

ADDIS ABABA UNIVERSITY
SCHOOL OF GRADUATE STUDIES
SCHOOL OF LAW



**The Interface between Access to Genetic Resources, Benefit Sharing and
Intellectual Property Right Laws in Ethiopia: Analysis of their Synergies**

By Nega Mirete

December, 2010

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**A Thesis submitted to Addis Ababa University, the school of Graduate
Studies, School of Law in Partial fulfillment of the Requirements for the
Degree of Master of Laws (LL.M) in Business Law**

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Declaration

I, the undersigned, declare that this thesis is my original work, has not been presented for a degree in any other University and that all sources of materials used have been appropriately acknowledged.

Name _____

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Addis Ababa University

December, 2010

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Acronyms and abbreviations

ABS	Access and Benefit Sharing
CBD	Convention on Biological Diversity
COP	Conference of the Parties
DRs	Disclosure Requirements
EIPO	Ethiopian Intellectual Property office
GRs	Genetic Resources
IP	Intellectual Property
IPRs	Intellectual Property Rights
ITPGRFA	The International Treaty on Plant Genetic Resources for Food and Agriculture
MAT	Mutually Agreed Terms
PBRs	Plant Breeders' Rights
PIC	Prior Informed Consent
PVP	Plant Variety protection
TK	Traditional knowledge
TRIPs	Agreement on Trade-Related Aspects of Intellectual Property Rights
UPOV	International Union for the Protection of New Varieties of Plants
WIPO	World Intellectual Property Organization
WTO	World Trade Organization

Abstract

The issue of the relationship between Access to Genetic Resources and Benefit Sharing (ABS) and Intellectual Property Rights (IPRs) is partly related to whether or not patents or other IPRs over genetic resource related inventions should be conditional up on Genetic Resources (GRs) being accessed legally as per ABS laws and regulations of the country from which they are accessed. Several national ABS laws now require that an application for IPR based on GRs or have made use of GRs disclose the source/origin of the GR, proof of prior informed consent (PIC) and proof of benefit sharing arrangements (the disclosure requirements). These requirements are put as a condition to access GRs under the Convention on Biological Diversity (CBD).

Disclosure requirements, as a way to prevent misappropriation of GRs through IPRs without benefit sharing arrangements, have been proposed in different international fora and national lawmaking processes. The recently adopted Nagoya Protocol on ABS has while addressing these issues it does not include mandatory DRs as a compliance mechanism. The issue is also being discussed in the TRIPs Council (Trade Related aspects of Intellectual Property Rights).

This study seeks to address the relationship between IPRs and ABS with a particular focus on the disclosure requirements. In that light analyses have been made on the pertinent international law on the subject as well as on Ethiopian laws having relevance to the issue. An attempt has also been made to examine the two ABS Agreements Ethiopia has concluded thus far. The analyses in the paper have come with the following findings: (1) the Ethiopian legal regime on access to GRs, with a view to create a link between ABS and IPRs, requires the access permit holder to recognize the locality from where the GR was accessed as origin in IPR applications; (2) the Proclamation on Inventions, Minor Inventions and Industrial Designs does not make the patentability of inventions based on GRs contingent up on lawful access of the resources thereto; (3) the legal regime providing for plant breeders' rights has made proof of access in accordance with access legislations as a condition for the grant of a plant breeder right; (4) the two ABS agreements Ethiopia has concluded thus far have included IPR related provisions and in particular, they have imposed an obligation on user companies to recognize Ethiopia as a country of origin in the former and source in the latter in IPR applications on products developed from the accessed GRs.

Based on the analyses, the paper has made a range of recommendations with a view to ensuring a coherent relationship between IPRs and ABS in Ethiopia.

Key words: Access and Benefit sharing, intellectual property rights, disclosure requirements

I. Introduction

A. Background

Before the Convention on Biological Diversity (CBD)¹ era, GRs were considered as the 'common heritage of mankind' and as a result they were treated as freely accessible commodities.² States had allowed access to their GRs and permitted their export for the purpose of scientific research, plant breeding or conservation, free of charge.³ Using the advancements in biotechnology, developed countries have utilized the freely accessed GRs to develop products of a commercial value. As a sector dependent on investment and highly skilled innovators, the biotechnological industry relies on IPRs to secure an option to obtain market exclusivity and capture benefits from marketed products.⁴ However, benefits have not been shared with the concerned state and local communities who have conserved the GRs utilized in the development of commercially valuable products.⁵ Let alone sharing benefits, developed countries have required users in developing countries to purchase these products from whom the GRs had been accessed.

