò. The definition of BRs is wide and it includes human beings as well. But the COP, the governing body of the CBD, in its Decision II/11 had decided to exclude human genetic resources (HGR) from the scope of the CBD[7]. It applies to all genetic resources both *in-situ* and *ex-situ* in the countries of origin/ providing countries that existed on 29th December 1993, the date on which the CBD became operational.

The access regulating laws of the Member countries of the CBD are also defining GRs/BRs in their respective legislations. True that they are in line with the definition given in the CBD, but many countries show a trend to expand the definition of GRs beyond the CBD. For example, the Biological Diversity Act of India defines BRs as plants, animals and microorganisms or

[4] The International Undertaking on Plant Genetic Resources for Food and Agriculture, 1983, Article 5

[5] *Supra* n.1, Article 2

[6] *Ibid.*

[7] COP Decision II/11. 2, ñ*Reaffirms* that human genetic resources are not included within the framework of the Convention.ò

parts thereof, their genetic material and by-products (excluding value added products) with actual or potential use or value, excluding human genetic material[8]. The Access Regulations of Cook Islands defines GRs as genetic material of actual or potential value and genetic material is defined as any material of plant, animal, microbial or other origin containing functional units of heredity and includes biochemicals and biomolecules[9]. The Biodiscovery Bill 2004 of Queensland defines a native biological material as a native BR or a living or non-living sample of the resources or a substance sourced from native BR[10]. Native BR is defined as a non-human living organism or virus indigenous to Australia[11]. Though there is no difference with regard to the definition of GRs from that provided by the CBD, the laws of ANDEAN[12], ASEAN[13], OAU[14] etc have extended their scope by incorporating the use of derivatives and progenies of GRs/BRs within the scope of access. In the law of Philippines, the framework is to regulate the prospecting of BRs and GRs, their by-products and derivatives[15]. In the Implementing Rules, by-product is defined as any part taken from BRs and GRs such as hides, antlers, feathers,

[8] The Biological Diversity Act, 2002, Sec. 2(c) , India
[9] Access Regulations 200X, Regulation 2, Cook Islands
[10] The Biodiscovery Bill, 2004 Schedule 2, Queensland
[11] *Ibid.*
[12] ANDEAN, Decision 391, Common Regime on Access to Genetic Resources, Article 1, ñAccess is defined to include the use of genetic resources and their by-products. By-product is a molecule, a combination or mixture of natural molecules, including crude extracts of live or dead organisms of biological origin that come from the metabolism of living beings.ò
[13] The ASEAN Framework Agreement on Access to Genetic Resources, 2000, Article 3, ñAccess is defined to include acquisition and use of biological and genetic resources as well as their derivatives wherein derivative is defined as something extracted from biological and genetic resources such as blood, oils, resins, genes, seeds, spores, pollen and the like, as well as the products derived from, patterned on, or incorporating manipulated compounds and/genes.ò
[14] OAU Model Law, Rights of Communities, Farmers, Breeders, and Access to Biological Resources, 2000, Article 1 defines access as ñé the acquisition of biological resources, their derivatives, community knowledge, innovations, technologies or practices as authorized by the National Competent Authority.ôò And derivatives are defined as ñé a product developed or extracted from a biological resource; a derivative may include such products as plant varieties, oils, resins, gums, proteins etc.ò
[15] Executive Order No. 247, Philippines, Prescribing Guidelines and Establishing a Regulatory Framework for the Prospecting of Biological and Genetic Resources, their By-products and Derivatives, for Scientific and Commercial Purposes, and for other Purposes, Section 1

fur, internal organs, roots, trunks, branches, leaves, stems, flowers and the like, including compounds indirectly produced in a biochemical process or cycle[16]. Derivative refers to something extracted from BRs and GRs such as blood, oils, resin, genes, seeds, spores, pollen and the like, taken from or modified from a product[17]. The impact of adding derivatives and progenies of GRs is that it helps to include value-added products within the ambit of access. Thus the scope and extent of access varies from raw BRs to high precision value-added products derived out of them. The value-addition could help in attaining more precision as to the features of the GRs thereby increasing their commercial utility.

The definition of GRs as provided by the CBD has two aspects, first the tangible genetic material and second the value contained in it, i.e., the genetic information it contains. The value of hereditary information is usually unknown and could be ascertained only by prospecting activities[18]. So GRs have a dual nature, both tangible and intangible, and its scope is further widened by State legislations permitting incorporation of purified forms of GRs to add more precision to the intangible information contained in it, thereby increasing the possibility to tap potential commercial returns. When we say that the value of hereditary information contained in GRs/BRs is unknown, we could not negate the fact that some properties of such materials could be revealed through constant interactions with them. GRs/BRs are closely associated with the traditional lifestyles of local people in terms of their healing knowledge, traditional medicine and agricultural systems directly linked to biodiversity conservation and environmental protection[19]. The

[16] Department Administrative Order No. 96-20, Implementing Rules and Regulations on the Prospecting of Biological and Genetic Resources, Sec. 2.1(j)
[17] *Id.* Sec. 2.1.(m)
[18] Michael Hassemer, ñGenetic Resourcesò in S. Von Lewinski, (Ed.), *Indigenous Heritage and Intellectual Property*, Kluwer Law International, Great Britain (2004), p.153
[19] Matthias Leistner, ñTraditional Knowledgeò in S. Von Lewinski, (Ed.), *Indigenous Heritage and Intellectual Property*, Kluwer Law International, Great Britain (2004), pp. 49-50

knowledge they hold over the resources is the value added to the resources by them. The finalized products of modern biotechnology are often manifestations of the traditional wisdom over the resources and as far as the value is concerned, the latter is in no way inferior to the former. Genetic information is a modern scientific term quite unknown to indigenous groups and as far as they are concerned, the value of the resources lies in their uses. The CBD definition of GRs is recognizing the value part as well as the physical part, and in most cases both are held by traditional and indigenous communities. The definition talks about the actual and potential value of the resources. Actual value of the resources is ascertained through the known uses over the resources i.e., the TK over the resources and the potential value could be ascertained through prospecting activities. The traditional wisdom and prospecting activities are revealing the value of the GRs through their own means. This value justifies the property status of GRs for even the western philosophy of property recognizes that anything of value is property when the legal system recognizes it with the bundle of rights[20]. It would be the nature of ownership with the tangible as well as the intangible part that determines the relationship of the subject matter and right holder with the property rights.

A close look at the GRs situation exposes multiple possibilities before us. There could be GRs with TK over them, with TK and subsequent value addition, GRs without value addition and TK, and GRs with value addition, but without TK. The third and fourth situations demonstrate the chances of existence of unknown/wild resources and a researcher trying to locate its unknown uses and properties. All these situations are different instances of the relationship of property rights on GRs with its holders. In the CBD context, ownership is associated with the idea of PIC and MAT), but the CBD does not

[20] J. E. Penner, *The Idea of Property in Law*, Clarendon Press, Oxford (1997), p.63; Penner says ñProperty comprises of any valuable resource in respect of which an individual has an exclusive entitlement.ò

detail much as to from whom PIC is to be obtained or with whom MAT are to be entered into. Article 15.5 of the CBD stipulates that

> ñAccess to GRs shall be subject to PIC of the Contracting Party providing such resources, unless otherwise determined by that Partyò.

It is also mandated that the Party providing GRs means the country of origin of such resources where they are found *in situ*[21]. The CBD further adds that access should be on MAT and subject to the provisions of Article 15[22]. So reading from the CBD, the ownership over the GRs is exclusively vested with the sovereign. It would be for each CP to decide internally through domestic ABS legislation the nature of this relationship. Since BRs are closely associated with the life of the people, the relationship would be very complex considering the diverse possibilities of such associations. Revisiting the previously mentioned possibilities where the GRs could be with TK, with TK and subsequent value addition, without TK but with value addition and without any TK and value addition, and where the resources are in the possession of the State or in the possession of the local people and indigenous communities builds up a regime complex for the State to decide the matter internally, taking into account the closeness of the communities and the people with respect to the GRs. Here the available options for the State would be to vest the full ownership of the GRs either over the State or with the communities or to own them jointly by the people and the State. When TK over the resources is involved, the inter-relationship between the GRs, people and the State is becoming more composite. So based on the social, cultural and ethical background of the people, it is for the State to decide the ownership issue.

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[21] *Supra* n.1, Article 15.3 ñFor the purpose of this Convention, the genetic resources being provided by a Contracting Party, as referred to in this Article and Articles 16 and 19, are only those that are provided by Contracting Parties that are countries of origin of such resources or by the Parties that have acquired the genetic resources in accordance with this Convention.ò

[22] *Id.* Article 15.4

Although it is possible from the CBD to assume that the intangible TK forms part of the GRs, the only visible provision in the CBD merely provides that the knowledge, innovations and practices of indigenous and local communities relevant for the conservation and sustainable use of biodiversity must be respected, preserved, maintained and utilized with their participation and approval and resulting benefits must be shared equitably with them[23]. Even though this mandate is diluted by terms like ñas far as possible and as appropriateò the provision could be treated as an express recognition of the intrinsic linkage between the GRs, associated TK and the local and indigenous communities.

Though the CBD has not defined TK, many implementing legislations have attempted the same with or without specifying the term as such[23(a)]. For example, the ANDEAN Pact provides that the intangible component over BRs means any knowledge, innovation or individual or collective practices of actual or potential value associated with the GR, its derivative or the BR containing them, whether or not it is protected by the IP systems[24]. In the ASEAN Framework Agreement, TK is defined to include knowledge, innovations and practices of indigenous and local communities relating to the use, properties, values and processes of any BRs and GRs or any part thereof[25]. The OAU Model Law defines indigenous knowledge as the accumulated knowledge that is vital for conservation and sustainable use of BRs and/or which is of socio-economic value, and which has been developed over the years in indigenous communities[26]. In India also, even though there is no definition for TK, the knowledge associated with the BRs is included

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[23] *Id.* Article 8(j)

[23(a)] Defining TK has proved to be one of the most difficult tasks. See Fikret Berks, ñTraditional Ecological Knowledge in Perspectiveò, in Julian T. Englis (ed), *Traditional Ecological Knowledge: Concepts and Cases*, IDRI, 1996 p.3. Also see Dutfield, ñTRIPS Related Aspects of Traditional Knowledgeò, 33 Case W. Res. J. Intôl L.233 (2001)

[24] Supra n.12

[25] *Supra* n.13

[26] *Supra* n.14

within the scope of access[27]. These countries have made the knowledge associated with GRs a subject of access.

The subject of TK with respect to biodiversity is the valuable information on some of its use, acquired by a group of people through their constant and continuous interaction with BRs[28]. This knowledge over the resource decreases the risk factor involved in the biotechnological research because if the use is not known, the researchers have to screen a large extent of various BRs for tracing the needed characteristic feature, spending much time and money. When it comes to TK associated with the BRs, it is the knowledge about the features of that intangible hereditary information contained in the tangible BR. As we have mentioned earlier, a BR or its by-product or derivative is having dual exchange value, primarily, the tangible component or the resource as such and secondly, the intangible component or the genetic information contained in it. The most pertinent point here is that the real exchange value of the GRs/ BRs is often determined by the value of the TK associated with it. Unless there is TK, the actual value of the resource could not be ascertained and the transfer or access will take place based on the potential value that could be calculated only after the research. The TK held over a particular resource is often a clue to/or the full-fledged genetic information contained in it. The nature and content of TK associated with GR could be treated equivalent to the properties of hereditary information contained in the resources with the difference that the latter is revealed through scientific and technological tools while the former is acquired through human intervention, to be more precise, through constant human interactions of generations. So, the knowledge acquired, held and maintained by the communities is not inferior to the investment and time spent by the researchers and multinationals in exploring the properties of the genetic information through technical devices. It is quite ironical that the uses of the genetic

[27] *Supra* n.8, Section 3
[28] *Supra* n.18, p.163

information explored by the researchers backed by huge investment is considered eligible for private property protection while the same information on uses attained through experience of generations is negated the same. While making this statement, it is emphasized here that the statement does not argue that patent protection is to be given to such TK holders. The intention is that from the value perspective, TK and scientific ventures stand on the same footing. Co-relating TK with the patentability of an invention, we could see that in the peculiar case of GRs and associated TK, the communities holding the knowledge over the GRs could be treated as the persons skilled in the art while determining the question of patentability of the invention. If their contributions are not recognized, the non-obviousness criteria of patentability would not be satisfied in the strict sense. Even if an invention is developed independently without any contributions from the TK holders, though the inventor has no obligation to share the benefits with anybody, it is doubtful whether the invention could satisfy the non-obvious requisition in its full depth. It will also affect the novelty of the invention as the specified use by the communities can be considered as a prior art.

The subject matter of access is of course the information on the properties of a resource, and based on the availability of this information, the mode of access differs. If the information is available through the existence of TK, the researcher would require access to TK as well as the resource from a pure CBD angle. If the information is not available, i.e. no TK is available over the resources, then access would be confined to the resources only and the researcher would be trying to locate the information. Though in a different manner, the researcher is doing the very same exercise done by the indigenous and local communities who hold TK over the resource. The two streams search for the same use value though end up with highly contrasting market value. It is also visible from the various implementing State legislations that exploitation of the commercial utility of GR and associated TK is the basic

philosophy reflected and to ensure the same, the countries are in the track of giving more precision to the subject matter through the inclusion of derivatives, by-products etc within the ambit of the subject matter or access. The above analysis of the subject matter of GRs and associated TK reveals vital information. In the context of access, the point of concern is not only the GRs, but also the value associated with it. So, the value or the uses are also becoming part and parcel of the system. When we say GRs of value, they are becoming inseparable. The tangible GRs and the intangible value together constitute the subject matter of access. The access is intended for ascertaining the value and without the tangible GRs, it could not be ascertained. This means without GRs, value is meaningless and without value GRs is meaningless. This shows the inseparability of GRs and their value. TK associated with GRs forms a type of this value component. So as far as GRs with TK are concerned, such TK also is an inseparable element of the GRs. Who owns it is an entirely different question determined in terms of its associations with the people and also based on the policy of the concerned nation. So the nature of GRs is that of upholding the inseparability of the tangible and intangible parts in them, including the TK associated with them. The trend of the majority of the nations is to extend it to derived, purified and extracted forms of GRs and associated TK and the issue of ownership is an internal question of domestic policy determination left to individual Member States.

2.2 GRs and TK – Demystifying the "Common" Concept

2.2.1 Genetic Resources and Common Heritage of Mankind

Prior to the enactment of the CBD, it was generally believed that natural resources, especially BRs were open to free access. For example, the IUPGRFA had proclaimed that the PGRs relevant for food and agriculture are

the heritage of mankind and therefore should be made available for all[29]. Many scholarly writings consider PGRs as a common heritage of mankind. The concept of common heritage of mankind is of recent origin in 1970s and whether access to BRs ever featured the characteristics of a common heritage regime is worth questioning. The term ñcommon heritage of mankindò was coined during the negotiations on the Law of the Sea and it was Ambassador Pardo of Malta who first proposed that the law of the sea must be governed by a new principle, the common heritage of mankind[30] instead of the earlier notion of the freedom of high seas as advocated by Hugo Grotius[31]. According to Pardo, the elements of the new principle are (i) non-appropriation and use by the international community as a whole, (ii) an international system of management, (iii) active sharing of benefits arising from management (iv) use only for peaceful purposes and finally (v) reservation for future generations[32]. Out of these five components, the first four have become the undisputed elements enunciated by the Law of the Sea Convention as well as the Moon Treaty.

Before proceeding to test whether natural resources are a common heritage of mankind, it would be better to know the property concept existing in a regime of common heritage. There is no legal consensus as to the *res* concept involved in the common heritage resources. Some argue that it is a version of the *res communis* regime, i.e., property owned in common and

[29] It is to be noted that the IUPGR initially in Article 1 provided that PGRs are the heritage of mankind and later in Resolution 4/89, the Agreed Interpretation of the IU, recognized them as the common heritage of mankind.

[30] There is also an argument that Alto Cocca is the founder of this principle. See Chika B. Onwuekwe, ñThe Commons Concept and Intellectual Property Regime: Wither Plant Genetic Resources and Traditional Knowledgeò, *Pierce Law Review*, Vol.2 No.1, (2004) p.73

[31] Jan van Ettinger, Alexander King, and Peter Payoyo, ñOcean Governance and the Global Pictureò in Peter Bautista Payoyo (Ed.), *Ocean Governance: Sustainable Development of the Seas*, UNU Press, New York, (1994) available at http://www.unu.edu/unupress/unupbooks/uu15oe/uu15oe0p.htm

[32] Kemal Baslar, *The Concept of Common Heritage of Mankind in International Law*, Martinus Nijhoff Publishers, (1998) p.81 : Also see Supra n.31

therefore preventing appropriation[33]. *Res communis* since being owned in common must be available for use by everyone and are not susceptible to appropriation by any private agent and it also excludes sovereign claims or national jurisdiction[34]. The term common heritage contemplates that ownership is vested with all the mankind and consequently there is no legal ownership over it.[35] Access is the key factor in the common heritage regime and the resultant benefits must be shared equitably by the mankind as a whole rather than by the States.[36]

Theoretically speaking, the common heritage of mankind envisages a regime where its subjects are owned by the humanity as a whole including the forthcoming generations[37]. It is an area where private ownership is completely absent and benefits if any generated out of it have to be shared by the mankind. According to Baslar, the spirit of the common heritage doctrine is the stewardship theology of conservation rooted mainly in the Judeo-Christian, Islamic and Buddhist values.[38] The term ñheritageò contemplates something to be inherited down to the heirs involving the rights of future generations over it[39]. As the trustees of the natural resources, the human beings have to use and manage the worldôs resources both for themselves and in the interest of all[40]. This ethic justifies the sharing of natural resources within and beyond national boundaries. The French and Spanish texts equated the term heritage with *patrimonie* or *patrimonio* wrongly associating it with the notion of property and no wonder, in the context of International Law, it was first suggested for the exploitation of natural resources[41].The essence of the common heritage

[33] *Id.* p.88
[34] Christopher C. Joyner, ñLegal Implications of the Concept of the Common Heritage of Mankindò, *ICLQ* Vol. 35, (Jan.1986), p.194
[35] *Ibid.*
[36] *Id.* p.195
[37] *Supra* n.32, pp.38-72
[38] *Id.* pp.14-15
[39] *Ibid.*
[40] *Ibid.*
[41] *Ibid.*

doctrine is non-appropriation and no rights while it can be used and enjoyed by everyone without destruction. It is not property at all or it is everyoneôs property and no enclosure can be made out of it. The notion of *res* is absent and the principle emphasizes only the use value of things[42]. If we think in terms of value addition being made to the resources under the common heritage regime, it does not entitle one to claim private enclosure over the value added since no rights emerge out of the system. In short, things covered by the common heritage regime lack exclusivity, the essential element to treat a thing as property. Private enclosure in the form of proprietary right is impossible in a common heritage area, leaving little applicability to the theories of private property.

Historically looking at the issue of access to natural resources, we could see that as Grotius said, the resources were not evenly distributed and the returns via their exploitation through new technologies like modern biotechnology was non-existent. Natural resources earlier meant land, trees, minerals etc and the nature of exploitation was physical. The great natural law philosopher Blackstone says:

> ñé the Earth and all things therein were the general property of mankind from the immediate gift of Creator. Not that the communion of goods seems ever to have been applicable, even in the earliest ages, to aught but the substance of the thing; nor could be extended to the use of it. For, by the law of nature and reason he who first began to use it acquired therein a kind of transient property that lasted so long as he was using it, and no longer; or to speak with greater precision, the right of possession continued for the same time only that the act of possession lasted. Thus the ground was in common, and no part was the permanent property of any man in particular; yet whoever was in the occupation of any determined spot of it, for rest, for shade,

[42] *Id.* pp.85-91

or the like, acquired for the time a sort of ownership, from which it would have been unjust and contrary to the law of nature to have driven him by force, but the instant that he quitted the use of occupation of it, another might seize it without injustice."[43]

Though common heritage is a natural law doctrine, it is completely against the natural law philosophy which justifies appropriation as a basic and inherent right of human beings[44]. When appropriation and acquisition were recognized as the inherent right of human beings, natural resources served as *res nullius* that is property owned by nobody to justify appropriation and resultant private property. This presumption is particularly true with respect to GRs/BRs and TK associated with them for they were in the earlier stages never a commodity that could generate income. Something is recognized as property only when it is capable of generating income and the historic period was devoid of the technology that could tap potential benefits out of GRs and TK. The general conception of the Anglo ï American law was that ñalmost everything can be owned and that ownership embraces the full range of uses that can be made so long as one does not invade the like rights of othersé ò[45] Joseph L. Sax rightly points out:

ñIn this system, there is almost no notion of use entitlements that are withheld because of some interest of the public; nor is there any affirmative obligation to use oneôs property in a way that is beneficial to the public. The system rests on a fundamental market driven assumption that ultimately what is good for the owner is good for the

[43] Blackstone, Commentaries on the Laws of England as cited in *Infra* n.77
[44] *Supra* n.32, p.16; Also see Leif Wenar, ñOriginal Acquisition of Private Propertyò, *Mind*, Vol.107. No.428, Oxford University Press (1998), pp. 799-820
[45] Michael I. Jeffery *et.al* (Eds.), *Biodiversity Convention, Law and Livelihood, Bridging the North South Divide*, IUCN Academy of Environmental Law Research Studies, IUCN, p.12

public, as public demand will generate private supply of that demand and not of what is not wanted or needed.ò[46]

Consequently, GRs and TK were never reduced into what we call property and it is believed to be shared by all in the common interest. So the conclusion is that GRs or TK never constituted a domain of common heritage as what the term actually connotes and physical appropriation was always there and was regulated through various State laws to achieve common good. When appropriate technology was found out to exploit them commercially, the law construed it as things owned by nobody and to be more particular in regard to TK a commodity which has no single owner. So it was interpreted as ópublic domainô a creation of law facilitating appropriation[47]. Another argument could be that GRs and TK by their nature constituted a *res communis* i.e., things incapable of appropriation by their nature in the early period. If we look at the value addition being done by the communities over their knowledge, we could see that no private right was asserted by the individuals in the communities over the improvement of existing knowledge they made. Whenever they found out new knowledge bases, those were also added to the pool of knowledge they already had and used for the benefit of the whole community. The added knowledge also passed on from generation to generation. It could be treated as the real notion of *res communis* in its full sense. This is the traditional notion of value addition quite unfamiliar to the western property philosophy where individual value addition qualifies for appropriation. With the intervention of appropriate technology, propertization came in misinterpreting the open access notion of the *res communis* as *res nullius,* which provided a perfect platform for appropriation through exploitation and private enclosure. Thus they began to be treated as an element of public domain by the interest groups including corporate entities and

[46] *Ibid.*
[47] *Infra* n.57

researchers. The Lockean and Hegelian philosophies provide the necessary support for this type of appropriation and privatization. Locke says,

> ñWhatever he tilled and reaped, laid up and made use of, before it spoiled, that was his peculiar right; whatsoever he enclosed, and could feed, and make use of, the Cattle and Product was also his.ò[48]

In the Hegelian view, by employing the

> ñabsolute right of appropriation with regard to all things, natural resources could become the property of the State or the people as a means to satisfy individual wants and desires or as an extension of personalityò.[49]

Though common heritage was proclaimed to govern natural resources for centuries, many major elements of the principle were never reduced into practice. States were using resources solely for their own development without taking into account the needs and aspirations of the humanity as a whole. Benefits arising out of the utilization of natural resources were enclosed using the institution of private ownership. The logic behind proclamation of common heritage over natural resources could be that it ensured free access to the resources. Common heritage, the *sui generis* principle was misinterpreted to constitute a *res nullius* domain, thereby justifying private appropriation. No one can argue that any appropriation and resultant benefits derived from the use of natural resources is legal, whether it is the mineral and oil exploration dominant in the 19th century[50] or the intellectual property rights obtained through bioprospecting in the 20th and 21st centuries. In light of this misinterpretation and misappropriation, common heritage principle became a

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[48] Locke, *Two Treaties of the Government*, (1690), p.309 available at: http://www.lonang.com/exlibris/locke/ Also available at http://www .fordham. edu/halsall/ mod/1690locke-sel.a sp

[49] Drahos, *A Philosophy of Intellectual Property Rights*, Ashgate Dartmouth, (1996), p.77

[50] Nico Schrijver, *Sovereignty over Natural Resources: Balancing Rights and Duties*, Cambridge University Press, UK, (1997), p.41

vehicle of exploitation in actual practice in respect of the natural resources, paying scant attention to the spirit of the principle. Consequently, it led to a paradigm shift in the proprietary regime over natural resources, making them subject to the permanent sovereignty of States through political interference and this is reflected in the CBD.

Even though the common heritage notion over the GRs is beaten in the previous section, the task is not over in demystifying the misconceptions surrounding GRs. Synonymous with the usage of common heritage of mankind, many scholars equate GRs so as to mean global commons, common property etc[51]. In really understanding the property concept of GRs, it becomes crucial to unveil such masks. The most interesting part is that global commons or simply commons, common property and common heritage do not contemplate the same meaning. So in unveiling the real notion of property in GRs and associated TK, the following section of this study will explore the meaning of the commons and common property and find their applicability with respect to the sphere of GRs.

2.2.2 GRs as Commons and Common Property

The word ócommonsô in relation to property means things owned by nobody but available for use for all without restriction[52]. They are characterized by non-excludability and non-rivalry[53]. Non-excludability implies that it would be expensive and almost impossible to exclude others from using such things[54]. Non-rivalry means use by one person does not diminish anotherôs use or access to them[55]. These commons are generally treated as public goods by economists. Sunlight, air etc are classic examples of

[51] *Supra* n.30, pp. 65-90; Also see Carolina Roa-Rodriguez and Thom van Dooren, ñShifting Common Spaces of Plant Genetic Resources in the International Regulation of Propertyò, *JWIP* (2008) Vol.11, No.3, pp.176-202
[52] *Ibid.*
[53] *Ibid.*
[54] *Ibid.*
[55] *Ibid.*

the commons. Another feature revealed from this description is that the commons know no boundaries. In a commons regime, appropriation and private enclosure in the form of property rights is not prevented as the enclosure no way diminishes the availability of the resources. Commons is an all-inclusive regime and it upholds the capitalist philosophy of survival of the fittest. Anyone can appropriate as much as one can and there is no reservation for future generations as in the case of common heritage resources. But the interesting feature is that it never results in the over-use and over-exploitation of the resources nor leads to resource depletion. It would be worth looking into the tragedy of the commons as popularised by Hardin where he explains that

> ñé the rational herdsman concludes that the only sensible course for him to pursue is to add another animal to his herd. Add another; and anotheré . But this is the conclusion reached by each and every rational herdsman sharing a commons. Therein is the tragedy. Each man is locked into a system that compels him to increase his herd without limit ï in a world that is limited. Ruin is the destination toward all men rush, each pursuing his own best interest in a society that believes in the freedom of the commons. Freedom in a commons brings ruin to all[56]ò.

By commons, here Hardin denotes an open access regime where the resources are left for the use of everyone without any control and individual accumulation is possible. All have equal right of appropriation though the capacity may vary and each one will accumulate according to oneôs capabilities. This uncontrolled use would result in over use and eventually lead to the depletion of the resources. But commons as we understand in the international law parlance and in the context of economics is something different. Though it envisions an unregulated system of access and use, the

[56] Garret Hardin, ñTragedy of the Commonsò, *Science* Vol. 162, (13 December 1968), p.1244

regime therein is not susceptible to overuse and depletion as the qualifications are non-excludability and non-rivalry. Whether Hardin is right or wrong is still under debate as the meaning of commons captures different meaning in the context of international law, economics, sociology and anthropology. But we could see that in the parlance of international law what is referred to as commons are situated beyond the limits of national jurisdictions and are open access regimes. Antarctica, high seas and the outer space which were initially conceived as the global commons are now treated as the common heritage of mankind with exquisite features of conservation for future generations and benefit sharing with the underdeveloped nations. Here the open access regimes are converted to areas with regulated and controlled uses and the overuse tragedy may be one reason behind this[57]. They were simply open access regimes and not commons. Both in the open access regime and the commons, the *res* concept is *res nullius* with the difference that the resources of the open access regime would deplete due to overuse while the same is not possible in the commons due to their character of non-exclusion and non-rivalry. Now, the pertinent question is whether GRs are commons. Do they feature non-excludability and non-rivalry?

A number of reasons are cited by many to argue that GRs are not commons. First is that unlike air or sunlight, GRs are found in the living beings situated within the borders of a sovereign State[58]. Coming to the non-excludability factor, the country where the resources are present can exclude others through legal intervention. The non-excludability of a GR is quite similar to the non-excludability we could perceive in the case of IP categories such as copyright in a computer software, the difference being that the copyright owner can prevent unauthorised use of his software with the help of national and international laws while no such recourse is available in the case

[57] Chander and Sunder, ñRomance of the Public Domainò, 92 *California Law Review*, (2004), p. 1356
[58] *Supra* n.30

of GRs[59]. The final factor with respect to non-excludability is that GRs and associated TK could be identified with definite owners in most of the cases. Their availability to the public does not mean that such resources are devoid of ownership rights. The availability that often seems to be with zero cost is because of their communitarian philosophy as opposed to the Western individualistic private ownership structure[60]. Considering the second aspect of non-rivalry, it is to be realised that a commons which exhibit the characteristic of a public good cannot get depleted as opposed to Hardin's postulates. Acknowledging the tangible as well as intangible elements in GRs and their inseparability, GRs is a unique proposition since the absence of the tangible element makes the intangible element meaningless and vice versa. So when GRs are removed from a living being whether plants, animals or microbes, their worth is grossly diminished because it is an established fact that in germplasm, value of the whole is in the part[61]. Since the worth diminishes, it cannot be treated as non-rivalry. So the conclusion is that GRs and associated TK can never be treated as commons. This may provoke one to ask whether GRs constitute an open access regime where Hardin talks about the tragedy. Open access regimes are *res nullius*. We have seen that the GRs could diminish their worth on use but are excludable as they are often found in sovereign territories with the possibility of identifying definite holders as owners. Same is the case with associated TK. While it is recalled that a State/international community can decide to treat a resource as an open access resource, the nature of GRs, associated TK, and their associations with the human beings does not by itself make them an apt subject for open access unlike in the case of sunlight, air, outer space or Antarctica. Thus, the inference is that GRs and associated TK can never be branded as common heritage, global commons or open access regimes.

[59] *Ibid.*
[60] *Ibid.*
[61] *Ibid.*

Yet another prevalent conception over GRs is that they constitute ócommon property resourcesô. But the difficulty in ascertaining the validity of this statement is that the term common property assumes different meanings in different disciplines. In international law, common property realms are equated with open access regimes where no one has the legal right to exclude others from the use of the resources due to their non-rival and non-excludable character[62]. But in other disciplines such as sociology and anthropology, common property resources are defined as resources co-owned and actively stewarded by a specific community, which is nearer in meaning to communal property resources[63]. Since the resources are effectively managed by the common property owners, there is hardly the possibility of their overuse[64]. Due to their characteristics, GRs cannot constitute a common property in the international law parlance. On the other hand, in the context of sociology and anthropology, they can constitute a regime of common property due to their territoriality as well as their associations with the local and indigenous people and farmers with respect to conservation mechanisms and identification of utilitarian values of the resources[65]. The preservation of the resources as well as the knowledge over them is through oral traditions or indigenous methods of record keeping and passed on from generation to generation in ways quite unfamiliar to the Western science. The intertwined association with the GRs and TK and the interrelationship between TK and GRs provides communal ownership to local and indigenous groups over them. But international law does not recognize such ownership rights over common property resources and it envisions an open access regime by the term. Since the term provides different while conflicting meanings in the two different contexts, it is quite unable to determine the correctness of the proposition that GRs and associated

[62] *Ibid*.; Also see Charlotte Hess and Elinor Ostrom, ñIdeas, Artifacts and Facilities: Information as a Common Pool Resourceò, 66 *Law and Contemporary Problems,*(Winter/ Spring 2003), pp. 111-145
[63] *Ibid.*
[64] *Ibid.*
[65] *Ibid.*

knowledge are common property resources, as it would create confusion in the two streams like what happened to Hardinôs ñTragedy of the Commonsò[66]. As a solution this study suggests that the GRs and TK associated with them constitute communal property. So it could very well be concluded that due to the prevalence of communal property rights in them, the GRs and associated TK do not fall within the ambit of any type of open access.

2.2.3 Public Domain and GRs and TK

The final question in relation to the ócommonô aspect of GRs and TK is whether they plunge into the public domain, yet another symbol of open access. Public domain is a relatively new concept emerged in the IP milieu. Its statutory origin is traced with the 1909 Copyright Act of the United States though the US courts started using the term from late 1890s[67]. Initially, scholarly interpretation of public domain was in negative terms as consisting of what is not covered by IPRs[68]. For example, William Kraisilosvky in his famous article ñObservation on the Public Domainò argues that

> ñPublic Domain in the field of literature, drama, music and art is the other side of the coin of copyright. It is best defined in negative terms. It lacks the private property element granted under copyright

[66] James A. Swaney, ñCommon Property, Reciprocity and Communityò, *Journal of Economic Issues*, Vol. 24, No. 2, (June, 1990), pp. 451-462; Daniel W. Bromley, ñThe Commons, Property and Common Property Regimesò, Paper presented at the first annual meeting of the International Association for the Study of Common Property, Duke University, (September 27-30, 1990); Achim Lerch, ñProperty Rights and Biodiversityò, *European Journal of Law and Economics*, Vol.6 (1998) pp. 285ï 304; Brewster Kneen, ñPrivate Property, the Commons and the Public Domainò, Seedling, (January 2004), p.2

[67] See *Singer Manufacturing Co*. v. *June Manufacturing Co.* dated May 18, 1896 in Vincenzo Vinciguerra, ñContribution to the Understanding of Public Domainò, *bepress Legal Series*, Paper 1639, (2006), p.10 available at http://law.bepress.com/cgi/viewcontent.cgi?article=7636&context=expresso

[68] See *Id.* p.4

that there is no legal right to exclude others from enjoying it and is free as the air to common useö[69].

Many scholars view public domain as representing nothing more than a repository for what is left over after positive property rights have been established[70].

The call for a positive approach towards public domain was raised by Prof. David Lange in late 1970s, inviting attention to the phenomenon that each increase in protection raises the cost of and reduces access to the raw materials for further development[71]. In framing a positive rule of law for public domain, Edward Lee opined that the concept embodies the affirmative rights of the public to unrestricted access and use of the public domain material[72]. He envisions it as a combination of public rights and public ownership/property merging to form the domain of things belonging to the public[73]. Diane L. Zimmerman corroborates this view by holding that public domain is a source of rights, and in particular, a right not to be excluded from the enjoyment of whatever is publicly accessible[74].

In the IP arena, public domain constitutes a base for appropriation. If we look at the *res* concept, no one can be excluded because everyone has the right to use it. But unlike in the *res communis,* it promotes appropriation in the form of private property rights in a fashion similar to the Lockean commons. Further, it cannot constitute a *res nullius,* as the appropriation is based on the like right of everyone to appropriate. In another way, it is not nobodyôs property, but everybodyôs property. So the best answer would be that it is an open access regime characterized by free use that too unregulated, though the

[69] *Ibid.*
[70] *Ibid.*
[71] *Ibid.*
[72] *Ibid.*
[73] *Ibid.*
[74] *Ibid.*

resultant product created out of it should have the prescribed qualifications to fit into the private property realm. Chander and Sunder provides that those advocating public domain as the corner stone of a robust IP system ignores the distributional inequalities created by the IP system[75]. It is emphasized that though the public domain keeps before us an ideal model of equality in access, the reality is that capacity to use is the pivotal element there. In other words, public domain highlights the capitalist philosophy of survival of the fittest. To ensure free flow of information, the recent trend in the philosophy of public domain is expansionist. In the process of this expansion to cover the GRs and associated TK, it negates the communal ownership claims of native people over them. Beautifully explaining this, Chander and Sunder opines thus:

> ñThe native people once stood for the commons. But in the advent of an awareness of the valuable genetic and knowledge resources within native communities and lesser developed nations, the advocates for the public domain ï and, in turn, propertization ï have flipped. Now, corporations declare the trees and the shamanôs lore to be the public domain, while indigenous communities demand property rights in these resourcesò[76].

The most ironical outcome of extending the public domain to GRs and TK is that it goes against the philosophy of communal ownership over them. The free access in the public domain is the result of equal right of all to access and use it while the communal ownership in GRs and associated TK bars universal access to them. The enjoyment of communal ownership resources are confined to the owners only, they can exclude others from using the same leaving no scope for free access.

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[75] *Supra* n.57
[76] *Ibid.*

Thus, the propaganda of ñcommonnessò in GRs and associated TK is a passionate effort to ensure free flow of resources as the foundations of technological advancements in major industries such as biotechnology, pharmacology, agriculture etc offering high commercial returns to the industrialized few. Equal right of access is professed, but not practiced. ñCommonò is the best brand name to ensure unregulated access. In this commotion, the legal conundrums like global commons, common heritage, common property and public domain were the best players in perpetuating ambiguities in mapping out the real nature of property in GRs and TK. Thus the GRs and TK became subject to tremendous exploitation that made the developing countries, the major stakeholders of the above, cautious about the value of their resources and the negative impact of property rights arising from the use of their resources. So they had intervened with the declaration of proprietary rights over their resources foreseeing the flow of benefits from the use of resources. With the help of the permanent sovereignty doctrine, the CBD calls for positive State action for regulation of the use of GRs /BRs. This could be seen as an excellent illustration for Benthamôs proposition:

> ñProperty and law are born together. Before laws were made, there was no property; take away laws and property ceases.ò[77]

Property rights are usually referred as a right to use it in exclusion of others and the contours of the property right are determined by law. In simple words, something assumes the status of property only when law declares the same as property and sets limits on its use as property. So the next section will detail what is the property regime that got established by the proclamation of the doctrine of permanent sovereignty through the CBD.

[77] See Bentham in Gopalakrishnan N. S., *Intellectual Property and Criminal Law*, National Law School of India University, Bangalore, India, (1994), p.1

2.3 GRs and the Doctrine of Permanent Sovereignty over Natural Resources

Coming to the permanent sovereignty doctrine, we could see that it is an outcome of the conflicting interest of the developed and developing nations over the use and control of natural resources for economic development within national boundaries by independent States. It is internationally treated as a direct consequence of the independence of colonies after the post world war period. Nico Schrijver observes the principle as a derivative of some international concerns and developments viz., (i) scarcity of natural resources in the developed States and their initiatives in the post-world war period for the development and optimum utilization of the resources, (ii) fluctuating price of raw materials in contra to the upward price of industrial products, (iii) promotion and protection of foreign investment and corresponding rights and duties of the host countries, (iv) rights of independent States emerged after decolonization and their international relations, (v) nationalization of natural resources, (vi) ideological differences during the cold war time, (vii) demand for economic independence after decolonization process and (viii) formulation of the right to self determination as an economic corollary especially in the context of the right of the people and nations to have free disposal of natural wealth and resources[78]. For developing and underdeveloped countries, natural resources stood as a means for their economic prosperity by way of exercising full control over them. On the other hand, the developed country perspective was that

> ñNo valid reason could be attributed for regarding every raw material as the monopoly of the State within whose boundaries it happens to exist or can be produced.ò[79]

[78] *Supra* n.50, pp. 3-4
[79] *Id.* p. 38

The background of this conflict was the dependence of developed countries on the raw materials and natural resources of the developing and underdeveloped nations and their interests to have free or cheaper access to them on the one hand and the demand for economic development from the developing and least developed countries in return for access on the other. Protection of foreign investment by the rich nations for resource exploitation was also a leading factor in the debate in the light of the unilateral nationalization trend shown by the developing nations. But eventually we could see that there was a wide spread opinion among the nations in 1952 itself that every State has the sovereign right to freely use and dispose of its own natural wealth and resources[80]. When the principle was adopted by the UN General Assembly Resolution 1803 (XVII) of December 14, a balancing of this conflicting interest was made by providing that ñthe right of people and nations to permanent sovereignty over their natural wealth and resources must be exercised in the interest of their national development and of the well-being of the people of the State concernedò[81] and that any nationalization, expropriation or requisitioning shall be based on the grounds of public utility, security or the national interest overriding individual/private interests followed by appropriate compensation in accordance with the domestic and international law[82]. So a genuine question may arise whether this appropriate compensation justifies State ownership over the GRs and associated TK in the CBD context. The answer is negative because the permanent sovereignty doctrine envisages compensation provided by the State while the CBD contemplates compensatory share from the person seeking access to the resources.

[80] UN General Assembly Resolution 626 (VII), The Right to Freely exploit Natural Wealth and Resources, December 21, 1952.
[81] Declaration of Permanent Sovereignty over Natural Resources, 1962, Principle 1
[82] *Id.* Principle 4

The meaning of the doctrine of permanent sovereignty is simply the right of the people and States to freely exploit their natural resources as adopted by the 1952 Resolution on Right to Exploit Freely Natural Wealth and Resources. In the 1962 Resolution on Permanent Sovereignty, it is specifically recalled that States are having the inalienable right to freely dispose of their natural wealth and resources in accordance with their national interest and on respect for the economic independence of States. Considering natural resources as a property under the permanent sovereignty principle is sufficiently featured by ownership over it in exclusion to other States, the distinguishing character of property[83]. Under the principle, the owner could be either the State or the people or both. The 1962 Declaration specifically declares that the sovereign right must be exercised for the well-being of the people[84]. It implies that the doctrine calls for due recognition of the rights of the people and their participation in the decision-making process. It places the State and the people on the same footing. Permanent sovereignty being a positive law doctrine needs a positive State action for recognition of proprietary rights over the resources. Unlike in the common heritage principle, State is directly recognizing natural resources as property although without defining the term. So the conclusion could be that the shift in property jurisprudence through the assertion of permanent sovereignty over natural resources is that legal status of property is conferred to natural resources. Otherwise, it simply forms a part of the Nature or Commons permitting appropriation by all. It is also interesting to note that the principle is specifically made for assertion of rights by nationals and foreigners in the course of exploitation of natural resources. When it comes to notice that the CBD, primarily enacted for conservation and sustainable use of the

[83] See R. S. Bhalla, *The Institution of Property*, Eastern Book Company, Lucknow, (1984), p.14 for discussion on property.
[84] *Supra* n.78, p.81

biodiversity is based on the principle of permanent sovereignty, a perusal as to how the principle is conceived by the CBD assumes significance.

The CBD recognizes conservation of biological diversity as a common concern of mankind[85] and aims at its sustainable use through legally regulated access to GRs[86]. By sustainable use, it implies optimum use of the biological diversity, maintaining its potential to meet the needs and aspirations of the present and future generations[87]. The term common concern is of course intended to dilute the issues created by the common heritage regime as the latter pre-supposes free access to the resources. Initially, in the IUPGRFA itself, PGRs were described only as a heritage of mankind and not as a common heritage[88]. But in later amendments, they were specifically categorized as common heritage resources[89]. During the initial stages itself of the negotiation of the CBD, the Member Countries opposed to the idea that GRs constitute common heritage since most of the components of biodiversity are situated in national jurisdiction or privately owned property unlike the global commons, the ocean and the atmosphere[90]. Thus emphasis was placed on sovereign rights making biodiversity a common concern endowing common but differentiated responsibility among the developing and industrialized countries[91]. Thus it took away the notion of free access based on *res nullius*, *res communis*, common property etc which gave way to interpret the resources as an international patrimony, the property of the international community. In the CBD, we could see a clear deviation from the resolutions

[85] *Supra* n.1, Preamble
[86] *Id.* Article 1
[87] *Id.* Article 2
[88] See Resolution 8/83 of the 22nd session of the FAO Conference, Rome 5-23, November, 1983.
[89] See Resolution 4/89, Agreed Interpretation of the International Undertaking, 25th Session of the FAO Conference, Rome 11-29, November, 1989
[90] Desiree M. McGraw, ñThe CBD ï Key Characteristics and Implications for Implementationò, *RECEIL* 11(1) (2002), p.22
[91] *Ibid.*

on permanent sovereignty providing for sovereign right of the people and the States; the former talks only about the sovereign right of the States[92].

The CBD has made natural resources and in particular, GRs and associated TK subject to the permanent sovereignty of nation States. Interestingly, it is silent as to the ownership of the resources. The permanent sovereignty doctrine gives nation States the power to regulate the use of natural resources and the doctrine is also silent as to the ownership over the resources. This is because within the State, the *in-situ* GRs may be within the possession, use and ownership of many in diverse ways one could imagine. The impact of CBD is that propertization of resources is made possible through the doctrine without specifying who is the owner. So the possible interpretation could be that State or the people could be the owner of the resources. This interpretation seeks support from Fenwick who argues that State appears as a corporate person having ultimate authority within the territorial borders without being the actual owner of the land itself[93]. He reiterates that the State can have private ownership, but territorial jurisdiction of the State implies a right of political control or ultimate authority and not right of property. He calls it an *imperium* as distinct from *dominium.* It could be further corroborated when Cohen opines that *dominium* over things is *imperium* over our fellow beings[94]. The statement simply means State can exercise its absolute political authority over its citizens through law. So the State can have full ownership over the resources or it can recognize the ownership of citizens over the resources as it deems fit.

Considering natural resources as property under the permanent sovereignty doctrine, one should look into how the element of exclusivity over them works within the framework. The right to exclude involves all the duties

[92] *Supra* n.1, Preamble and Article 3
[93] Charles G. Fenwick, *International Law*, Allied Pacific Pvt. Ltd., Bombay, (3rd edn. ï 1962) p.342
[94] Cohen, Morris R., *Law and the Social Order,* Archon Books, (1967), p.49

imposed on the people generally towards it[95]. As far as natural resources are concerned, possession forms an essential element for assertion of right. But CBD itself recognizes the possibility that country providing the resources need not always be the country of origin where the latter is the owner of the resources. So in all other forms of property where a person can become the owner even if he is not in possession of the thing is applicable in the case of natural resources too. This safeguards the interests of the country of origin in cases where the transfer had occurred unintentionally. When it comes to enjoyment of exclusive right over natural resources, CBD poses many interesting situations. For example, Regulation 14(i) of the Sarawak Biodiversity Regulations 1998 vests proprietary rights over the resources upon the State and PIC is to be obtained only from the State[96]. Here both nationals and foreigners have to apply for access permit[97]. If the State declares itself as the owner of the resources, the exclusivity theory works well, though it will create tensions with the communities and individuals who were in possession of the resources from pre-historic times. But if the people are the owners of the resources, how will we interpret the theory of exclusiveness considering the scattered nature of the resources? Let us examine an ideal situation where a particular plant is widely seen in a territory of a State. So many people may be in possession of the plant in their respective areas and the question is how one will assert exclusionary rights. Theoretically everyone is the owner of the particular plant within the limits of the land area they own, but does not enjoy an exclusionary right in the access context. With respect to all other territories of the State, they enjoy exclusivity. But within the territory all who hold the plant in their land stand on an equal footing overwhelmingly suggesting a joint ownership over the resources. When both the State and the people enjoy ownership over the resources, two situations can arise. One is where the State

[95] *Supra* n.20, p.71
[96], Sarawak Biodiversity Regulations, 1998, Regulations 5, 14, 20 and 24
[97] *Id.* Regulation 3(1)

acts in a supervisory role exercising control and the people are having final decisive authority (State and people on the same status). Second is that along with the supervisory role, the State also acts as the owner of the resources within its political control. Different State practices give us a correct picture of the issue. In the ANDEAN framework, it is provided that the ownership over the resources is vested with the Member States, but during the process of access connected with GRs or their by-products, there is possibility of entering into ancillary contracts by the applicant with the owner, possessor or manager of the land where the BR is located[98]. It implies that consent of the holders or the community is needed for access. This consent does not result in access and the authority for granting access is vested with the competent national authority to be established in the State, taking into account the rights and interests of the suppliers of the resources or the TK[99]. The result is that the State cannot exclude the stakeholders and vice versa. In the ASEAN countries, Brazil, Costa Rica etc. which do not expressly mention about the ownership over GRs, it has been made mandatory to obtain PIC from the Stakeholders along with the competent national authorities. Many countries mandate that the government should play an active role in ensuring PIC from the communities. This gives the impression that such systems envisage an ownership regime of both the government and the people with the government playing a supervisory role. In these situations also, the exclusion theory fails. This failure is the result of the inherent nature of natural resources, the difficulty in getting associated with single ownership, the basis of the property concept of western jurisprudence.

The CBD is silent in respect of the rights that could be enjoyed by the State/individual or the community as the case may be during and after the process of access. The omission is justified since the freedom of implementation is given to the Member Countries in accordance with their

[98] *Supra* n.12, Article 41
[99] *Id.* Article 34

socio-economic conditions. The sovereign right of the State is to exploit natural resources pursuant to national policies and the CBD mandate in respect of the people is only that their due participation must be ensured, as far as possible and as appropriate, during the process of access paying due respect to the contributions they have made in conserving and preserving the nature[100]. Though it envisages a purely commercial regime of access and benefit sharing, it is quite interesting to note that nowhere it talks about complete transfer of the GRs/ BRs or the knowledge associated with it. And none of the legislations of the Member Countries have enacted any provision to that effect. This means when a country is providing access to its resources, the State is just giving a license to use the resource in connection with the specified activity. Neither the country nor the individual or the community, as the case may be, parts with the ownership over the resources. To be more precise, though it recognizes partial transfer of the resources, there is no scope for complete alienation of the resources or the knowledge bases. Its unique proposition of the country of origin never allows the country to get itself parted with the ownership over the resources or the knowledge. In this context, it would be worth quoting Penner who says:

> ñIf a person is unable to free himself of a thing, then to that extent he is controlled by his relationship to the thing, if not by the thing itself. Such control is antithetical to the idea of propertyò.[101]

When ownership over the resources is jointly held by the people and the State, a serious question arises as to who is having an upper hand in the determination of access. We can look into this question from two aspects, (i) can the people prevent the State from granting access to the resources in question and (ii) if the people are willing to grant access, on what grounds the State can restrict access? Many State legislation are not addressing the first

[100] *Supra* n.1, Article 8 (j)
[101] *Supra* n.95, p.78

aspect. But the OAU Model Law provides that local communities have the right to refuse access when that is detrimental to the integrity of their natural or cultural heritage.[102] They will also have a right to withdraw consent or place restrictions on the activities relating to access on the above grounds[103]. So there are instances where the people can exercise their will over the will of the State. Considering the second aspect of State control, many countries are placing restrictions mostly on the grounds of public interest and the protection of environment or biological diversity. In any case, the people cannot permit access overriding the restrictions placed by the State for public interest or protection of the environment and biological diversity. This makes it clear that the ABS process is a domain of compromise on proprietary rights between the State and the people where the state has to safeguard the interest of the people as well as the economic prosperity of the nation out of which it can determine what is to be given priority.

Owing to the economic importance of TK associated with GRs/BRs, the knowledge bases nurtured and nourished by the local and indigenous population have also been made subject to the ABS system. Considering the extensive misappropriation of TK[104], this effort seems to be highly legitimate. This assertion of right could be viewed as a positive State action to prevent attacks on its indigenous wisdom[105]. The representative justification plays well in the international level with strong implications on the proprietary rights domestically. The exclusionary right in relation to the knowledge is similar to that of GRs including the extent of State control over the knowledge. Taking traditional wisdom over biodiversity as a diverse and scattered resource, the State can declare ownership over it provided it is difficult to trace the holders

[102] *Supra* n.14, Article 19
[103] *Id.* Article 20
[104] For an account of cases of misappropriation, see Graham Dutfield, *Intellectual Property Rights, Trade and Biodiversity*, Earthscan Publications Ltd., (2000), pp.65-67
[105] Fenwick argues: ñSince members of States are not recognized in individual capacity, any right belonged to them must be clothed in the grab of State rights before they can be put forward internationally.ò Supra n.93

of the knowledge base. In such cases, the knowledge will be generally in use by the public[106]. But in a given situation where the knowledge holders are identifiable, it is very difficult to define the relationship of the State with respect to the knowledge and its holders. Considering the knowledge as a property, its exclusive owners will be its holders who have developed, preserved and maintained it for centuries probably before the constitution of the State itself. In such instances, if the State wants exercise of complete autonomy in access to TK as the sole decisive agency, without regard to the community rights, it would amount to State-aided misappropriation. It is also worthy of note that for the transfer of the resources and the knowledge associated with them, the stakeholders are getting only a share in the profits arising out of their commercial utilization, an unseen provision in the law relating to property.

The above attempt well establishes that after the declaration of permanent sovereignty, GRs and associated TK clearly shows the features of private property in the form of communal ownership and exclusiveness to recognize its collective management by the custodians. Its notable distinguished characteristic is inalienability, the difficulty to get parted with the owners. It is worth noting that categories of this type find its place even in the TRIPS. What is emphasized here is the property concept in geographical indications (GIs). TRIPs defines GIs as indications which identify a good as originating in the territory of a member or a region or locality in that territory, where a given quality or reputation or other characteristics of a good is essentially attributable to its geographical origin. It is quite interesting to note that without specifying the owner of the indication, the TRIPS mandates the Member States to provide the interested parties the legal means to prevent the

[106] For classification of traditional knowledge, see Gopalakrishnan, N. S., ñTraditional Knowledge, Information Technology and Development ï The Challengesò, [2005] *Cochin University Law Review*, pp.132-147.

misleading use of the mark[107]. The State practices in recognition of ownership of the indication varies from the State, traders and dealers, actual manufacturers, consumers and other interested groups with *bonafide* interest[108]. Conceptually speaking, GI represents a collective ownership philosophy where all the people belonging to the specified locality can claim ownership in exclusion to the rest of the world. When legal protection is conferred, the group which owns the GIs represents all involved in it. Similar is the case with BRs and associated TK, i.e., conceptually, the person/community who holds the resources or the knowledge is the owner, but the State practice may vary depending upon, political, economic, cultural and social reasons. Now, if one argues that BRs are naturally occurring without any intellectual input from humans unlike in the case of other categories like patent, trademark, copyright etc, the concept of GI also establishes that intellectual input is not a *sine qua non* for being kept under the TRIPS umbrella. It is wrong to conclude that the ambit of TRIPS Agreement is not wide enough to respect and recognize the property jurisprudence laid down by the CBD. Whether all forms of TK and folklore come within the purview of TRIPS is out of the scope of enquiry of the present chapter. It is given emphasis here that the property concept established by the CBD can legally and ethically go in tune with the broad philosophy of property (individual and collective) under TRIPS, taking justification from the inclusion of GI as a protectable subject matter under the TRIPs. So the protection offered to GRs and associated TK need not be confined to CBD alone, an option to include them as a category to be protected under the TRIPS Agreement is hereby established. But the feasibility of the same is out of the reach of this chapter[109].

[107] TRIPS, 1994, Article 22.2

[108] For a detailed account of ownership on GIs, see Gopalakrishnan, N. S. *et.al*, ñExploring the Relationship Between GIs and TK: An Analysis of the Legal Tools for the Protection of GIs in Asiaò, *ICTSD Program on Intellectual Property and Sustainable Development*, ICTSD, Geneva, Switzerland, (2007)

[109] For a detailed analysis, see Chapter 5 & 6.

2.4 Conclusion

The above analysis helps us to infer that GRs and associated TK never legally or philosophically constituted a domain of unregulated ñcommonò use as believed. The natural law theory of occupation and acquisition was the practice and the philosophy that governed natural resources for centuries. With the advancements in biotechnology, appropriate technology came in to reap potential benefits from raw resources and associated knowledge bases. The propertization we see in the CBD is the reaction towards propertization of resources through patent monopoly. We could say that CBD has put forward a regime that legalizes the appropriation of the resources. The ownership regime established under the CBD is complex involving multiple owners. It has also created tensions by diluting the principle of permanent sovereignty, vesting ownership of the resources completely over the States and it is for the State to decide how to respect right of the stakeholders. The most interesting fact is that the intention of the CBD is only to protect the resources and knowledge from misappropriation and not from exploitation. The CBD is facilitating and legalizing exploitation and resultant propertization through its framework. It gives the country of origin the right to retain ownership over the resources in all transactions and the proposition is so tightly constructed that it is impossible to get parted with the ownership over the resources. Jurisprudentially, through the proclamation of permanent sovereignty replacing the ambiguities regarding the conception of common heritage over GRs, the CBDôs contribution is that it has imparted and legalized the notion of property in them. The doctrinal shift is visible in the sense that GRs and associated TK have now become tools for income generation through the CBD mandate to facilitate access. Let BRs be heritage, common heritage or private property, the interest over them is purely exploitative and not conservative. The final and most relevant observation is that the communal ownership we could see in GRs and TK is not a strange phenomenon to TRIPS framework.

But what will fall within the TRIPS is based upon the economic importance involved in such things and rather who holds such economic interest. Again, it is not the problems with the nature of the subject matter or the philosophies regarding property that create problems in recognizing the property in GRs and TK; what is important is who is paying and who is paid. In simple words, the politics is based on economics. Historically, it is revealed that IP is for the protection of the investment of corporations and not for the intellectual inputs of the common man[110]. After tracing the legal foundations of the property rights in GRs and associated TK in this chapter, the next task would logically be to analyze the ABS mechanism established by the CBD. So the next chapter explores the agreement reached in the Nagoya Protocol on ABS.

[110] Ha-joon Chang, ñIntellectual Property Rights and Economic Development: Historical Lessons and Emerging Issuesò, *Journal of Human Development*, Vol.2 No.2 (2001) pp.287-309

Chapter-3

INTERNATIONAL REGIME ON ACCESS TO GENETIC RESOURCES AND BENEFIT SHARING: NAGOYA PROTOCOL

The most recent progression in the international level regarding the issue of access to GRs is the adoption of a new protocol to the CBD system, the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization (The Nagoya Protocol), 2010. The Nagoya Protocol is the outcome of eight years prolonged political agenda of the developing countries towards an international regime particularly aimed at ensuring the fair and equitable benefit sharing arising from the utilization of GRs, one of the long-cherished goals of the CBD. The adoption of the Nagoya Protocol is considered a giant step towards this objective of the CBD. It has produced positive impressions on the outcome of negotiations aimed at operationalising the benefit sharing obligation under the CBD. Unlike the Bonn Guidelines, it imposes positive obligations on the Parties as the Nagoya Protocol is a legally binding instrument. Still, it takes us by surprise that at the end of the second decade, after the CBD has become functional and after eight years of conclusion of the Bonn Guidelines, we need another legally binding international instrument to accomplish one of the basic objectives of the CBD, i.e. benefit sharing. So the primary question stemming up is why there is such a protocol in place? This will be followed by other queries like (i) Whether CBD and the Bonn Guidelines failed in ensuring fair and equitable benefit sharing? (ii) If so, what are the reasons? and (iii) Is the Nagoya Protocol effectively taking care of the issue of benefit sharing, and how? Other aspects that could be interesting in this regard are comparison of the protocol with the benefit

sharing system of the ITPGRFA, the coherence of the Nagoya Protocol with the philosophy of property as reflected in the CBD and the efficacy of it to deal with misappropriation in the context of TRIPS.

3.1 International Regime on Access and Benefit Sharing: Briefing the Past

The benefit sharing obligation as spelt out by CBD is that access is conditional to the PIC and MAT with the concerned provider in the country of origin[1] and for ensuring fair and equitable sharing of benefits, access to and transfer of technology and handling of biotechnology and distribution of its benefits. To achieve this, Parties are mandated to make appropriate legislative, administrative or policy measures[2]. The Bonn Guidelines are also detailing the measures to be taken by the providing country while providing access and ensuring benefit sharing[3]. So the sole means to administer the whole process of ABS is the concerned domestic legislation in the providing countries which are mostly developing, but diversity rich and these domestic ABS legislations are handicapped in many respects[4]. This could be best understood in the words of Tvedt:

> ñUntil the COP VII, focus has been foremost on access legislation. The Bonn Guidelines illustrate this by almost exclusively addressing measures to be taken in the provider country. There is an emerging common understanding that perhaps access legislation is not the only accurate approach needed to achieve fair and equitable benefit sharing. States are parties to the CBD. Value in biotechnology is created foremost by private parties under the

[1] The convention on Biological Diversity, 1992, Article 15
[2] *Supra* n.1, Article 16 & 19
[3] The Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of Benefits Arising out of their Utilization, 2002, Para 16, 18 & 42
[4] See MS Suneetha and Balakrishna Pisupati, ñBenefit Sharing in ABS: Options and Elaborationsò, UNU-IAS Report, 2009, pp. 8-24

jurisdiction of another country or under the jurisdiction of a number of countries. A general principle of law is that if private persons or companies shall be legally obliged, the obligation must be implemented in the relevant jurisdiction. The principle of legality applies if the State or anyone other than a contractual partner seeks to establish a burden upon a private person. In most countries, the parliament must have implemented such an obligation in the national legal system before a private party shall be obliged to share a part of the benefits. A major obstacle for access legislation is that the law of one country is to be enforced upon private parties under the jurisdiction of another country[5]ò.

It is evident that there is total absence of an international mandate to ensure the proprietary rights of the country of origin and the legal vacuum also pertains to enforcement obligations in foreign jurisdictions[6]. This made the developing countries to push limited binding obligation in the TRIPS to prevent non-compliance with the ABS regime[7]. Similar concerns are raised during the discussions for the preparation of Nagoya Protocol also and the international regime should be treated as a parallel mechanism which is particularly designed for ensuring benefit sharing. Together with this unease, lack of clarity in the CBD mandate as well as the voluntary nature of the Bonn Guidelines resulted in poor implementation of ABS legislations, rendering them unclear and uncertain. Even countries who have well-defined national laws on ABS find it difficult to successfully achieve the third objective of CBD, benefit sharing. So the developing countries started

[5] Martin Walloe Tvedt, ñElements for Legislation in User Countries to Meet the Fair and Equitable Benefit Sharing Commitmentò, JWIP (2006) Vol.9, No.2, p. 191
[6] See *Infra,* Chapter 5
[7] *Infra,* Chapter 6

feeling that an international regime imposing obligations upon countries where the users are domiciled is the need of the hour[8].

The felted need for an international regime on ABS could be traced back from the concern raised by G-77/China during COP II that adequate attention is not devoted to equitable benefit sharing, PIC and capacity building[9]. Accordingly, it became a separate agenda in 1998 and COP 4 established a regionally balanced Panel of Experts for ABS[10]. The work of this expert group, together with that of the Ad-hoc Open-ended Working group on ABS and a multiplicity of other actors, culminated as the Bonn Guidelines on ABS. It aims to assist Parties and stakeholders in the implementation of the CBD by providing guidelines to establish administrative, legislative or policy measures on ABS[11]. During the negotiation of the Bonn Guidelines regarding benefit sharing, the negotiators as well as the Parties were of the opinion that the diverse nature of the benefit sharing arrangements would hamper the possibility of a strict international protocol[12]. But during the final negotiation of the Bonn Guidelines, developing countries started having an impression that the Guidelines did not sufficiently address the user obligations in relation to access and that continued misappropriation had been prevailing in the whole process of ABS[13]. It was augmented by the reported instances of the so-

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[8] Kabir Bavikatte and Daniel F. Robinson, ñTowards a Peopleôs History of the Law: Biocultural Jurisprudence and the Nagoya Protocol on Access and Benefit Sharingò, 7/1 *Law, Environment and Development Journal* (2011), p. 41

[9] Stephen Tulley, ñThe Bonn Guidelines on Access to Genetic Resources and Benefit Sharingò, RECIEL 12 (1) 2003 p.85

[10] *Ibid*

[11] *Supra* n.3, para. 1

[12] W. Bradnee Chambers, ñWSSD and an International Regime on Access and Benefit Sharing: Is a Protocol the Appropriate Legal Instrument?ò, RECIEL 12 (3) 2003, pp.310-320

[13] See the presentation made by Hamdallah Zedan, Executive Secretary to the CBD, ó Biodiversity and Access to Genetic Resourcesô, WIPO Seminar on Intellectual Property and Development, Geneva, Switzerland, 2-3 May 2005 available at http://www.wipo.int/edocs/mdocs/mdocs/en/isipd_05/isipd_05_www_103974.pdf

called biopiracy.[14] This resulted in the formation of a group called ñLike-Minded Mega Diverse Countriesò consisting of Bolivia, Brazil, China, Columbia, Ecuador, India, Indonesia, Kenya, Madagascar, Malaysia, Mexico, Peru, Philippines, South Africa and Venezuela, at the Cancun Declaration of February 2002 as a mechanism to promote a common agenda relating to conservation and sustainable use of biodiversity[15]. During the World Summit on Sustainable Development in September 2002, they called for a negotiation within the framework of the CBD for an international regime to promote and safeguard the fair and equitable sharing of benefits arising from the utilization of GRs which was later endorsed by the UN General Assembly[16]. Based upon this mandate, in February 2004, the COP had entrusted the task of negotiations with the Open-Ended Working Group on ABS who developed the Bonn Guidelines[17]. It was asked to consider the process, nature, scope, elements and modalities of an international regime. In their second meeting in December 2003 in Montreal, the Working Group prepared recommendations on the terms of reference for negotiation of an international regime and submitted the same to the seventh meeting of the COP in February 2004[18]. The COP in its decision VII/19D mandated the Ad-hoc Open Ended Working Group to elaborate and negotiate an international regime on ABS in collaboration with the Ad-hoc Open Ended Inter-sessional Working Group on Article 8(j) and different other actors involved, and with the aim to adopt an instrument/instruments to effectively implement Article 15, Article 8(j) and the three objectives of CBD. The terms of reference for negotiation of the international regime was also agreed upon by the COP[19].

[14] *Ibid*
[15] *Ibid*
[16] *Ibid*, Paragraph 44(o) of the WSSD Plan of Implementation contains this mandate.
[17] See COP Decision VII/19 D
[18] For recommendations, see Report of the Ad-hoc Open-ended Working Group on ABS on the Work of Its Second Meeting, UNEP/CBD/COP/7/6 dated 10 December 2003
[19] Terms of reference available in annex to Decision VII/19 D, Report of the Seventh Meeting of the Conference of Parties to the Convention on Biological Diversity, UNEP/CBD/COP/7/21 dated 13 April 2004 pp.298-303

The Working Group started its negotiations in the third and fourth meetings and recommendations were forwarded to COP VIII wherein it was directed to continue its work and finalise the regime before COP X[20]. In COP IX, it was directed to convene three meetings before the COP X and established three distinct groups of technical and legal experts[21] to assist the working group by providing legal and technical advice. In the seventh meeting, the Ad-hoc Open-ended Working Group addressed the objective, scope, compliance, fair and equitable benefit sharing and access and entered into negotiations on operational text of these issues. In its eighth meeting the working group addressed the components of the international regime related to TK associated with GRs, capacity building, compliance, fair and equitable benefit sharing and access wherein the Parties agreed on a single negotiating text incorporating all the elements of an international regime. The meeting also met with progress on the nature of the international regime. In the ninth meeting of the Working Group in March 2010, a draft protocol was tabled by the co-chairs of the Working Group and accepted by the Parties as a basis for further negotiations. Since the text did not get finalised in that meeting, they resumed the ninth meeting in July 2010. An Interregional Negotiating Group (ING) was convened at this Ninth meeting to continue negotiations and there was significant progress in reaching a common understanding on core issues. But this meeting also failed to finalise the text for adoption by the 10th COP. This made the ING to again convene its meeting during 18-21 September 2010 where substantial progress was made towards an improved understanding on the key elements of the international regime on ABS,

[20] See COP Decision VIII/4

[21] See COP Decision IX/12 Para 11 in Decisions Adopted by the Conference of the Parties to the Convention on Biological Diversity at its Ninth Meeting, Bonn, 19-30 May , 2008, UNEP/CBD/COP/9/29, dated 9 October 2008. Expert Groups on (i) Compliance, (ii) Concepts, Terms, Working Definitions and Sectoral Approach and (iii) Traditional Knowledge Associated with Genetic Resources. Annex II contains the terms of reference of the Groups.

especially on the concept of utilization, benefit sharing and access[22]. Finally, the international regime was finalised and adopted during the COP 10 held at Nagoya, Japan during 18-29, October 2010.

From the different submissions of the Parties, we could see that the developed countries were largely trying to rectify the gaps in the ABS system through national measures within the Member States rather than opting for international solutions[22(a)] while developing countries like India stood for creation of binding international legal obligations in the area of ABS. Interesting proposals were tabled by different interest groups on the various elements of the international regime like access, PIC, benefit sharing, compliance, international certificate of source etc[22(b)]. Rather than going into the niceties of such proposals, the chapter takes a pragmatic approach to describe the protocol system and analyse the effectiveness of the protocol in ensuring benefit sharing

3.2 A Brief Sketch of the Nagoya Protocol System

The explicit objective of the Nagoya Protocol is the fair and equitable sharing of the benefit arising from the utilization of GRs, by appropriate access to GRs, appropriate transfer of relevant technologies and appropriate funding[23]. The scope of the Nagoya Protocol is confined to GRs covered under Article 15 of CBD, associated TK and the benefits arising from their utilization[24]. It was reiterated by the COP 10 that HGR are not included

[22] Draft Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity, Annex to the Meeting of Interregional Negotiating Group, UNEP/CBD/WG-ABS/9/ING/1 dated 21 September 2010

[22(a)] See submission of EU and Canada in UNEP/CBD/WG-ABS/4/INF/4

[22(b)] See Submission of India in UNEP/CBD/WG-ABS/3/7 on behalf of the Like Minded Mega-diverse Countries. Also SEE UNEP/CBD/WG-ABS/6/INF/3 for submissions of countries on the various elements of the international regime

[23] The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization, 2010, Article 1

[24] *Id.* Article 3

within the framework of the Nagoya Protocol. As regards benefit sharing, the Nagoya Protocol mandates that each CP shall take legislative, administrative or policy measures as appropriate to ensure fair and equitable benefit sharing with the country of origin or the country that has acquired the GRs in accordance with the CBD[25]. As far as the GRs held by indigenous communities are concerned, the benefits arising from utilization are to be shared with them fairly and equitably based on MAT and the CP have to implement appropriate measures to this effect[26]. Similar obligation is created in respect of TK associated with GRs held by indigenous and local communities[27]. In the context of access, it is mandated that benefit sharing should be with the country of origin or the country that has acquired the GRs in accordance with the CBD[28] conditional to PIC. In the case of GRs held by communities, appropriate measures to obtain PIC or approval and involvement of such communities should be implemented[29]. Measures to ensure PIC should (a) have legal certainty, clarity and transparency regarding domestic ABS requirements,(b) be fair and non-arbitrary rules and procedures, (c) provide clear and transparent written decision by a competent national authority within a reasonable period of time in a cost-effective manner, (d) ensure the issuance of an access permit or its equivalent at the time of access as evidence of PIC and MAT and notify the ABS Clearing House accordingly, (e) where applicable, set out the criteria/procedures for obtaining PIC or approval and involvement of local and indigenous communities, and (f) establish clear rules and procedures for requiring and establishing MAT, setting out in writing a dispute settlement clause, terms on benefit sharing including IPR, terms on subsequent third party use, if any,

[25] *Id.* Article 5.1&3
[26] *Id.* Article 5.2
[27] *Id.* Article 5.5
[28] *Id.* Article 6.1
[29] *Id.* Article 6.2

and terms on changes of intent, where applicable[30]. Concerning access to TK associated with GRs held by local and indigenous communities, the Parties are bound to take appropriate measures to ensure PIC and MAT from them[31]. Thus, it is the duty of the country providing GRs or the country of origin to ensure that all conditions regarding PIC and MAT are complied with in their domestic jurisdiction. Parties are mandated to provide simplified measures of access for non-commercial research purposes, taking into account the possibility of change in the intent of research[32]. Special consideration should be given to cases of present or imminent emergencies threatening or damaging human, animal or plant health and to PGRFA[33]. Where it is difficult to obtain PIC or where the resources and associated TK occur in transboundary situations, the CPs have to consider the need for and modalities of a multilateral benefit sharing mechanism to address the issue of benefit sharing[34]. Transboundary cooperation is called for in instances where the same GRs are found in *in-situ*, within the territory of more than one party, or where the same TK is shared by one or more indigenous and local communities in several Parties, with the involvement of the communities concerned[35]. There should be a national focal point on ABS in each country providing information on procedures for obtaining PIC and establishing MAT including benefit sharing when access is sought to GRs and associated TK, and information on competent national authorities, relevant indigenous and local communities and relevant stakeholders[36]. The national focal point shall liaison with the Secretariat of the CBD as regards its functions and competent national authorities should be established for the grant of access, issue of written evidence as to the fulfilment of access requirements and to

[30] *Id.* Article 6.3
[31] *Id.* Article 7
[32] *Id.* Article 8.a
[33] *Id.* Article 8.b & c
[34] *Id.* Article 10
[35] *Id.* Article 11
[36] *Id.* Article 13.1

advise on applicable procedures and requirements for obtaining PIC and MAT[37]. An ABS Clearing House is established under the Nagoya Protocol as a means for sharing of information related to ABS relevant to the implementation of the obligations[38]. CPs have to make available to the ABS Clearing House the information relating to legislative, administrative and policy measures on ABS, information on the national focal point and competent national authorities, and permits and other equivalents issued as the evidence of complying with the requirements of PIC and MAT[39].The modalities of operation of the ABS Clearing House will be decided upon by the Parties to the Nagoya Protocol in its first meeting[40].

In order to ensure compliance with the PIC and MAT requirements under the domestic ABS legislation, the Nagoya Protocol stipulates that all CPs shall take appropriate, effective and proportionate administrative, legislative or policy measures to affirm that GRs utilized within its jurisdiction have been accessed after fulfilling the ABS requirements of the providing Country[41]. Accordingly, measures to address situations of non-compliance should be adopted and Parties are asked to cooperate in cases of alleged violation of domestic ABS requirements[42]. Similar obligation is imposed in respect of compliance with the ABS requirements as regards access to TK held by indigenous and local communities[43]. The Nagoya Protocol also provides that to support compliance, measures to monitor and enhance transparency about the utilization of GRs should be established. Such measures shall include designation of one or more check points that would collect or receive relevant information related to PIC, source of GRs, establishment of MAT, and about utilization of GRs. Users have to be

[37] *Id. Article* 13. 2, 3 & 4
[38] *Id.* Article 14.1
[39] *Id.* Article 14.2
[40] *Id.* Article 14.4
[41] *Id.* Article 15.1
[42] *Id.* Article 15.2&3
[43] *Id.* Article 16

required to provide such information to the designated check points and measures should be taken to address situations of non-compliance[44]. Such information should be communicated to the relevant national authorities, the party providing PIC and to the ABS Clearing House without prejudice to the protection of confidential information[45]. Check points must be effective and should have functions relevant to utilization of GRs or to collection of relevant information at any stage of research, development, innovation, pre-commercialization or commercialization[46]. An access permit or its equivalent issued at the time of access as the evidence to grant PIC and establishment of MAT and made available to the Clearing House should serve as an internationally recognised certificate of compliance that is to be furnished with the check points[47]. Such international certificate of compliance should contain the minimum information regarding the issuing authority, date of issuance, the provider, the unique identifier of the certificate, the person to whom PIC is granted, subject matter or the GR covered by the certificate, confirmation that MAT are established, confirmation that PIC is obtained and should specify commercial and/or non-commercial use[48]. Parties are asked to encourage providers and users to include provisions in the MAT to cover dispute resolution stipulating jurisdiction, applicable law and options for alternative dispute resolution[49]. The CPs are obliged to ensure that an opportunity to seek recourse is available under their legal system in cases of disputes arising from MAT, based on the principle of access to justice and

[44] *Id.* Article 17.1(a) (i)&(ii)
[45] *Id.* Article 17.1(a) (iii)
[46] *Id.* Article 17.1(a) (iv)
[47] *Id.* Article 17.2 & 3
[48] *Id.* Article 17.4 For a detailed discussion on certificate of compliance, see Miriam Dross and Franziska Wolf, ñNew elements of the International Regime on Access and Benefit Sharing of Genetic Resources ï The Role of Certificate of Originò, BfN - Skripten 127, 2005 available at www.dnl-online.de
[49] *Id.* Article 18.1

the utilization of mechanisms relating to mutual recognition and enforcement of foreign judgements and arbitral awards[50].

3.3 An Appraisal of the Nagoya Protocol Efficacy to Ensure Sharing of Benefits

We have found that the major handicap of the CBD and Bonn Guidelines in guaranteeing benefit sharing is the lack of appropriate user country measures to enforce the obligations of PIC and MAT including benefit sharing. So, the major concern is to find out how adequate are the Nagoya Protocol tools in ensuring benefit sharing. In exploring the efficacy of the Nagoya, the first enquiry is into the conceptual clarity in relation to the subject matter covered, i.e. GRs, associated TK, their coverage and uses. The second issue that requires examination is the concept of ownership over the GRs, and the beneficiaries covered. The third important issue examined is the obligations of provider country to ensure a speedy and effective access and the obligations of user country to ensure compliance and monitoring. Finally an attempt is made to find out whether the Nagoya Protocol alone or together with the CBD and the Bonn Guidelines could effectively prevent the issue of misappropriation and if not, the possible options.