This inequity has led developing countries to air out their concerns on the need to have a regulatory framework on access to GRs and benefit sharing. The result had been the adoption of the CBD in 1992 and the demise of the notion of the common heritage of mankind and the recognition of national sovereignty over GRs. Under the CBD, in return for facilitating access to GRs, countries are entitled to a fair and equitable share in the benefits that flow from the utilization of these resources.⁶ This is the third of the three objectives of the CBD; the other two being, conservation and sustainable use of biological diversity. The CBD emphasized that access

¹ The CBD is a convention adopted during the Rio Earth Summit in 1992 under the auspices of the United Nations. The convention came in to force 1993 having three main objectives: the conservation, sustainable use of biological diversity and benefit sharing of genetic resources. The CBD is a legally binding framework for the conservation and sustainable use of all biological diversity and is intended to establish processes for the equitable sharing of benefits arising from the use of biodiversity. To this, governments have created a number of instruments including the conference of the parties (COP). See Secretariat of the CBD, Handbook of the Convention on Biological Diversity including its Cartagena Protocol on Biosafety, (3rd. 2000), P. 12

² Oldham, P., Global Status and Trends in Intellectual Property Claims: Genomics, Proteomics and Biotechnology, UNEP/CBD/WG-ABS/3/INF/4, 2004

³ Fikremarkos Merso and Imiru Tamrat, Some Thoughts on the Benefits and Costs of the Regulatory Framework on Access to Genetic Resources and Benefit Sharing in Ethiopia, JEL, V.24, No.1, 2010, P. 124

⁴ The Feasibility, Practicality and Cost of a Certificate of Origin System for Genetic Resources: Preliminary Results of a Comparative Analysis of Tracking Material in Biological Resources Centers of Proposals for a Certification Scheme, 2005, UNEP/CBD/WG-ABS/3/INF/5

⁵ Ibid

⁶ CBD, Article 1

to GRs should be based on PIC of the concerned state authority and based on benefit sharing arrangements made on mutually agreed terms (MAT).⁷

But, after the adoption of the CBD, the objective of fair and equitable sharing of benefits arising from the utilization of GRs is far from being achieved and continued to stir up heated debates, nationally and internationally.⁸ This is partly attributable to the limitation of the standalone ABS legislation in ensuring compliance with ABS conditions. This, in turn, links ABS with IPRs as the IPR system, Patent and Plant Breeder's Right Laws in particular, are believed to be an important checkpoint for the incorporation of disclosure requirements (DRs hereinafter) to verify compliance with ABS requirements and support the realization of the ABS objectives as outlined in the CBD and national ABS legislations.⁹

Therefore, incorporation of DRs in IPRs laws in order to give a panacea to the problems of illegal access and ensuring compliance with ABS conditions emerged as one of the most prominent issues in international foras and national law making processes. This is because the idea of creating synergies between different legal regimes- ABS and IPRs- raises considerable policy, legal and practical challenges that have been addressed over time in various countries' laws and regulations.¹⁰ At present, legislations which have included DRs have multiplied around the world, albeit not without debate and opposition.¹¹

Of course, there has been much debate about the role or impact of IPRs in relation to the conservation, sustainable use and ABS. The relationship between the abovementioned principal objectives in relation to GRs enshrined under the CBD and national access legislations and IPRs is the subject of continuing debate at national, regional and global level.¹²

⁷ CBD, Article 15(7)

⁸ Manuel Ruiz and Isabel Lapena (eds.), A Moving Target: Genetic Resources and Options for Tracking and Monitoring Their International Flow, 2007, available at: <http://www.earthprint.com/product/focus.php?id=IUCN2230>; accessed on 4 October 2010

⁹ Ibid

¹⁰ Jorge Cabrera Medaglia and Christian López Silva, Addressing the Problem of Access: Protecting Sources while Giving Users Certainty, 2007, available at: http://www.islandpress.com/bookstore/details5869.htm?prod_id=1560; accessed on 3 September 2010

¹¹ Ibid

¹² Richard G. Tarasofsky, A Study on the Relationship between Intellectual Property Right Regimes and the Conservation of Genetic Resources, 2002, available at <http://www.Ecologic.de> ; accessed on April23/2010