3.3.1 Subject Matter, Scope and Coverage of the Nagoya Protocol

Assessment of the subject matter of the Nagoya Protocol takes us first to Article 3 providing that the Protocol shall apply to GRs within the scope of Article 15 of the CBD, the benefits arising from the utilization of such resources, TK associated with GRs within the scope of the CBD and to the benefits arising from the utilization of such knowledge. So we could assume that the definition of GRs is the same as that in the CBD[50(a)]. TK associated

[50] *Id.* Article 18. 2, 3 & 4

[50(a)] There was unanimity among the countries during the negotiations that the definition of GRs be the same as that in the CBD

with the GRs is left undefined, but there is a definition for the term ñutilization of GRsò as to ñconduct research and development on the genetic and/or biochemical composition of genetic resources including through the application of biotechnology as defined in Article 2 of the Conventionò.[51] Biotechnology means ñany technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use[52]ò. Derivative is in turn defined as ña naturally occurring biochemical compound resulting from the genetic expression or metabolism of BRs or GRs, even if it does not contain functional units of heredity[53]ò. In short, the subject matter of the Protocol system could cover GRs, their derivatives, and GR associated TK with the express exclusion of HGRs[54]. Comparing this with the CBD, we could see that the CBD ambit is wide enough to cover BRs even as raw materials, GRs and the country practices mostly incorporated derivatives within the coverage of domestic ABS legislations. There was general consensus during the ABS negotiations that BRs used as commodities are subject to a separate set of international norms and rules and there was general agreement that commodities should be outside the scope of the international regime for the purposes of PIC[55]. For example, fruits like banana would come under the definition of BRs, but when exported, separate sets of rules are applicable to

[51] *Id.* Article 2(c)
[52] *Id.* Article 2(d)
[53] *Id.* Article 2(e)
[54] COP Decision X/1 Section I para. 5
[55] ñOutcome of the Meeting of the Legal and Technical Experts on Concepts, Terms and Working Definitionsò, Annex para. 10 in Report of the Meeting of the Group of Legal and Technical Experts on Concepts, Terms, Working definitions and Sectoral Approaches, UNEP/CBD/WG-ABS/7/2 dated 12th December 2008; Also see submission from the International Workshop on the topic ñAccess and Benefit Sharing in Non-commercial Biodiversity Researchò, 17-19 November 2008 Bonn in ñConcepts, Terms, Working Definitions and Sectoral Approaches Relating to the International Regime on Access and Benefit Sharingò, UNEP/CBD/ABS/GTLE/1/INF/2 dated 29 November 2008 p.4. Also see Mexico in UNEP/CBD/WG-ABS/7/INF/1/Add.1 at p.80-81 and Access and Benefit Sharing Alliance at p.85

them[56]. This is manifested in the Protocol by avoiding any reference to the term BR throughout the text though in the initial stages of negotiations, there was specific demand for incorporating BR also from the part of some developing countries[57]. Next issue relates to the inclusion of the term ñderivativesò. Some Parties submitted during the development of the draft text of the Protocol that by referring only to BRs and GRs and by going through their definitions, CBD aims to contain only those material containing functional units of heredity[58]. It was also mentioned that CBD does not contain terms like derivatives or products[59]. The term derivative takes its origin from the Bonn Guidelines in the context of the ABS issue and inclusion of the same in the international regime was a theme of hot debate[60]. There was no consensus on the definition of the term initially and the definition as seen now is the result of compilation of various understandings on the term. While trying to carve out conceptual clarity during negotiations, the Group of Technical and Legal Experts on Concepts, Terms, Working Definitions and Sectoral Approaches in the Context on the International Regime on ABS reported COP that a derivative can be the result of a natural metabolic process or it can be the end product of a synthetic procedure depending on the scientific context[61]. They also opined that in some research areas, derivatives could be interpreted and understood as GRs, if they are the

[56] Morten Walloe Tvedt and Olivier Rukundo, ñFunctionality of an ABS Protocolò, FNI Report 9/2010, p.8

[57] For a detailed account, see Submission from the Government of Japan in Compilation of Submission by Parties, International Organisations, Indigenous and Local Communities and Stakeholders on Concepts, terms, Working Definitions and Sectoral Approaches, UNEP/CBD/ABS/GTLE/1/2/Add.1 dated 21st November 2008; Also see Compilation of Submissions from Parties, International Organizations, Indigenous and Local Communities and Stakeholders on Concepts, Terms, Working Definitions and Sectoral Approaches, UNEP/CBD/ABS/GTLE/1/2 dated 6th November 2006

[58] *Supra* n.51

[59] *Ibid.*

[60] The debates at an advanced stage can be had from the Earth Negotiation Bulletin, Wednesday, 24 March 2010 available at http://www.iisd.ca/biodiv/abs9 /

[61] Concepts, Terms, Working Definitions and Sectoral Approaches Relating to the International Regime on Access and Benefit Sharing UNEP/CBD/ABS/GTLE/1/INF/2 dated 29 November 2008 p.4

result of developmental pathways controlled by genes which provide information on the functional units of heredity[62] and still GRs and derivatives could be interpreted as separate and distinct concepts[63]. The expert group distinguished GRs as the information contained in functional units of heredity and derivatives as the functional outcomes of the expression of that information mitigated by environment and therefore not a GR in the strict sense[64]. They also recommended to the COP that whatever meaning is attached to these terms, Article 15 of the CBD should be interpreted to include only the utilization of GRs and not the broader category of BRs as the latter could be viewed as all-inclusive, reaching beyond the applicability of the CBD where other national and international regulations applicable to BRs would stand independent of the requirements under Article 15[65]. It was further clarified that making the focus of Article 15 of the CBD on the proposed utilization of GRs, the information in the functional units of heredity, for the purpose of access and benefit sharing, the other national and international legislations applicable to BRs will not be applicable to the utilization of GRs covered by Article 15[66]. Incorporation of derivatives within the ABS Protocol was a purported agenda of developing countries and as regards the utilization of derivatives, the two options remaining were (i) referring to research and development from genetic material accessed under Article 6 ie, access provision of the Protocol or (ii) to research and development on genetic expression or metabolism of GRs[67]. The language of the adopted Protocol is that derivative is a naturally occurring biochemical compound resulting from genetic expression or metabolism of BRs or GRs,

[62] *Ibid*
[63] *Ibid.*
[64] *Ibid.*
[65] *Ibid.*
[66] *Ibid.*
[67] Tenth Meeting of the Conference of Parties to the Convention on Biological Diversity, 18-29 October 2010, reported in Earth Negotiations Bulletin, Vol.9 No.534 dated 18 October 2010; Also see Mikyung Yun, ñThe Structure of Trade in Genetic Resources: Implications for the International ABS Regime Negotiationò, *Journal of East Asian Economic Integration,* Vol. 14, No. 1, (June 2010), p.192

even if it does not contain functional units of heredity. Looking specifically at the scope of the Protocol, it is clear that it covers only GRs, TK associated with GRs and the benefits arising from their utilization. Even though the definition of derivatives is there in the definition clause, it does not find reference in any other place in the adopted text of the Protocol, except in the definition of biotechnology. Interestingly, the benefit sharing clause, i.e. Article 5 of the Protocol, without mentioning the term derivatives provides that benefits arising from the utilization of GRs as well as subsequent applications and commercialization shall be shared in a fair and equitable way. These indirect references of the term in scope, in the definition of utilization and in the benefit sharing clause create ambiguities in implementation, allowing the Parties to choose whether to include or exclude derivatives in the domestic ABS framework. Thus theoretically, the Protocol regime consists of GRs, derivatives and associated TK, thereby keeping pace with the property concept established by the CBD. Since the intention of the developing countries was to include derivatives within the scope of access, it is assumed that their national regimes pursuant to the Nagoya Protocol will include derivates as an integral component falling within the ABS process.

Now the subject matter of the Protocol is ascertained to include GRs, their derivatives and associated TK. Next task is to map out the scope of the subject matter. The Protocol extends to all GRs covered by Article 15 of the CBD, associated TK and to the benefits arising from the utilization thereof[68] meaning to cover the GRs that belong to the country of origin or the country that has acquired the resources in accordance with the CBD. So it becomes pertinent to find out the GRs covered by the Protocol especially in light of the presence of other international instruments, in particular the ITPGRFA. ITPGRFA covers all PGRFA while its MLS theoretically covers only those listed in Annex I. In this regard the reiteration of the COP X while adopting

[68] *Supra* n.23, Article 3

the Protocol is worth recalling that ñé the international regime is constituted by the CBD, the Protocol on Access to Genetic Resources and the fair and Equitable Sharing of Benefits Arising from Their Utilization as well as complementary instruments, including the ITPGRFA and the Bonn Guidelinesé .ò The COP also recognises the objectives of the treaty and notes the ABS system created by it in its preamble. The Protocol also provides that when a specialized international ABS instrument that is consistent with and does not run counter to the objectives of the CBD as well as the Protocol is present, the Protocol will not apply to the Party or Parties to the specialised instrument in respect of the specific GRs covered by and for the purposes of the said instrument[69]. If we look at the MLS created by the ITPGRFA, it covers only the Annex I resources which implies that the ITPGRFA has created an ABS system only for the Annex-I resources. So naturally, the other PGR not covered by the ITPGRFA will be covered by the CBD system for the purpose of access. In addition to this, the Annex I resources will also be covered by the Protocol, if they are used beyond the purposes of the Treaty[69(a)]. This finds justification from the principle of interpretation *'generalia specialibus non derogant'* means when there is a general statute and a special statute on the same subject matter, the special statute will prevail over the general one for the purposes it is created. Since the MLS covers only the Annex I resources when there is a mandate for benefit sharing, the other PGRs will automatically fall within the purview of the CBD. But interestingly this point is not made clear in the Protocol, especially while setting out the obligation to take PIC, creating ambiguity. Unless it is demystified, it could hamper the benefit sharing objective of the CBD as well as the Protocol as there is no express obligation in this regard.

[69] *Id.* Article 4.4

[69(a)] The Parties were generally of the opinion that the ITPGRFA system need not be affected by the International ABS regime. See Brazil in UNEP/CBD/WG-ABS/4/INF/3/Add.1 p.5

Yet another point to be addressed is that the scope of the Article is confined to Article 15 of the CBD[70]. So it refers to GRs provided by the countries of origin or the country that has acquired the resources in accordance with the Convention. This contention leaves out some issues undefined. First relates to whether the Protocol has a retrospective or prospective effect. If it is prospective, then it would legalise all the illegal acquisitions that had taken place before the entry into force of the Protocol creating such a devastating effect on the developing countries whose GRs and TK had been plundered. If it has to operate retrospectively from the date of coming into force of CBD, then past uses which are over will not be covered, but it will bind the past, but still continuing uses. The Vienna Convention on the Law of Treaties provides that a treaty shall not be applied retroactively unless a different intention appears from the treaty or it is otherwise established[71]. It also clearly stipulates that in the absence of a contrary intention, a treaty cannot be made applicable to acts or facts which took place or situations which ceased to exist before the date of its entry into force[72]. Thus in principle, the retroactive operation of the Protocol is applicable only in cases of GRs taken after the entry into force of the domestic ABS legislation, but prior to the commencement of the Protocol where the uses are still ongoing[73]. This seems to be the correct interpretation since the attempt in the Protocol is to stream line the uses that took place after CBD and not to create any new obligations. Even though there were discussions in this regard during negotiations, it is not reflected in the text of the Protocol

Another serious issue regarding the scope of the Protocol is that it covers GRs transferred by country that has acquired the resources in

[70] *Id.* Article 3
[71] The Vienna Convention on the Law of Treaties, 1969, Article 28
[72] *Ibid.*
[73] For a detailed discussion see *Supra* n.55

accordance with the CBD. The proposition means a country that has acquired the GRs from the country of origin complying with the requirements of PIC and MAT. It is a serious question whether a country or a user who has legally obtained a resource or TK has a right to transfer such resource or TK. The answer is negative and that is why countries insist for the consent of the country of origin in the context of third party transfer.

While delimiting the contours of the subject matter, it is interesting to observe that the scope of the Protocol also covers the benefits arising from the utilization of GRs as well as the benefits arising from the utilization of TK associated with GRs. The Protocol seems to have taken an approach to distinguish between the GRs and TK over GRs and this inference is drawn here only from Article 3 entailing the scope of the Protocol as detailed analysis will follow in the coming sections of this chapter. Conceptually, the protocol is limited in its scope compared to the wide ambit of the CBD that incorporates BRs. The minimalist approach followed in the Protocol may be to avoid the operation of GATT principles like TBT (Technical Barriers to Trade) and SPS (Sanitary and Phyto-sanitary conditions) and the limited definition of utilization also corroborates this. But it could not be left unsaid that the limited definitions of utilization and GRs anticipates uses only for the development of new products and discards the value of BRs as raw materials for production, thereby accelerating the chances of availability of the resources from places other than the country of origin.

While assessing the subject matter and scope of the Protocol, a remarkable provision grabs our attention, i.e. instances where special consideration is to be given during the ABS process. First is the case where the Parties are encouraged to provide simplified access procedures in relation to non-commercial research, also considering the possibility of change of

intent in such research[74]. It is not clear what is meant by simplified access procedure. Does it mean that in such cases the benefit sharing obligation can be evaded? If that is the case, it would be practically difficult to differentiate between commercial and non-commercial research as the latter may any time turn to be commercial. If not, it would amount to legalised misappropriation. Next relates to cases of present or imminent emergencies that threaten or damage human, animal or plant health as determined nationally or internationally[75]. It is argued that it is an encroachment upon the sovereign rights since emergent situations are to be declared nationally and not internationally[76]. During the negotiations, there was a concerted effort from the developed countries to ensure that pathogens that fall under the scope of international agencies like WHO be given immediate access when requested[77]. Such immediate access would be without the benefit sharing obligation but the inventions developed out of such access are eligible for patent protection. This was fought nail and tooth by the developing countries and eventually, the provision was deleted from the Protocol[78]. But Article 4.3 of the Protocol provides that due regard should be given to useful and relevant ongoing work or practices of international instruments and relevant international organisations which are supportive and not counter to the objectives of the CBD and the Protocol. This was actually a relationship clause and the developing countries argued that it is not proper to include international organisations in this regard. Again, the stipulation as to the ongoing work also brings in uncertainty. Many view this as a purported effort to exclude the pathogens from the scope of the Protocol as access can

[74] *Supra* n.23, Article 8(a)
[75] *Id.* Article 8(b)
[76] Gurdial Singh Nijar, ñThe Nagoya Protocol on Access and Benefit Sharing of Genetic Resources: An Analysisò, *CEBLAW brief, January,* (2011), pp.24-25
[77] *Ibid.* Also see Access and Benefit Sharing Alliance in UNEP/CBD/WG-ABS/7/INF/1/Add.1 p.85
[78] *Ibid.*

be had by the international organisations and there is a possibility to develop patents out of them[79].

Another interesting examination in this regard is whether the philosophy of property outlined by the protocol keeps resonance with the CBD philosophy. But this could be done only after analysing the niceties of the concept of ownership as enshrined in the Protocol. So the next task obviously is to elucidate the concept of ownership revealed in the Protocol.

3.3.2 Concept of Ownership in the Protocol

In an ABS context, ownership over the GRs and associated TK is basically ascertained from two aspects, viz. the entity from whom PIC is to be taken and who the beneficiaries are. The Nagoya Protocol portrays a very interesting picture in this regard. Article 6.1 of the Protocol provides that for access to GRs, PIC is to be taken from the providing country that is the country of origin or the country that has acquired the resources in accordance with the CBD. Article 6.2 adds that if the local and indigenous communities have established rights to grant access to the resources, PIC from them or their approval and involvement is needed for the process of access. Access to TK associated with GRs is dealt under a separate head providing that when such knowledge is held by local and indigenous communities, PIC shall be obtained from them[80]. Thus, the Protocol elaborates three instances where PIC is needed. First, it reiterates the State ownership over the resources in the exercise of sovereign rights. Second, it recognises the rights of the communities over the resources and mandates PIC from them in such circumstances. Thirdly, the Protocol has separated the knowledge over the resources and provides that PIC should be taken from the communities holding such knowledge while accessing them. Thus, the protocol is showing

[79] *Supra* n.76
[80] *Supra* n.23, Article 7

a clear departure from the flexible situation of the CBD to decide the ownership issue internally. It gives a specific mandate to the Member States to recognise the rights of the communities over the resources as well as TK by making PIC from them a mandatory requirement for access. Or we could say that the Protocol is directing the State to vest the ownership of the resources as well as TK with the communities when they have specific claims/ rights over them. Thus the communities are also forming part of the access framework and their participation can also be ensured. This takes us to Article 8(j) of the CBD which calls for inclusion of the knowledge and practices of the traditional communities within the access framework and to ensure their involvement, participation and approval in the whole process of access. Even though the Protocol qualifies that the above-said measures for PIC are "in accordance with domestic law"[81], the treatment of GRs and TK as those held by State and those held by the communities in all instances of access makes the intention of the Protocol clear that it does not envisage a regime of complete State ownership over the GRs. So the conclusion is that the ownership over the resources are held by the State or the community as the case may be and there can be chances where both the State and the communities can together hold such rights. As far as TK associated with GRs is concerned, the communities holding the same are the owners. Thus, to a large extent, the Protocol has curtailed the rights of the State in deciding the question of ownership. So, it is emphasized here that the Protocol provides a better link in exploring the relationship between Article 8(j) and the ABS provisions of the CBD. The Protocol has succeeded in establishing the rights of the communities and has gone positively much beyond the general provisions of the CBD. One may very well doubt, is it possible for the communities to hold TK without holding the resources and does access to TK envision a situation without access to the resources. It should be noted that when GRs and TK are constructed as separate elements, the

[81] *Id* Article 6 and Article 7

communities are conferred with an additional right over the TK associated with the GRs even if they do not own the GRs. The Protocol foresees such possibilities and tries to address such situations also. Reading Article 6 and 7 together, the Protocol appreciates the possibility of the GRs and TK associated are held by the communities, thereby vesting the ownership rights over them.

Another genuine doubt could be the status of TK that has diffused throughout the country creating difficulty in identifying the rightful holders. Thus, when a TK becomes common knowledge throughout the country of origin as in the case of turmeric, who owns such knowledge? Can the country of origin regulate access to such knowledge bases? What would be the status of knowledge available to public as in the case of digital libraries where no PIC from the communities is needed for access to the knowledge? Especially when knowledge is available in state-owned digital libraries and the rightful holders are identifiable, who owns such knowledge and from whom PIC is to be taken? The Protocol seems to be silent on many such aspects of the ownership concept, though there were discussions in this regard during negotiations[81(a)]

There are many serious ramifications for the PIC situation put forward by the Protocol. Earlier, we have seen the ambiguity as regards the incorporation of derivatives within the scope of the Protocol. Taking for granted that the derivatives are covered within its scope, one pertinent question that may arise would be the authority from whom PIC is to be taken for access to derivatives. Since the ownership of the GRs is vested with the State, would PIC for derivatives from the State suffice? When it comes to the resources held by the people, is it mandatory to obtain PIC from them for a derivative that had resulted from a previous access or is there only the need

[81(a)] Though there were discussions on this area during negotiations, the actual positions tabled are not available to the author

to share benefits with them and not to obtain the PIC? Do the holders of TK associated with GRs have a right over the derivative developed out of the utilization of their TK? A close reading of Article 6, 6.1 and 2(c) makes it clear that for the resources vested with the State, PIC for access to derivatives should be from the State. But when it is vested with the people, the language of Article 6.1 is different that it talks about PIC in the context of access and not utilization. Similarly Article 7 provides that for access to TK held by communities, PIC from them is mandatory and utilization is not specified. To obtain a clear picture, it would be better to find out the benefit sharing obligation propounded by the Protocol. Article 5.1 provides that benefits arising from the utilization of GRs, subsequent applications and commercialization are to be shared with the providing country that is the country of origin or the country that has acquired the GRs in accordance with the CBD. So in the case of resources held by the State, PIC and benefit sharing is mandatory for access to derivatives. Article 5.2 provides that benefits arising from the utilization of GRs held by ILCs are to be shared with them upon MAT. True that the definition of utilization is interpreted to include derivatives also, but the obligation is only to share benefits and not to take PIC for access to derivatives. Since it is provided that sharing shall be upon MAT, there is a possibility for the Member States to make it clear in their legislation that even for the utilization of derivatives, PIC from the communities is mandatory. Similar is the case with benefit sharing upon the utilization of TK associated with GRs held by communities where sharing upon MAT is mandatory in the benefit sharing clause, but PIC for use of derivatives could not be ascertained from the access provision. What is meant by utilization of TK associated with GRs is not clear. This is also left for the Member States to implement domestically after proper appreciation of the provision. The ambiguity is the result of the treatment of TK associated with GRs under a separate head different from GRs. In the previous chapter, we have seen that the tangible and intangible part in the

GRs cannot be separated and TK over the resources form an intangible part of the resources. TK is the actual value of the resources. The entity who owns the tangible part can extend ownership to the intangible part and vice versa as the absence of one makes the other meaningless. We have also found in the previous chapter that the CBD never envisages a system where it can completely alienate the ownership rights over the resources and associated TK due to the unique formulation of the country of origin. So looking from that perspective too mandates that access to derivatives requires PIC from the State, the communities and the communities who hold the TK as the case may be. But this approach is not clear in the Protocol. The double stand taken in the case of access to GRs held by the State on the one hand and GRs and TK held by the people on the other blurs the ownership concept. The better approach would have been to keep separate provision for access to GRs which in rare cases do not have any TK associated with it and treat those GRs with associated TK together in one clause.

When the Protocol specifies the circumstances where PIC is mandatory for access, it would be interesting to find out the instances where it does not seem to be mandatory and the implications of such an impression. The above said stipulation of mandatory requirement of PIC can generate an impression that the State has no ownership over the TK available in the country. The Protocol creates a flux without mentioning the ownership rights over the publicly available TK both in cases where the right holders identifiable and not identifiable. The implication is that in both the cases, it is impossible to regulate access to the knowledge by conditioning with PIC. But the TK is the actual value of the GRs and it is a property that can generate income. If PIC is not taken and benefits are not shared in such circumstances, it would amount to typical cases of biopiracy, the long haunted dilemma faced by developing countries. It was a major concern that even though the country of origin and the knowledge holders are identifiable,

access to the knowledge is possible through other sources. There was prolonged discussion during the negotiation of the Nagoya Protocol regarding this issue wherein developing countries led by India and China argued that such knowledge is not freely accessible and conditions of PIC and MAT would be applicable in such cases[82]. It was further clarified that when the knowledge holder is not identifiable as regards the TK available in public, PIC and MAT should be made with the Party, i.e., the country of origin[83]. The major opposition of the developed countries regarding publicly available TK was that it formed part of the public domain and developing countries opposed this contention that public domain is a concept showing the existence of prior art with respect to patent applications which could not be extended to defeat the CBD mandate relating to ABS. To deal with the situation, developing countries proposed that Article 9.5 of the Protocol should provide that ñParties shall take appropriate legislative, administrative or policy measures so that users of TK associated with GRs, whether oral or documented or in other forms, obtained from a source other than the indigenous and local communities (ILCs), to enter into fair and equitable benefit sharing arrangements with the rightful holders of such knowledge as may be determined by the provider Party.ò[84] And to deal with the situation where holders are not identifiable Article 9.5 [bis] was proposed stating that ñWhere TK is held by a Party on behalf of the ILCs and the original holders within these communities cannot be identified, such Parties may take legislative, administrative or policy measures, as appropriate, so that users of such TK enter into fair and equitable benefit sharing arrangements with that Party for the benefit of the ILCs.ò[85] Interestingly, in these two proposals, there is no mention to PIC requirement, but simply talks about benefit sharing. The major questions confronted in this regard at the time of

[82] *Supra* n.76
[83] *Ibid.*
[84] *Ibid.*
[85] *Ibid.*

negotiation, were the need of such a provision itself and the binding or non-binding language to be used with regard to the measures Parties should adopt for benefit sharing[86]. Indonesia and China insisted on using mandatory language and it was opposed by Canada[87]. Both sides preferred deleting the reference if their demand was not accepted[88]. Later African Group and Philippines joined China on this issue and Philippines explained that this provision refers to typical cases of biopiracy[89]. After this a compromise text was reached stating that Parties shall take measures in order that users of TK obtained from a source other than the ILCs enter into benefit sharing arrangements[90]. This was accepted by Canada which requested to qualify the measures as legislative, administrative or policy as appropriate. The African Group, China, India and Philippines welcomed it as long as there is explicit reference to publicly available TK, which was opposed by Australia, Canada and Japan[91].These divergences persisted throughout the negotiations and eventually the provision was excluded from the adopted Protocol[92]. Thus the issue remains outstanding even after the adoption of the protocol, leaving the Parties free to decide upon the matter. Since TK is included in the scope of the Protocol, States can include TK available in public to be covered by benefit sharing obligation. PIC is not possible in such cases and how far the sharing of benefits could be ensured is to be looked into in the context of compliance and monitoring provisions of the Protocol. If we finely look into the reason for the flaw of the Protocol in this regard, it could be the purported agenda of the developed countries to deal with TK associated with GRs as a separate subject matter distinct from GRs. Though the Protocol

[86] Report of the Tenth Meeting of the Conference of Parties to the Convention on Biological Diversity, 18-29 October 2010, Earth Negotiation Bulletin Vol.9 No.534 (2010), p.42 Original texts are not available to the author
[87] *Ibid.*
[88] *Ibid.*
[89] *Ibid.*
[90] *Ibid.*
[91] *Ibid.*
[92] *Ibid.*

recognizes the inseparable nature of GRs and associated TK[93], the provisions on access and benefit sharing with respect to the two are dealt separately. If TK was dealt as an inseparable part of the GRs in the ABS context, this situation would not have been occurred. In such a case, the State would have been able to claim ownership rights over the TK and its uses could have been regulated through PIC and MAT using the sovereign right principle. The State could then regulate the issues internally to ensure benefit sharing to the local and indigenous communities. This would have resulted in a situation where PIC of the country of origin is a pre-requisite for use of the TK associated with GRs. This is very important in cases where the knowledge over the resource is diffused in the country of origin only and nowhere else. It is highly distinguishable from cases where TK over a resource occur in transboundary situations where the modalities of a multilateral benefit sharing mechanism could be an option to facilitate the process of benefit sharing. But in the first situation, it is the rights of the country of origin as well as its communities that is getting undermined

Coming to the beneficiaries under the Protocol, the benefits arising from the utilization of GRs, subsequent application and commercialization shall be shared upon MAT with the providing country that is the country of origin or a country that has acquired the resources in accordance with the CBD[94]. As far as GRs held by the communities are concerned, benefits arising from utilization shall be shared with them upon MAT[95]. As regards the utilization of TK associated with GRs, there must be fair and equitable benefit sharing with the communities holding the TK[96]. As discussed earlier, by specifying that as regards TK held by communities, PIC and benefit

[93] *Supra* n.23, Preamble. For a detailed account on inseparability, see, Report of the Meeting of the Group of Technical and Legal Experts on Traditional Knowledge Associated with Genetic Resources in the Context of the International Regime on Access and Benefit-Sharing, UNEP/CBD/WG-ABS/8/2 p.9
[94] *Id.* Article 5.1
[95] *Id.* Article 5.2
[96] *Id.* Article 5.5

sharing is solely with the communities, the Protocol creates an impression that the rest of the TK forms part of the public domain with nobody ascertaining ownership over the same. In effect, a large part of the TK associated with GRs is left out of the ABS regime created by the CBD as well as the Protocol. Thus, in *toto*, the Protocol has failed to appreciate the spirit of Article 8(j) of the CBD that speaks about the significance of associated TK in the context of biological diversity. As discussed earlier, the Protocol talks about the possibility of establishing a global multilateral benefit sharing mechanism to address benefit sharing in the context of utilization of GRs and TK that occur in transboundary situations or where it is not possible to obtain PIC[97]. The benefits shared through this mechanism are to be used to support the conservation of biological diversity and sustainable use of its components globally[98]. It is noteworthy that a multilateral benefit sharing mechanism may be pivotal when it is difficult to ascertain the ownership rights. But when the country of origin of TK could be ascertained, the benefits should naturally go to it which has to decide internally how to distribute the benefits. Since the modalities of the proposed mechanism are not considered yet, it is not clear whether the country of origin could assert its rights in such cases. Considering the language of the Protocol that such benefits should be used to conserve and support global biodiversity, the assertion of the rights of the country of origin is normally not possible. Thus the Protocol fails in ensuring due benefits to the real conservators of biodiversity and it also dilutes the rights of the country of origin. A positive impact is that it has gone a step forward in theoretically ensuring the rights of the local and indigenous communities over the resources and TK they hold by mandating PIC from and benefit sharing with them. As far as misappropriation of TK is concerned, the Protocol is not only a failure; it even creates disastrous effects by leaving a vacuum in its text.

[97] *Id.* Article 10
[98] *Ibid.*

Another interesting question that may arise in the context of ownership is the status of the resources held by *ex-situ* centres and gene banks like the International Agricultural Research Centres (IARCs) when they are used for purposes beyond what they are actually meant for. Usually, access to such *ex-situ* centres are governed by the ITPGRFA system, especially in the case of the Annex I resources. These collections are considered legal and the ownership over the resources transferred prior to the entry into force of the CBD is still a moot point. When access is obtained from an *ex-situ* centre and it results in a commercially successful venture and the resource accessed does not belong to Annex I, what would be the obligation in relation to PIC and benefit sharing? Even though ITPGRFA extends to all PGRFA, the applicability of the MLS is confined to the Annex I resources and access provided by the *ex-situ* centre would be against the sovereign rights of the country of origin. The *ex-situ* centre has no legal rights to provide access in such cases under the CBD jurisprudence. But no mandate could be seen in the Protocol for access in this regard. Similarly, with whom benefits are to be shared is the second question. Though we can theoretically argue that CBD is the operative instrument and regulation of access and benefit sharing is the prerogative of the country of origin, practically it seems impossible without an express mandate and without a specific mechanism. This lacuna weakens the proprietary rights of the country of origin.

Thus the above analysis makes it clear that the ownership rights created by the Protocol, the building blocks of the property rights, is not properly addressing many serious concerns pertinent to benefit sharing. First and foremost, it has failed to appreciate the inseparability of GRs and associated TK. The absence of benefit sharing obligation in cases where TK could be obtained from a source other than the communities is yet another peril generated by the Protocol throwing such knowledge away from the

umbrella of the ownership right to public domain. So it will constitute *res nullius* legalising appropriation without PIC and benefit sharing. It is obvious that the failure of the Protocol in this regard is the result of separation of GRs and associated TK. The requirement of PIC is uncertain in the context of access to derivatives, producing ambiguities in the ownership rights of communities over the resources and TK. Similarly, the ownership over the resources held by *ex-situ* centres is also not made clear by the Protocol. Anyway, philosophically it reiterates that ownership is vested with the country of origin in exclusion to others. Comparing the property jurisprudence expanded by the Protocol with that of the CBD, there is not much progress conceptually as well as practically and the Protocol has even retarded many possibilities left out by the CBD.

3.3.3 Obligations on ABS

Since access to GRs and associated TK mandates PIC from the State or the communities as the case may be, the Protocol elaborates the obligations imposed on Member States at the access point as well as during and after utilization by the user. Analysis of these obligations would be significant as the CBD is placing only the minimum requirement that access shall be upon PIC from the Party providing the resources unless otherwise determined by that Party[99]. So under the CBD, the State has the choice whether or not to regulate access to its resources and the mode of regulation too is within the scope of its choice. The Protocol also provides that access to GRs for their utilization shall be subject to PIC of the country of origin unless otherwise determined by that Party[100]. If a Party requires PIC for access to its resources, it has to take appropriate legislative, administrative or policy measures with legal certainty, clarity and transparency[101] and the rules

[99] *Supra* n.1, Article 15.5
[100] *Supra* n.23, Article 6.1
[101] *Id.* Article 6.3(a)

and procedures for access should be fair and non-arbitrary[102]. This is imposing more targeted specific obligations than the CBD and the call for fair and non-arbitrary rules and procedures could even lead to enforcement problems. If we look at the history of incorporation of this provision, this was first proposed by Canada in the Seventh Working Group Meeting in Paris in 2009 to provide foreign applicants national treatment and most favoured nation treatment in the WTO line[103]. In 2007 itself, it was differently coined by the European Union (EU) in the Sixth Working Group Meeting for an international commitment for application of access rules in a non-discriminatory way[104]. Right from the beginning, this was vehemently opposed by developing countries on the ground that it is an encroachment upon the sovereign rights to decide the conditions of access and questioned the relevance of such trade related provisions in an instrument aimed at securing benefit sharing[104(a)]. But this resistance did not persist in the 2010 September negotiations and the developing countries accepted the modified version of the proposal as seen in the present text of the Protocol. The outcome is that the user country can refuse to enforce the access agreements and obligations on the ground of unfair and arbitrary rules and procedures. To illustrate this point, the Biodiversity Act of India requires foreign applicants to take approval from the National Biodiversity Authority for access to its resources[105] while its citizens are only bound to inform the concerned State Biodiversity Boards while accessing the resources[106]. There is differential treatment of foreigners and nationals and it is absolutely for the user country to decide fairness and arbitrariness as there is no hard and fast rule in the Protocol as to how to decide them. The game could get worse in light of the fact that unfairness is a ground for not enforcing judgements in

[102] *Id.* Article 6.3(b)
[103] *Supra* n.76, p. 16
[104] *Ibid.* For details, see EU in UNEP/CBD/WG-ABS/7/INF/1/Add.1
[104(a)] Actual texts are not available to the author
[105] The Biological Diversity Act, 2002, India, sec.3
[106] *Id.* sec.7

foreign jurisdictions. Hence this CBD plus obligation is not only curtailing the sovereign rights, it could even hamper the benefit sharing objective of the Protocol.

When PIC constitutes a requirement for access as per the domestic law, such countries have the obligation to supply information as to how to apply for PIC[107]. When access to GRs requires PIC from the local and indigenous communities, the country has to set out the criteria or processes for obtaining PIC or the approval and involvement of such communities[108]. For access to TK held by communities, the providing country has to take measures to ensure that PIC or approval and involvement of such communities is secured prior to the access[109]. In the CBD and the practice of the majority of the nations was to put the burden to ensure PIC from the communities on the shoulders of the person seeking access. In contra, the Protocol is creating an express mandate upon the providers to provide mechanism ensuring PIC from the communities. Thus it is a CBD plus obligation as far as the providing countries are concerned and the Protocol language reverses the burden from the applicant to the provider country. The Protocol again specifies that the providing countries have to establish clear rules and procedures for requiring and establishing MAT and such terms should be in writing spelling out a dispute settlement clause, terms on benefit sharing including IPR, subsequent third party use if any and terms on change of intent where applicable[110]. The first part of this obligation viz. to establish rules and procedures for requiring and establishing MAT has also reversed the obligation that was previously on the applicant towards the providing country. Likewise, it is also expressly provided that the providing country has to put its decision regarding access, in writing and such decision shall be

[107] *Supra* n.23, Article 6.3(c)
[108] *Id.* Article 6.3 (f)
[109] *Id.* Article 7
[110] *Id.* Article 6.3 (g)

clear, transparent, cost-effective and within a reasonable period of time[111]. The specific stipulation to issue an access permit or its equivalent as the evidence of the decision to grant PIC and of the establishment of MAT and communication of the same to the ABS Clearing House Mechanism[112] also goes beyond the CBD.

Article 13 of the Protocol is a very interesting provision that talks about the establishment of national focal points and competent national authorities. It provides that each Party shall designate a national focal point on ABS and the same is assigned with the duty to make available the information on procedures for obtaining PIC and establishing MAT including benefit sharing for applicants seeking access to GRs; information on procedures for obtaining PIC or approval and involvement of local and indigenous communities and MAT including benefit sharing for applicants seeking access to TK associated with GRs; and information on competent national authorities, relevant ILCs and relevant stakeholders[113]. It is also responsible for liaisoning with the Secretariat of the CBD[114]. What is interesting is that the provision spells out obligations relating to the providers of the resources and associated TK and not the users. Though the obligation is cast on all Members of the Protocol, as far as a user country is concerned, its national focal point has no role to provide information on the uses and the users within its jurisdiction. Similarly, there should be one or more competent national authorities established by the Member countries to be responsible for granting access or issuing written evidence that access requirements have been met[115]. The competent national authority is also responsible to advise on applicable procedures and requirements for ensuring

[111] *Id.* Article 6.3 (d)
[112] *Id.* Article 6.3 (e)
[113] *Id.* Article 13.1
[114] *Ibid.*
[115] *Id.* Article 13.2

PIC and MAT[116]. The competent national authority and the national focal point could also be a single entity[117]. As we have observed earlier, the obligation of the competent national authority is in similar line with that of the national focal point i.e. to regulate access and the national authority in the user country has no corresponding obligations in relation to the users in its domestic jurisdiction.

As far as a user country is concerned, the obligations in respect of the ABS process come in the form of compliance measures in the Protocol. Nijar observes that:

> ñWhat developing countries had maintained throughout the negotiations with respect to compliance were: clear obligations by countries with users in their jurisdictions to take effective measures against misappropriation, a specification of the measures, the establishment of monitoring and tracking measures in support of compliance, designated check points to track and monitor the use of genetic resources, derivatives and TK, patent offices as one such check point, and finally, sanctions for non-compliance.ò[118]

The adopted text of the Protocol provides that each Party is bound to take appropriate, effective and proportionate measures to provide that the GRs utilized within its jurisdiction are accessed in accordance with PIC and that MAT have been established as required by the domestic ABS legislation or regulatory requirements of the other Party[119]. It is also provided that Parties are bound to take appropriate, effective and proportionate measures to address situations of non-compliance with such measures adopted[120]. Parties are also asked to cooperate as far as possible and as appropriate when

[116] *Ibid.*
[117] *Id.* Article 13.3
[118] *Supra* n.76
[119] *Supra* n.23, Article 15.1
[120] *Id.* Article 15.2

there is violation of domestic ABS legislation or regulatory requirements[121]. Very similar wordings are used in the context of compliance with domestic ABS legislation or regulatory requirements for TK associated with GRs[122]. But to answer the question how far these provisions impose positive obligations on the user countries, we could see that it is reaching nowhere expected. First, it does not mention what are the effective, appropriate and proportionate measures to ensure compliance with the domestic ABS laws. One can even think how to determine the effectiveness, appropriateness and proportion of such measures. It is noteworthy that the Protocol talks about compliance with the regulatory measures / ABS legislation of the other Party and not specifies that it is the country of origin. Is it an attempt to foresee and legitimise cases where access was obtained from a country other than the country of origin? Thus is it making clear that the user country has no duty to ensure that its users have obtained the resources from the country of origin, but its job is to validate and enforce only the prevailing contract whosoever be the other Party? If it is the case, who will listen to the country of origin? Let us listen to Nijar who says:

> ñé the laws or regulatory requirements that must be adhered to must be that of the ó*other Party*ô. This last qualifier departs from the language elsewhere in the Protocol (for example in Article 4.1), based on Article 15.3 of the CBD, that the resources accessed must be those that are provided by the countries of origin of such resources or the Parties that have acquired the resources in accordance with the CBD. The language in the Protocol condones the legitimacy of access from countries that are not such countries. Hence if resources have been accessed illegally from a country of origin X, by another country Y, and a user accesses these from country Y in accordance with the ABS provisions of country Y, the

[121] *Id.* Article 15.3
[122] *Id.* Article 16

user country does not have to ensure compliance with the ABS requirements of the country of origin X. This legitimizes biopiracy.ò[123]

Nijar observed that though developing countries tried to bring consonance with the provisions of the CBD, the developed countries suggested that tracing country of origin would be burdensome and would add to legal uncertainty[124]. And as regards non-compliance with such measures adopted, the Protocol has incorporated the same loose language that appropriate, effective and proportionate measures are to be taken to address them without specifying what the measures are and what are the criteria to be followed in setting them. Looking into the final clause of Article 16 dealing with alleged violation of domestic ABS laws, the language used is that ñé Parties shall cooperate as far as possible and as appropriateé ò in addition to the uncertainty and vagueness, it is silent on another aspect, i.e. what measure the user country has to adopt if the *locus standi* of the providing country is challenged by another country claiming to be the country of origin. Not only at this point, nowhere the Protocol discusses this question, except providing that transboundary cooperation is needed in such circumstances[125].

The Protocol envisages monitoring obligation to effectively implement compliance measures. The most important means provided for monitoring is the designation of one or more check points that would collect or receive, as appropriate, relevant information relating to PIC, source of the GRs, the establishment of MAT and the utilization of GRs[126]. Users would be required to provide information to such check points depending upon the particular characteristics of each check point and effective, appropriate and

[123] *Supra* n.76
[124] *Ibid.*
[125] *Supra* n.23, Article 14
[126] *Id.* Article 17.1(a)(i)

proportionate measures should be implemented to address situations of non-compliance[127]. Such information will be provided to relevant national authorities, to the party providing PIC and to the ABS Clearing House as appropriate and without prejudice to the protection of confidential information[128]. Check points have to be effective with functions relevant to the implementation of this obligation and should be relevant to the utilization of GRs, or to the collection of relevant information at any stage of research, development, innovation, pre-commercialization or commercialization[129]. The design of check points looks very tactical. The function of the check points as we could read from the Protocol is to receive information relevant to access as submitted by the users. It is not clear from the language of the Protocol what is meant by functions of a check point relevant to implementation of the present provision. It is assumed from the wording ñthe information collected by the check point has to be communicated to the relevant national authorities, to the ABS clearing House and the Party providing PICò that the information is to be passed to the national authority of the user country. As regards the communication of such information, the language of the Protocol is not strict; it provides that the information will be made available as *appropriate* and without prejudice to the protection of confidential information. So it is not a mandatory obligation as far as the check points are concerned. The confidentiality is also determined by the Parties. Some observe this as the notorious euphemism in international treaties that leaves the discretion to a Party to decide whether or not to implement a particular provision[130]. It is to be noted that the information a user is required to provide to the check point is *inter alia* regarding the

[127] *Id.* Article 17.1(a)(ii) Also see Evanson Cheg Kamau *et.al*, ñThe Nagoya Protocol on Access to Genetic Resources and Benefit Sharing: What is new and What Are the Implications for Provider and User Countries and the Scientific Community?ò, 6/3 *Law Environment and Development Journal* (2010) pp. 256-257
[128] *Id.*Article 17.1(a)(iii)
[129] *Id.*Article 17.1(a)(iv)
[130] *Supra* n.76

source of the GRs used and not the country of origin. Another notable matter is the absence of any reference to TK associated with GRs. The Protocol is also quiet on the different aspects of the check points like its nature, role and functions. The reference that check points should be relevant to the utilization of GRs or to the collection of relevant information at any stage of research, development, pre-commercialization or commercialization is rather unconvincing. What is the effect of such an institution which has roles in the above specified stages? It is a clear departure from the stand taken by the Protocol as far as the obligations of the provider countries at the access point are concerned. There the functions of the competent national authority as well as the national focal points are clearly defined with less space for choice of the providers. In sharp contrast to this, the compliance measures are featured by ultimate freedom of the user countries in determining the check points and their functions. The country can decide at what stage a check point has to operate, what would be the relevant information it has to receive, whether it is to be communicated to the relevant authorities including the provider and the ABS Clearing House and the mechanism to deal with issues of non-compliance. In short, the negotiations had ended up with detailed obligations on the developing countries regarding clear and transparent procedures for access while there is complete uncertainty and vagueness regarding the obligations of the user countries to ensure compliance.