In this regard, there are different opinions on the negative or positive linkages between IPRs and biodiversity in general and ABS in particular. A number of commentators have suggested that the IP system thwarts ABS objectives.¹³ One impact of IPRs -specifically patents- on the control and sustainable use of GRs has been the direct or indirect misappropriation of GRs or which has been called “biopiracy”.¹⁴ Such a claim is particularly true with the increased application of GRs, which has increased the economic and commercial utility of such resources.¹⁵ This, in turn, has resulted in the emergence of a new era of discovery and patent filings, in the form of biological processes and plant varieties.¹⁶

The arguments forwarded in claiming that IPRs are not supportive of the ABS objectives do not end here. Some opine that IPR rules do not support placing safeguards that would ensure that the ABS arrangements under the laws of different countries are being properly implemented.¹⁷ This claim is advocated by those who are urging for the incorporation of DRs in the process of acquiring IPRs over inventions involving GRs.¹⁸

On the other hand, there are claims made on the positive roles of IPRs on the conservation, sustainable use and benefit sharing of GRs. For instance, IPRs can help attain the ABS objectives set forth on the ABS laws of different countries. This is precisely because IPRs can help facilitate transfer of knowledge and technology and so much so that providers of GRs can get access to the important knowledge and technology for sustainable use and conservation of GRs

¹³ Kim Connolly Stone, A Paper Presented in an International Workshop on Access to Genetic Resources and Benefit Sharing, Specific Issues for Consideration in the Elaboration of the IPRs: Interface with existing IP systems and limits and opportunities for existing IP Rights, available at [Http://www. IPRsonline.com](http://www.IPRsonline.com); accessed on 23 April 2010.

¹⁴ Manuel Ruiz, a Background Paper for Workshop on TRIPS and CBD on Intellectual Property Rights and Biodiversity: Processes and Synergy, 2002, P.5. Biopiracy refers to the appropriation of GRs without the prior informed consent of the local community and/or of the competent authority of the respective state, for access and benefit sharing, under mutually agreed terms. See the Crucible II Group, Policy options for Genetic Resources: People, Plant and Patents Revisited, V.1, 2000, P.22.

¹⁵ Teshager Worku, The Application of Intellectual Property Rights for Biodiversity Resources: a Technique for the South Counties to Maintain control over the Biodiversity Resources in their Territories, available at <http://ssm.com/abstract=13566664>; accessed on 12 April 2010.

¹⁶ Ibid

¹⁷ Ibid

¹⁸ Tarasofsky, Supra note 12 at 27.

through licenses, joint ventures, research and development projects and disclosure of the protected invention in public patent specifications.¹⁹

Besides this, IPRs are considered as an incentive to conserve GRs as they create value in them.²⁰ The argument here is that by attaching IPRs to inventions involving GRs, these resources increase value and therefore create an incentive to conserve such resources. In relation to benefit sharing, IPRs are one possible forms of benefit that could be shared and therefore they can be considered as an important instrument in ensuring benefit sharing providers of GRs claim to get after the commercialization of same.

These claims on the positive and negative roles of IPRs on the achievement of ABS objectives suggest that there is a sound reason to be concerned about the impacts of IPRs on ABS and harnessing its positive role. The areas of interface between IPRs and ABS have been considered in different international regimes. In this regard, the CBD and the Trade Related Aspects of Intellectual Property Rights²¹ (TRIPS Agreement) are worth mentioning.

Of the many issues contained on CBD, the relationship between IPRs and ABS has been controversial over the past few years.²² The provision of the CBD that relates directly to IPRs and ABS is Article 16(5) which states that: “The Contracting Parties, recognising that patents and other intellectual property rights may have an influence on the implementation of this Convention, shall co-operate in this regard subject to national legislation and international law in order to ensure that such rights are **supportive of and do not run counter to its objectives.**”(Emphasis added) This provision is linked to the very heart of the relationship between IPRs and ABS since it compels us to pose the question: are IPRs a positive or negative incentive for the realization of ABS objectives?

¹⁹ Stone C., What To Do about Biodiversity: Property Rights, Public Goods and the Earth’s Biological Riches, 68 Southern California Law Review (1994-1995), P.577

²⁰ Ibid.

²¹ The TRIPs Agreement was concluded in the packages of agreements in the World Trade Organization in 1993. And the agreement sets minimum standards for patents and other IPRs for its member countries.

²² Supra Note 4

In any case, being considerate of the fact that the relationship between IPRs and ABS is blurred under the CBD, the conference of the parties²³ (COP) has taken a number of decisions. Nonetheless, none of them have resolved the issue once and for all.