An examination of the negotiation history of the provision on compliance and monitoring reveals that it was a demand from the developing countries who vehemently argued that user countries must establish effective monitoring, tracking and reporting measures to support compliance. They argued that users should disclose at the check points information regarding the country of origin of the resources or associated TK, PIC, MAT and its

essential terms[131]. They also argued that check points to be effective must be institutions where applications or reporting is made regarding the use of the GRs and the associated TK[132]. So the developing countries proposed mandatory disclosure of information at IP examination offices, authorities involved in regulating products or giving market approval, research institutions subject to public funding and entities publishing research results relating to the utilization of GRs[133]. These check points were recommended by an Expert Technical and Legal Group set up by COP VIII in 2006[134]. An indicative list of the check points was suggested by them[135]. They also demanded that there should be clear criteria for establishing check points, a time limit for Parties to notify check points to the secretariat and that where IP offices are included as check points, they should be officially designated[136]. But the compliance provisions in the Protocol do not respond to the concerns raised by developing countries. There is no indicative list of the possible check points. Also it contains no obligation to designate patent office as a check point and require mandatory disclosure of information at that stage. Some developed countries suggested that their competent national authorities would serve as the check points but it is disgusting that the functions of the competent national authority made out in the Protocol do not co-relate to this new role. Again, the role of a competent national authority with respect to the utilization of GRs of a providing country especially in stages like research, development, innovation, pre- commercialization and commercialization too does not seem logical. Yet another disappointing fact

[131] *Ibid.*
[132] *Ibid.*
[133] *Ibid.*
[134] *Ibid.*
[135] *Ibid.*
[136] *Ibid.*See UNEP/CBD/WG-ABS/6/INF/3 p.8

is that there are no sanctions to deter non-disclosure at the designated check points[137].

Another new proposition to ensure compliance is the monitoring mechanism through the issue of an internationally recognised certificate of compliance. It is a permit or equivalent issued at the time of access by the providing country as the evidence of the decision to grant PIC and of the establishment of MAT and to be notified to the ABS Clearing House[138]. The minimum information such a certificate has to carry, when not confidential, relate to the issuing authority, the provider, date of issuance, unique identifier of the certificate, the person or entity to whom PIC was granted, subject matter or GRs covered by the certificate, confirmation that MAT is established, confirmation that PIC is obtained and commercial and/or non-commercial use[139]. It is surprising that the Protocol reserves the countries the right to disclose the above crucial details on the ground of confidentiality. The concept as proposed by the Protocol is preposterous mainly because one can genuinely doubt the international recognition conferred on a certificate issued by a national authority. Not only that, what will happen to the ñinternationally recognisedò status of the certificate of compliance when its validity is challenged by another country. It is to be noted that even though the Protocol insists that PIC and MAT must be from the country of origin[140], its later provisions on compliance do not repeat the similar concern. The compliance and monitoring provisions tactfully omits any reference to country of origin. If a certificate of compliance is issued by country X and its validity is challenged by country Y claiming to be the country of origin, this compliance mechanism fails. Yet another serious flaw is that the certificate of compliance talks only about GRs and not associated TK. Thus there is no

[137] *Ibid.*
[138] *Supra* n.23, Article 17.2, 17.3 and 6. 3(e)
[139] *Id.* Article 17.4
[140] *Id.* Article 6

obligation to pass any information regarding the TK used at the checkpoints, and the certificate of compliance too will not carry any information regarding the same. If we look at the mode of operation of the compliance and monitoring system of the Protocol, it is that the users have to submit the certificate of compliance or the permit issued to them at the check points in whose jurisdiction, utilization of GRs occur. But when it is not done, the mechanism to deal with such instances does not form part of the Protocol. Thus its deterrent effect is very minimal. The only positive outcome is that the developing countries have succeeded in imposing an obligation on the user countries to cross-check the compliance of ABS legislations in their jurisdiction which might be implemented in a minimum to zero level. Many developing countries consider this as a big step and the general attitude is that something is better than nothing.

Yet another aspect of compliance the Protocol has discussed is compliance with MAT where users and providers of GRs and TK are encouraged to enter into MAT setting out the jurisdiction for dispute resolution, the applicable law and options for alternative dispute resolution[141]. There should be opportunity to seek recourse to the legal systems in the respective jurisdictions of the Parties[142]. For enforcing the access contract in foreign jurisdictions, the developing countries demanded access to justice in the jurisdiction of the user countries; and access to justice as proposed by them meant granting of access to courts or other impartial adjudication bodies in those jurisdictions, fair procedures, effective remedies and appropriate assistance mechanism to remove or reduce financial or other barriers to such access[143]. This was qualified as facilitated access and when this was claimed, the developed countries resisted on the ground that the term had unacceptable implications even resulting in preferential treatment

[141] *Id.* Article 18.1
[142] *Id.* Article 18.2
[143] *Supra* n.76

to foreign litigants than their nationals[144]. The final provision in the Protocol stands without chances of facilitation for access to justice and calls for the use of mechanisms for the enforcement of foreign judgments and arbitral awards[145]. The provision on compliance with MAT is subject to review by the COP/ (Meeting of Parties) MOP[146].

Thus an analysis of the niceties of the compliance and monitoring provisions reveal that it is rather a dream far from reality. The obligations are very minimal and more is the chance to evade such obligations. Even if such check points are created, there is no clear rule as to their functions and the Protocol provides ample scope for non-enforcement of the contractual obligations with many vague propositions and the rules of fairness and non-arbitrariness. Though there was a concerted effort by the developing countries to ensure compliance through IP offices by designating them as one of the check points and calling for mandatory disclosure of compliance, the effort did not succeed. If this was made a reality, this would have to some extent bridged the gap between the CBD and the TRIPS Agreement, imposing positive obligation to respect the CBD mandate. The outcome of the compliance and monitoring provisions is really disappointing and cannot be counted as a milestone achievement.

3.3.4 Protocol and Interface with IPRs

The most disparaging aspect of the Protocol is its silence with respect to issues related to IPRs. The issue was not at all discussed during the negotiations as the developed countries were of the opinion that CBD is not the best forum to address the issue. But as a legal instrument to ensure benefit sharing that could arise from all possible aspects the CBD permits, it is bound to at least open up a way for carrying out a discussion in that line.

[144] *Ibid.*
[145] *Supra* n.23, Article 18.3
[146] *Id.* Article 18.4

The omission in this regard has rendered the Protocol toothless. The result is that still there is no means to render a patent invalid on the ground of non-compliance with the domestic ABS legislation for PIC and benefit sharing. Thus the game ends where it had begun. It is pathetic that even at the verge of two decades after the adoption of the CBD, we are still in the vicious circle of misappropriation and nothing is there in place to condone the same.

The above evaluation of the Protocol has proved that it is a failure in many respects. In this regard, it would be interesting to have a critical look at the observations of Manuel Ruiz Muller who too finds the Protocol a failure, and tries to find out the reasons and solutions for the same. According to him, the primary reason behind the failure of the Protocol is the over-emphasis in the CBD itself on the rights of the country of origin rather than concentrating on the informational nature of GRs[147]. Secondly, he argues that the bilateral contract system would result in price war among the nations offering the same resources. So he argues that it should be acknowledged that the GRs are shared among the countries at the informational level and this requires reconsideration of the notions of sovereignty and country of origin. He postulates that

> ñWhen it is accepted that genetic resources are information, the idea of creating walls, barriers or frameworks suited for tangibles, become obsolete and useless.ò

He proposes a new Protocol with an internationally recognised database or information system with specific data regarding spatial distribution of families, genus or species. It would have an international financial mechanism to receive monetary benefits received from products

[147] Santiago Pastor Soplin and Manuel Ruiz Muller, ñThe Development of an International Regime on Access to Genetic Resources and Fair and Equitable Benefit Sharing in a context of new Technological Developmentsò, *Andean-Amazon Initiative for the Prevention of Biopiracy of the Peruvian Society for Environmental Law*, Year IV No.10 April 2009, p.11

generated out of access and utilization. The national ABS frameworks would be simple, flexible and open stimulating research and would provide for model Material Transfer Agreements (MTAs) setting out non-monetary benefits to be shared and the potential and future monetary benefits. Next element of his proposition is an internationally recognised certificate of origin simply indicating the species, family or genus from which the specimen, sample or biodiversity component was obtained regardless of the actual country of origin or source. The certificate would travel along the route of research and development. For the successful operation of this system, there should be an international agreement reached to modify the patent procedures so as to ensure disclosure of the certificate in the patent application. When commercial benefits are generated by the patent, the obligation to share benefits is triggered and countries which conserve that specific species in *in-situ* conditions will share benefits according to spacial distribution. He proposes that 13% of the sales of the patented product are to be directed to the international financial mechanism which will distribute these benefits according to the spacial distribution of species as indicated in the certificate. The advantages he claims are that (i) access truly gets facilitated and research promoted, (ii) true equity in sharing of benefits according to conservation efforts by countries, (iii) elimination of price war among countries, (iv) effective incentive to conserve ecosystem and species in *in-situ* conditions, (v) rents could be extracted from access and use of biodiversity, (vi) simple and cost-effective system and (vii) low probability of monetary benefits, but high returns when they do occur. He adds that by committing to such a Protocol, the countries are reaffirming sovereignty rather than renouncing it.

What Muller envisages is truly a management system operating under the principle of common heritage. It alleviates the possibilities of any ownership claims. Though it appears to be a good proposal, it has two

inherent disabilities. First, it ignores the fact that though natural information, GRs do have a high trade potential. The common management system does not consider this aspect. Second, the proposal completely ignores the TK associated with GRs. The property jurisprudence reveals that TK and GRs are inseparable. Access and use of TK cannot call for an international or common management system as proposed as there are specific ownership claims. TK is the human intervention done to realise the natural information contained in it and use of the same cannot be managed in this way.

3.4 Conclusion

Even though the Protocol is the result of eight years prolonged negotiation, it has failed to address many serious concerns of the developing countries. The reason may be the weak negotiating status and strategy of the developing nations. But it is a fact that the progress of the Protocol towards furthering the CBD objectives is very minimal and on many areas, it has not moved much beyond the CBD. Ironically, the developing countries had ended up with more obligations to implement to make their access legislation more transparent and certain. As far as the user obligations are concerned, the protocol uses vague propositions and provide unclear obligations. Uncertainty is the chief attribute of the Protocol. In the context of the benefit sharing objective of the CBD, the Protocol is unable to carry it forward, especially in light of the absence of provisions linking it with the TRIPS. What gets reflected is that the CBD or its subsidiary agencies are not the best platform to address the issue of misappropriation. So the best suitable option would be to carve out a trade regime for the ABS process separate from the CBD, but taking lessons from the CBD. The reason is that so long as GRs remain the subject matter of two separate legal instruments, inconsistencies are bound to occur and people will go on talking about finding of solutions, but reaching none. Is it not possible to think of a mechanism that stands for the protection of trade potential of GRs and

associated TK? A proper understanding of the philosophy of property in GRs and associated TK, together with the wide range of issues like the other international agreements involved, problems with respect to patentability and the need to ensure benefit sharing will form the basic tools to carve out such a regime. The best platform for this would be none other than the TRIPS. The exploration of the benefit sharing model of the CBD draws our attention to another benefit sharing structure for PGRFA which is functional prior to the Nagoya system and forms part of the Nagoya. In this backdrop, the next chapter examines the multilateral system of benefit sharing propounded by the FAO system and compares the same with the Nagoya protocol of the CBD.

Chapter 4

THE INTERNATIONAL TREATY ON PLANT GENETIC RESOURCES: A MULTILATERAL BENEFIT SHARING APPROACH

GRs and associated TK find place in a series of activities in relation to pharmaceutical, industrial, biotechnological, biochemical, biomedical, agricultural and other areas of research and all such industries are keen on the issue of access to them. The International Convention for the Protection of New Plant Varieties (UPOV) and the TRIPS stand as agencies, offering private property protection to such industries using GRs and TK as base materials for research. On the contrary, CBD plays a pivotal role in access regulation and sharing of the resultant benefits arising out of the utilization of the resources through the proclamation of national sovereignty. In addition to the bilateral contractual regime created by the CBD, there exists a specialised ABS regime for PGRFA created by the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA). This specialised ABS regime invites our special attention owing to a number of reasons. First reason that invokes special interest in the ITPGRFA is that it operates on a multilateral framework within the universally accepted manoeuvre of State sovereignty over GRs. Second, it creates a common pool of resources for the humanity, in sharp contrast to the exclusive property rights created by the CBD. Third, its full-fledged benefit sharing mechanism is in place well in advance to that of the CBD. Finally ITPGRFA operates on open access principle while CBD upholds regulated use of resources through PIC and MAT[a]. This chapter first traces the history of the ITPGRFA and

[a] Bram De Jonge & Michiel Korthals, ñVicissitudes of Benefit Sharing of Crop Genetic Resources: Downstream and Upstreamò, Developing World Bioethics, Vol.6 No.3 (2006) pp.114-154. Also see Stephen B. Brush, ñThe Demise of ócCommon Heritageôand Protection for Traditional Agricultural Knowledgeò in Charles R. McManis, *Biodiversity*

from this background moves on to the provisions with the enquiry how far it is in consonance with the CBDôs property jurisprudence. Then the analysis dwells on the ABS system under the ITPGRFA and on how far the benefit sharing end is achieved through the Treaty. It also tries to find out the major hurdles in achieving benefit sharing.

4.1 History of the ITPGRFA

The ITPGRFA takes its origin from the IUPGRFA which was specifically aimed at conservation of PGRs through free exchange of material as well as information[1]. The green revolution after the post colonialization period had resulted in promotion of monoculture of industrialized high yielding varieties, reducing the farmersô dependency on traditional varieties resulting in an alarming rate of genetic diversity loss of such traditional varieties[2]. Being concerned with this phenomenon, the IUPGRFA was an effort by the international community to promote collection of such valuable PGRs relevant for food and agriculture based on the principle of heritage of mankind and free flow of the resources[3]. The notion of heritage of mankind was particularly due to the interdependence among nations over the valuable PGRs[4] to ensure the food security of the world. The numerous transfers that occurred across the nations also

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and the Law: Intellectual Property, Biodiversity and Traditional Knowledge, Earthscan 2007 pp.297 - 305

[1] Michael Galewood and Kent Nnadozie, ñGiving Priority to the Commons: The International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA)ò, in Geoff Tansey and Tasmine Rojotte (Eds.), *The Future Control of Food: A Guide to International Negotiations and Rules on Intellectual Property*, Earth Scan, London (2008), Chapter 6

[2] Shawn N. Sullivan, ñPlant Genetic Resources and the Law: Past, Present and Futureò, *Plant Physiology*, Vol.135 May (2004), pp.10-15; Joseph Savirimuthu, ñFarmersô Rights: Lessons for Policy Makers in South Asian Developing Countriesò, CUTS Centre for International Trade, Economics and Environment, (2003), pp.8-9

[3] Chidi Oguamanam, ñIntellectual Property Rights in Plant Genetic Resources: Farmersô Rights and Food Security of Local and Indigenous Communitiesò, 11 *Drake J. Agric. L.* 273 (2006) p.281

[4] For a detailed account on interdependence, see Gerald Moore and Witold Timousky, *Explanatory Guide to the International Treaty on Plant Genetic Resources for Food and Agriculture*, IUCN, Gland, Switzerland and Cambridge, (2005), pp.4-5

augmented this philosophy. Many scholars consider IUPGRFA as a response to the IPR created over PGRs especially the patents and Plant Breedersô Rights (PBRs) and the consequential genetic erosion[5]. The IUPGRFA always tried to maintain a balance between the conflicting interests of the North and the South as regards PGRs and the same is visible in its subsequent resolutions for accepting the PBRs and the concepts like farmersô rights and permanent sovereignty over PGRs. History tells that for the preservation and ensuring accessibility to crops and wild relatives and genetic materials of PGRs, gene banks were established as *ex-situ* repositories[6]. This ensured unhindered access to plant germplasm for the industrialised countries along with the common heritage notion over them leaving them open for free access even in countries where the PGRs have originated. But for the high yielding crop varieties and plants developed out of such varieties through the process of plant breeding, this common heritage notion was not applicable, and they were, often, protected by PBRs established through the UPOV or through patents. Chetan Gulati wondered that

> ñé PGRs leave the South as the ócommon heritage of mankindô and returns as óindividually ownedô commodities for sale at prices that inhibit many citizens of the LDCs, from which the PGRs originated from having access to them.ò[7]

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[5] Susan Bragdon, Kathryn Garforth and John E. Haapala Jr., ñSafeguarding Biodiversity: The Convention on Biological Diversity (CBD)ò,in Geoff Tansey and Tasmine Rojotte (Ed.), *The Future Control of Food: A Guide to International Negotiations and Rules on Intellectual Property*, Earth Scan, London (2008), pp. 82-114

[6] Dora Schaffin *et.al*, ñThe International Treaty on Plant Genetic Resources for Food and Agriculture ï Implications for Developing Countries and Interdependence with International Biodiversity and Intellectual Property Lawò, Final Report IPDEV Work Package ï 5, Produced with support from European Commissionôs IPDEV Project, November 2006, p.9

[7] Chetan Gulati, ñThe ñTragedy of Commonsò in Plant Genetic Resources: The Need for a New International Regime Centered Around an International Biotechnology Patent Officeôò, *Yale Development & Human Rights L.J.* Vol.4, (2001), p.67

The objective of the non-binding IUPGRFA was to explore, preserve, evaluate and make available for plant breeding and scientific purposes, PGRs of social and economic interest, in particular for agriculture, based on the principle of heritage of mankind[8]. The IUPGRFA reiterated that allowing access to PGRs and permitting their export for scientific research, plant breeding or GR conservation had to be the policy of governments and institutions adhering to it[9]. But some countries showed reluctance to ratify the IUPGRFA because of this provision and expressed reservations on the ground that the provision was in conflict with Article 5 of the UPOV Act 1978 which granted the breeder of a new variety, the exclusive rights to commercial production, offering for sale and marketing[10]. The only exception to the breedersô rights as conferred by the 1978 UPOV was in relation to the utilization of the variety as an initial source for creating other varieties or marketing of such varieties though consent should be obtained if

[8] The International Undertaking on Plant Genetic Resources for Food and Agriculture, 1983, Article 1

[9] *Id.* Article 6

[10] The International Union for the Protection of New Plant Varieties, 1978, Article 5

(1) The effect of the right granted to the breeder is that his prior authorisation shall be required for

- the production for purposes of commercial marketing
- the offering for sale
- the marketing

of the reproductive or vegetative propagating material, as such, of the variety.

Vegetative propagating material shall be deemed to include whole plants. The right of the breeder shall extend to ornamental plants or parts thereof normally marketed for purposes other than propagation when they are used commercially as propagating material in the production of ornamental plants or cut flowers.

(2) The authorisation given by the breeder may be made subject to such conditions as he may specify.

(3) Authorisation by the breeder shall not be required either for the utilisation of the variety as an initial source of variation for the purpose of creating other varieties or for the marketing of such varieties. Such authorisation shall be required, however, when the repeated use of the variety is necessary for the commercial production of another variety.

(4) Any Member State of the Union may, either under its own law or by means of special agreements under Article 29, grant to breeders, in respect of certain botanical genera or species, a more extensive right than that set out in paragraph (1), extending in particular to the marketed product. A member State of the Union which grants such a right may limit the benefit of it to the nationals of member States of the Union which grant an identical right and to natural and legal persons resident or having their registered office in any of those States.

repeated use of the protected variety is necessary for the commercial production of another variety. This provision was in sharp contrast with the open access regime proposed by the IUPGRFA. In order to alleviate the reservations made to it, the IUPGRFA adopted an agreed interpretation for it in 1989 that the breedersô rights guaranteed by the UPOV are not incompatible with the IUPGRFA[11]. The agreed interpretation provided that a State can impose such minimum restrictions on the free exchange of materials covered by the IUPGRFA so as to conform to its national and international obligations[12] and noted that free access does not mean ófree of chargeô[13]. Through this document, the IUPGRFA introduced a new concept in the history of international law, namely, farmersô rights. It provided that the recognition of the undertaking of the enormous contributions of farmers of all region towards the conservation and development of PGRs, which constitute the basis of plant production throughout the world, form the basis also for the concept of farmersô rights[14]. It further stated that the best way to implement the concept of farmersô right is to ensure the conservation, use and management of the PGRs for the present and future generations of farmers[15]. It also proposed an international financial mechanism to the realization of this end from the contributions of countries who have mostly benefitted from the use of germplasm together with the contributions of adhering governments[16]. In another resolution in 1989 itself, the IUPGRFA further affirmed that the farmers rights vest with the international community as trustee for present and future generations of farmersô for ensuring full benefits to farmers and also for supporting the continuation of their

[11] The International Undertaking on Plant Genetic Resources for Food and Agriculture, Resolution 4/89 Agreed Interpretation of the International Undertaking para. 1
[12] *Id.* para. 2
[13] *Id.* para. 5 (a)
[14] *Id.* para. 3
[15] *Id.* para. 4
[16] *Ibid.*

contributions.[17] This proposition of farmersô right in the IUPGRFA was aimed at calming down the countries which were irritated at the recognition of breederôs rights in the instrument[18]. The heated negotiations went on at the CBD discussions also showed its influence on the IUPGRFA through the resolution in 1991 whereby it was endorsed that nations have sovereign rights over their PGRs[19]. The 1991 resolution also asserted that the breederôs line and farmerôs breeding material are available only under the developerôs discretion during the period of development[20]. It further added that conditions of access to PGRs need further clarification. Thus, the IUPGRFAôs proposed open access regime was complicated by the recognition of breedersô rights, farmersô rights and sovereign rights.

When the CBD was in force in 1992, there was a need to bring harmony with the two instruments and also to find a solution for the outstanding issues like farmersô rights and the status of *ex-situ* collection prior to the entry into force of the CBD[21]. This was specifically because during the negotiations of the CBD, Article 15.3 was a moot point[22]. Article 15.3 provided that for the purpose of ABS, GRs provided by a Contracting Party are only those provided by Contracting Parties that are countries of origin or a country that has acquired the resources in accordance with the CBD. Many commentators argued that the provision specifically excludes *ex-situ* collections of GRs prior to the entry into force of the CBD situated in most gene banks of the IARCs of the Consultative Group on International

[17] The International Undertaking on Plant Genetic Resources for Food and Agriculture, Resolution 5/89 on Farmersô Rights
[18] *Supra* n.1.
[19] *Supra* n.17, Resolution 3/91 para. 1
[20] *Id.* para. 2
[21] Susan H. Bragdon and David R. Downs, ñRecent Policy Trends and Developments Related to the Conservation, Use and Development of Genetic Resourcesò. *Issues in Genetic Resources* No.7, June 1998, International Plant Genetic Resources Institute, Rome, Italy, p.13
[22] *Supra* n.4, p.9

Agricultural Research (CGIAR) and many other national collections[23]. So, when the CBD was adopted by the Nairobi Conference in 1992, it recognised the need to resolve the above issue as well as the issue of farmersô rights within the FAO system itself and also the need to seek harmony between the CBD and the IUPGRFA[24]. In furtherance of this invitation, through the resolution 7/93, the FAO conference called for revision of the IUPGRFA[25]. This resolution sought the Director General of the FAO to provide a forum for negotiation regarding the adoption of the IUPGRFA in harmony with the CBD, consideration of the issue of access with MAT to PGRs including *ex-situ* collections not addressed by the CBD and on the issue of realizing farmersô rights[26]. Six and a half years of arduous negotiations from 1994 culminated into the present ITPGRFA which was adopted in November 2001 and entered into force in June, 2004. In order to make the Treaty operational, four years negotiations again continued for the finalisation of the terms of ABS. It was in June 2006 that the terms of the Standard Material Transfer Agreement (sMTA) were adopted by the Governing Body (GB) of the ITPGRFA.

4.2 Nature of PGRs and the Scope and Extent of Access under ITPGRFA

The ITPGRFA is formulated with the express objective of conservation and sustainable use of PGRFA and the fair and equitable sharing of benefits arising from their use in harmony with the CBD for the purposes of food and agriculture[27]. It defines PGRFA as any genetic material of plant origin of actual or potential value for food and agriculture wherein

[23] *Ibid.*
[24] *Ibid.*
[25] Svanhild-Isabelle Batta Bjørnstad, ñBreakthrough for ótheSouthô: An Analysis of the Recognition of Farmersô Rights in the International Treaty on Plant Genetic Resources for Food and Agricultureò, FNI Report 13/2004, p.38
[26] *Ibid.*
[27] The International Treaty on Plant Genetic Resources for Food and Agriculture, 2001, Article 1

genetic material is in turn defined as any material of plant origin, including reproductive and vegetative propagating material, containing functional units of heredity[28]. The ITPGRFAôs scope extends to all PGRFA[29]. Examination of the subject matter of ITPGRFA reveals that the definition of PGRFA is in tune with the CBD definition of GRs. The value of genetic material holds a significant role in the definition part. So the logic under the CBD property regime could be extended that as a thing of value, the PGRFA is eligible to be considered property. The scope of the ITPGRFA is not extended to all PGRs, but confined to PGRFA only. So, one could assume that all other PGRs will fall within the purview of the CBD, for the purpose of ABS.

The ITPGRFA recognises that States have sovereign rights over their PGRFA and the authority to determine access to them rests with national governments and subject to national legislation[30]. In the exercise of sovereign rights, ITPGRFA envisages a unique multilateral system (MLS) of ABS for the PGRFA covered in Annex I of the Treaty. The MLS is intended to facilitate easy access to PGRFA in an effective, efficient and transparent manner and to share the benefits arising from their utilization in a fair and equitable way[31]. The Annex I GRs are established based on the criteria of food security and interdependence[32] and the CPs are bound to include in the MLS all Annex I resources that are under their control and also within the public domain[33]. The Treaty also invites all other holders of Annex I PGRFA, including natural and legal persons within the jurisdiction of the CPs to include them in the MLS[34]. The coverage of the MLS also extends to the *ex-situ* collections held by the IARCs of the CGIAR who have signed agreements with the GB of the Treaty in order to open them for access

[28] *Id.* Article 2
[29] *Id.* Article 3
[30] *Id.* Preamble
[31] *Id.* Article 10 (1) & (2)
[32] *Id.* Article 11.1
[33] *Id.* Article 11.2
[34] *Id.* Article 11.2 &3

through the Treaty system[35]. The provision regarding access to the *ex-situ* collections held by the IARCs following the Treaty system is designed to the effect that there is no difference between the IARCs as well as the CPs with respect to the legal effects of access[36]. In effect, we could see that the coverage of the MLS extends to crops listed in Annex I of the ITPGRFA. But it is to be noted that all Annex I crops are not included in the system. The Annex I resources included in the MLS should be in the control of the CPs and in the public domain. In the context of GRs, especially after the entry into force of the CBD, GRs in the public domain found in the *in-situ* conditions of a State is subject to sovereign rights and does not constitute a regime for unregulated access. The people within the State may be using it freely, but it will not render free access to foreigners like our traditional notion of public domain. Thus, it foresees the possibility of the Annex I PGRFA subject to other private rights such as the rights of local and indigenous groups and other institutions which cannot be overridden by the State. It means there are chances of getting access to the Annex I PGRFA outside the MLS. Therefore all other holders of Annex I PGRFA are encouraged to include such resources within the MLS. In order to ensure a smooth ABS system within the Treaty, the ITPGRFA calls for review of the provision regarding inclusion of Annex I PGRFA within the MLS by non-

[35] *Id.* Article 11.5 & 15.1 (a) &(b)

[36] *Id.* Article 15. Considering the importance of ex-situ collections held by IARCs of the CGIAR, the CPs invite the IARCs to sign agreements with the GB in relation to such ex-situ collections on conditions that the Annex 1 PGRFA be made available to the MLS and the non annex 1 resources and collected before the entry into force of the treaty be governed by the existing agreements which are to be subsequently amended as per the provisions of the treaty. Subsequent to MTA agreed between the IARCs and the GB, the IARCs have to periodically inform the GB about the MTAs entered into with the recipients. The CPs who possess PGRFA in in-situ conditions shall be provided access without MTA and benefits arising from the MTA that goes to the Trust fund shall be applied for sustainable use of PGRFA in question, especially in centres of crop diversity and least developed countries. The CPs have to provide facilitated access to Annex 1 PGRFA to the IARCs that signed agreements with the GB. Regarding the non-annex 1 PGRFA received by the IARCs after the entry into force of the treaty shall be available for access in consonance with the agreement entered into between the IARCs and the country of origin of the resource or the country that has lawfully obtained the material under the CBD or other applicable law.

Parties and natural and legal persons and other institutions so as to determine further access to them[37]. But no such revision is made till date due to the non-availability of adequate data. For the *ex-situ* centres, separate agreements should be signed by them with the GB of the Treaty for inclusion of Annex I resources within the MLS[38]. The non-Annex I resources collected prior to the entry into force of the Treaty should also be governed by the provisions of the MTA currently in use pursuant to agreements between the IARCs and the FAO and this MTA has to be amended by the GB not later than its second regular session in consultation with the IARCs and in accordance with Article 12 and 13 of the ITPGRFA.[39] In effect, they should be regulated by the provisions of the MLS. This leads to the fact that non-Annex I resources could also form part of the MLS, especially when such resources are collected prior to the entry into force of the ITPGRFA. For the non-Annex I resources collected after the entry into force of the Treaty, the access shall be governed by the MAT between the *ex-situ* centre and the country of origin of the resources or the country that has acquired the resources in accordance with the provisions of the CBD[40].

The coverage of the MLS creates complex situations. Even though Annex I provides an indicative list of the resources that are to be included in the MLS, the Members have to expressly specify which are the resources included by them. Even if a member country has included some of the listed resources into the MLS which is in its control and in the public domain, the same resources could be in the possession of private parties within and outside the country, creating avenues of access other than the MLS. There is every possibility of non-Annex I resources getting included in the MLS for such *ex-situ* collections prior to the entry into force of the IT has to be

[37] *Id.* Article 11.4
[38] *Id.* Article 15.2
[39] *Id.* Article 15. 1 (b)
[40] *Id.* Article 15.3

governed by the provisions of the sMTA. So it cannot be said that the coverage of the MLS is confined only to Annex I resources. Again, nothing in the ITPGRFA expressly bars a CP from including non-Annex I resources into the MLS. It is opined that by the expression PGRFA in public domain, it is intended that the MLS does not cover PGRFA protected by IPRs even though the holder of such rights is free to include them[41].

The MLS allows access solely for the purpose of utilization and conservation for research, breeding and training for food and agriculture and does not include chemical, pharmaceutical and/or other non-food/feed industrial uses[42]. Access is usually free of charge[43] together with all available non-confidential information regarding the concerned PGRFA[44]. When the access under the ITPGRFA is restricted for the specified purposes, it resembles the common heritage regime that was dealt in a previous chapter[45]. There, the use of the resources in a common heritage regime is confined only for peaceful purposes. The Member States within the exercise of their sovereignty are creating a common pool of PGRFA for the purposes of research, breeding and training. It is not that other uses are not permitted, but such uses are outside the scope of the MLS and would be violating the MLS. So clearly, this common pool does not constitute a public domain offering unregulated use of the resources. The benefits are managed internationally and for the benefit of the farmers who are in the process of sustainable use and conservation of the PGRFA. The MLS is created for the

[41] *Supra* n.4, p.84
[42] *Supra* n.27, Article 12.3 (a)
[43] *Id.* Article 12.3 (b) Access shall be accorded expeditiously without the need to track individual accessions and free of charge, or, when a fee is charged, it shall not exceed the minimal cost involved.
[44] *Id.* Article 12.3 (c) All available passport data, and subject to applicable law, any other available non-confidential descriptive information, shall be made available with the plant genetic resources for food and agriculture provided;
[45] The important elements of the common heritage system are non-appropriation, international system of management, sharing of benefits arising from management, use only for peaceful purposes and reservation for future generations.

present as well as the future generations. The management of the MLS vests with the GB of the Treaty. The clear departure that could be seen from the common heritage regime is that the access is regulated through the terms of the sMTA. So impliedly, there is an ABS system for the ITPGRFA in sharp contrast to the open access system under the common heritage regime. This reiterates that the common pool is under an effective international management system and the common pool takes its origin from the sovereign rights of the countries transferred to it. Access conditional to the terms of the sMTA thus upholds the sovereign rights of nations over their natural resources even though they are within the common pool and thus conforms to the CBD jurisprudence. When access is provided at no or minimal cost, the recipient gets access to all non-confidential information related to the concerned PGRFA. It means that the information associated with the resources, usually the contributions of farmers, form an indispensable part of the PGRFA. The value of the tangible part vis-à-vis the value of the information regarding the known traits of the resources is inseparable. Thus the subject matter of the ITPGRFA is akin to the subject matter of the CBD. It is logical to argue that the PGRFA form part of the larger GRs domain propounded by the CBD.

Regarding the question of ownership over the resources, it could be seen that for the purpose of the ITPGRFA, ownership is vested with the MLS or the international community of nations. One could also argue that the State has transferred its ownership over the resources for the purposes of the ITPGRFA and such ownership is with the MLS. MLS has thus adopted the concept of collective ownership and collective sharing based on the use value. The ITPGRFA recognises ownership of nations over PGRFA, but adopted a different management system considering the global importance of PGRFA in food and agriculture. States retain their ownership over the resources and manage the specified resources by creating a common pool

and vesting the same with the GB. To be more precise, there is conceptually, no deviation from the CBD principle of sovereign rights and sovereign ownership. But as regards the ownership rights of the individuals and local and indigenous groups within the State, the State is mandated only to encourage all the legal, natural and juristic persons who hold the Annex ï I resources to include them in the MLS. The State is not taking over the rights of the citizens. But when such persons who have not put the Annex ï I materials into the MLS come for access from the MLS, the GB can prevent them access as there is no *quid pro quo*.

4.3 ABS Terms under the sMTA

The mechanism for facilitating ABS under the ITPGRFA is the sMTA[45(a)]. It constitutes the MAT and PIC for access to the PGRFA covered and minimises the cost and time for individual negotiations at the time of every access[46]. It standardises the level, form and manner of equitable benefit sharing payments to be implemented[47]. The sMTA was adopted by the GB of the Treaty by Resolution 1/2006. It defines genetic material and PGRFA in line with the ITPGRFA[48]. The PGRFA specified in Annex I of the ITPGRFA (the sMTA uses the term ómaterialô interchangeably with óPGRFAô) and all the related available information constitute the subject matter of the agreement[49]. Thus, the sMTA recognises the inseparability between the tangible and intangible part of GRs. The sMTA imposes certain obligations upon the provider as well as recipient of the material.

[45(a)] For history of the adoption of sMTA, see Carlos M. Correa, Considerations of the Standard Material Transfer Agreement under the FAO Treaty on Plant Genetic Resources for Food and Agriculture, JWIP (2006) Vol.9 No.2 pp.137-165

[46] South Centre and CIEL, ñIntellectual Property and Development: Overview of Developments in Multilateral, Plural and Bilateral Foraò, *IP Quarterly Update* 3 Q (2004), p. 1-25

[47] Claudio Chairolla, ñPlant Patenting, Benefit Sharing and the Law Applicable to the Food and Agricultural Organisation Standard Material Transfer Agreementò, JWIP (2000) Vol.11, No.1, p.4

[48] Standard Material Transfer Agreement of the ITPGRFA. Article 2

[49] *Id.* Article 3

4.3.1 Obligations of the Provider

While transferring a material, the provider should ensure that expeditious access is provided at free or minimal cost without the need to track individual accessions[50]. The provider is also bound to transfer all available passport data and non-confidential information subject to applicable law[51]. Access to a PGRFA under development, including development of material by farmers, during the period of development, shall be at the discretion of the developer[52]. PGRFA under development is defined as a material derived from the accessed material and therefore distinct from it, but not yet ready for commercialization[53]. The developer intends to develop it or transfer the material to another person or entity for further development and the period of development will cease when the resource is commercialised as a product[54]. The provider has also the duty to notify the GB when each material transfer occurs[55].

The language in the body of the ITPGRFA that "access to PGRFA protected by IPRs and other property rights to be consistent with relevant international instruments and national laws"[56] also find place in the sMTA as an obligation of the provider[57]. So it means if a PGRFA protected by IP is put into the MLS, the right holder can charge royalties for its use which is in contrast to the facilitated easy access obligation under the system. Conceptually, the ITPGRFA stands for free access towards Annex I PGRFA and it is at the will of the Parties that the Annex I resources are put to the MLS. Even if protected by IPR or other property rights, once the material is put into the MLS, the intention is that the Party transfers his claim over the

[50] *Id.* Article 5(a)
[51] *Id.* Article 5(b)
[52] *Id.* Article 5(c)
[53] *Id.* Article 2
[54] *Ibid.*
[55] *Ibid.*
[56] *Supra* n.27, Article 12.3(f)
[57] *Supra* n.48, Article 5(d)

material for the specified purposes of the Treaty and that the material is open for access under the terms and conditions of the MLS. So it could be interpreted that when the material protected by IPRs is put into the MLS, the right holder is transferring his private right over the material to be managed internationally through the common pool. So he has to be governed by the provisions of the Treaty which means there would not be any reciprocal benefit sharing taking place between the provider of the resources and the recipient. The result is that the holder of IP has no incentive to include his protected resources within the MLS. There is no mention in the ITPGRFA as regards this issue which simply provides that IP and other property rights over the resources put to the MLS should be respected. This is a grey area of the ITPGRFA that perpetuates ambiguity.

4.3.2 Obligations of the Recipient

As far as a recipient is concerned, he/she has to use or conserve the material solely for the purpose of research, breeding and training for food and agriculture[58] and cannot claim any IPR or other right limiting the facilitated access to the material or its genetic parts or components in the form received from the MLS[59]. If the recipient is conserving the material accessed, he is bound to make available the same to the MLS through new sMTAs[60]. If the recipient transfers the material to another person or entity, it should be under the terms and conditions of the sMTA; should be through a new sMTA and has the corresponding obligation of a provider to notify the GB[61]. On compliance with the above obligations, the recipient shall have no further obligations regarding the actions of the subsequent recipient[62]. If the recipient transfers a PGRFA under development to another person or entity,

[58] *Id.* Article 6.1
[59] *Id.* Article 6.2
[60] *Id.* Article 6.3
[61] *Id.* Article 6.4
[62] *Id.* Article 6

he shall do so under the terms and conditions imposed by the sMTA he had entered into and through a new sMTA wherein he could impose additional conditions including monetary considerations[63]. For transferring the material under development, in Annex I to the new sMTA, he has to identify the material he had obtained from the MLS and specify that the PGRFA under development was being derived from the said material[64]. He will also have the notifying obligation of a provider and compliance with all the above requirements will make him free from the actions of the subsequent recipient[65].

It is a specific restriction both under the ITPGRFA as well as the sMTA that IPRs limiting access to PGRFA or their genetic parts or components in the form received from the MLS could not be claimed. This restriction is very vague. It is not clear whether there is total ban in obtaining IPRs from the materials covered by the MLS or whether the meaning is that IPRs can be obtained but such acquisition will amount to benefit sharing. So this will be looked in detail in the subsequent parts of this chapter.

4.3.3 Conditions for Benefit Sharing

The sMTA imposes benefit sharing obligations on the recipient upon the cumulative occurring of three conditions. The benefit sharing obligation will be triggered when the recipient commercializes a product that is a PGRFA and such product should have incorporated the material accessed from the MLS[66]. Along with these two conditions, the product shall not be available without restriction to others for further research and breeding[67]. If these three conditions are satisfied, the recipient is required to pay 1.1 % of

[63] *Id.* Article 6.5(a) & 6.6
[64] *Id.* Article 6.5(b)
[65] *Id.* Article 6.5(c) & (d)
[66] *Id.* Article 6.7
[67] *Ibid.*

the sale of the product to the benefit sharing fund of the ITPGRFA[68]. Annex 2 of the sMTA specifies three instances where the recipient is not bound to make payments; (i) when the product is available without restriction (ii) when the recipient has purchased the product from a person who has already made payments with respect to the product or who is exempt from making payment on the first ground mentioned above and (iii) where the products are sold or traded as commodity. Even if the material is accessed through two or more sMTAs, only one payment is due to the MLS[69] and the recipient has to submit an annual report before the GB setting forth the sale of the products for the twelve month period ending on December 31st, the amount of the payment due and information that allows for identification of any restrictions giving rise to benefit sharing payment[70]. Payment due to the GB is to be deposited in the ITPGRFA ï Benefit Sharing Fund of the FAO trust Fund[71]. It is not specified how long the payments are due to the Benefit Sharing Fund and it is assumed that payments are due till the product becomes available without restriction. If the product commercialised is available without restriction to others, the recipient is encouraged to make voluntary payments to the GB through the benefit sharing fund[72]. The sMTA mandates to make available to the MLS all non-confidential information resulting from research and development carried out on the material and encourages sharing of the non-monetary benefits through the MLS[73]. After expiry of IPR protection over a product developed out of the Treaty system, the recipient is encouraged to place a sample of the product in the MLS for research and breeding[74]. Transfer of IPR over the products resulting from the

[68] *Id.* Article 6.7 r/w Annex 2 para. 1
[69] *Id.* Annex 2 para.2
[70] *Id.* Annex 2 para. 3
[71] *Id.* Annex 2 para. 4
[72] *Id.* Article 6.8
[73] *Id.* Article 6.9
[74] *Id.* Article 6.9

MLS access to third parties would involve the transferring of the benefit sharing obligations too[75].

4.3.3 (i) Availability without Restriction

The benefit sharing obligations under the ITPGRFA requires careful scrutiny. The paramount consideration for benefit sharing is the availability of the product for research and breeding. If the product is not available without restriction for further research and breeding, then the recipient incurs the duty to share the benefits. The phrase ôavailable without restrictionô is defined by the sMTA as availability for research and breeding without any legal or contractual obligations or technological restrictions that would preclude using it in the manner specified in the Treaty[76]. Starting point of the benefit sharing obligation is the formation and commercialization of a product. Product is defined as PGRFA that incorporate the material or any of its genetic parts or components that are ready for commercialization, but does not include commodities and other products used for food, feed and processing[77]. Commercialization is the selling of the product/products in the open market for monetary consideration and does not include transfer of PGRFA under development[78]. Now falling back to the phrase, ôavailable without restrictionô, such restrictions can be legal, contractual or technological[78(a)]. Legal restrictions on access can be in place due to patents and PBRs. Patents can install access restrictions due to the monopoly rights conferred by them, keeping in mind that some jurisdictions do not allow research exceptions for patent rights. But in the context of PBRs, there are express exceptions for research and breeding and the interpretation of many

[75] *Id.* Article 6.10
[76] *Id.* Article 2
[77] *Ibid.*
[78] *Ibid*
[78(a)] *Supra* n.45(a) at p.154

of the scholars is that it will not prevent the facilitated access[79]. But there is yet another version for this interpretation. It is argued that the UPOV 1991 breedersô right do not literally limit access to PGRFA for further research and breeding. But facilitated access is not intended solely for the formal breeding sector. The informal breeding sector of farmers also is eligible for access to the MLS. In the 1991 UPOV, it is optional for a Member Country to restrict the breedersô rights for the interest of the farmers. A country can permit the farmer to use on their own holdings, the product of harvest obtained by planting the protected variety or essentially derived varieties and varieties which are not clearly distinguishable from the protected varieties[80]. The informal sale, offer for sale and exchange of the protected varieties is outside the scope of the farmersô privilege as permission is limited to use in their own holdings. If a country is not providing such exception to farmers, then there is a visible access restriction which can *per se* trigger the responsibility to share the benefit[81]. The language of the ITPGRFA justifies this argument by specifying the measures to promote sustainable use of PGRFA. Such measures may include fair agricultural policies promoting the development and maintenance of diverse farming systems enhancing the sustainable use of agricultural biodiversity and other natural resources; research enhancing and conserving biological diversity by maximizing intra and inter-specific variation for the benefit of farmers who generate and use their own varieties and apply ecological principles in maintaining soil fertility and combating diseases, weeds and pests; promotion of plant breeding efforts to strengthen the capacity to develop varieties adapted to social, economic and ecological conditions with the participation of farmers in developing countries; broadening the genetic base of crops and increasing

[79] *Supra* n.2, p.12. Also see *supra* n.45(a) p.149

[80] The International Convention for Protection of New Plant Varieties, 1991 Article 15.2

[81] Claudio Chiarolla and Stefan Jungcurt, ñOutstanding Issues on Access and Benefit Sharing under the Multilateral System of the International Treaty on Plant Genetic Resources for Food and Agricultureò, Background Study Paper, The Development Fund& The Bern Declaration, March (2011), p.47

the range of genetic diversity available to farmers; promotion of the expanded use of local and locally adapted crops, varieties and underutilized species; supporting the wider use of diversity of varieties and species in on-farm management, conservation and sustainable use of crops and creating strong links to plant breeding and agricultural development in order to reduce crop vulnerability and genetic erosion and promote increased world food production compatible with sustainable development etc[82]. The restrictions imposed by the UPOV to save, sell and exchange the harvest is opposed to the farmersô rights as well as the sustainable use of PGRFA, thereby hindering the facilitated access and therefore attracts benefit sharing obligation.

The issue of restrictions caused by patenting is more complex. The benefit sharing obligation is resultant to commercialization of the product that incorporates the material accessed from the MLS or its genetic parts or components. This should be read along with the obligation of the recipient not to obtain any IPR that limit facilitated access to the material or its genetic parts or components in the form received from the MLS. The reception of IPR hindering access to PGRFA and its genetic parts or components is prevented on the one hand while some kind of restrictions is permitted. A plain reading of these two obligations may seem contradictory. The basic question is can there be IPRs triggering benefit sharing without violating the restriction on acquisition of IPRs on PGRFA in the form received and their genetic parts or components. One could argue that when there is a mandate negating IPR over the PGRFA covered by MLS through the construction ómaterial in the form received from the MLSô, the ITPGRFA intends to specify that there is total ban of IPR over the materials covered in the MLS. The extended restriction to genetic parts or components of the PGRFA covered in the MLS creates much ambiguity. Considering the general

[82] *Supra* n.27, Article 6.2

practice of seed banks to provide access only to seed samples called accessions- distinct, uniquely identifiable samples of seeds representing a cultivar, breeding line or population, maintained in storage for conservation and use ï some scholars opine that the expression ógenetic parts and components in the form receivedô should correspond to the concept of óunmodified derivativesô ï all substances created by the recipient that constitute an unmodified functional subunit or product not changed in form or character and expressed by the provided material[83]. This interpretation would justify that unmodified derivatives include genetic components and gene sequences obtained from the MLS through isolation and purification[84]. This results in the conclusion that isolation and purification of gene sequences and gene components of the PGRFA of the MLS will not qualify for patent protection. The repeated use of this phrase in the body of the ITPGRFA vis-à-vis the sMTA logically tempts us to conclude that the unmodified derivatives of the PGRFA covered in the MLS is outside the scope of patent protection. So the primary question will be the possible modifications that could attract patent protection and the incorporation requirement solves the issue substantially. The incorporation requirement provides that the product should have incorporated the material from the MLS or it genetic parts or components. It means incorporation of the material in the product which may create a restriction on the availability of the product itself is permissible under the system while it will not allow a restriction on the availability of the MLS material, or its genetic parts or components. To be clear, if the incorporation of the material in the product itself can create limitation on availability of the MLS material or its genetic parts or components, such incorporation will not qualify for patent protection.

[83] *Supra* n.81, p.49
[84] *Ibid.*

Apart from the legal restrictions, contractual and technological restrictions can also hinder facilitated access to the MLS, creating an obligation to share the benefits. Contractual restrictions arise from certain licensing practices. Claudio Chiarolla cites Monsantoôs practice as an example of access restriction wherein it licenses its insect resistant technology to producers who are obliged to sublicense the technology to customers with certain restrictions[85]. Especially, seeds cannot be saved from one yearôs crop to sell or give to others or to plant another crop. Buyers are also barred from doing research on seeds[86]. This is clearly an access restriction that attracts benefit sharing. As regards technological restrictions, commercialization of products like cytoplasmic male sterile (CMS) varieties[87], hybrid varieties[88] and varieties that incorporate genetic use restriction technologies (GURTs) would bring in benefit sharing obligation[89]. This is based on the general idea that non-reproductive seeds produce access restriction to breeders and especially to farmers[90].

[85] *Supra* n.47, p.5
[86] *Id.* p.12
[87] Cytoplasmic male sterile varieties are the result of a particular type of three-way cross that prevents the female parent from being selfed because it is male sterile (i.e. it does not produce functioning pollen). In order to pollinate the female parent, a restorer is needed (R), which is genetically the same as the CMS mother, except for the male sterile cytoplasm ï i.e. the restorer is not sterile and produces viable pollen. The progeny that is obtained as a result of this first cross (F1 generation) is identical to the CMS mother. The cytoplasmic male sterility rests in the cytoplasm ï that is to say, under extra nuclear genetic control ï and is always inherited from the mother. By further crossing the male sterile plant (F1) with a fertile plant A, a commercial hybrid can be obtained (F2 generation). The result is that access to the parents (F1) of a commercial hybrid (F2) does not allow for recreating commercial hybrid seeds, because the CMS line must be maintained by repeated crossing with the restorer line R.
[88] Conventional hybrids are generally deemed not to restrict access for research and breeding, because, in theory, their genetic composition is freely available. However, if a breeder does not have access to the parental lines, it is very complicated to use hybrids as the basis for further development. Thus, hybrids limit on-farm breeding and effectively prevent farmers from using the material for selection and breeding and also ï to a large extent ï from replanting farm-saved seeds
[89] *Supra* n.81, p.43-44
[90] *Ibid.*

After the expiry of the term of protection over the product that incorporates the material acquired from the MLS, the recipient is encouraged to place a sample of the product into a collection that is part of the MLS for further research and breeding[91]. Similarly, when a recipient obtains IPRs over a product that has incorporated the material or its genetic parts or components derived from the MLS assigns such rights to a third party, it will result in the transfer of his benefit obligations too to the third party[92]. It means the obligation is not applicable when the transfer relates to the material in the form received and also to the PGRFA under development. It relates only to a finalised product covered by IPR being commercialised.

4.3.3 (ii) Incorporation of Material in the Form Received

Again, we need to analyse the obligation to share the benefits which starts at the commercialization of a ñproductò that incorporates the material from the MLS or its genetic parts or components. So the product need not be completely derived from the MLS, the requirement is that the material or its genetic parts or components should have been incorporated in the product. So it gives us the possibility that the recipient can use patented materials or patented technologies that are outside the MLS in conjunction with the MLS material or its genetic parts or components which could cover unmodified derivatives and progenies which results in the final product[93]. So, the patent protection offered to the material or technology outside the MLS could be extended to the resultant product. This is an ideal situation which can instigate sharing of benefits without violating the MLS conditions. But the practice of most of the CGIAR centres is not in this line. The guidance provided to them elaborates that

[91] *Supra* n.48, Article 6.9
[92] *Id.* Article 6.10
[93] *Ibid.*

ñWhere a variety or gene is protected by certain forms of patent, the material may not be available without specific authorization from the breeder. If the recipient ó[é] use germplasm of crops listed in Annex 1 of the Treaty [é] AND [é] breed a new PGRFA product AND [é] commercialize that product, AND [é] take out a patent on that product that restricts the further use of that product by others for research or breeding, or otherwise take legal or technological measures that restrict the further use of that product by others for research or breeding, then [those recipients] will be required to make a payment to the international fund established by the Treatyôò[94]

The Guidelines make no distinction between the patenting of materials *per se* from the MLS and other patent related restrictions that can activate benefit sharing[95]. The ITPGRFA has not yet made any clarification in this regard and this issue continues as a grey area.

4.3.3 (iii) Voluntary Contributions

When the product commercialized is available without restriction, the recipient of the material from the MLS is not bound to share the benefits though he is encouraged to share the benefits. So the logical deduction is that every product resulting from the MLS access does not call for benefit sharing. In the CBD context, any benefits resulting from the facilitated access is to be shared with the provider. When a product is commercialized, monetary benefits evolve out of the same which are to be shared under the mandate of the CBD. If the ITPGRFA allows that benefits arising from the commercialization of a product that is available without restriction need not

[94] *Supra* n.91, p.49
[95] *Ibid.*

be shared, its justifiability is a fundamental issue to be clarified in the light that the ITPGRFA seeks to create harmony with the CBD.

As already seen, the definition of the term product does not include commodities and other products used for food, feed and processing. Commercialization is the selling of a product in the open market for monetary consideration. When a product is available without restriction, there will not be any legal, contractual or technological restrictions limiting its availability for research and breeding. Thus, commodities and products used for food/feed and processing are available to the public for consumption upon payment. Similarly, the product that calls only for voluntary contributions is available to the public only for the purposes of the ITPGRFA, i.e. for research and breeding. So availability without restriction does not mean availability of the product at no or minimal cost for further research and breeding. Even for the purpose of research and breeding, one has to purchase the product by making payment. Thus, ultimately the ITPGRFA is recognising the private property right created by IPR over the MLS materials without calling for any benefit sharing obligation. This is because for the creation of the MLS, the parties are making a common pool of resources, transferring their sovereign claims for the purpose of research and breeding where the recipient need not pay or is required to pay only the minimum cost involved. Here access is facilitated for making the resultant products available without restriction and it calls for sharing of benefits on creation of restrictions. The grave set back of the ITPGRFA is that it permits benefit sharing only at the cumulative happening of commercialization, incorporation and restricted availability of the resultant product unlike the CBD/Nagoya system where all instances of commercialization will trigger benefit sharing. This narrows down the scope of benefit sharing under the ITPGRFA when compared to the CBD, especially taking into account the

possibilities of evading benefit sharing even though IPR is taken. Eventually, it will lead to the same misappropriation the CBD wants to stop.

4.3.3 (iv) Alternative Payment Scheme

The development of a product out of the MLS usually takes a minimum of 10 years and this will substantially affect the initial flow of benefits to the MLS as the recipients are not required to make payments during this term[96]. In order to deal with this issue, the ITPGRFA has introduced an innovative alternative payment scheme which can offer immediate flow of financial resources to the benefit sharing fund[97]. A recipient has to specifically opt for this scheme when he signs the sMTA. If this scheme is opted, the recipient will not be bound by the compulsory payment scheme during the period of validity of the option on the commercialisation of a product incorporating a material or its genetic parts or components obtained from the MLS. An option for this scheme is valid of a period of 10 years and is further renewable[98]. If the alternative payment scheme is voluntarily chosen, the recipient has to pay the discounted rate of 0.5% of the sale of any product belonging to the same crop species obtained from the MLS in return for the access[99]. The payment is to be made irrespective of whether or not the material is available without restriction. For further accessions done on the same crops with additional sMTAs, the recipient will be relieved from the obligation to pay[100]. It means only one payment is needed for the same crop species of the Annex I PGRFA. To illustrate more clearly, if X who has opted for this scheme has accessed the crop ôBrassica complexô which comprises more than 10 genera[101], irrespective of the number of sMTAs he has entered into for accessing each

[96] *Supra* n.47, p.5-6
[97] *Ibid.*
[98] *Supra* n.48, Article 6.11(b)
[99] *Id.* Article 6.11(a) r/w sMTA Annex 3
[100] *Id.* Article 6.11(f)
[101] *Id.* Annex 1

of these genera, only one payment that too for the initial genera he had accessed will exonerate his benefit sharing obligation. His benefit sharing obligation has to be satisfied from the sale of any product belonging to the crop complex obtained from the MLS. So he need not wait for the result of his research to come out to satisfy his benefit sharing obligation. If he is already selling any product belonging to any genera of that crop complex, he can start making payments from the sale of such products. When the period of validity of this option expires, the recipient is required to make payments to the Trust Fund in respect of any products incorporating the material obtained from the MLS developed during the period of the option when such products are not available without restriction[102]. But the rate of payment will be 0.5% instead of the 1.1% under the compulsory payment scheme. If the alternative payment scheme is not specifically opted, the recipient will be governed by the compulsory payment scheme under Article 6.7 of the sMTA. In case of transfer of PGRFA under development, the transfer shall be made on the condition that subsequent recipient shall pay to the GB 0.5% of the sale of any product derived from such PGRFA under development, whether the product is available with or without restriction[103]. One of the most attractive features of this system is that when a recipient opts for this scheme, single payment in respect of a crop is needed in relation to all the sMTAs for all the PGRFAs belonging to that crop[104]. The alternative payment scheme was proposed by Africa and was claimed to be simple, transparent and reducing monetary cost[105]. It also promotes voluntary contributions to the trust fund. The discounted rate offered and the single

[102] *Id.*Article 6.11(g)
[103] *Id.*Annex 3 para, 3
[104] *Id.*Annex 3 para. 4&5
[105] *Supra* n.47, p.6

benefit sharing obligation in respect for all the PGRFA in a crop species makes the scheme attractive to recipients[106].

4.4 Benefit Sharing to Farmers: Mechanism under the ITPGRFA

In the benefit sharing clause of the ITPGRFA, access to PGRFA itself is considered as a benefit and the benefits accruing there from are to be shared fairly and equitably as per the provisions of the Treaty[107]. The benefit sharing mechanisms under the Treaty include exchange of information[108], access to and transfer of technology[109], capacity building[110] and sharing of benefits arising from commercialization[111], under the guidance of the GB in

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[106] *Ibid.*

[107] *Supra* n.27, Article 13.1

[108] *Id.* Article 13.2 (a) All available non-confidential information encompassing catalogues and inventories, information on technologies, results of technical, scientific and socio-economic research, including characterization, evaluation and utilization regarding PGRFA covered under the MLS is to be made available as per the applicable laws and national capabilities through the Global Information System established under the Treaty.

[109] *Id.* Article 13.2(b) Access to technologies including those that could be transferred through genetic material should be facilitated and access to these technologies and the improved varieties must be in conformity with applicable property rights and national laws and in accordance with national capabilities. For access to and transfer of technology to developing countries and countries with economies in transition, measures such as establishment and maintenance of, and participation in, crop-based thematic groups on utilization of PGRFA, all types of partnership in R&D and in commercial joint ventures relating to the material received, human resource development and effective access to research facilities should be carried out. Access to and transfer of technologies including those protected by IPR should be under fair and most favourable terms including concessional and preferential terms as mutually agreed through partnerships in R&D and must be adequate and consistent with effective protection of IPR.

[110] Capacity building needs to be carried out taking into account of the needs of the developing countries and countries with economies in transition and priority should be given to (i) establishing and/or strengthening programs for scientific and technical education and training in conservation and sustainable use of PGRFA, (ii) developing and strengthening facilities for conservation and sustainable use of PGRFA in particular in developing countries and countries with economies in transition and (iii) carrying out scientific research and developing capacity for research in fields where they are needed.

[111] Commercial benefit sharing is through the involvement of public and private sectors through partnerships and collaboration and the standard material transfer agreement has to contain a requirement that the recipient who commercialized a product developed from a material through the MLS shall pay to the mechanism for utilization of financial resources established under Article 19.3 (f) an equitable share of the benefits arising from commercialization of that product if it is not available without restriction for further research and breeding. If it is available without restriction for research and breeding, then the recipient who commercializes shall be encouraged to make such payment.

accordance with the priority areas established under the rolling Global Plan of Action[112]. The benefits arising from the use of PGRFA through the MLS shall flow primarily, directly and indirectly to farmers in all countries, especially developing countries and countries with economies in transition who conserve and sustainably utilize PGRFA[113]. The Funding Strategy to be adopted by the GB under Article 13.4 would help to formulate the relevant policy and criteria for specific assistance in relation to conservation and sustainable use of PGRFA in developing countries and countries with economies in transition[114].

For the implementation of the Treaty objectives, Article 18 of the ITPGRFA mandates its CPs to formulate a funding strategy with the objectives to enhance the availability, transparency, efficiency and effectiveness of the provision for financial resources to implement activities under the Treaty[115]. The aims of the Funding strategy are to develop the ways and means by which adequate resources are available for the implementation of the Treaty and the transparent, efficient and effective utilization of all resources made available under the funding strategy, consistent with the Treaty and other international instruments[116]. The potential resources available under the Funding Strategy are (a) financial resources provided by CPs that are developed countries which are to be availed by CPs that are developing countries and countries with economies in transition through bilateral, regional and multilateral channels; (b) financial resources for priority activities, plans and programs relevant to the implementation of the Treaty provided by relevant international mechanisms, funds and bodies; (c) financial resources for national activities

[112] *Id.* Article 13.2
[113] *Id.* Article 13.3
[114] *Id.* Article 13.4
[115] *Id.* Article 18 r/w IT/GB-1/06/Report Appendix F, Funding Strategy for Implementation of the International Treaty on Plant Genetic Resources for Food And Agriculture, para. 1
[116] *Id.* Para. 2

for the conservation and sustainable utilization of PGRFA in accordance with the national capabilities and financial resources of each CPs; (d) financial resources resulting from sharing of monetary benefits arising from the commercial utilization of PGRFA; (e) voluntary contributions from CPs, private sector, non-governmental organizations and other sources; and (f) financial resources provided through the Regular Program of FAO[117]. Out of this, resources (d) to (f) constitute resources under the direct control of the GB and (a) to (c) constitute resources not under the direct control of the GB[118]. The extent to which CPs that are developing countries and countries with economies in transition implement their commitment will largely depend on the effective allocation of funds by developed country CPs[119]. The initial priorities for allocation of funds under the direct control of the GB are (i) information exchange, technology transfer and capacity building[120], (ii) managing and conserving PGRs on farm[121] and (iii) sustainable use of PGR[122]. Operational procedures for the use of resources under the direct control of the GB involve opening a call for proposals, submission of pre-proposals, screening and response to pre-proposals, submission of project proposals from approved pre-proposals, appraisal of project proposals, approval of projects for funding within the project cycle, disbursement,

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[117] *Ibid.*

[118] Funding Strategy for Implementation of the International Treaty on Plant Genetic Resources for Food and Agriculture, IT/GB-1/06/Report Appendix F para. 6&11

[119] *Supra* n.27, Article 18.4 (b)

[120] Funding Strategy for Implementation of the International Treaty on Plant Genetic Resources for Food and Agriculture, IT/GB-2/07/Report, Appendix D1 Draft Priorities. It reflects priority activities 15 & 19 of the rolling Global Plan of Action. Building strong national programs is essential for capacity building in developing countries and furthering the implementation of the treaty. Expanding and improving education and training in developing countries is a sine qua non in order to build capacity.

[121] *Ibid.* It reflects priority activity area 2 of the Global Plan of Action. Supporting on farm management and conservation of PGRFA is the most direct way of reaching farmers, indigenous and local communities in developing countries to whom the benefits should flow. It forms a strong contribution to the maintenance of on-farm diversity of PGRFA. Only by strengthening these efforts can on-farm diversity contribute to ex-situ conservation.

[122] *Ibid*. Reflecting GPA priority area 9, 10 &11. involves expanding the characterization and evaluation of collections.

reporting and monitoring and independent evaluation[123]. Selection criteria is based on the project relevance, feasibility, effectiveness and efficiency, benefits and beneficiaries, team composition and capacity, collaboration, planning and monitoring, sustainability, geographic extension and crop relevance[124]. In order to get eligible for the use of resources under the direct control of the GB, the projects must meet the objectives of the International Treaty, fall within the priority areas established from time to time by the GB, benefit CPs that are developing countries, and be presented through the CP(s) concerned[125].

Some projects have been selected by the GB under its benefit sharing scheme from the voluntary contributions made by Norway, Italy, Spain and Switzerland[126]. Out of them, the Costa Rican project relates to testing useful potato genetic material for its ability to adapt to climate change[127]. The aim is to develop varieties with tolerance to stress by exploiting the existing biodiversity of potato[128]. The Cuban project aims at deepening the conservation of maize seed and beans, to determine how much diversity exists and what nutrient inputs are necessary to ensure food security and biodiversity conservation. The goal is to develop molecular techniques to characterise the diversity covered in target communities. It also includes workshops on management and purchase of quality seeds, efforts to determine the impact and efficacy of traditional storage methods and identify the nutritional composition and food consumption and resulting impact on the family diet[129]. The two year project proposed by Egypt will integrate farmers into a national PGR system, supporting conservation of citrus agro-

[123] Supra n.120, Appendix D.3 Operational Procedures for the Use of Resources under the Direct Control of the GB
[124] *Ibid.*
[125] *Id.* Appendix D.2, Eligibility Criteria for the Use of resources under the Direct control of the GB
[126] www.planettreaty.org
[127] *Ibid.*
[128] *Ibid.*
[129] *Ibid.*

biodiversity maintained on-farm in partnership with farmers, local communities and NGOs. The objectives of the Kenyan project are to improve finger millet productivity using improved genotypes and to arrest the decline of finger millet production in western Kenya. To promote revitalisation of finger millet farming, selected varieties or lines will be multiplied using farmers and women groups in Western Kenya. Dissemination of selected varieties and better processing techniques will be done in participation with the farmers. The Nicaraguan project is based on a participatory approach, working with farmers to produce sustainable products and services that generate additional income to rural families without endangering the habitat of ecosystem and while creating a culture of preservation of the species teocintle and its relatives. The Peruvian project seeks to enhance the capacity of six communities of potato parks in the management, conservation and sustainable use of agrobiodiversity, enhance the resilence of the local agroecosystem, food sovereignty, promote the development of a creative economy based on the sustainable use of the native crops and TK and support the national implementation of the Treaty in a responsible manner. The Senegal project aims at the conservation of agrobiodiversity in millet, maize and sorghum. The project proposes to conduct more research to strengthen and preserve biodiversity, promote increased use of varieties adapted to local conditions and broaden the genetic base and increase the diversity of genetic material available to farmers. The Tanzanian project plans to produce seeds of new and old wheat varieties and identify the most promising for wider distribution, involving farmers in evaluating and identifying varieties that perform better in their fields. Farmers will be trained in processing and marketing quality wheat seed with a goal to provide wider access to small and medium size farms. The Uruguay project is one to expand the genetic base of the varieties of potato planted in the region through the introduction of genes from wild relatives of potato. The objective is to increase the genetic variability of potato germplasm. One

project is sanctioned to India which relates to cultivation and dissemination of some locally developed and traditionally bred varieties of crops such as cassava, yam and ash gourd and species such as pepper, cardamom and nutmeg. It is sanctioned to the NGO, Peermade Development Society which has collaborated with the Central Tuber Crops Research Institute which provides training in developing value-added products from such crops and species. In this process, 80% of the project participants are local women in Idukki District of Kerala. Anyway, the present study does not aim to ascertain the practical issue how far all the benefits reach the farmers directly, indirectly and ultimately.

4.5 Compliance and Dispute Settlement

Article 21 of the ITPGRFA provides that there should be cooperative and effective procedures and operational mechanisms to promote compliance with the provisions of the Treaty and to address issues of non-compliance. Under this mandate, through the resolution of March 2011, the ITPGRFA had adopted the procedures and operational mechanisms to ensure compliance. In the resolution, the GB approved the procedures and affirmed that they are separate from any other procedures and mechanisms[130]. The objective of the procedures is to promote compliance with all the provisions of the ITPGRFA and to address issues of non-compliance. The procedures and mechanisms shall be based on the principle that they should be simple, cost-effective, facilitative, non-adversarial, non-judicial, legally non-binding and co-operative in nature. Their operation shall be guided by the principles of transparency, accountability, fairness, expeditiousness, predictability, good faith and reasonableness. The task of compliance is entrusted with the Compliance Committee which has to pay particular attention to the needs of

[130] IISD, Summary of the Fourth Session of the Governing Body of the International Treaty on Plant Genetic Resources for Food and Agriculture, 14-18 March 2011, *Earth Negotiation Bulletin* vol.9 No.550 Monday 21 March (2011), p.5

parties that are developing countries and countries with economies in transition. The Compliance Committee shall consist of a maximum of 14 members elected by the GB on the basis of two nominations from each of the seven FAO regions and the members will hold office for a period of four years.

The functions of the Committee are consideration of information submitted related to compliance and non-compliance; offering advice or assistance to any party on compliance-related issues, assisting the GB in monitoring ITPGRFA implementation; addressing issues of non-compliance; addressing statements and questions concerning ITPGRFA implementation; and submitting a report to each GB session. Consideration of any questions related to interpretation, implementation or compliance with the sMTA by Parties or potential parties to it is excluded.

The ITPGRFA envisages a binding dispute settlement mechanism for the disputes relating to the MLS. Though the sMTA is entered into between the provider and the recipient, there are no corresponding rights and duties between them. The flow of benefits from the access provided also does not directly reach the provider. Consequently, the CPs may not show any interest in initiating legal proceedings against the violation of the terms of the sMTA. Therefore the FAO of the UN is designated as the third party beneficiary under the sMTA which has the right to initiate dispute settlement procedures regarding the rights and duties of the providers as well as the recipients[131]. The FAO will also have the right to request appropriate information regarding subsequent MTAs entered into by the providers and recipients[132] together with information allowing identification of any restrictions giving rise to benefit sharing payment. Chiarolla cites the inclusion of third party beneficiary as totally unique and without any

[131] *Supra* n.48, Article 8(1) &(2)
[132] *Id.* Article 4.5

precedents in international law[133]. The *locus standi* of the FAO provides it with the capacity to uphold the interests of the MLS.

The disputes arising from the sMTAs shall be resolved first by amicable dispute settlement where the parties have to attempt in good faith to resolve the dispute by negotiation[134]. If the dispute is not resolved through negotiation, the parties may choose mediation through a neutral third party mediator as mutually agreed[135]. If the dispute continues after mediation, any party can submit the dispute for arbitration under the Arbitration Rules of an international body as agreed by the parties. Upon failure of this arrangement, the dispute has to be finally settled through the Rules of Arbitration of the International Chamber of Commerce and the result of such arbitration will be binding[136].

Thus, what becomes visible from the compliance and dispute settlement mechanism under the Treaty is that they are quite unrelated to each other. The compliance mechanism propounded by the ITPGRFA is only in respect of the provisions of the ITPGRFA and not with respect to the terms of the sMTA. That part has to be taken care of by the FAO which is the third party beneficiary under the Treaty. The procedure for the same is not yet elaborated by the ITPGRFA.

4.6 Interfaces between IPRs and PGRFA under the ITPGRFA

The interaction of the ITPGRFA with IPRs is a crucial point of discussion although most points falling under this head are already analysed in different sections of this chapter. The IPR-ITPGRFA interface could be seen at three instances in the ITPGRFA, two of them directly and one indirectly. The first instance is the negative mandate in respect of acquisition

[133] *Supra* n.47, p.7
[134] *Supra* n.132, Article 8.4(a)
[135] *Id.* Article 8.4(b)
[136] *Id.* Article 8.4(c)

of IPRs limiting facilitated access to materials, their genetic parts and components in the form received from the MLS. The second case relates to access to PGRFA respecting the IPR and other rights over them. The final obligation relates to the benefit sharing clause which talks about the obligation to share the benefits upon the commercialization of a product incorporating the MLS material, where the product is not available without restriction. All the three instances are adding to the complexity involved in the interface between IPR and GRs in general and such complex issues discussed above are not repeated here. Ambiguity prevails over so many fundamental issues in this regard. It is not clear whether IPRs could be obtained over the materials covered in the MLS. Again, there is no answer to the question if IPRs can be obtained, what is the scope of such acquisition. Further it is not clear whether all acquisition of IPR triggers the benefit sharing obligation or is it confined only in cases of non-availability. Yet another fundamental question is regarding the notion of non-availability which does not mean access at no or minimal cost. The confusions and contradictions created at the interception of IPRs can very well facilitate misappropriation. The interface with IPRs is a grey area in the ITPGRFA and it does not effectively address the concerns of misappropriation as well as benefit sharing. It appears that the ITPGRFA would have been more stronger if the benefit sharing obligation is triggered at all instances of commercialization as well as all instances of acquisition of IP instead of the cumulative occurring of the triple requirement of incorporation, restricted availability and commercialization.

4.7 Farmers Rights

It is recalled here that the third mandate for the revision of the IUPGRFA as per the FAO resolution 7/93 was the realization of farmersô rights. In furtherance of this, the ITPGRFA recognises the enormous and continuing contributions of the local and indigenous communities and

farmers of all regions of the world, especially those in the centres of origin and crop diversity for the conservation and development of PGRs, and provides that such contributions form the basis of food and agricultural production throughout the world[137]. It further provides that the responsibility of realizing farmersô rights vis-à-vis the PGRFA rests with the national governments in accordance with the needs and priority of the farmers and subject to national legislation[138]. The measures to protect and promote farmersô rights include protection of TK relevant to PGRFA, right to equitably participate in benefit sharing from the utilization of PGRFA and the right to participate in decision making at the national level on matters related to conservation and sustainable use of PGRFA[139]. The provision reaffirms that nothing in it shall be interpreted to limit any rights farmers have to save, use, exchange and sell farm saved seed/propagating material, subject to national law and as appropriate[140]. In the preamble, it is provided that all the recognised rights under the ITPGRFA (right to save, use, sell and exchange farm saved seed/propagating material, right to take part in decision making and right to equitable share of the benefits) are fundamental to the realization of farmersô rights at the national and international levels. The right holders are the farmers and farming communities at the centres of origin or crop diversity[141].

Under the framework of the ITPGRFA, farmersô rights are subject to national laws. The Treaty talks about the rights only in a conceptual level and does not elaborate the niceties of the same. We cannot readily elucidate the nature and scope of farmersô rights under the Treaty. From the body of the Treaty, it is clear that the farmersô rights include the right to save, use, sell and exchange farm saved seed/ propagating material, the right to protect

[137] *Supra* n.27, Article 9.1
[138] *Id.* Article 9.2
[139] *Ibid.*
[140] *Id.* Article 9.3
[141] *Id.* Preamble

TK, right to take part in decision making and the right to have equitable share of the benefits. So their rights relate to the knowledge they hold and the practices they follow. Even though the contributions date back to centuries and are still continuing, the rights are made subject to national laws and other international norms quite unrelated with their evolution and development. So it is for the Nation States to decide the nature and scope of farmersô rights within their respective jurisdiction. The ITPGRFA gives no clue as to what should be the content of such rights and whether such rights fall into the category of IPRs. In the IUPGRFA, the farmersô rights were coined as a way to reward the contributions of the farmers though this phrase is not present in the ITPGRFA. The logic of IUPGRFA takes us to the reward and incentive theory of IPRs[142]. Though the wordings of the Treaty demand a higher construing of the rights rather than as a moral obligation and an equitable right[143], it does not set any ways and means to achieve the same.

The ITPGRFA background depicts an ironical relationship between the farmersô rights and IPRs. The IP counterpart of the farmersô rights is prominently PBRs. The propositions in the ITPGRFA that farmersô rights are subject to national laws and that the ABS system under the MLS should respect the IP and other property rights on materials covered by the MLS undermine the farmersô rights. In the national level, a Member State has to consider three elements in the implementation of farmersô rights, namely national priorities, national laws and international obligations. Usually, the national laws reflect national priorities. For developed countries, the national priorities and national laws would normally reflect stronger protection of IPRs and less consideration to farmersô rights. This is because the whole private IP regime over the living resources is the creation of developed

[142] Supra n.3, p.289
[143] Carlos M. Correa, ñOptions for the Implementation of Farmers' Rights at the National Levelò, South Centre Working Paper, December 2002

countries. Actually, the evolution of farmersô rights is considered as a means to counterbalance the inequitable property rights over PGRs[144]. Most of the national laws permit patenting over GRs, gene sequences and DNAs. So national priorities and national laws do not seem to bring in the effective implementation of farmersô rights. Implementation of farmersô rights through national laws by developing countries, setting forth the achievement of the same as a national priority, is not yet in motion and so we have to wait and see how countries are taking up the issue domestically. Yet another ironical thing is that the ITPGRFA itself weakens the realization of farmersô rights through ambiguous propositions in relation to IP paving way for interpretation resulting in strong IPR protection. The divide between the developing countries and developed countries over IPR issues is not settled in the IT. This divide will be reflected in the national laws and national policies hindering the successful implementation of farmersô rights. So realization of farmersô rights in the midst of IPRs is rather a dream far from the reality.

4.8 Bilateral V. Multilateral: The Benefit Sharing Perspective

Finally, it would be interesting to have a comparison of the two available benefit sharing mechanisms under the ITPGRFA as well as the CBD/Nagoya. By comparing and contrasting, it could be seen that the former stands for a multilateral benefit sharing system while the latter is bilateral. To put in another way, both are different systems for management of GRs created using the sovereign right. In the multilateral system, the resources are managed internationally and the resultant benefits are shared collectively. The system evades all possibilities of individual ownership claims over the resources covered and the absence of reciprocal benefit sharing is a manifestation of this principle. In order to ensure compliance with the terms of access, the ITPGRFA system has the unique provision for

[144] *Supra* n.142, p. 295

designation of a third party beneficiary with *locus standi* to initiate legal proceedings. Considering the widely spread nature of PGRFA, the MLS provides a good mechanism to ensure easy access and benefit sharing, though with certain limitations. The success of ITPGRFA lies in facilitating access to a common pool of resources conditional to contractual terms. The contract is still bilateral, but the sharing of benefits is in a multilateral level. When compared to this, the bilateral mechanism of the CBD/Nagoya is a regime complex with unsettled ownership claims. The CBD system perpetuates ownership conflicts between nations, within the nations and among the individuals and communities. Unlike the inbuilt PIC and ABS regime of the MLS, the access itself is a complex issue in the CBD where ABS is a reciprocal process. In the ITPGRFA, the benefits to be shared are also definite while the CBD leaves it to bargaining. Similarly, the enforcement capability under the CBD system is weaker when compared to ITPGRFA as the obligation is vested with the State or the individuals or the communities as the case may be. Despite its many positive elements, the ITPGRFA could not act as a model suitable for all the ABS transactions on GRs. The widely spread nature of the PGRFA and their importance to food security is the motivating factor behind the conclusion of a legally regulated common pool of resources under the ITPGRFA. But in the CBD context, in most cases, there could be identifiable individuals or communities as custodians with substantial knowledge over the use value of the resources. A multilateral approach for benefit sharing in such instances is not justifiable. It should also be noted that the bilateral approach provides more benefits to the beneficiaries as they can be ascertained at different stages of the access, research and commercialization of the resultant products. A close look at both the systems also reveal that the CBD bears a high benefit sharing potential when compared to ITPGRFA as in the latter, the benefit sharing obligation is triggered upon the cumulative happening of specified conditions. But in the CBD, all instances of commercialization can generate

a benefit sharing obligation. These factors point to the fact that though the ITPGRFA is simple, easy and well-functioning, the same mechanism cannot be a tailor made solution to address the issues in respect of the CBD.