Be that as it may, the provision of the TRIPs Agreement which has a direct or indirect bearing on ABS is Article 27. This provision provides for patentable subject matters and exclusions from patentability. In addition to this, Articles 8 and 29 which address principles under which members may adopt necessary legal measures (when developing their IPR legislation) in order to promote the public interest are relevant as regards to the inclusion of DRs. But then, the impact of the TRIPs Agreement on the achievement of ABS objectives is not clear.²⁴ That is why, it is one of the agendas in the review of Article 27 (3) (b).

These international legal regimes have an impact on Ethiopia's legal regime on the promotion of IPRs and the achievement of ABS objectives. This is because Ethiopia is a party to the CBD and it is on the process of accession to the WTO. As a result of this, the country has adopted a law for the implementation of the CBD - Proclamation No. 482/2006 on Access to Genetic Resources and Community Knowledge and Community Rights (hereinafter the ABS Proclamation). This law, *inter alia*, has the objectives of conservation and sustainable use of GRs and ensuring the fair and equitable sharing of the benefits arising out of its use. In addition to this, it has enacted Proclamation No.123/1995 - a Proclamation on Inventions, Minor Inventions and Industrial Designs (the Proclamation on Inventions) to reward inventors and thereby encourage innovation.

What is more, the country has also promulgated Proclamation No.481/2006- a Proclamation to Provide for Plant Breeders' Right- (PBRs Proclamation hereinafter) in order to improve agricultural production using new plant varieties developed through research and development,

²³ COP 2 adopted decision II/12 which requested the CBD Secretariat to liaise with the WTO and undertake a preliminary study on the impacts of IPRs on conservation and sustainable use of biodiversity and the equitable sharing of benefits derived from its use. COP 3 (Decision III/17) on IPRs called for a case study to be developed on the impacts of IPRS on achieving the objectives of the CBD and stressed the need for cooperation among the CBD, the WTO and the world intellectual property organization-WIPO. COP 4 (decision IV/15) addressed the relationship between CBD and the WTO- the TRIPs Agreement. In addition to this, COP 6 (decision VI/24 - the Bonn Guidelines) includes several references to IPRs. According to paragraph 16(d), parties should consider taking measures to encourage the disclosure of the country of origin of the genetic resources in application for IPRs. See *supra* note 9 at 10-11.

²⁴ *Supra* Note 4

to reward an economic benefit to those engaged in plant breeding and to ensure the rights of the farming communities to continue using their customary practice of use and exchange of seeds as can be inferred from the preambular statement of the law. In fact, it can be conjectured that enacting TRIPs compliant laws has necessitated the coming in to existence of this law.

B. Statement of the Problem

As mention has already been made in the background, within the framework of the CBD and national ABS laws, access to GRs requires the PIC of the designated state authority and Mutually Agreed Terms (MAT) on the share of the benefits arising from the use of GRs.²⁵ However, after the adoption of the CBD and putting in place ABS laws and regulations at national level, misappropriations of GRs remain a problem; and implementation of ABS conditions (PIC and benefit sharing) remains a challenge. In particular, IPRs have been granted for inventions based on these resources and their subsequent commercial exploitation by multinational corporations, without securing PIC and without any benefits returning to them.²⁶ One reason for this is believed to be the unresolved relationship between ABS and IPRs; which in turn, has led calls for reform of the IPR system.²⁷ To this effect, the introduction of DRs, with all the controversies surrounding it, has been proposed as one important measure at national and international level.²⁸

Ethiopia on its part has enacted IPR laws on the one hand and ABS law on the other whose cooperation is believed to be important for ensuring the equitable share of the benefits arising out of the utilization of GRs and the implementation of ABS conditions in general. Recognizing the positive and/ or negative effects of IPRs (Patent and Plant Breeders' Rights in particular), the ABS Proclamation has made a reference to IPRs under the provisions of Arts.17 (12) (13) & (14) and 19(6). By the same token, the PBRs Proclamation has made a reference to the ABS Proclamation under Article 14(3). Therefore, it is important to determine where conflicts between the ABS and IPR regimes may arise, as well as how synergies between these regimes may be achieved.