4.9 Conclusion

Conceptually, the ITPGRFA envisions an ideal common heritage regime for PGRFA in the process of ensuring ABS. It theoretically manifests all the features of a common heritage regime and is a bold attempt to initiate an internationally regulated easy access system of PGRFA. If effectively implemented, it would become a greatest achievement in the history of regulation of PGRs and ABS. The most fascinating features of the ITPGRFA are the free access system for research, breeding and training, the MLS system of benefit sharing through the sMTA, designation of third party beneficiary and farmersô rights. But the vague language of these components in the Treaty has made it a very shallow instrument. Though the ITPGRFA stands for free access, it is incapable of maintaining the same at all instances of access. Even though the sMTA sets out benefit sharing obligations, due to the possibility of varying interpretations, it creates chances of evading such obligations which has serious and far reaching ramifications which may question the very purpose of the Treaty itself. The question of IPRs in PGRs seems to be the most critical unresolved issue in the whole make-up of the Treaty system. The ambiguity in the relationship between IPRs and the ITPGRFA makes the Treaty very weak. The most sympathetic is the chance of legitimizing typical cases of misappropriation which the CBD wanted to stop. The proposition of farmersô rights though upheld as an inalienable right by the ITPGRFA, its attainment is a dream quite far away than the sky due to the tendency of the developed countries to offer stronger protection to the IPRs over PGRs. So the conclusion is that the difficult interface with IPRs prevents the ITPGRFA from achieving the task of effective, fair and equitable ABS process. Clear scrutiny of the ITPGRFA as well as the

Nagoya Protocol reveals that both the benefit sharing models collapse at the intersection of IPRs with GRs and associated TK. So, the next chapter deals with this interface between IP and GRs and associated TK.

Chapter 5

ABS: INTERFACE BETWEEN THE CBD AND IPRS

The long-cherished goals of the CBD as set out in Article 1 are conservation of biological diversity, sustainable use of its components and fair and equitable sharing of the benefits arising out of the utilization of GRs. The system envisaged to achieve these goals is contractual regulation of access to GRs[1] conditioned by PIC from the stakeholders of the resources together with MAT for benefit sharing[2]. The motivating factor behind the conclusion of the CBD as well as the major challenge in achieving its objectives is the prevention of misappropriation of GRs. Misappropriation could be understood in simple terms as obtaining GRs without taking consent from their custodians and also not in compliance with the requirements of the domestic law designed for regulating access. The range of misappropriation varies from taking the resources for commercial as well as non-commercial use and research without paying due diligence to the concerned regulatory laws. Notably, the CBD has never tried to mention anywhere the term misappropriation or the so-called ñbiopiracyò. It is also interesting to note that though it talks about conservation, the CBD operates on and elaborates mainly the commercial exploitation of biological diversity and its components. When it comes to notice that the GRs misappropriated could be enclosed and huge profits could be made using the strong private property regime of patent monopoly, the stakeholders who hold proprietary rights over the resources under the CBD mandate are completely thrown out of the picture. The nature of GRs is such that they could be easily taken out and transferred across the borders. Adding to this, its proprietary value is doubled by the knowledge associated with it regarding various uses and properties. It is quite interesting to see that many countries have established

[1] The Convention on Biological Diversity, 1992, Article 1
[2] *Id.* Article 15 (4) & (5)

their national access laws for preventing misappropriation and ensuring the CBD goals. But the general impression of the CPs to the CBD is that the national laws premised on the CBD alone cannot deter the persons against misappropriation, especially facilitated through the IP system which lacks corresponding obligation to respect the CBD objectives while granting patent rights to inventions based on GRs and associated TK. The present chapter deals with this highly conversed issue that attracts the attention of a multitude of international agencies.

Respecting the rights of holders of GRs and associated TK before using it is the central objective of the CBD and the principles of PIC and MAT are devices to this end. Regulation of access is directly related to sharing of benefits and instruments like ITPGRFA treats access to GRs itself as a benefit. The CBD intends that the benefit sharing aspect should not be undermined while dealing with GRs and associated TK. Use of GRs and associated TK generates maximum benefits when use is for research and development that results in patenting and subsequent commercialization of inventions. This is because the grant of patent confers a monopoly right on the patent owner to exclusively make, use and sell the product. This exclusive monopoly in the event of commercialization enables the patentee to derive huge returns in respect of his invention. So the benefits arising from patenting could be channelized to the owners of the GRs and TK involved in the invention. Thus obtaining a share of the benefits of patenting and subsequent commercialization of inventions using GRs and associated TK assumes much significance in the ABS process.

If we look at the instruments governing IPR that are crucial to GRs and associated TK, the TRIPS Agreement and the UPOV Convention are of profound importance. The TRIPS is an umbrella convention that lays down the minimum international standards of IPR protection to be offered in national legislations. TRIPS for the first time mandated patent protection for

inventions based on biological materials. GRs and associated TK constitute the raw materials for research and development to bring out new biotechnological inventions resulting in grant of patents. Hence grant of patents gets linked with the ABS process of the CBD. The UPOV Convention stands for protection of new varieties of plants where breeding of such varieties is done on PGRs which are the subject matter of the CBD too. So the possibility of ensuring benefit sharing conforming to the principle of PIC assumes much significance in the context of its relationship with IPR. Based on this proposition, the present chapter will explore the relationship between CBD and IPRs in the context of TRIPS and UPOV and enquire whether the relationship could promote the benefit sharing objective of the CBD. Since the interrelationship is between two different property regimes, the study will also help us to understand the practical issues and frictions that could arise at the operational and implementation levels of the two property regimes. Ultimately, the focus of the chapter is the issue of compatibility between the present IPR regime and the CBD mechanism in light of the findings in the previous chapters that when IPR interferes, the benefit sharing mechanisms under the CBD, the Nagoya protocol as well as the ITPGRFA fail to achieve their purported goals effectively. The chapter further probes deep into the compatibility issue by examining the contract-based ABS regime of the CBD.

5.1 Relationship between TRIPS and CBD – A Brief History of the Issue

TRIPS and CBD were negotiated almost simultaneously in point of time and shared similar concerns on different issues pertaining to patenting of biotechnological inventions[3]. During the negotiation of Article 27 of the

[3]See UNCTAD-ICTSD Project on Intellectual Property Rights and Sustainable Development, *Resource Book on TRIPs and Development*, Cambridge University Press, New York, USA, (2005) pp.388-412 Also see Committee on Trade and Environment on Environment and TRIPS in WT/CTE/W/8 dated 8 June 1995; Conference of the Parties to

TRIPS, the idea of extending patent protection to life forms or biotechnological inventions was highly contested[4] and equilibrium was set in Article 27.3 giving the parties the right to exclude from patentability plants and animals other than microorganisms and diagnostic and surgical methods for treatment of humans and animals. It also mandated to ensure some form of protection to plant varieties either through patents or through *sui generis* system and called for the review of Article 27.3(b) in 1999. Many writers consider the affirmation of national sovereignty over natural resources through the CBD as a response to the developments in the GATT in the area of IPR[5]. While negotiating the CBD, matters related to IPR came up for consideration, but there was no consensus as to how to link the two issues due to politico-economic reasons. The importance of the negotiations on TRIPS within the framework of Uruguay Round was also noted, but there was no agreement as to the link between the two negotiations. Impact of IPR over biodiversity was a major area of discussion during the negotiation of the CBD and the concern continues still though it is the end of the second decade after its adoption[6]. The wordings of the CBD strive to provide a delicate balance calling for the harmonious operation of the two instruments[7]. Immediately after the adoption of the CBD, in 1996 itself,

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the CBD, Environment and the TRIPS Agreement, Note by the Secretariat of the WTO, UNEP/CBD/COP/3/Inf.9 dated 4-15 November 1996

4 G. Kristin Rosendal (1999), ñBiodiversity: Between Diverse International Arenasò, in Helge Ole Bergesen, Georg Parmann, and Øystein B. Thommessen (Eds.), Yearbook of International Co-operation on Environment and Development 1999/2000 (London: Earth scan Publications), p. 39ï 47. The major opposition from the developing countries include: patents benefitting only economically and technologically strong countries, patenting of animal and plant varieties and food and pharmaceutical products raising serious concern for basic human needs, application of IPR system hindering transfer of technology to the developing world, probability that IPR system would disregard the very real contributions of generations of farmers to the worldôs plant genetic resources thereby threatening global food security etc.

[5] *Ibid*.

[6] The deliberations during the Nagoya Protocol is also containing references to IP aspects of biological diversity.

[7] *Supra* n.1, Article 16.5 ñThe Contracting Parties, recognizing that patents and other intellectual property rights may have an influence on the implementation of this Convention, shall cooperate in this regard subject to national legislation and international

some of the Member States of the CBD started expressing concern that the TRIPS Agreement and the CBD are inherently in conflict with each other which brought the matter before the Committee on Trade and Environment of the WTO[8].

The Committee on Trade and Environment (CTE) is a body of the WTO constituted under the 1994 Marrakesh Ministerial Decision on Trade and Environment[9], mandated to identify the relationship between trade and environmental measures. It aims to promote sustainable development and to make appropriate recommendations on whether any modifications are required in the provisions of the multilateral trading system, compatible with the open, equitable and non-discriminatory nature of the system[10]. The CTE works around the ten items listed in the Decision on Trade and Environment out of which Item 8 relates to the relevant provisions of the TRIPS Agreement[11]. The CTE work programme prior to the 1996 Ministerial

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law in order to ensure that such rights are supportive of and do not run counter to its objectives.ò

[8] Report of the Committee on Trade and Environment WT/CTE/1 dated 19 July 1996 para.149; Also see Rahul Goel, ñProtection and Conservation ï TRIPS and CBD: A Way Forwardò, *Journal of Intellectual Property Law and Practice*, (2008), pp.334-338

[9] www.wto.org

[10] *Ibid.*

[11] *Supra* n.8 The Items include 1) the relationship between the provisions of the multilateral trading system and trade measures for environmental purposes including those pursuant to MEAs, 2) the relationship between environmental policies relevant to trade and environmental measures with significant trade effects and the provisions of the multilateral trading system, 3) (A) the relationship between the provisions of the multilateral trading system and charges and taxes for environmental purposes, 3) (B) the relationship between the provisions of the multilateral trading system and requirements for environmental purposes relating to products, including standards and technical regulations, packaging, labelling and recycling, 4) the provisions of the multilateral trading system with respect to the transparency of trade measures used for environmental purposes and environmental measures and requirements which have significant trade effects, 5) the relationship between the dispute settlement mechanism in the multilateral trading system and those found in the MEAs, 6) the effect of environmental measures on market access, especially in relation to developing countries, in particular to the least developed among them, and environmental benefits of removing trade restrictions and distortions, 7) the issue of export of domestically prohibited goods, 8) the relevant provisions of the TRIPS agreement, 9) the work programme envisaged in the decision on Trade in services and Environment and 10) input to the relevant bodies in respect of appropriate arrangements for relations with intergovernmental and non-governmental organisations referred to in Article V of WTO

Meeting in Singapore contained three relevant items, i.e., Items 1, 5 and 8[12]; regarding Item 8 *inter alia*, the CTE was not able to come to a resolution wherein the issues discussed related to the relationship of the TRIPS agreement to the environment generally, the generation of, access to and transfer of environmentally sound technology, environmentally unsound technologies, indigenous and traditional knowledge and certain Multilateral Environment Agreements, in particular the CBD[13]. Views differed on the impact of IPRs on the achievements of the objectives of the CBD, but the discussions characterised uncertainty over several matters[14].The two matters about which greater certainty of views seemed present were in relation to technology transfer and knowledge of traditional and local communities[15]. Some developed country delegations asserted that strong IPR regimes in developing countries facilitated the transfer of technology. Scepticism about this assertion was expressed by some developing countries. As regards traditional and local knowledge, several developing countries expressed concern that IPRs are not broad enough to be a basis for appropriate compensation for use of such knowledge. Regarding the relationship between TRIPS Agreement and the CBD, the Members expressed divided opinions as to whether there is any inconsistency or conflict between the two instruments[16]. Some countries submitted that the two instruments have different scope, subject matter and intent but do not conflict with each other in terms of obligations and objectives[17]. Another group of countries wanted

[12]Richard G. Tarasofsky, ñThe Relationship Between the TRIPS Agreement and the Convention on Biological Diversity: Towards a Pragmatic Approachò, RECIEL, Vol.6 Issue.2 (2002) p.153

[13] *Supra* n.8, para. 132

[14] *Supra* n.12

[15] *Ibid.*

[16] *Id.* para. 146

[17] *Ibid.* Other submissions in this regard include: ñBy ensuring adequate protection for the innovator, the TRIPs Agreement promotes the CBD's objective of furthering technology transfer related to the commercialization and use of genetic resources. By setting as an objective the equitable sharing of the benefits of commercialization or other uses of genetic resources, the CBD addresses IPRs indirectly and identifies technology transfer as one form of benefit sharing its Parties should promote. The CBD does not address

to examine the possible inconsistencies between the CBD provisions and the TRIPS and in this regard, a non-paper submitted by India on 19 July 1996 proposed some changes in the TRIPS to accommodate the CBD[18]. One recommendation was to modify Article 29 of the TRIPS to require a clear mention of the biological source material, the known country of origin and all information pertaining to knowledge and practices of the use of biological source material by indigenous communities in the country of origin[19]. This part of the patent application was suggested to be open to full public scrutiny immediately after filing of the application. In order to remedy the lack of PIC mechanism in the TRIPS Agreement, the document made the suggestion that MTA with the country of origin would serve the purpose when the inventor wants to use the biological material and an Information Transfer Agreement (ITA) would be needed while making use of TK[20]. It was also suggested that an obligation must be imparted upon the patent owners to execute ITAs for any traditional or indigenous knowledge which is already in the public domain or is a part of the recorded or otherwise publicly accessible knowledge systems[21]. In another submission made before the CTE[22], India had categorically stated that

> ñé TRIPS and CBD represent two significantly separate multilateral approaches to the utilization of living resources. While TRIPS seeks

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specific IPR systems or the particular characteristics of IPRs but it does provide that mechanisms used to promote technology transfer should recognize and be consistent with adequate and effective IPR protection, which is the standard demanded by the TRIPs Agreement. Both agreements are viewed as having the flexibility to achieve environmental objectives. The TRIPs Agreement permits Members to carry out national policies in favour of sustainable development and to take adequate measures in conformity with the CBD. Accordingly, they did not see the need for further work in this area.ò

[18] *Id.* para. 149

[19] *Ibid.*

[20] *Ibid.*

[21] *Ibid.*

[22] Committee on Trade and Environment, ñThe Relationship Between the TRIPS Agreement and the Convention on Biological Diversityò, Communication from India on Item No:8, WT/CTE/W/65 dated 29 September 1997

> to promote and foster technological innovation by ensuring the certainty of IP protection and of world markets for at least some biotechnological inventions, its provisions are silent on how this protection can achieve the objective of sustainable development, especially in developing countries. The CBD seeks to facilitate access to living resources, while focusing on conservation and sustainable use, as well as the equitable sharing of the benefits of such use. In its effort to create a stake for developing countries in conservation and sustainable use, as well as the equitable sharing of benefits of such use the CBD emphasizes the need to share with them benefits which include the need to share in the development and transfer of technology.ò[23]

Ultimately, the CTE decided that further work is required on Item 8, and called for exchange of information between the CTE and the CBD.[24] In the Singapore Ministerial Declaration, December 1996, the CTE was directed to carry out its work under the existing terms of reference[25].

Though there were no significant changes recommended by the CTE, its work has led to the conversion of some trade and environment issues as the key components of the Doha negotiation round[26]. The negotiations focussed on three main themes; (i) relationship between WTO rules and Multilateral Environmental Agreements (MEAs), (ii) collaboration between WTO and MEA Secretariats, and (iii) elimination of tariff and non-tariff barriers on environmental goods and services[27]. In the Doha negotiations, the main aim of the developing countries in relation to the issue of biodiversity was to stress on the need to incorporate the CBD objectives within the text of

[23] *Id.* para. 12
[24] *Supra* n.12
[25] See Singapore Ministerial Declaration, 1996, para 16
[26] See www.wto.org
[27] *Ibid.*

the TRIPS agreement[28]. For this, in the pre-Doha phase, they used the review of Article 27.3(b) and the work undertaken by the CTE as the major tools and succeeded in obtaining an international mandate to find out the relationship between the two agreements in the form of an outstanding implementation issue[29]. In the Doha declaration implementation issues are divided into two, one for immediate action as contained in the decision on Implementation Issues and the other for future actions as contained in the Compilation of Outstanding Implementation Issues raised by Members. Actually, in the Ministerial Conferences of the WTO, it was the developed countries who tried to bring linkages between the issue of trade and environment and we could see the developing countriesô resistance to this agenda as they feared that environmental standards may hinder their economic development[30]. But during the Doha Negotiation Round, the developing countries had changed their strategy and accepted the inclusion of trade and environment debate in the negotiating mandate, realising that they cannot achieve economic development without the cost of environment[31]. Along with this they also tried to bring in their own agenda of linking the environment-trade debate with that of sustainable development so as to derive economic benefit out of trade liberalisation[32]. The handicap of Doha is that though it recognised the importance of most of the issues raised by the developing countries, it had failed to provide any specific commitment to provide for their resolution[33].

In the Doha Ministerial Declaration, 2001, the General Council of the WTO had instructed the TRIPS Council to examine the relationship between

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[28] David Vivas Eugi, ñIssues Linked to the Convention on Biological Diversity in WTO Negotiations: Implementing Doha Mandatesò, available at *http://www.ciel.org/Publications/Doha_CBD-10oct02.pdf*

[29] *Ibid.*

[30] Shawkat Alam, ñTrade and Environment Linkage in the Post-Uruguay Round Contextò, available at *http://www.austlii.edu.au/au/journals/JCULRev/2004/3.html*

[31] *Ibid.*

[32] *Ibid.*

[33] *Ibid.*

the TRIPS Agreement and the CBD, the protection of TK and folklore and other new relevant developments raised by Members pursuant to Article 71.1 while pursuing its work programme under Article 27.3(b) and 71.1[34]. So the result of the Doha Declaration in relation to access to GRs is that the CTEôs agenda to enquire the relationship between the TRIPS and the CBD was assigned to the TRIPS Council. Paragraph 19 of Doha poses an interesting situation as far as the GRs are concerned. In the previous chapter, we have found that the subject matter of GRs is the tangible resource along with the intangible information contained in it whether it is in the form of actual value that is TK associated with it or the potential value that is the hitherto unknown hereditary information. So the TRIPS Council has to also deal with the TK associated with GRs. Under the paragraph 19 mandate, the TRIPS Council has also to deal with the protection of TK and folklore. So the knowledge over biodiversity which falls under the larger framework of TK will also form part of the second agenda. It is not clear how the international community is going to address this issue particularly in light of the new dialogues requiring disclosure of origin of GRs, PIC and MAT which may result in overlapping. Attention is drawn to the fact that CBD established proprietary right only for TK associated with GRs. Such a specific legal background is not available for other forms of TK and folklore. Universal adoption of the CBD (with notable exception of the US) had made a strong case before the international community to find out the ways and means for the harmonious operation of the same with the TRIPS Agreement. The CBD had also devised a sufficient platform for defining the scope, extent and nature of the proprietary rights involved in GRs and associated TK. As regards other forms of TK and folklore, even though much hues and cries are there, invariably nothing in concrete could be traced to legally assert the nature of property rights involved in them. TK associated with GRs forms a part of the larger framework of TK throwing us uncertain whether the TRIPS

[34] Doha Declaration, 2001, para. 19

Council will exclude biodiversity related TK from the discussion of its second agenda.

COP is the governing body of the CBD and its decisions are binding on the Members. Considering the importance of IPRs in the implementation on the CBD, in its decision II/12, it requested its Executive Secretary to laise with the WTO and inform it about the goals of the CBD and to invite the WTO Secretariat to assist the COP in the preparation of a paper that identifies the synergies and relationship between the objectives of the CBD and the TRIPS to be submitted as an input to the CTE meeting[35]. The COP also requested the Executive Secretary to undertake a preliminary study analysing the impact of IP system on the conservation and sustainable use of biodiversity and equitable sharing of benefits out of the use of its components to gain a better understanding on the implications of Article 16.5 of CBD[36]. Accordingly the two documents were submitted to the CTE[37]. In Decision III/17, it recognised the importance of implementing IPR provisions of the CBD and of international agreements relating to IPR in a mutually supportive way and encouraged governments and various national and international agencies to carry out studies in this regard. It also recognised the need for further study to develop a common appreciation of the relationship between IPR and the relevant provisions of the TRIPs and the CBD, especially in relation to technology transfer, conservation, sustainable use and benefit sharing under the CBD[38]. It has requested for

[35] See COP Decision II/12 (a)
[36] *Id.* Decision II/12(c)
[37] The Impact of Intellectual Property Rights Systems on the Conservation and Sustainable Use of Biological Diversity and on the Equitable Sharing of Benefits from Its Use, UNEP/CBD/COP/3/22 dated 22 September 1996; The Convention on Biological Diversity and the Agreement on Trade Related Aspects of Intellectual Property Rights: Relationships and Synergies, UNEP/CBD/COP/3/23 dated 5 October 1996
[38] COP decision III/17, para. 8

observer status in the TRIPS Council the application for which is still pending since 1999[39].

The TRIPS Council started reviewing Article 27.3(b) in 1999 itself and the mutual supportiveness of the agreement with the CBD was one of the topics for its discussions. In this connection, the TRIPS Council has requested information from various international agencies linked to the system like the CBD Secretariat[40], FAO[41], UPOV[42], etc. Various State positions[43] submitted in this regard had differed in respect of the possible inconsistencies between the two agreements. Pursuant to the Doha mandate, the TRIPS Council started receiving specific documents from Member States detailing different views on inconsistencies between TRIPS and CBD and the different ways to resolve the same. Thus we could see that though the three international agencies are intrinsically linked in enquiring the

[39] Conference of the Parties to the Convention on Biological Diversity, ñNote by the Executive Secretary on Access to Genetic Resourcesò, UNEP/CBD/COP/5/21 dated 1 March 2000, para. 25

[40] CTE, ñReview of the Provisions of Article 27.3(b)ò, ñRelationship between the TRIPS Agreement and the Convention on Biological Diversity and Protection of Traditional Knowledge and Folkloreò, IP/C/W/347/Add.1 dated 10 June 2002. Also cited as WT/CTE/W/210

[41] FAO, ñReview of the Provisions of Article 27.3(b)ò, ñRelationship between the TRIPS Agreement and the Convention on Biological Diversity and Protection of Traditional Knowledge and Folkloreò, IP/C/W/347 dated 7 June 2002.

[42] UPOV, ñReview of the Provisions of Article 27.3(b)ò, ñRelationship between The TRIPS Agreement and the Convention On Biological Diversity and Protection Of Traditional Knowledge and Folkloreò, IP/C/W/347/Add.3 dated 7 June 2002

[43] Venezuela, ñPreparations for the 1999 Ministerial Conference, Proposals regarding the TRIPS Agreement (Paragraph 9(a) (ii) of the Geneva Ministerial Declarationò, WT/GC/W/282 of 6 August 1999 ; General Council, the Challenge of Integrating LDCs into the Multilateral Trading System, WT/GC/W/25 of 13 July 1999 by the Least Developed Countries; Bolivia, *et.al,* ñProposal on Protection of the Intellectual Property Rights Relating to the Traditional Knowledge of Local and Indigenous Communitiesò, WT/GC/W/362 dated 12 October 1999 ; Cuba, *et.al,* "Proposal on Protection of the Intellectual Property Rights of the Traditional Knowledge of Local and Indigenous Communitiesò, IP/C/W/166 of 5 November 1999; India, ñProposals on Intellectual Property Rights Issuesò, IP/C/W/195 of 12 July 2000 ; Brazil, ñReview of Article 27.3(b)ò, ódIP/C/W/228 of 24 November 2000; African Group, ñReview of the Provisions of Article 27.3(b)ò, IP/C/W/206 of 20 September 2000; and, United States, ñViews of the United States on the Relationship Between the Convention on Biological Diversity and the TRIPS Agreementò, IP/C/W/257 dated 13 June 2001

relationship between the TRIPS and the CBD, the active player is the TRIPS Council. The CTEôs recommendation to the WTO will be based on the outcome of TRIPS Council deliberations. The latter would be having serious impact on the functioning of the CBD under the Nagoya protocol that has set an international framework for benefit sharing. This shows the need for a detailed analysis of the work of the TRIPS Council in exploring the relationship between TRIPS and CBD, and the potential conflict between the two instruments. In achieving this task, the issue of compatibility and the effectiveness of the contract based approach of the CBD as worked out by the TRIPS Council will be dealt in this chapter and further deliberations in the TRIPS Council on the possible solutions to alleviate the inconsistency will be discussed in the next chapter.

5.2 CBD and TRIPS: Conflicting Relationship? – An Analysis

Three major views emerged in the TRIPS Council regarding the relationship between the TRIPS and the CBD. One is that there is a conflicting relationship between the two. Second is that there is no conflict, but foresees a need to ensure mutually supportive implementation of the two and the third view is that there is no conflict[44]. Regarding the conflicting relationship, it is contented that there are many areas of actual and potential conflict between the two instruments and are the result of lack of recognition of the CBD principles in the TRIPS[45]. One conflicting area is that TRIPS permits the grant of patents which are private rights over products based on GRs and contains no provisions preventing such patent claims in one country over GRs that are under the sovereignty of another country[46]. Many writers

[44] *Supra* n.28; Also refer Note by the Secretariat, ñThe Relationship between the TRIPS Agreement and the Convention on Biological Diversity, Summary of Issues Raised and Points Madeò, IP/C/W/368/Rev.1 dated 8th February 2006 para. 7 which states about the four different approaches of the nations in this regard.
[45] *Ibid.*
[46] See Disclosure Group, ñThe Relationship between the TRIPS Agreement and the Convention on Biological Diversity and the Protection of Traditional Knowledgeò

view this statement as to mean that TRIPS is placing supremacy to private rights over public rights[47]. Though the statement regarding the conflict is correct, the view taken by the writers does not seem to be true. In the previous chapter we have seen that the CBD has established strong property jurisprudence for the protection of BRs and associated TK. The property in BRs has both tangible and intangible components the ownership of which could be in different hands. The CBD is recognising state sovereignty over the resources without mentioning anything about ownership. So there is flexibility for the government to decide whether the ownership rests with the State or the people or held collectively by both. If the intangible component in the GRs is in the form of TK over the resources, the holder of such knowledge could be an individual or a community depending upon the customary practices. Without considering these varying and differing aspects of ownership, we cannot explore the possible synergies between the two agreements. The first question is whether CBD is talkingabout any public rights as different from the TRIPS Agreement. Private rights are considered rights associated with individuals, thus involving the concept of single ownership. It is to be noted that all the TRIPS categories of IP are not showing the feature of single ownership and the classic example is GIs. We have discussed this aspect in one of the previous chapters and found that GIs do not show the single ownership attribute. Again, for the intellectual input of humans as a *sine qua non* for IP protection, it becomes clear from the definition of GI that the only intellectual activity as regards many items covered by GIs is the name of the items covered and no single person can be virtually identified as the master mind behind the creation of that name. GIs are specifically protecting the quality of the product based on human input like some technique or other knowledge or the quality arising from natural

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IP/C/W/356 dated 24 June 2002 para. 8. Also see Communication from India IP/C/W/195 dated 12 July 2000, para. 13 &14

[47] *Supra* n.28; Also see *supra* n.30

input like geographical location, soil, climate etc. Given the broad definition of the term GI in the TRIPS there is a possibility of indirectly protecting the genetic materials and associated TK in limited case where the protection is given to the indication[48]. But the nature of protection so offered is so limited affording just the defensive means to prevent the use of the indication that is entirely different from misappropriation. Conceptually, the difference between the GRs and GIs is that the link between the GI and the man is an established property right while no such link is established between GR and man even though the bondage is stronger compared to GIs. The human contribution of naming to geographical properties is present in GIs which is ultimately protected there. For GRs, value rests with its uses/properties which are identified and maintained by human beings for generations, but not protected by means of any sort of IPRs. GRs do have the economic value and property background to be protected even as a TRIPS category, if we apply the logic behind the inclusion of GIs as a form of IP. The present analysis does not intend to assert that TRIPS is consistent with the sovereign rights guaranteed in the CBD. It is absolutely true that there is no obligation under the TRIPS framework that mandates an inventor to respect the property rights recognised for the GRs or associated TK under the CBD while making use of the same in his invention. This is irrespective of the question whether an invention results in patenting or not. The importance of patenting in this regard is that it gives way to enclosure through another private (individual) property regime which is internationally recognised with strong enforcement mechanism. Both the rights of the patentee and sovereign rights over the resources are internationally recognised but the enforcement of the former is properly executed while the latter is completely

[48] For a detailed account see, Gopalakrishnan, N. S. *et.al* ñExploring the Relationship Between GIs and TK: An Analysis of the Legal Tools for the Protection of GIs in Asiaò, *ICTSD Program on Intellectual Property and Sustainable Development*, ICTSD, Geneva, Switzerland, (2007)

neglected in the TRIPS scenario. This could be treated as discrimination instead of differentiation. The reason is that as far as the patent regime is concerned, GRs and associated TK constitute things in public domain that is meant for appropriation without consent. It has failed to appreciate the full-fledged property (collective) regime created over GRs and associated TK under the auspices of the CBD though evolved simultaneously in point of time. In order to keep the TRIPS domain dynamic and vibrant, it should cater to the evolving needs of the society. There must be recognition in the TRIPS Agreement of the fact that the GRs and associated TK do not fall within the public domain, instead they represent strong private property characteristics quite similar to many of the TRIPS components.

Regarding the conflicting relationship between the TRIPS and the CBD, another argument put forward is that TRIPS allows the genetic material to be used in an inventive process without regard to the CBD principles of PIC and benefit sharing leading to illegal access. It is further argued that national laws alone cannot prevent such situations of illegal access outside their national jurisdictions[49]. Reference has also been made to TRIPS facilitated use of TK associated with GRs in the same way that result in the grant of bad patents that do not adhere to the standards of patentability viz., novelty, inventive step and industrial application[50]. This submission could be treated as an extension of the first statement that the TRIPS is not recognising the sovereign or proprietary rights of the countries as well as the concerned communities/ individuals, for the underlying reason behind non-recognition of the principles of PIC and benefit sharing is that natural resources and the knowledge associated with them constitute a public domain for the inventor under the TRIPS framework. Appropriation with

[49] See Note by the Secretariat, ñThe Relationship Between the TRIPS Agreement and the Convention on Biological Diversity, Summary of Issues Raised and Points Madeò, IP/C/W/368/Rev.1 dated 8 February 2006; Also see *Supra* n.46; *Supra* n.28 p.7

[50] *Supra* n.46, para. 7, India, ñProtection of Biodiversity and Traditional Knowledge: The Indian Experienceò, IP/C/W/198 dated 14 July 2000

human intervention makes a natural resource eligible for patent protection in the TRIPS domain[51] and this principle is supported by various theories for justification of private property[52]. For a proper appreciation of the position, it would be better to refer to the relevant arguments of those who see no conflict between the two systems. One view is that there is no conflict between the two instruments and that they could be implemented in a mutually supportive way through national measures[53]. This proposition is founded on the reasons that the two have differing non-conflicting objectives and purposes and they deal with different subject matter and that by correctly applying the patentability criteria, valid patents could be issued for inventions containing genetic material that do not run counter to the CBD objectives and sovereign rights[54]. Another view that sees no inherent conflict between the two instruments, does not hide the concern that the implementation may not be mutually supportive; this could be taken as an argument that goes in line with the possibility of potential conflict. Now to ascertain the situation, the view that both the agreements have different and non-conflicting objectives and purposes and are dealing with different subject matter is partially correct. Rightly pointed out by India, TRIPS is talking about appropriation of living resources by means of Article 27 while CBD is talking about the already prevailing proprietary rights over them[55]. The argument that by correctly applying the patentability standards, patents that do not run counter to the sovereign rights guaranteed by the CBD could be ensured is absurd. This is because, even though an invention may be satisfying the patentability criteria, it need not be complying with the CBD requirements of prior informed consent for accessing the resources and sharing of the benefits arising out the utilization of the GRs. The reason is

[51] *Diamond* v. *Chakrabarthy* 447 US 303 (1980)
[52] Labour Theory of Locke, Personality theory of Hegel etc supports this view.
[53] *Supra* n. 49, para. 7
[54] *Ibid.*
[55] See TRIPS Council, Communication from India IP/C/W/195 dated 12 July 2000

that there is no corresponding obligation in the TRIPS framework to comply with the CBD requirements while applying for a patent for an invention containing GRs and /or associated TK.

The argument of some countries that there is no crisis in the existing patent system[56] though has some justification is not completely true. As far as the large number of patents issued worldwide on various fields is concerned, the mistakenly granted patents in the area of GRs and associated TK constitute bare minimum. But there are a large number of patents granted on inventions based on GRs and associated TK resulting in misappropriation. The reason being the difficulty in establishing whether it satisfied the requirement of patentability given the differences in the knowledge systems and the tests applied for finding out inventive step[57]. The case of absence of sufficient material to prove that the contract-based domestic regimes are *per se* inefficient to deal with the alleged issue of misappropriation[58] is also not logical. True that the Member States of the CBD have enacted biodiversity legislations only recently and are at very nascent stage to provide concrete examples of misappropriation. But anyone familiar with the TRIPS system of IP enforcement can foresee that so long as there is no TRIPS mandate to respect and comply with the CBD requirements of PIC and benefit sharing, an inventor need not go for the same to obtain a patent. Many countries have provided the TRIPS Council the actual or potential cases of biopiracy they have come across[59]. Non-compliance with the access law of a providing country is not a ground for opposition or revocation of a granted patent also. The implication is that however stringent the laws of a providing country may be, the lack of an

[56] *Supra* n.49
[57] For example, States like the US follow a lower patentability standard in interpreting novelty and inventive step in the case of biotechnology patents. The whole issue of life patenting is illustrative of this.
[58] *Supra* n.49
[59] Peru, Analysis of potential cases of Biopiracy, IP/C/W/458 dated 7 November 2005

international mandate in the TRIPS level will make the whole effort futile. One may argue that a contract stipulating that no IPRs could be obtained in violation to the law of the providing country would help in this situation and we could see similar line of arguments by the United States in its various submissions[60]. The problem with such contract lies when it crosses the national borders for enforcement. The recognition and enforcement of foreign judgement is limited by means of many defences such as fraud, breach of natural or substantial justice and public policy. Especially the public policy defence sets a limit to accept the foreign law and legal system as part of the enforcing courtôs duty to protect the fundamental social norms prevailing in the society in which enforcement is sought[61]. Yahoo! ï Nazi case illustrates this point very well. The French Jewish and anti-racist groups initiated legal action against the California based Yahoo! web portal when the latter allowed Nazi memorabilia (items such as SS daggers, swastikas, photos of death camp victims, replicas of Zyklon B poison gas canisters etc.) to be sold on its US auction pages[62]. As the French laws bar the display or sale of racist materials, the French court ordered that French internet surfers should be denied access to US pages hosting the auction. Though Yahoo! banned the sale of hate- related items from all the sites, it challenged the decision on the ground that the offending sites were aimed primarily at the American market and were therefore protected by the US freedom of speech laws. Subsequently, the US Federal Court ruled that Yahoo! was not bound to tailor its non-French sites to French laws. This clearly demonstrates the difficulty of enforcing foreign judgments based on contractual obligations in

[60] See IP/C/W/434; IP/C/W/469

[61] See Alan Reed, ñA New Model of Jurisdictional Propriety for Anglo-American Foreign Judgement Recognition and Enforcement: Something Old, Something Borrowed, Something New?ò, 25 *Loy. L.A. Int'l & Comp. L. Rev.* 243. Also see Mark D. Rosen, ñShould ñUn-Americanò Foreign Judgments Be Enforced?ò *Minnesota Law Review*, Vol. 88:783, (2004).

[62] See http://www.guardian.co.uk/international/story/0,3604,893642,00.html ; also see http://www.theinquirer.net/?article=21207, htthttp: //www. cyber- rights. org/ documents/ yahoo _ya.pdfp:/ /www.vnunet. com/ personal- computer- world/ news /2042963/ yahoo-backs -nazi-case,

US that are not expressly regulated in US through legislation. In the contract-based access regime, the authority dealing with its violation will always be the courts in the country of origin and enforcement of such judgments in foreign countries is always problematic. Especially in the US context, which is not a Party to any of the international treaties or Conventions in relation to foreign judgment enforcement, many of the case laws suggest that it is enforcing such judgments only in its best interest. The recognition and enforcement of foreign judgment is limited by many defences such as fraud, breach of natural or substantial justice and public policy which operate as ñsafety valvesò against judgments and legal processes which they cannot accept. Especially the public policy defence sets a limit to accept the foreign law and legal system as part of the enforcement court's duty to protect the fundamental social norms prevailing in the society in which enforcement is sought[63]. The cost of enforcement is also very high. In countries which are not party to the CBD, the policy of the State is to promote patenting and enforcement of a norm other than provided under the TRIPS Agreement need not be in line with its domestic policy. In that way, it would be easy for foreigners to access the resources without consent rather than going for the complex access and benefit sharing procedures. So this will not ensure that misappropriation of TK/resources could be effectively prevented. Patents cannot be revoked since there is no such ground for revocation of the patent and commercialization of products also cannot be prevented. It is doubtful whether such a contract could do anything before a patent office abroad. The other claim of options outside the patent system like information sharing between the patent offices and searchable databases[64] are only supplementary measures and will not constitute a substitute for a TRIPS mandate to stick on to the CBD objectives.

[63] *Supra* n.61
[64] *Supra* n. 49

Another point to be noted is that though the Nagoya Protocol of the CBD for benefit sharing is in place, there is no effort to bridge the gap between the TRIPS and the CBD in that instrument too. So as regards the IP interface of the CBD, there is little contribution from the side of the Protocol.

The contentions that TRIPS permits appropriation of genetic material and associated TK without recognising the sovereign rights promised by the CBD and that TRIPS promotes patenting or securing of IPR without giving due regard to the CBD goals of PIC and benefit sharing are true. In the present TRIPS framework, the GRs and associated TK constitute the raw material for biotechnological research and are considered as the part of nature forming a public domain. The structure permits the researcher to take his share and invent on it without seeking anybodyôs consent. This is because for centuries, the domain of BRs and the knowledge associated with them lacked the recognition by the modern legal systems the traditional property rights it enjoyed. It was only through the CBD that people began to have a perception of property over them that too different from the common western notion of individual property. The proponents of inherent conflict talks about the struggle the new property is facing within the TRIPS system. The newly recognised property which conventionally formed part of the public domain strives to have its own existence simultaneously with the IP system. The main characteristic of the property propounded by the CBD is that in the natural form itself, the BRs and associated TK over them constitute one form of property and in the modified form that go for IP protection or commercialization, the owners of the resources still retain their right though in a compensatory nature. This subsequent right could be equated with the right of a patentee over his patented invention when a subsequent researcher wants to improve upon it. The struggle confronted by the BRs and the knowledge over them is because of the absence of any

provisions in the TRIPS agreement to treat them as property. And the proponents are absolutely right in arguing that this could be eliminated only through an amendment in the TRIPS.

5.3 Efficacy of the National Contract-Based Framework of the CBD in Combating Misappropriation

During the TRIPS deliberations, majority of the nations shared the view that there is incompatibility between the TRIPS Agreement and the CBD at the very outset or at the implementation level. Even though the US restated its stand that there is no conflict apparently or at the operational level, it also took active role in bringing out solutions to combat the issue of misappropriation and granting of bad patents. According to the US, the best way to deal with this issue is contractual arrangements and tailored legislative requirements outside the IP system. The other solutions suggested relates to disclosure of the country of origin and source of the genetic material/TK involved in the invention, evidence of PIC from the country of origin of the GRs/TK in different regulatory planes like the TRIPS and PCT with differing legal effects. So the present section of this chapter will be dealing only with the favouring and opposing views on the national contract based solutions and its efficacy to create synergies between the TRIPS and the CBD. Other solutions suggested will be discussed in detail in the next chapter.

The proponents of the national contract based approach are of the view that to effectively deal with the issues of erroneous patents and to ensure that the goals of the CBD are met with, tailored national solutions outside the IP system incorporating legislative requirements must be opted[65]. Such legislative requirements must facilitate persons who wish to make use of the resources and associated TK to conclude contracts with the concerned

[65] *Ibid.* para. 29

authorities competent to grant access wherein such contract could include various components such as use of permits, contractual obligations, visa systems and civil and/or criminal penalties for non-compliance[66]. Such contractual arrangements could be used for establishing the rights and duties of the parties to the contract. Permit systems imposing criminal and civil liabilities could serve as the evidence of PIC. It is argued that contract based system could effectively regulate collection of resources and ensuring of benefits from their use. The proponents also submitted that contracts could include requirement of mandatory disclosure to appropriate authorities of any future commercialization utilizing the GRs or TK irrespective of patenting. It was further provided that clearly defined national focal points authorised to provide access could be delineated, facilitating the researcher to get PIC. Reporting obligation could be established regarding progress of research. In case of developing an invention out of the resources or the knowledge, an obligation to notify the relevant authorities could be established in a contract system along with the obligation to share the benefit arising out of the commercial and non-commercial use of the invention. The contract could be made mandatory to be disclosed in any patent application claiming any invention utilizing the GRs. These are some of the features of the national based system as proposed[67]. It is also argued that the civil and criminal liability provisions could be directly used to effectively regulate and enforce the ABS regime and suits for breach of contract could result in specific performance and damages[68]. Contracts can specify choice of law provisions and jurisdiction and the judgements could be enforced worldwide under international provisions relating to enforcement of foreign judgements[69]. Contracts could be associated with Member Countryôs visa

[66] *Ibid.*
[67] *Id.* para.30
[68] *Id.* ara.31
[69] *Ibid.*

systems for proper appreciation of the domestic law by foreigners[70]. Regarding the question of erroneously granted patents, it is contented that the solutions within the patent system like post grant opposition, re-examination and revocation proceedings are directly addressing this issue and additional measures like the establishment of searchable databases of TK could increase the available information on prior art thereby helping the patent examiners[71]. Production and use of such databases would also help in locating the stakeholders thereby promoting the objective of CBD under Article 8(j) to enable the wider application of the knowledge, innovations and practices of the local and indigenous communities with their approval and participation and to encourage sharing of benefits with them[72]. Introduction of a provision in the patent legislation requiring the applicant to reveal information material to patentability would also help in preventing the grant of erroneous patents[73]. It is also argued that the contract based approach is flexible enough to take into account the difference of interests in negotiations and the importance of the GRs and the knowledge in the development of the claimed invention and cites the possibility that if the GR is available from many sources, the researcher may opt the country providing it on most favourable terms[74]. It is also submitted that by implementing a contract based system, there is no need to wait for the result of TRIPs deliberations[75]. Such a system could effectively take care of those violating the domestic legal requirements and will not cause unintended and negative effects on the IP system[76]. Another merit claimed of this approach is the possibility to clarify the present ambiguities like the definition of various terms, clarify the rights and obligations on both the sides thereby avoiding

[70] *Ibid.*
[71] *Id.* para.32
[72] *Id.* ara.23
[73] *Id.* para.32
[74] *Id.* para.33
[75] *Ibid.*
[76] *Ibid.*

confusion and misunderstanding[77]. Thus the contractual system is suggested as highly adaptable to each countryôs legal system providing flexibility to protect their TK and GRs without undermining the economic incentives of IP protection and without negating the share of benefits where there is no patent protection.[78] Contractual means also provide for effectively serving the CBD provision for handling biotechnology and distribution of its benefits under Article 19[79]. Contractual arrangements pose the possibility to share both monetary and non-monetary benefits[80]. The United States is the strongest proponent of the national contract based approach and most of the arguments cited above are its submissions in the TRIPS Council[81].

In response to this national contract law based approach, it is submitted that considering the transboundary use of GRs often involving acquisition of the material in one country and patenting in another country, reliance on the national or regional measures would not be sufficient to deal with the problem and to increase transparency, multilateral approach is warranted[82]. It is argued by Brazil and India that country practices may differ where acts illegal in one jurisdiction need not be the same in another and the situation makes it clear that contractual remedies are effective only when they are obligatory and enforceable across the borders[83]. It is also submitted that contracts alone cannot deter those acting in bad faith as there is every possibility to supersede domestic ABS regimes[84]. It is also contended that internationally there is no obligation to legislate on the issue of PIC and ABS

[77] *Ibid.*
[78] *Ibid.*
[79] *Ibid.*
[80] *Id.* para.34
[81] The major submissions of the US in this regard could be seen in IP/C/W/434, IP/C/W/449, IP/C/W/469
[82] *Supra* n.49, para. 60
[83] *Ibid.*, see also Brazil and India, ñThe Relationship Between the TRIPS Agreement and the Convention on Biological Diversity and the Protection of Traditional Knowledgeò , IP/C/W/443 dated 18 March 2005
[84] *Ibid.*

especially for countries not Parties to the CBD[85]. A national contract based regime with an international outlook cannot be a proper remedy for the problems prevailing the ABS system since misappropriation and issuance of bad patents are continuing even where such system is already established and that there is no need to bring in unnecessary matters of State responsibility for enforcement of foreign contracts when WTO could serve as the proper forum to deal with the matter[86]. Unequal bargaining power of the parties and lack of obligation to enter into and enforce the terms of the contract are the other defects advanced in relation to the contract system[87]. TRIPS council has shown a divided opinion in relation to the transaction cost involved in the contract system, its fragmented nature and the generally long term nature of research and its implications on the contract[88]. Regarding the effectiveness of the remedies proposed, it is provided that civil and criminal remedies will not do much of a deal in third countries where the use is without permission from the competent authorities and without entering into ABS agreements with the country of origin[89].

The fact that national ABS solutions alone are not a remedy to solve the question of misappropriation and grant of erroneous patents is made clear in the previous section of the present chapter and the same is not discussed in detail here. To be effective, an international mandate in the TRIPS level is needed since WTO members cannot be compelled to enforce non-WTO instruments. This could be better understood from the US submission above where the US argues that the contractual system could facilitate the researcher to obtain the resource from the country that provide the material

[85] *Ibid.*; Also see Jonathan Curci Staffler, ñTowards a Reconciliation Between the Convention on Biological Diversity and TRIPS Agreement: An Interface Among Intellectual Property Rights on Biotechnology, Traditional Knowledge and Benefit Sharingò, 2002 available at *www.iprsonline.org*
[86] *Id.* para. 62
[87] *Id.* para. 63
[88] *Id.* para. 65 and 66
[89] *Id.* para. 67

on most favourable terms when the genetic material is available from many sources. This is against the philosophy of the CBD that vests the ownership of the resources with the country of origin that has the exclusive right to provide access. The US proposition is thus not only against the principle of CBD, it also departs from the basic principle of contract law *"nemo dat quod non habet"* no one can confer a better title than what he actually has. The authority to provide access emanates from the ownership and for GRs, it is established only through the CBD. This makes it clear that the US understanding of the contractual solution itself is basically flawed especially in light of the fact that the question of obtaining the resource on most favourable terms does not and could not arise in the CBD context. Rightly proposed by the US, there are many positive elements for a contractual agreement in clearly defining the rights and obligations of the parties. To be more precise, the very existence of the CBD system is the contractual arrangement for ABS and the purpose of the CBD could be achieved only through the creation of a contractual relationship. A contractual relation can adequately take care of many of the concerns in relation to ABS like what is to be accessed, quantum of the material to be accessed, permitted uses, duration of access, mutual rights and obligations, reporting obligation, nature, quantum and mechanism of benefit sharing etc and contract is a prerequisite for the purpose of ABS. But in the context of obtaining of IPR, the contractual obligation fails in ensuring the CBD objectives. For example, if a company or a researcher enters into an access contract for research, it/he might later realise the commercial potential of the research result and might opt for obtaining a patent protection and commercialization of the same. In this process, even though there may be a contractual obligation that consent should be taken before obtaining of IPRs and benefits are to be shared, in the patent context, they are not forming a condition precedent for the grant. The patent application will only be examined as to whether they fulfil the patentability criteria of novelty, inventive step and industrial application and

not whether the raw materials are legally acquired. Similarly, the argument of the US that solutions within the patent system like re-examination and revocation proceedings can directly address the issue of mistakenly granted patents is not correct. Even if there is a contractual obligation that consent is to be taken before obtaining a patent, non-performance of that obligation cannot affect the validity of a granted patent. For developing nations, these procedures are costly and time consuming. Thus the absence of a corresponding obligation in the TRIPS regime weakens the contractual framework created by the CBD. Yet another instance is the obtaining of GRs not for research, but once the same crosses the borders, it is used for research purposes and later IPRs is obtained over them. In such circumstances also, the contract based solution fails. Problems in the enforcement of judgments upholding contractual obligations across the boarders are similar in the context of IP as well as non-IP related situations in the case of GRs, but the differing aspect is that such a judgment even if enforced across the borders cannot affect the validity of a granted patent. It is very important to distinguish the access for research and obtaining of IPRs over the resources and associated TK from other instances of access and subsequent commercialization. IP protection turns them the subject matter of another property regime which is seldom related to the goals of the CBD. Considering the prime objective of CBD as benefit sharing, the private enclosure facilitated through TRIPS does not incorporate any mandate to respect this obligation. The contract entered into between the provider and the patent applicant does not constitute a relevant document before the patent office which makes the whole game of ABS at the mercy of the recipient. Moreover, this result in conceptual incoherence with the nature of the property we have discussed in the earlier chapter i.e., the difficulty of the owner to get parted with the ownership over the resources even in the advanced and purified forms. The present situation upsets this by creating new property rights over it and making the inventor the owner of the same.

This does not and could not arise in other contexts where IPR is not involved. So theoretically and practically, contract based approach can effectively take care of other forms of ABS while access for research and IPR demands a TRIPS based solution.

There is another argument put forward by the US that a requirement in the patent legislation to disclose the information material to patentability can also effectively deal with the situation. But such a requirement imposed in the patent legislation of the provider country cannot deal with a case where the patent is obtained in a foreign jurisdiction. Such a requirement can create an impact provided the same is mandated in the TRIPS level imposing deterrent effect by affecting the validity of the patents granted and that is what is precisely argued by some countries to impose disclosure requirements in the TRIPS in relation to source and country of origin of the GRs and the TK used in the invention and evidence in relation to PIC and benefit sharing.

To sum up, the national contract based approach alone cannot act as an effective solution to address the issue of misappropriation and the grant of bad patents. The contractual tools together with domestic ABS legislation could effectively take care of situations other than the obtaining of IPRs without consent and benefit sharing, but are useless in the context of patenting where the mandate is that no additional conditions could be imposed for the grant of a patent other than those specified in the TRIPS. This makes it clear that only a TRIPS based solution can adequately deal with the issue.

5.4 UPOV

UPOV is another international instrument that has linkages with the CBD as the subject matter of the former forms new varieties of plants. The

Convention stands for protection of breedersô rights[90] in relation to new varieties of plants which are novel[91], uniform[92], stable[93] and distinctive[94]. For the development of new varieties of plants, access to PGRs is essential. Just like the vacuum found in the TRIPS, the UPOV is also silent with respect to enforcement of the CBD goals of PIC and benefit sharing. In an exchange of dialogue with the CBD Secretariat, the Members of the UPOV had made it very clear that they do not want to impose any additional conditions for the grant of rights upsetting the present system[95]. Till date, there is no effort on the part of the Convention to address the above said gap. The problem becomes more pertinent noting the fact that there is space in the ITPGRFA system also that may facilitate a breeder to obtain plant variety protection without any responsibility to share the benefits while creating hindrance to the open access system of the ITPGRFA.

5.5 Conclusion

The lesson learned from chapters 2, 3 and 4 as well as the present chapter is that even though there is no conceptual incoherence between the property regimes under the TRIPS and the CBD, the IPR system is creating unrest in the proprietary domain of the CBD. Unless this turmoil is properly addressed, the ultimate objective of the CBD viz., sharing of benefits from the commercial exploitation of GRs and associated TK will collapse. The treatment of natural resources as the product of nature or public domain or public goods is the starting point of this issue and the resultant appropriation was legalised and qualified through the TRIPS. The basis of extension of

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[90] International Convention for the Protection of New Varieties of Plants, Article 14
[91] Article 6
[92] Article 8
[93] Article 9
[94] Article 7
[95] C/37/22, Annex IV, ñAccess to Genetic Resources and Benefit-Sharingò; Reply of UPOV to the Notification of June 26, 2003, from the Executive Secretary of the Convention on Biological Diversity.

patent monopoly to life forms was purely the commercial interest involved in it, practically ignoring the social dimensions of the issue. From the analysis of the contract based CBD framework, it is very clear that a stand-alone CBD system before the mighty TRIPS is like David before Goliath. It leads us to accept the fact that a solution purely based on the CBD cannot undo the situation of misappropriation of GRs and associated TK. So the possible conclusion is that only a TRIPS based solution can adequately deal with the situation by creating a link between the CBD and the TRIPS.

Chapter 6
BRIDGING THE GAP: ADEQUACY OF TRIPS BASED SOLUTIONS

The inconsistency between the TRIPS and the CBD is found to be the legal vacuum in the TRIPS to promote the CBD goals of PIC and benefit sharing through MAT. It is also evident that the CBDôs bilateral contractual framework alone cannot prevent misappropriation of GRs and associated TK through patenting. Basically being an environmental framework, efforts purely from the part of the CBD could not produce much progress in this regard. The complete silence of the Nagoya Protocol on IP provisions is exemplifying this. In bridging the gap between the TRIPS and the CBD framework, different proposals have been put forward in the TRIPS Council. Due to lack of consensus, these proposals are in stalemate and some of the developing countries are trying to keep the deliberations going on by calling for text-based negotiations on the issue. Efforts are going on in the WIPO also to provide adequate protection, *inter alia* to GRs and associated TK. The present chapter outlines these various proposals and analyses their effectiveness to solve the issue of misappropriation facilitated through IPRs.

The remedial measures suggested are in the form of certain disclosure requirements in different regulatory planes. Three types of disclosure requirements have been suggested. The group of countries headed by Brazil and India known as the disclosure group suggested addition of a requirement in the TRIPS mandating disclosure of the source and country of origin of the GRs and associated TK used in the invention together with the evidence of PIC and fair and equitable benefit sharing. This proposal is known as TRIPS disclosure requirement or triple disclosure requirement. The next proposal by EC relates to the disclosure of the source and country of origin of the GRs

and associated TK used in the invention at the time of filing the patent application and has no reference to PIC and benefit sharing. This too relates to an amendment in the TRIPS. A third suggestion made by Swiss delegation was to bring in changes in the PCT Regulations of the WIPO so as to enable the national legislations to incorporate a disclosure requirement in relation to the source of the GRs and TK used in the invention. Each of these proposals is having varying scope and dimensions which will be discussed in the present chapter.

6.1 TRIPS Disclosure Proposal

A proposal put forward by many of the developing countries to bridge the gap between the TRIPS and the CBD is an amendment in the TRIPS so that Members are bound to require a patent application involving GRs or TK to provide information regarding (a) the source and country of origin of the BR and/or the TK used in the invention, (b) evidence of PIC obtained from competent national authorities under the relevant national regime and (c) evidence of fair and equitable benefit sharing under the relevant national regime[1]. This proposal makes it obligatory on the members to incorporate required changes in domestic patent legislations requiring the patent applicants to mandatorily disclose the three aspects whenever the invention contains GRs or associated TK together with a reporting obligation in the event of patenting or commercialization[2]. A declaration in the patent application accompanied by a certificate issued by the relevant national authority or a duly certified contract between the applicant and the national authority of the country of origin would serve as the evidence of PIC[3]. The

[1] Secretariat, ñThe Relationship Between the TRIPS Agreement and the Convention on Biological Diversity : Summary of Issues Raised and Points Madeò, IP/C/W/368/Rev.1 dated 8 February 2006, para. 71

[2] *Id*. para. 72; Also see the Disclosure Group, ñThe Relationship Between the TRIPS Agreement and the CBD and the Protection of Traditional Knowledgeò, IP/C/W/356 dated 24 June 2002, para. 10

[3] *Id*. para. 73

obligation to provide evidence of benefit sharing would be discharged by providing evidence, at the time of patent application, of a future or existing benefit sharing agreement premised upon MAT which are fair and equitable in the given circumstances[4]. The terms of benefit sharing would cover elements relating to the conditions, obligations, procedures, types, timing, distribution and mechanism of the benefits to be shared[5]. There should be an indication in the application as to how the arrangement would be enforced and the burden of proof is limited to providing information and evidence known to the applicant or should have been known to him[6]. Considering the weak status of the traditional communities in the negotiating process, it is recommended that the benefit sharing agreement primarily entered into with them should be subsequently supplemented and confirmed by the national regulatory authority[7]. Even in countries where there is no national regime to ensure the CBD goals of PIC and benefit sharing, the applicant has to mention the same and also provide evidence to the effect that consent has been obtained at least from the authority or community in charge of the GRs or TK accessed or that there is a benefit sharing agreement or a future one is envisaged with the concerned authorities or that access is obtained in full compliance with the other applicable laws, regulation and practices of the country of origin[8]. When it is found that there is inadequate, wrongful or non-disclosure by the applicant, it is proposed that at the stage of processing of the patent application, processing will be denied until the necessary declaration and evidence of PIC and ABS reaches the patent office and this would be accompanied by penalties and time limits within which the applicant is required to produce the relevant evidence failing to do which will result in the application deemed to have been withdrawn; at the post

[4] *Ibid.*
[5] *Ibid.*
[6] *Ibid.*
[7] *Ibid.*
[8] *Id.* para. 74

grant stage, on establishing the fraudulent intent, the patent would be revoked; criminal or administrative sanctions must be invoked to ensure punitive damages or adequate compensation outside the IP structure; full or partial transfer of the right to the invention would also follow when full disclosure would have shown that any other person, community or governmental agency is the inventor or part inventor; and narrowing down of the scope of the claims when the claims are affected due to lack of novelty or fraudulent intention or where full disclosure would have resulted in rejection of those parts of the claims and all the above remedies are proposed to be subject to judicial review[9]. Members should be having an obligation to ensure that the effect of insufficient, wrongful or non-disclosure is having adequate deterrent, compensatory and equity value and the countries could define in their domestic legislations, the penalties applicable in case of failure to comply with the requirements and the legal effects mentioned in the proposal are different options available[10]. The remedies are proposed to have retrospective effect so as to cover past uses[11]. The triple disclosure obligation would be triggered by any use including the incidental use of a GR or TK in an invention the disclosure of which is necessary to determine the existence of prior art, inventorship or entitlement to the claimed invention and the scope of the claim and/or is necessary for understanding or carrying it out[12]. Such uses could include those that result in forming part of the invention, use during the process of developing the claimed invention, use that is a necessary pre-requisite for the development of the claimed invention, or use to facilitate the development of the claimed invention where it forms part of the necessary background material for the development of the invention[13]. Regarding the burden of proof in case of

[9] *Id.* para. 75
[10] *Id.* para. 76
[11] *Ibid.*
[12] *Id.* para. 77
[13] *Ibid.*

non-compliance, it is limited to prove that the resource and/or the knowledge have been legally and legitimately accessed and that benefit sharing had taken place or would take place on the grant of the patent. Applicants are expected to employ all reasonable measures to find out the country of origin and the source of the material used, but the onus is limited to the disclosure of evidence that is known or should have been known to him[14]. Regarding the legal form of the proposed amendment in the TRIPS agreement, three suggestions have been made; (a) an amendment in Article 27 of the TRIPS Agreement[15], (b) amendment to Article 29[16] or (c) introduction of a new article in the TRIPS[17]. The advantages of the proposed system are summarised as: increasing transparency in the ABS system and helping the source countries to monitor and keep track of compliance with ABS rules in a cost effective way within the patent system, facilitating and simplifying the enforcement of CBD obligations through the provision of incentives on

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[14] *Id.* para. 78

[15] Peru, Article 27.3(b), ñThe Relationship between TRIPS Agreement and the Convention on Biological Diversity and Protection of Traditional Knowledge and Folkloreò, IP/C/W/447 dated 8 June 2005 proposes an amendment to Article 27 in the form of a further exception to patentability with the wording that

ñ[Members may also exclude from patentability]:

(c) products or processes which directly or indirectly include genetic resources or traditional knowledge obtained in the absence of compliance with international and national legislation on the subject, including failure to obtain prior informed consent of the country of origin or the community concerned and failure to reach agreements on conditions for the fair and equitable share of benefits arising from their use.

Nothing in TRIPS shall prevent Members from adopting enforcement measures in their domestic legislation, in accordance with the principles and obligations enshrined in the Convention on Biological Diversity.ò

[16] Consisting of the addition of a paragraph as set out in the following alternative sets proposed.

ñMembers shall require an applicant for a patent to disclose the country and area of origin of any biological resources and traditional knowledge used in the invention, and to provide confirmation of compliance with all access regulations in the country of origin.ò (African Group, Taking Forward the Review of Article 27. 3(b) of the TRIPS Agreement, IP/C/W/404 dated 26 June 2003)

or

ñWhere appropriate, Members shall require the disclosure of origin and legal provinence in the patent applications to be submitted.ò (Peru, *Supra* n.15)

[17] Disclosure Group, ñThe Relationship between the TRIPS Agreement and the Convention on Biological Diversity and the Protection of Traditional Knowledgeò, IP/C/W 403 dated 24 June 2003

patent applicants for the conclusion of contracts such as MTAs and ITAs; resulting in the grant of better patents through more focused search in the patent office and lessening the burdensome challenges regarding patent validity, contributing to additional information on prior art regarding TK enabling search that might be outside the scope of established databases; building more confidence in the patent system restoring the trust of all stakeholders and inspiring resource rich countries to provide less complex national ABS regimes; developing a predictable environment for government, investors, traditional communities and researchers that could lead to more biotechnological research and development in developing countries, thus creating a win-win situation for both providers and accessors and finally creating respect for the rights and beliefs of indigenous people and safeguarding the sovereign interest in GRs[18].

One of the major disagreements with the disclosure approach was that this would not achieve its purported objective of ensuring PIC and benefit sharing and nor will it prevent the grant of erroneous patents[19]. It was also argued that the disclosure requirements would introduce many negative consequences, uncertainties in the patent system, impose additional administrative burdens and hinder the role of the patent system in promoting innovation and would also undermine potential benefit sharing[20]. The counter argument is that the new disclosure requirements would help the source countries to monitor and keep track of compliance with ABS rules in a cost-effective way[21]. It would also facilitate and simplify the enforcement of obligations under the CBD through incentive measures for patent

[18] *Supra* n.1, para, 93

[19] US on Article 27.3(b), ñRelationship Between the TRIPS Agreement and the Convention on Biological Diversity and the Protection of Traditional Knowledge and Folkloreò, IP/C/W/434 dated 26 November 2004 ; Also see US, Article 27.3(b), ñRelationship between the TRIPS Agreement and the Convention on Biological Diversity and the Protection of Traditional Knowledge and Folklore, IP/C/W/449 dated 10 June 2005

[20] *Ibid.*

[21] *Supra* n.1, para. 112

applicant for conclusion of contracts, especially where the legal effects include revocation of patents[22]. As regards the disclosure of evidence of PIC and benefit sharing it was counter stated that it would not be feasible to require evidence of PIC and ABS in addition to the information regarding source of the genetic material since the patent office is not capable of verifying the same[23]. The terms and conditions of a contract that is confidential may not be accessible to the patent office and the terms may vary with regard to the benefits to be shared and what is fair and equitable differs on case-by-case basis and the patent offices have no way of judging fairness and equity[24]. It is also argued that determinations by patent office and other authorities may affect contractual autonomy[25]. Another point made against the evidence of PIC and benefit sharing was that if the country of origin has no benefit sharing infrastructure in place, there would not be any compensation to the custodians of the resource or knowledge even if a patent relating to these materials is identified[26]. It was also submitted that it is premature to consider introducing a requirement on PIC and benefit sharing since many countries do not possess fully operational and effective national regimes capable of providing certificates of evidence[27]. Another argument was that the requirement of PIC and benefit sharing would bring in incoherence with the ITPGRFA since the latter does not foresee any PIC or benefit sharing making the requirement operational only for resources acquired as per CBD and not for ITPGRFA and the patent offices would be

[22] *Ibid.*
[23] *Id.* para. 118
[24] *Ibid.*
[25] *Ibid*., Also see Switzerland , ñThe Relationship Between the TRIPS Agreement and Convention on Biological Diversity and the Protection of Traditional Knowledge and Folklore and the Review of Implementation of the TRIPS Agreement under Article 71.1ò, IP/C/W/446 dated 30 May 2005
[26] *Ibid.* Also see *Supra* n.19
[27] *Ibid.*

burdened with distinguishing the applications[28]. Yet another argument made was that there is some incoherence in the proposal between ñrequiring as a condition for acquiring patent rights that applicants furnish evidence of PICò and ñrequiring applicants to provide information known to them or which they should reasonably knowò[29]. In response to the above concerns, the disclosure group submitted that what is fair and equitable will be decided by the national authorities of the country of origin according to the CBD and not by the patent offices[30]. It was also reinstated that the burden on the patent offices would be reasonable as the burden would be on the country providing access to prove that the evidence submitted in relation to PIC is false or the benefit sharing is not fair and equitable. If there is any allegation as to the fairness or equity in benefit sharing, the alleger has to take relevant action as per the domestic ABS regime and produce the result before the patent office. The patent office would have to accept the same and is not required to interpret foreign laws on ABS[31]. As regards the issue of fairness and equity in benefit sharing, it is submitted that there would be a reporting obligation casted upon the person seeking access to the resources or communities in the instance of patenting and commercialization and if this obligation is not carried out, it would be deemed that there is no fair and equitable benefit sharing, and any dispute regarding the same would be dealt by the appropriate national authorities under the domestic ABS regime and not by the patent office[32]. As regards the contractual autonomy, India submitted that contractual autonomy is subject to the provisions of PIC and benefit sharing and it cannot be used as a tool to prevent implementation of the CBD

[28] *Ibid.* ; Also see, Switzerland, ñArticle 27.3(b): The Relationship Between TRIPS Agreement and Convention on Biological Diversity and the Protection of Traditional Knowledgeò, IP/C/W/400/ Rev.1 dated 18 June 2003.
[29] *Ibid.*
[30] *Id.* para. 119
[31] *Ibid.* ; Also see, Brazil and India, ñThe Relationship Between the TRIPS Agreement and the Convention on Biological Diversity and the Protection of Traditional Knowledgeò , IP/C/W/443 dated 18 March 2005
[32] *Ibid.*

provisions[33]. Regarding the issue of absence of benefit sharing infrastructure, it is submitted that inclusion of TK within the scope of access as well as mandatory requirement of PIC from the TK holders is a matter of national policy. If the knowledge over the resources vests with the communities and the domestic law requires PIC from them, the person seeking access would be obliged to ensure PIC from them[34]. The anomaly suggested regarding the need to distinguish between the patent applications on the access resulting from CBD and those from ITPGRFA is also not correct since the ITPGRFA has an inbuilt mechanism to ensure benefit sharing and PIC. So a reference to the effect that the source of the resource is the MLS of the ITPGRFA will completely relive the applicant.

Another point that came up for discussion during the negotiation on the triple disclosure requirement relates to the remedies for non-compliance including revocation of granted patents. As regards its implications on the effective functioning of the patent system, one concern expressed was that instead of singling out patent applications and trying to deal them with the new disclosure requirements that may negatively affect technological development, an appropriate solution would be strengthening of national regimes outside the patent system so as to address all instances of commercialization of the misappropriated resources or TK and needs to be addressed outside the patent system in any event[35]. Another submission was that there is no adequate data to the effect that sanctions outside the patent system would have no deterrent effect on the defaulters[36]. Another issue raised was that there is no clarity as to the circumstances that would justify

[33] *Ibid.*
[34] *Ibid.*
[35] US, ñArticle 27.3(b): Relationship Between the TRIPS Agreement and the Convention on Biological Diversity and the Protection of Traditional Knowledge and Folkloreò, IP/C/W/449 dated 10June 2005 para 121
[36] *Ibid.* ;Also see, EC, ñReview of Article 27.3(b) of the TRIPS Agreement and the Relationship Between the TRIPS Agreement and CBD and the Protection of Traditional Knowledge and Folkloreò, IP/C/W/383 dated 17 October 2002

revocation of the granted patent and full or partial transfer of the rights over the claimed invention and also the question who would be the recipient of such transferred rights[37]. In response to these concerns, the disclosure group submitted that failure to comply with the disclosure requirement should be dealt with in the patent system lest it should nullify the requirement and transform it into a mere formality[38]. This is because of the fact that there is no effective remedy to deal with the deliberate omission from the part of the patent applicant to comply with the CBD requirements[39]. Also fines or other penalties outside the patent system would not substantially affect the validity of the patent lessening the deterrent effect of the action against misappropriation[40]. Revocation or invalidation will be applicable only when nondisclosure is accompanied by fraudulent intention and is similar to existing procedures in the patent system with respect to cases of revocation when fraudulent intention is found for insufficient, wrongful or lack of disclosure and where a proper disclosure would have lead to the refusal of the grant of patent for reasons of lack of novelty, *ordre public* or morality[41]. The disclosure group also argued that the instances of commercialization other than patents could be effectively taken care of by the national ABS regimes and it should not be taken that since the disclosure requirements does not cover all instances of commercialization, such a requirement is not necessary[42].

An interesting point of discussion was that such sanctions themselves would reduce the benefits available to be shared because (i) invalidation of a

[37] *Ibid.* Also see *Supra* n.25,
[38] *Id.* para. 122; Also see, Disclosure Group, The Relationship Between the TRIPS Agreement and the Convention on Biological Diversity and the Protection of Traditional Knowledge, IP/C/W/403 dated 24 June 2003
[39] *Ibid.*
[40] Minutes of the TRIPS Council on Brazil, IP/C/M/48 dated 15 September 2005 para. 41
[41] Brazil *et.al*, ñThe Relationship Between the TRIPS Agreement and the Convention on Biological Diversity and the Protection of Traditional Knowledge, Technical Observations on the US Submission *IP/C/W/449*ò, IP/C/W/459 dated 18 November 2005
[42] *Ibid.*

granted patent or non-issuance of patent to an application will render the invention to be freely used and commercialised by third parties without the obligation to share the profits[43]; (ii) the requirement may prevent a person from applying for patent protection, but still he would be able to commercialise the same without sharing the benefits[44]. This would destroy benefit sharing and is neither in the interest of innovation nor in the interest of securing benefit sharing. In response, it was contented by the disclosure group that such instances are not different from situations involving any invention or patent and is not limited to patents involving disclosure of source and country of origin. Such situations could be dealt by other remedies outside the patent system within the national regimes in conjunction with other international rules including trade secret laws and competition laws[45].

As regards the consistency of the requirement within the TRIPS, it was argued that bringing in such a requirement under Article 27 would result in discrimination among some fields of technology in the context of patent availability[46] and this was countered on the ground that there is inherent difference in patent applications for inventions involving GRs and associated TK demanding additional conditions so as to enable better assessment of such applications[47].

Yet another point of departure was the necessity of furnishing evidence of PIC and benefit sharing to ensure the goals of ensuring PIC and benefit sharing. Against this requirement, it was contented that the patent disclosure requirements *per se* cannot ensure PIC and benefit sharing as they

[43] TRIPS Council Minutes on US, IP/C/M/40 dated 22 August 2003 para. 122
[44] *Supra* n.1 Similar concern is expressed by Canada, EC, Japan, Korea and US
[45] *Supra* n.31
[46] TRIPS Council Minutes on Japan, IP/C/M/29 dated 6 March 2001 para. 155
[47] Disclosure Group, ñThe Relationship Between the TRIPS Agreement and the Convention on Biological Diversity and the Protection of Traditional Knowledgeò, IP/C/W/403 dated 24 June 2003

convey only the required information and do not serve any benefit sharing mechanism[48]. Another line of argument was that when there is no patenting, the disclosure requirements would be of no use[49]. Since the sanctions like revocation would negatively affect the incentives to go for patent protection, it may negatively affect the benefit sharing objective of the CBD. In response the disclosure group submitted that all the three elements are necessary in ensuring mutual supportiveness between the TRIPS and CBD. The requirements to furnish evidence of PIC and benefit sharing are essential in ensuring that domestic ABS regimes are respected and implemented effectively through remedial action at the global level through the TRIPS[50]. Disclosure requirements are not intended as a stand-alone requirement, instead, they have to complement the domestic ABS regimes[51].

As regards the usefulness of the disclosure requirements in preventing erroneous patents, one view was that the requirement would be ineffective since (i) information regarding source and country of origin is not information material to patentability without which the examiners can understand the invention properly and examine the application as to judge patentability[52]; (ii) determination of inventorship is generally based on a countryôs patent law and on acts of invention, and information regarding source or country of origin have little relevance in these considerations[53] and (iii) lowering the standards of the requirement to information that is known or should have known to the applicant will render such disclosure

[48] IP/C/M/40 Para 122 US
[49] *Supra* n.19
[50] *Supra* n.41
[51] Brazil and India, ñThe Relationship between the TRIPS Agreement and the Convention on Biological Diversity and the Protection of Traditional Knowledgeò, IP/C/W/443 dated 18 March 2005.
[52] US , Article 27.3(b), ñRelationship between the TRIPS Agreement and the Convention on Biological Diversity and the Protection of Traditional Knowledge and Folkloreò, IP/C/W/449 dated 10June 2005
[53] *Ibid.*

irrelevant[54]. This was strongly countered by the disclosure group emphasising that a reason for questionable patent is insufficient disclosure of existing knowledge and the inadequacy of the existing patent system to check the relevant details[55]. The disclosure requirements would give the patent office useful hints to enquire into the novelty and inventiveness claimed in the invention in the form of information regarding the source and country of origin of the material or the knowledge[56]. If the requirements are made mandatory, the examiners can require more information from the applicants to ensure that the invention is eligible for patent protection[57]. The disclosure group also argued that though mere information on source and country of origin may not help in ascertaining inventorship or patentability, it would be helpful in determining whether the resource or knowledge used is forming part of the claimed invention; during the process of developing the claimed invention; as a necessary prerequisite for the development of the claimed invention; to facilitate the development of the invention; and/or as a necessary background material/information for the development of the invention. Such information would be relevant in determining the existence of prior art and non-obviousness of the claimed invention, inventorship or entitlement to the patent, scope of the claim and for understanding or carrying out the invention[58]. It was also contended that when an invention is based on GRs or associated knowledge, information on source and country of origin would be useful in ascertaining whether the applicant has invented what he is claiming or just found the invention in nature or obtained from traditional cultures[59].

[54] TRIPS Council Minutes on Japan, IP/C/M/48 dated 15 September 2005 para. 75
[55] *Supra* n.19
[56] *Supra* n.54 on India in para. 55
[57] *Supra* n.41
[58] *Ibid.*
[59] *Supra* n. 54 on Brazil in para. 37

The implications of the disclosure requirements on the patent system were also subject to discussion. As regards the burden on the patent offices, one view was that they would have both legal and administrative difficulties in determining the geographical origin of the GRs and the TK[60]. It was also argued that the patent offices would be unable to verify compliance with PIC and benefit sharing for (i) they may not have the technical and legal competence to verify the evidences provided, (ii) the terms and conditions of a contract would remain confidential and may not be available to the patent granting authority and (iii) even if the terms are made available, the verification task would overburden the patent offices, creating problems of legal interpretation in relation to compliance with foreign laws[61]. The requirements were also alleged to cause additional administrative costs for training and system development in patent offices[62]. Against these propositions, the disclosure group submitted that the role of the patent offices would be to ensure that the applications are complete, confirming that the patent application contains a declaration in the prescribed form indicating that PIC has been obtained and that benefits have been shared or/and that there exists an arrangement for future benefit sharing as per the domestic law[63]. It is routine for the patent offices to ascertain necessary evidence in cases of allegation of fraud and the disclosure requirement does not impose any additional burden on them[64]. The disclosure evidences need to be ascertained only when the validity of a patent is challenged in the pre or post grant opposition or revocation stage where the patent office would have evidence from both the parties facilitating it to do the usual assessment at the

[60] US, ñReview of the Provisions of Article 27.3(b) - Further Views of the USò, IP/C/W/209 dated 3 October 2000
[61] *Supra* n.36; Also see *Supra* n.28; *Supra* n.25 ,
[62] *Supra* n.26
[63]India, ñProtection of Biodiversity and Traditional Knowledge ï The Indian Experienceò, IP/C/W/198 dated 14 July 2000
[64] *Supra* n.41

stage of opposition or revocation[65]. The proposed requirements are argued to increase the capacity of the patent offices in examining applications dealing with GRs and associated TK[66] and the costs and burdens in implementing the requirements should be considered in the light of the high costs of collecting evidence in revocation proceedings in the absence of such requirements[67]. As regards the burden on the patent applicants, it was contended that the requirements may discourage applicants from seeking patent protection and may prompt them to keep their inventions secret[68]. Against this, the disclosure group argued that the onus of the applicant is limited to providing information and evidence that is known to him or should have been known to him imposing minimal administrative and cost burden and that the recording and collection of information relating to meet the disclosure obligation fall squarely within the efforts undertaken in the process of developing a patent application for an invention[69]. It was also argued that in most of the countries, evidence of PIC is a pre-requisite for the grant of access to GRs and associated TK, thus not creating any additional burden[70].

As regards the consequence of the disclosure approach on the operation of the patent system and its ability to fulfil its public policy objectives, one argument was that the information from the new disclosure requirements regarding source and country of origin is not relevant to considerations of novelty and inventive step, thereby of little help to patent examiners in making such decisions[71]. It was also argued that the disclosure requirements together with sanctions like revocation would cause additional avenues of litigation, cause uncertainties and would undermine the role of

[65] *Supra* n.19
[66] *Supra* n.54 on Brazil in para. 36
[67] *Supra* n.19
[68] *Supra* n.26
[69] *Supra* n.41**,** India *et.al,* ñElements of the Obligation to Disclose the Source and Country of Origin of the Biological Resources and/or Traditional Knowledge Used in an Inventionò, IP/C/W/429/Rev.1 dated 27 September 2004
[70] TRIPS Council Minutes on India, IP/C/M/49 dated 31 January 2006 para. 143
[71] *Supra* n.19

the patent system in promoting innovation and technological development[72]. Another contention was that patent law is not designed to regulate misconduct issues such as misappropriation of TK or GRs and that a contract based ABS system can effectively and adequately achieve domestic policy goals of conservation and sustainable use of GRs[73]. In contra, the disclosure group submitted that the requirements would facilitate the process of examination by adding information on prior art regarding TK and also enable searches outside the scope of existing databases, resulting in the grant of better patents[74].

6.2 Appraisal

The TRIPS disclosure proposal poses a very interesting situation. At the very outset, it argues for disclosure of three elements, viz., source and country of origin of the GRs and associated TK, evidence of PIC and benefit sharing. But as regards the legal form of amendment to be carried out in the TRIPS, Peru suggests that Article 27 could be amended as to

> ñ(c) Members may also exclude from patentability:(c) products or processes which directly or indirectly include genetic resources or traditional knowledge obtained in the absence of compliance with international and national legislation on the subject, including failure to obtain prior informed consent of the country of origin or the community concerned and failure to reach agreements on conditions for the fair and equitable share of benefits arising from their use. Nothing in TRIPS shall prevent Members from adopting enforcement measures in their domestic legislation, in accordance with the principles and obligations enshrined in the Convention on Biological Diversity.ò

[72] *Ibid.*
[73] TRIPS Council Minutes, IP/C/M/47 dated 3 June 2005 para. 48
[74] *Supra* n.1

Ironically, the proposal is silent on the disclosure of source and country of origin of the resources or associated TK. With respect to amendment in Article 29, the disclosure group suggest insertion of Article 29 bis[75] as

"Disclosure of Origin of Biological Resources and/or Associated Traditional Knowledge

1. For the purposes of establishing a mutually supportive relationship between this Agreement and the Convention on Biological Diversity, in implementing their obligations, Members shall have regard to the objectives and principles of this Agreement and the objectives of the Convention on Biological Diversity.
2. Where the subject matter of a patent application concerns, is derived from or developed with biological resources and/or associated traditional knowledge, Members shall require applicants to disclose the country providing the resources and/or associated traditional knowledge, from whom in the providing country they were obtained, and, as known after reasonable inquiry, the country of origin. Members shall also require that applicants provide information including evidence of compliance with the applicable legal requirements in the providing country for prior informed consent for access and fair and equitable benefit-sharing arising from the commercial or other utilization of such resources and/or associated traditional knowledge.
3. Members shall require applicants or patentees to supplement and to correct the information including evidence provided under

[75] Disclosure Group , ñDoha Work Programme ï The Outstanding Implementation Issue on the Relationship Between the TRIPs Agreement and CBDò, IP/C/W/474 dated 5 July 2006

paragraph 2 of this Article in light of new information of which they become aware.

4. Members shall publish the information disclosed in accordance with paragraphs 2 and 3 of this Article jointly with the application or grant, whichever is made first. Where an applicant or patentee provides further information required under paragraph 3 after publication, the additional information shall also be published without undue delay.

5. Members shall put in place effective enforcement procedures so as to ensure compliance with the obligations set out in paragraphs 2 and 3 of this Article. In particular, Members shall ensure that administrative and/or judicial authorities have the authority to prevent the further processing of an application or the grant of a patent and to revoke, subject to the provisions of Article 32 of this Agreement, or render unenforceable a patent when the applicant has, knowingly or with reasonable grounds to know, failed to comply with the obligations in paragraphs 2 and 3 of this Article or provided false or fraudulent information.ò

Even though this recommendation has been put in place by the disclosure group, since there was no progress in the work of the TRIPS Council, in furtherance to carry on the discussions, the disclosure group now calls for text based negotiations on this issue and the draft modality text as submitted by them in this regard reads:

ñMembers agree to amend the TRIPS Agreement to include a mandatory requirement for the disclosure of the country providing/source of genetic resources, and/or associated traditional knowledge for which a definition will be agreed, in patent

applications. Patent applications will not be processed without completion of the disclosure requirement.
Members agree to define the nature and extent of a reference to Prior Informed Consent and Access and Benefit Sharing.

Text based negotiations shall be undertaken, in Special Sessions of the TRIPS Council, and as an integral part of the Single Undertaking, to implement the above. Additional elements contained in Members' proposals, such as PIC and ABS as an integral part of the disclosure requirement and post-grant sanctions, may also be raised and shall be considered in these negotiations.ò[76]

So the implication is that the proposed mandate under the Draft Modality Text relates to disclosure of country providing/source of GR and associated TK and the requirement on PIC and benefit sharing are not yet developed. This has deteriorated the ownership concept under the CBD as the obligation does not expressly confer rights on the country of origin. From the point of view of ABS, recognition of the CBD goal of benefit sharing pursuant to access is again belated.

The triple disclosure obligation is proposed to be initiated by any use of the resources in the invention and this proposition is further explained providing that such disclosure must be essential for determining the prior art, inventorship, entitlement to the claimed invention or the scope of the claims. Use of the resources and knowledge so as to form part of the invention, during the process of developing the claimed invention, use that is a necessary pre-requisite for the development of the claimed invention, or to facilitate the development of the claimed invention where it forms part of the necessary background material for the development of the invention are also

[76] Albania *et.al*, ñDraft Modalities for TRIPS Related Issuesò, TN/C/W/52 dated 19 July 2008

recommended to trigger the obligation. But it leaves the fact that the CBD regime provides for claims in respect of any use of the resources and the knowledge even if its contribution to the alleged invention is very minimal. Though the disclosure requirements seem very effective, there is no consensus among the international community to insert evidences in relation to PIC and benefit sharing and to invoke sanctions within the patent system to deter acts of non-compliance. These requirements should also be weighed in light of the report that the examination policy of some countries is that the patent office is not the best forum to deal with issues of novelty and inventiveness and that the best way to deal with such issues is to grant patents which will be later contested in the courts[77]. If this is the case, there is a need to develop specific examination guidelines in this regard. From an assessment of the triple disclosure requirement, what is made clear is that such a requirement can be included in the TRIPS only if it has a relationship with the substantive patentability criteria of novelty, inventive step and utility. Only if the developing countries can establish that relationship, then only they represent a valid case for amending the TRIPS whether it is in Article 27 or Article 29. Even though some relationship could be established with reference to the disclosure of source and country of origin, the other two disclosures in relation to the PIC and ABS stand protracted. The present section does not go into the details of possibility of the three requirements being linked with the patentability criteria, instead, it further analyses the other proposals suggested and tries to find out their efficacy.

6.3 Mandatory Disclosure Proposal

[77] CBD, ñMeasures, Including Consideration of their Feasibility, Practicality and Costs, to Support Compliance with Prior Informed Consent of the Contracting Party Providing Genetic Resources and Mutually Agreed Terms on Which Access was Granted in Contracting Parties with Users of such Resources under their Jurisdictionò, UNEP/CBD/WG-ABS/2/INF/2 dated 29 September 2002 p.38

Another approach suggested is that each country would accept an obligation to require all patent applicants to disclose information on the country of origin or source of the genetic material used in the invention which the patent applicants know or have reason to know and this proposal is referred to as mandatory disclosure proposal[78]. It is also proposed that the applicant could be required to declare the specific source of the TK associated with the GRs if he is aware that such invention is directly based on such TK and this requirement is proposed to have necessitated an in-depth understanding of the definition of GR[79]. The requirement would be legally binding and universal and would apply to all national, regional and international patent applications at the earliest stage possible[80]. This requirement will be only a formal requirement and will not constitute any additional formal or substantial patentability criterion[81]. In case of failure or refusal to give the specific information, the patent application will not be further processed, and once the patent is granted, the legal effects of non-compliance on finding that the information was incorrect or incomplete, would fall outside the ambit of patent system through civil or administrative sanctions[82]. The obligation to disclose would be triggered when the TK or the resource forms part of the claimed invention or has been necessary for the development in the claimed invention or to put in, the invention must be directly based on the GRs in question[83]. The burden of proof in relation to non-compliance would lie on the alleger[84]. With respect to PIC and benefit sharing, a simple notification procedure to a centralised body could be followed by the patent office every time it receives a declaration[85]. A list of governmental agencies competent to receive information about patent

[78] *Supra* n.1, para 87.
[79] *Ibid.*
[80] *Ibid.*
[81] *Id.* para. 88
[82] *Ibid.*
[83] *Ibid.*
[84] *Ibid.*
[85] *Id.* para 89

applications containing declaration of the source of the GRs could be established and the list could be maintained by WIPO in close cooperation with the CBD[86]. Or the Clearing House Mechanism of the CBD could act as the central body to which the patent offices could send the information that would then be available to all parties of the CBD as well as the public[87]. Regarding the legal form of this proposal, it is submitted that it is too early to discuss on this aspect since it would depend on what substance it would be agreed upon[88]. The possible options would be to insert a new article on the TRIPS or a new obligation in an existing Article[89]. Some argue for a mandatory provision in the TRIPS with a possibility to bring it under Article 29 of TRIPS[90]. It is also submitted that the proposal is facilitating the implementation of the objectives of the CBD without affecting the balance of rights and obligations set out in the TRIPS while creating a favourable environment for research and development in the field of biotechnology in the WTO Member States[91].

The proponents further elaborated that the applicant should disclose the country of origin, i.e. the country possessing the GRs *in-situ* and if it is not known, the applicants obligation would be to disclose the source of the specific GR to which the inventor has had physical access and which is known to him[92]. This could be the research centre, gene bank or the entity from which the inventor acquired the resource[93]. It is further clarified that if the country of origin is not known to the applicant, he can indicate the source which could, sometimes, be the country providing the GRs[94]. The proponents also clarify that the term ñdisclosure of sourceò is preferred to ñdisclosure of

[86] *Ibid.*
[87] *Ibid.*
[88] *Id.* para. 90
[89] *Ibid.*
[90] *Ibid.*
[91] *Id.* Para. 95
[92] TRIPS Council Minutes on EC, IP/C/M/47 dated 3 June 2005 para.58
[93] *Id.* on EC, IP/C/M/46 dated 11 January 2005 para.42
[94] *Id.* para. 14

geographic originò as all applicants know the source of the GRs or TK; and in certain circumstances, it would be impossible or unduly burdensome for the patent applicant to investigate the entire chain backward to the origin. No additional research would be needed to ascertain the country of origin and it is the inventor who has to decide whether he knows the country of origin.[95] As regards the problem of genetic material originating from more than one country should be resolved through arrangements with the source countries and in the context of the CBD[96]. The other discussions on the TRIPS disclosure proposal other than those relating to the sanctions like revocation and on evidence relating to PIC and ABS are also applicable in the context of mandatory disclosure proposal.

6.4 Appraisal

Though the proposal resembles the TRIPS disclosure requirement detailed in the previous section, it varies from the same being proposed as a formal requirement with no implications on the validity of the patents granted. It beautifully develops the coordination needed for the proper functioning of the system, but does not envisage recognition of PIC and benefit sharing within its purview. Emphasis on the declaration of source rather than the country of origin and geographical origin is a clear dilution of the rights of the country of origin. Moreover, when it is emphasised that for TK associated with GR, the disclosure obligation will be triggered only when the invention is directly based on the TK in question, the proposal accepts the link between novelty, inventive step and TK. It ignores the fact that even though the invention is not directly based on the TK, such disclosure can lead to redefining and narrowing down of broad claims. Following such a strict construction will also reduce the chances of the TK holder to be benefitted by providing access to his knowledge which could

[95] TRIPS Council Minutes on EC, IP/C/M/48 dated 15 September 2005 para. 66
[96] *Supra* n.36

become a part of the invention though the invention need not be directly based on the TK. The object of this proposal is not to bring in harmony with the goals of the CBD as to PIC and benefit sharing, but only to prevent the grant of bad patents that do not conform to the patentability standards. So from an ABS perspective, the proposal is only an eye wash. This proposal could be seen only as a partial acceptance of the triple disclosure requirement, politically accepting that there is a relationship between the source and country of origin of a GRs/ associated TK without clearly defining the relationship. It is accepting the relationship which the triple disclosure requirement had unsuccessfully tried to convey. More interestingly, it does not address the issue of creating a mechanism to ensure the CBD goal of benefit sharing.

6.5 The PCT Disclosure Proposal

Another proposal envisaged is that the regulations under the Patent Cooperation Treaty (PCT) of WIPO must be amended so as to explicitly enable the national patent legislation of the CPs to the PCT to require the declaration of the source of GRs or TK in the patent application if an invention is directly based on such resource or the knowledge[97]. There is sufficient freedom for the applicant to fulfil the requirement either at the time of filing the international application or later during the international phase[98]. This declaration of the source is to be included in the international publication of the application[99]. Incorporation of the requirement is optional but once incorporated in the national patent legislation, it would be obligatory for the patent applicants applying for patent within those territorial limits of such Member States if the invention is directly based on GRs or associated TK[100]. In the requirement to disclose the source, the term

[97] *Supra* n.1 para. 81
[98] *Ibid.*
[99] *Ibid.*
[100] *Id.* para. 82

source is to be interpreted in the broadest sense possible since a multitude of entities under the CBD and FAO might be involved in ABS[101]. The entity competent to be declared as the source should be the one to grant access to the resources and/or the knowledge or the one to participate in the sharing of benefits arising out of their utilization[102]. Regarding the legal effects, it is proposed that the requirement should be a formal one and not substantive[103]. The legal effects for wrongful disclosure or non-disclosure currently existing under the PCT and Patent Law Treaty (PLT) should apply in case of wrongful disclosure and non-disclosure of the source of the GRs and associated TK[104]. If the applicant fails to comply with the requirement within the set time limit of two months, the national law may foresee that in the national phase the PCT application is not processed any further until the applicant has furnished the required declaration or consider it withdrawn on grounds of non-compliance[105]. On duly complying with the requirement, i.e. the proposed declaration containing standardised wording relating to the declaration of the source, the designated office must accept this declaration and may not require any further document or evidence relating to the source declared unless it reasonably doubts the veracity of the declaration concerned[106]. Based on Article 10 of the PLT of WIPO that is also affected by the proposed amendment, if it is discovered after the granting of a patent that the applicant failed to disclose the source or submitted false information, national law may envisage the validity of the granted patent being affected by a lack of or an incorrect disclosure of the source only if this is due to fraudulent intention[107]. The possibility for judicial review and sanctions under national law including criminal sanctions such as fines etc are other

[101] *Id.* para. 83
[102] *Ibid.*
[103] *Id.* para. 84
[104] *Ibid.*
[105] *Ibid.*
[106] *Ibid.*
[107] *Ibid.*

suggestions[108]. For GRs, the obligation would be triggered only when ñthe invention is directly based on a specific GR to which the inventor has had accessò[109]. This implies that the invention must make immediate use of the GR, i.e. depend on the specific properties of the concerned resource and that the inventor must have had physical access to the resource, i.e. its possession or at least contact that is sufficient to identify the specific properties of the resource that are relevant for the invention[110]. In relation to TK, the inventor must know that the invention is directly based on the knowledge, i.e., the inventor must consciously derive the invention from this knowledge and such knowledge in question must be related to the GR in question[111]. For the proper functioning of the disclosure requirement, a list of governmental agencies competent to obtain information about patent applications containing the required declaration is to be established so that patent offices receiving such applications could inform the competent government agency in another country that it had been declared as the source[112]. By making the list available on the internet, patent offices would have easy access to it and could provide the requisite information to such authority without much administrative burden or cost, thereby evading the need to verify patent applications worldwide to verify whether a country is declared as the source and its domestic access law concerns are duly met with[113]. The obligatory disclosure requirement at the national level coupled with the information system could enable the parties to verify compliance with contractual obligations and would also simplify enforcement of such obligations[114]. The particular advantages of the disclosure proposal are claimed to be: explicitly enabling the CPs to introduce a disclosure requirement in their national laws;

[108] *Ibid.*
[109] *Id.* para. 85
[110] *Ibid.*
[111] *Ibid.*
[112] *Id.* para. 86
[113] *Ibid.*
[114] *Ibid.*

providing adequate freedom to Members to make tailored legislations as per their needs; not creating a deterrent effect on filing of patent applications and encourages maintenance of secrecy over inventions; enabling the patent applicant to declare the source most appropriate with regard to the invention in question thereby reducing the risk of lack of knowledge about the source; enabling mutually supportive implementation of international instruments; and representing a specific measure in implementing the Bonn Guidelines by ensuring participation of stakeholders in the process of benefit sharing.[115]

The proponents also clarify that if the patent applicant has information at hand about the primary source, this must be disclosed; if he has information on the primary source and several secondary sources, the primary source should be disclosed whereas disclosure of the secondary ones are optional. If he has information about a secondary source and not the primary source, this secondary source must be disclosed. If he has information about several secondary sources and not the primary source, the secondary source with the closest relationship to the primary source should be disclosed and the others would be optional[116]. The proponents also make clear that the term ñsourceò should be broadly understood to cover terms like ñCPs providing GRsò, ñoriginò, ñgeographical originò, ñcountry of origin of GRsò, the MLS established by the ITPGRFA and any other sources that may be relevant[117]. It is further explained that primary sources are the CPs providing GRs, ILCs and the MLS established by the ITPGRFA; and secondary sources are ex-situ collection centres such as gene banks, botanical gardens, scientific literature and databases on GRs and TK[118]. The

[115] *Id.* para. 94
[116] Switzerland , ñFurther Observations by Switzerland on its Proposals Regarding the Declaration of the Source of Genetic Resources and Traditional Knowledge in Patent Applicationsò, IP/C/W/433 dated 25 November 2004
[117] Switzerland, ñAdditional Comments by Switzerland on its Proposals Submitted to WIPO Regarding the Declaration of the Source of Genetic Resources and Traditional Knowledge in Patent Applicationsò, IP/C/W/423 dated 14 June 2004
[118] *Supra* n.116

proponents further elucidate that the source/s to be declared must be the most appropriate one/s where an entity is competent to grant access to GRs and/or TK or to participate in benefit sharing. If such a source is not known, a declaration would be made to this effect as a multitude of entities may be involved in the process of ABS and the objective of disclosure must be to increase transparency[119]. The proposal does not use the term ñcountry of originò and the proponents reason the same on the ground that the CBD refers to ñcountry providing GRsò in the context of ABS and also on the ground that it excludes the MLS established by the ITPGRFA[120].

As regards the immediate use of the GRs in the invention, it was explained that the invention should have made the immediate use of the resources and the inventor must have had physical access to the resource i.e. he must have possessed or at least have had contact which is sufficient to identify the properties of the GRs that were relevant for the invention[121]. With regard to TK, the proposal would require that the inventor knows that the invention is ñdirectly based onò the knowledge, i.e. he had consciously derived the invention from this knowledge. Since TK is of intangible nature, physical access is not possible and would not constitute a pre-requisite. The term directly is not intended to have any time dimension[122].

6.6 Appraisal

It is quite worthy of note that the PCT disclosure proposal emphasizes for disclosing only the source of the GRs used instead of the country of origin. The proposal is not taking into account of the fact that the CBD has categorically indicated that for the purpose of Article 15, 16 and 19, the GRs provided by a country means those provided by the country of origin or

[119] *Supra* n.117
[120] *Supra* n.92 on Swiss para. 76
[121] *Supra* n.117
[122] *Ibid.*

acquired according to the provisions of CBD[123]. The ownership over the resources rests with the country of origin and only it has the right to provide access to the resources. So it is submitted that the PCT disclosure proposal is basically a faulty one, not understanding the spirit of CBD. This argument is not negating the fact that the proposal seeks to expand the ambit of source by including within its meaning terms like CP providing GRs, origin, geographical origin, country of origin, MLS under the FAO and other relevant sources, considering the multitude of entities involved in the process[124]. But when the CBD makes it clear that for the purpose of access, country providing GRs means the country of origin, there is no need to make confusions like this. The proposal tends to be very soft on the patent applicants on the one hand and negating actual benefits to the real stakeholders on the other by taking such an approach. True that there is a possibility to get access from a multitude of entities considering the enormous transactions that have already taken place in this field. But in such cases, under the CBD, an obligation is cast upon the applicant to employ a reasonable amount of research in tracing the country of origin and to designate the country which is more in proximity as the country of origin.

Another shortcoming of the proposal is in relation to the trigger of the disclosure obligation where it recommends that the obligation sets in motion only when the invention is directly based on the GR to which the inventor has had access. This is also one limiting the scope of property rights envisaged under the CBD which could cover any use including incidental use of the resources. What CBD envisions is a system where the country of origin and the stakeholders of the GRs can retain a right over the resource in its raw, natural, purified, refined, extracted and derived forms. So whenever an invention uses GRs irrespective of its importance to the claimed invention, as per the CBD, the country of origin and the custodians can have

[123] The Convention on Biological Diversity, 1992, Article 15.3
[124] *Supra* n.1 para. 115

a claim for sharing of benefits. A further remarkable contention is that in case of TK, the obligation would be triggered only when the inventor consciously derives the invention from such knowledge. It is true that to fall under the scope of CBD, the knowledge must be associated with the GRs and when the inventor consciously uses the knowledge for developing his invention, he has an obligation to share the benefits. What if the invention is developed independently by the inventor, but it is typically an embodiment or application of an already prevailing TK over the resource? He has of course no obligation to share the benefits. But is his invention eligible for patent protection provided such knowledge is not in secret use? If the invention is granted patent monopoly, it will definitely dilute the patentability standards. Just like the mandatory disclosure proposal, the PCT proposal is also aimed at the prevention of the grant of erroneous patents and not intended to bring in synergy with the CBD goals through recognition of PIC and benefit sharing.

Over and above all, the PCT disclosure proposal is highly inadequate to solve the incoherence between the TRIPS and the CBD as it cannot act as a TRIPS level mandate for the WTO members cannot be made bound by non-WTO instruments.

6.7 Effectiveness of the Disclosure Requirements to Deal with Misappropriation and Erroneous Patents

A perusal of the solutions suggested to ensure the CBD goals and to prevent the grant of bad patents, the inference is that there is no consensus in incorporating the PIC and benefit sharing goals of the CBD within the TRIPS system. TRIPS Council, being a forum to discuss matters related to IP, is more focussed only on the IP related issues during the process of ABS and their strategy is to devise a system that can effectively deal with the issue of erroneously granted patents without upsetting the present patent

policies. It is disappointing to note that despite the constant push from the developing countries to insert the disclosure requirements including PIC and benefit sharing within the TRIPS regime, the developed countries are managing to limit the demand to declaration of source and country of origin only, that too with so many dilutions on the concept of the country of origin. It appears that the developed nations who benefit from the present system do not want to disturb the conventional private property regime that forms the edifice of the TRIPS, for incorporation of PIC and benefit sharing principles expressly recognise the rights of the country of origin and/or the ILCs concerned. As far as the requirement in relation to source and country of origin of the GRs and associated TK is concerned, it seems that there is a general willingness to accept this in principle, but many of them do not want to mention the country of origin. They also want this requirement not to affect the validity of the patent granted. The reason to confine the requirement to disclosure of only the source is pointed out as the difficulty in tracing the country of origin. But if this is allowed, the misappropriation will continue to persist. It is because, in the CBD context, taking of GRs from any source other than the country of origin will constitute misappropriation unless there is a reasonable effort from the part of the person taking it to find the actual country of origin. Even after reasonable enquiry, if the country of origin cannot be ascertained, then he can make a declaration to that effect and obtain the resources as per the domestic law of the source country from where he had obtained the resource. As per the proposed dilutions in the disclosure requirement, there is no possibility for the country of origin to assert its rights. It is because if the source is declared, the inventor would fulfil the legal requirements in relation to his invention. If at a later point of time, it is proved that the country of origin is not the source country, then the former will not have any say and there will be no forum available to listen to it. And no action in this regard will affect the validity of the patent also. The most important point is that if the disclosure requirement is confined only to

disclosure of the source, insisting the evidence of PIC and benefit sharing from the patent applicant would not have any substantial effect in providing any *locus standi* to the country of origin. Thus, the diluted disclosure of source of GRs proves to cause disastrous effects on the very purpose of the CBD itself.

It is to be noted that there is wide disapproval in bringing in requirements relating to the evidence of PIC and benefit sharing. The main reason cited is that they are not information having relevance to the patentability of an invention and that an examiner can judge the patent eligibility without any reference to them. PIC and benefit sharing relate to the legal acquisition of the materials used for the invention. It is true that the requirements of PIC and benefit sharing have nothing directly to do with patentability. But viewing patent as the exclusive monopoly right, is it philosophically wrong to consider the legal acquisition as an eligibility criteria at least in the context of GRs and associated TK? It should be noted that the TRIPS Council deliberations were also a response to the Doha mandate to enquire the relationship between the TRIPS and the CBD and if the triple disclosure requirement proves the sole way to link the two, the countries should accept the reality. Now the question is whether the triple disclosure requirement is compatible with the TRIPS. Some scholars opine that since the patentability criteria spelled out in Article 27.1 ie novelty, inventive step and industrial application are substantive conditions that result from the invention *per se* or that they result from the technical characteristics of the invention[125]. It is argued that

> ñThe requirement quite obviously is not compatible with Article 27.1. The manner of obtaining genetic resources used in the

[125] Nuno Pires de Carvalho, ñRequiring Disclosure of the Origin of Genetic Resources and Prior Informed Consent in Patent Applications without Infringing the TRIPS Agreement: The Problem and the Solutionò, *Re-Engineering Patent Law*, Vol.2, 2000, p.379

development of inventions is an external condition. The outcome of inventive activity is indeed independent of the ways and means employed to reach it. The situation that arises from an invention derived from use of genetic resources that have been illegally extracted from their *in-situ* environment is similar to the situation of an invention that has been developed with the assistance of a stolen microscope. This event would infringe the Common Law, but not patent law under Article 27.1 of the TRIPS Agreement. In both situations inventor would still be entitled to the patent, provided the conditions of patent eligibility were met. Nonetheless they would be subject to criminal and civil liability for stealing (both the genetic resources, depending on the existence of appropriate legislation, and the microscope) in the country from which the resources had been taken[126].ò

As regards Article 29, it is opined that

ñArticle 29 of the TRIPS Agreement contains disclosure conditions. Disclosure of the invention must be in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the arté .. As a matter of course, the present language of article 29 is not an appropriate framework for the Requirement. The indication of the origin of the genetic resources and of other circumstances related to their acquisition is not generally necessary for the invention to be carried out by a person skilled in the art. Where the biotechnological invention does require the use of the natural resource to be carried out, the knowledge of where to obtain the resource may be relevant for the practical exploitation of the invention. In this context, the United Statesô statement at the November 24-25, 1997 meeting of the WTO

[126] *Ibid.*

Committee on Trade and Environment applies: where the source of the resource is unique, it must be disclosed under article 29. There is no need for additional language to be included in the Agreement. However, sometimes the source of the material may be relevant, even though it may not be of essence. In that case the information may even constitute a trade secret. For instance, a natural extract obtained in some particular geographical area may be more effective than a similar extract obtained somewhere else. However, the scope of Article 29 does not reach beyond the obligation to explain how the invention works. Therefore, the Agreement does not require disclosure of the materialôs source where knowledge of that source is not essential to reduce the invention into practice.ò[127]

In relation to Article 62 of the TRIPS, it is provided that

ñArticle 62 authorizes Members to require compliance with reasonable procedures as a condition of the acquisition or maintenance of patentsé .. Article 62.1 establishes that such procedures and formalities shall be consistent with the provisions of the Agreement. In other words, they shall comply not only with the basic principles of the Agreement, including the national treatment and the most-favoured- nation treatment principles but also with specific relevant provisions. This means that a link exists between the reasonable procedures admitted by article 62 and the conditions of patentability established in section 5 of part II, namely Article 27.1 and Article 29. Second, Article 62.2 clarifies that the procedures, subject to compliance with the substantive conditions for acquisition of the right established by Article 27.1, should permit the granting of the right within a reasonable period of time so as to avoid unwarranted curtailment of the period of protection.

[127] *Ibid.*

> Therefore, it appears that reasonable procedures are those that assist patent administrations to assess whether the substantive conditions, such as novelty, inventive step, and industrial applicability have been met by the invention the patentability of which is under examination. In addition, moderate fees are admitted. This understanding results not only from the reading of the text of the TRIPS Agreement, but also from the history of the negotiations. During the negotiations members never proposed that conditions that did not relate to the characteristics of the invention or the fees to be charged by patent offices would be admitted.ò[128]

Now, the major issue to be ascertained is whether there are any inconsistencies between the proposed disclosure requirements and the TRIPS. The above argument is an outright denial of any possible effort to link the two agreements. Carlos M. Correa is of the opinion that the obligation to disclose the origin of the biological material is not a patentability criterion, but a component of the disclosure requirement under Article 29 of the TRIPS and that inclusion of the proposal via an amendment is in no way violating any provision in the TRIPS[129]. He also argues that such an amendment will not discriminate the field of technology as prohibited by Article 27.1 based on the reasoning of the WTO Panel that Article 27 does not prohibit bonafide exceptions to deal with problems that may exist only in certain product areas[130]. Adopting the reasoning of Correa, we can come to the conclusion that there is nothing wrong in incorporating the triple disclosure requirement that it is not creating any compatibility problems with the TRIPS. The reason behind emphasising triple disclosure requirement instead of confining it to source and country of origin is clear

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[128] *Ibid.*
[129] Carlos M. Correa, ñThe Politics and Practicalities of a Disclosure of Origin Obligationò, QUNO Occasional Paper 16 January 2005
[130] *Ibid.*

from the interpretation of the WTO Panel. This is because what the Panel has asserted is Article 27 of the TRIPS as a whole and not to Article 27.1 only. From this, we can read that bonafide exceptions can be adopted even in the context of patentability criteria to deal with extreme cases in relation to certain product areas. Even if this reasoning is not adopted, it is possible to establish link between the patentability criteria vis-à-vis the associated TK over the GRs involved in the invention. It is an accepted fact that TK associated with GRs could constitute prior art when they are considered the known uses prevalent regarding the resource[131]. It can have a relationship with the question of inventive step when a resource holder is considered as the person skilled in the art in relation to the uses of a GR. But its application is limited in the context of CBD because even though a reference to the community/ knowledge holder is given and the benefits are shared with him/them, it cannot cover the whole range of misappropriation taking place through patenting. Such a linking will only help in cases where the TK is involved, and cannot ensure benefit sharing by providing access to the resources only. Now, considering the question of inclusion of requirements in relation to PIC and benefit sharing into the TRIPS, the main bottleneck is the argument that they are not related to the substantive patentability criteria. Based on the present proposals, the only possible way is to accept Correaôs reasoning together with the WTO Panel decision as discussed above and accept the proposal as a political agenda. To keep the TRIPS as a vibrant document responding to the needs of the society at large, such a compromise seems inevitable.

From the CBD point of view, the ultimate aim is to secure benefit sharing from the use of GRs and associated TK. The purpose of integrating CBD goals within the TRIPS is to reap maximum benefits from patenting and subsequent commercialization of the inventions using GRs and TK. But,

[131] This could be understood from the consideration of novelty in *Neem* and *Turmeric* patent cases.

finally the TRIPS deliberations do not seem to be in line with this objective and are mostly concentrated on the issue of prevention of bad patents. So it is assumed that the outcome of the present negotiations is not going to satisfy the benefit sharing objective of the CBD. This reveals the need of some mechanism within the TRIPS itself which could generate benefits to the countries of origin and the local and indigenous communities concerned and the strategy should not be to confine the same to the IP aspects of ABS, instead should take a holistic approach treating the GR and associated TK as a potent category for IP protection.

6.8 Initiatives in WIPO: A Brief Overview

WIPO is an UN agency for promotion of IPRs among the Member States. WIPO started its work on the interrelationship between GRs, TK and folklore and IP, leading to the creation of an Inter Governmental Committee (IGC) to act as a separate forum to deal with issues related to interfaces between IP and GRs, TK and folklore[132]. IGC is the negotiating and decision-making body of WIPO. In the initial stages, WIPO envisioned a system of positive protection to TK, comprising the major elements such as PIC and benefit sharing, and prevention of misappropriation[133]. For GRs, WIPO wanted to devise a defensive protection model with three clusters of options[134]. Cluster A relates to providing defensive protection for GRs through (i) inventory of databases and information resources on GR; (ii) information systems on GR for defensive protection[135] and (iii) guidelines or

[132] WIPO IGC, ñMatters Concerning Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore: An Overviewò, WIPO/GRTKF/IC/1/3 dated 16 March 2001 para. 1 &2

[133] Secretariat, ñThe Protection of Traditional Knowledge: Revised Objectives and Principlesò, WIPO/GRTKF/IC/16/5 dated 22 March 2010

[134] Secretariat , ñGenetic Resources: Revised List of Optionsò, WIPO/GRTKF/IC/16/6 dated 22 March 2010

[135] This envisages creation of online portal of registries and databases as a one-stop shop for genetic resources.

recommendations on defensive protection[136]. Cluster B relates to disclosure requirements in patent applications for information related to GR used in the claimed invention and the options in this regard include (i) mandatory disclosure requirement on source and country of origin of GRs in patent applications; (ii) further examination of issues relating to disclosure requirements; (iii) development of guidelines and recommendations on disclosure and (iv) alternative mechanisms to bring in consistency between ABS measures for GR and national and international patent law practices. Cluster C relates to IP issues in MATs for fair and equitable sharing of benefits from the use of GR and the options include (i) online database of IP clauses in MATs on ABS; (ii) draft guidelines on contractual practices and (iii) study on licensing practices on GR. Since the negotiations on these items reached nowhere, WIPO, in its sixteenth session of the IGC held during May 2010, called for the creation of three Inter-sessional Working Groups (IWG) to deal with Traditional Cultural Expressions (TCEs), GRs and TK[137]. The IWGs have to provide legal and technical advice and analyses for the consideration of the IGC. The IWGs are mandated to devote equal time to the three items under the consideration of the IGC and to report the outcome of their work to the IGC and to submit recommendations and texts relating to the discussion in the IGC[138]. On GRs and TK, WIPO/GRTKF/IC/16/6[139] and 16/5[140] constituted the working documents respectively for the IWGs. The third IWG developed objectives and principles for GRs and requested the 18th Session of IGC to consider the same. The 18th session adopted the recommendations of third IWG and narrowed down the options in the objectives and principles and forwarded

[136] Guidelines or recommendations for search and examination procedures for patent applications to ensure that they better take into account disclosed genetic resources.
[137] Decisions of the Sixteenth Session of the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore , 3-7 May 2010
[138] *Ibid.*
[139] *Supra* n.134
[140] *Supra* n.133

the same to 19th IGC as working document WIPO/GRTKF/IC/19/6[141]. The 19th IGC further reduced the options and recommended for the development of appropriate international legal text for the protection of IP associated with GRs. It also suggested two other documents namely, óOptions for Future Work on Intellectual property and Genetic Resourcesõ[142] and óLike-Minded Countriesô Contribution to the Objectives and Principles on the Protection of Genetic Resources and Preliminary Draft Articles on the Protection of Genetic Resourcesõ[143] to be transmitted as working documents along with other existing working documents for the next session of the Committee[144]..

A glimpse of the Draft Objectives and Principles as contained in IC/19/6 comprises of five different objectives in relation to IP and GRs. The document provides different options for the five objectives and also tries to fix the principles behind such objectives through different options. The first objective is to require compliance with national laws of the country of origin requiring PIC, MAT and disclosure of origin by persons accessing the resources including those who apply for IPR[145]. It is based on the principle of recognising ownership rights over GRs and associated TK, including the sovereign rights, rights of ILCs and other private property rights[146]. The second objective is to prevent the grant of IPRs over GRs and in this area, the language of the different options show two clearly divergent views[147]. One option is to prevent the grant of IPR over GRs and associated TK when they are obtained in violation of national laws requiring PIC, MAT, benefit

[141] Draft Objectives and Principles Relating to Intellectual Property and Genetic Resources, IGC 19th Session, Geneva, July 18-22, 2011
[142] Secretariat, ñOptions for Future Work on Intellectual Property and Genetic Resources", WIPO/GRTKF/IC/19/7 dated 20 May 2011
[143] Indonesia, ñLike-Minded Countriesô Contributions to the Objectives and Principles on the Protection of Genetic Resources and Preliminary Draft Articles on the Protection of Genetic Resourcesò, WIPO/GRTKF/IC/19/11 dated 18 July 2011
[144] Draft Decisions of the 19th Session of the Committee, Geneva July18-22, 2011
[145] Secretariat, ñDraft Objectives and Principles Relating to Intellectual Property and Genetic Resourcesò, WIPO/GRTKF/IC/19/6 dated 20 May 2011, Objective 1
[146] *Id.* Principle of Objective 1
[147] *Id.* Objective 2

sharing and disclosure of origin. The other options give emphasis to prevent grant of IPR when the invention do not satisfy the eligibility conditions of novelty and inventive step. Two problems could be identified with the second option. One is that the grant of IPR will not become conditional to benefit sharing obligation. Second is that as of now, there is no universally accepted standards for novelty and inventiveness, which could still lead to potential cases of biopiracy. So the first option seems to be the best considering the interrelationship between GRs, associated TK and patentability standards. As regards the principle behind the objectives, the same divergence could be perceived[148]. One option talks only about prevention of the grant when patentability criteria are not satisfied and emphasises that the patent system should provide certainty of rights for legitimate users of GRs. On the other hand, the other options talk also about the rights of the legitimate providers of GRs insisting that there should be mandatory disclosure requirements in the IP system, ensuring compliance with the domestic ABS laws. It further adds that patent office should be key check points to ensure disclosure. This could be viewed as an aim which was not achieved at the Nagoya Protocol and if this could be realized, this will up to a great extent, adequately address the gap prevailing in the Nagoya Protocol. The third objective is to link the patent system with the available information on GRs and associated TK through internationally recognised certificate of compliance[149]. The principle behind it is that the IP office should consider all relevant prior art[150] and among the two available options for the principle, one view asserts that to facilitate prior art assessment, the patent applicant should disclose the background information which can be regarded as useful for understanding, searching and examination of the invention. The negative side of this option is that it allows a possible

[148] *Id.* Principle of Objective 2
[149] *Id.* Objective 3
[150] *Id.* Principle of Objective 3

argument that disclosure in relation to PIC and benefit sharing has nothing to do with the patentability requirement. But the other option is more stringent, providing that IP offices should consider all relevant prior art information relating to GRs, their derivatives and associated TK when assessing the eligibility for the grant of IPRs. Further, it imposes a mandate on the IP applicants to disclose all background information on GRs, their derivatives and associated TK relevant for determining eligibility conditions. The fourth objective is to promote a mutually supportive relation with international agreements and regional arrangements dealing with IPRs, GRs and associated TK[151]. This objective is based on the principle of bringing in consistency between TRIPS and other international instruments on GRs and associated TK[152]. The fifth objective is to recognise the role of IPR in promoting innovation, and transfer and dissemination of technology and use the same for the mutual advantage of holders and users of GRs, their derivatives and associated TK conducive to social and economic welfare[153]. This is based on the principle that a mandatory disclosure obligation in relation to the country of origin, PIC and benefit sharing would increase the legal certainty and transparency of the IP system[154]. The attempt is to develop a legal text linking these objectives and principles to the cluster of options identified in the document dealing with ówOptions for Future Work on Intellectual Property and Genetic Resourcesô. There are many proposals on the table on mandatory disclosure[155] which are similar to those tabled in the TRIPS Council, including the draft Articles presented by the Like-Minded Countries[156]. These documents are going to be considered together in the next IGC for development of a legal instrument on GRs. Now the WIPO has

[151] *Id.* Objective 4
[152] *Id.* Principle of Objective 4
[153] *Id.* Objective 5
[154] *Id.* Principle of Objective 5
[155] Switzerland, ñFurther Observations by Switzerland on its Proposals Regarding the Declaration of the Source of Genetic Resources and Traditional Knowledge in Patent Applicationsò, WIPO/GRTKF/IC/7/INF/5
[156] *Supra* n.143

adopted a draft negotiation text on Intellectual Property and the Protection of Genetic Resources [Their Derivatives] and Associated Traditional Knowledge in February 2012 containing many items discussed on the interrelationship between IPR and CBD as discussed in previous chapters. So the present chapter omits similar discussions on WIPO negotiations as it stands today.

A close look at the recent WIPO initiatives on GRs gives the impression that the effort is mainly to address the gap created in the Nagoya Protocol as much emphasis is given to disclosure requirements and to impose obligation upon the patent office as a check point in the process of ABS. It is interesting to note that on GRs, WIPO is specifically looking into the interrelationship between IP and GRs and no other issues. The positive protection of GRs lies in the CBD based domestic framework. The present work concentrates on the grant of IPR for inventions based on GRs and associated TK. WIPO is also addressing the issue of developing a *sui generis* law for the protection of TK including TK associated with GRs[157]. In Article 3 dealing with scope of protection some countries suggested positive protection including linking TK protection with grant of IP[158]. In case of GRs what becomes more important is the link between IP and GRs and associated TK through mandatory disclosure requirements which the IGC is rightly focussing in the GRs document. Given the differences reflected in the objectives and principles it is doubtful whether there is going to be any agreement on developing appropriate legal instrument for solving the issues relating to IP and GRs. Assuming that there is a positive outcome its inability lies in the impossibility of the forum to offer any binding obligations. Further and more pertinent is the principle that its work should

[157] Secretariat, ñThe Protection of Traditional Knowledge, Draft Articlesò, WIPO/GRTKF/IC/19/5 dated 20 May 2011
[158] *Id.* Article 3

not prejudice the work pursued in other fora[159]. As such there is no linkage between the WIPO initiatives and the TRIPS Council deliberations which makes the status of WIPO efforts uncertain. In light of this uncertainty, TRIPS seems to be the best platform to deal with the issue of conflict between CBD and IP protection.

[159] *Supra n.*145 Option for Principle of Objective 4.

Chapter 7
CONCLUSION

To quote Mahatma Gandhi, ñIt 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.ò 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 anybodyøs 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 ñcommonò 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 óderivativesô 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 ófairnessô 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

sovereignty 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 worldôs 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 breedersô 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 ón the form received from the MLSô 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

[1] Peter Drahos, ñIndigenous Knowledge, Intellectual Property and Biopiracy: Is a Global Bio-collecting Society the Answerò, E.I.P.R., 2000, 22(6), 245-250
[2] Dutfield and Posey, Beyond Intellectual Property: Toward Traditional Resource Right for Indigenous Peoples and Local Communities, IDRC, 1996
[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.