²⁵ Janak Rana Ghose, access and benefit sharing systems: an overview of the issues and the regulation, 2003, available at: [Http://www.ranaghose.com/research/](http://www.ranaghose.com/research/); accessed on 13 December 2010

²⁶ Ibid

²⁷ CISDL, overview of the national and regional implementation of access to Genetic resources and benefit sharing measures, 2005, available at: [Http://www.cisd.org/pdf/CISDL_ABS_imp_study_final.pdf](http://www.cisd.org/pdf/CISDL_ABS_imp_study_final.pdf); accessed on 10 December 2010

²⁸ Ibid

C. Research Questions

This research which studies the relationship/interface between ABS and IPR legal regimes in Ethiopia will answer the following questions:

- ♣ Do IPR laws (the Proclamation on Inventions and the PBRs Proclamation) in Ethiopia support/facilitate the implementations of the ABS objectives incorporated in the ABS Proclamation?
- ♣ What synergistic relationship do these laws have, positive or negative? Do the Proclamation on Inventions and the PBRs Proclamation run counter to the ABS objectives of ABS Proclamation?

D. Objectives of the Study

The main purpose of this research is to explore the interface between the ABS Proclamations and IPR Laws under the Ethiopian Legal System. The research will see to it whether the IPR laws- the Proclamation on Inventions and PBRs Proclamation in particular- in the country are supportive of the objectives of ABS Proclamation or run counter to it. It will also assess the possible mechanisms in order to create cooperation between the two legal regimes at the law making process and at the implementation stage. In particular, the research has the following specific objectives:

- ♣ To appraise the impacts (negative and/or positive) of IPR laws in Ethiopia in facilitating the fair and equitable share of the benefits arising out of the utilization of GRs;
- ♣ To examine international legal instruments having a direct or indirect bearing on the interface between IPRs and ABS objectives;
- ♣ To make survey of the laws of some countries on the issue under consideration;
- ♣ To analyze the interplay between Ethiopian Legal regimes which have a direct nexus with the issue at hand;
- ♣ To enquire whether the ABS Agreements so far made by the country have taken in to account the impacts of IPRs on the achievement of ABS objectives;

E. Significance of the Study

The significance of this study stems from the background stated above. This research which will examine the interplay between IPRs and the ABS objectives in Ethiopia will have a significant contribution to different stakeholders as it stimulates thinking among policymakers and academics. To begin with, it will help policy and law makers in IPRs and ABS to understand and give informed decisions on issues which link IPRs with ABS. Apart from this, it will be significant for law makers in order to understand the impacts of some international regimes (the TRIPs agreement for example) on the ABS objectives. This is particularly true in for a country which is in the process accession to the World Trade Organization (WTO). Besides these, it would serve as a base for future research on the current contentious issue of the interface between IPRs and ABS

F. Methodology

The research will employ a combination of different approaches. Literature review will provide the conceptual basis on the subject matter. Analysis of the concerned legal regimes will be made by exploring a number of international and national laws that have a direct or indirect bearing on shaping national IPR and ABS laws. Apart from this, discussions with the concerned authorities in the area will be conducted as it could be of help in searching for different mechanisms for the cooperation of the two legal regimes (the IPR and ABS) in the process of law making and at the stage of implementation.

G. Limitation and Delimitation

The research embarks on a relatively recent issue and there are only few published materials. In fact, there are no published materials which take in to account the Ethiopian situation. And therefore reliance is made on foreign literatures which can be found in an electronic form. Even in this case, the majority of the relevant sources are not freely available. This will hinder accommodation of diverse views on the issue at hand.

This being so, the research will not deal with the interface between all IPR Laws and the ABS Proclamation. Ethiopia has so far enacted numerous IP laws, such as, the Proclamation concerning Inventions, Minor Inventions and Industrial Design (Proclamation No.123/1995), the

Proclamation on Copyright and Neighbouring Right (Proclamation No. 410/2004), the Proclamation on Trademark Registration and Protection (Proclamation No. 501/2006), and the Plant Breeders' Right Proclamation (Proclamation No.481/2006). This is, of course, without taking in to account the Geographical Indications law which is at its draft stage. The research will primarily focus on the Proclamation on Inventions and the PBRs Proclamation. This is because these are IPR laws which have a direct nexus with ABS. And, it will be difficult, if not impossible; to deal with all these IP Laws.

H. Organization of the Thesis

To achieve the objectives set above, the thesis is divided in to four chapters. The first chapter attempts to establish the relationships between ABS and IPRs at conceptual and theoretical level. The second chapter discusses the place given to IPRs for the implementation of ABS requirements and the problems thereto in the CBD and it gives a snapshot of the different COP decisions on the matter. The chapter also highlights the debates on the issue of incorporating DRs in the TRIPs Agreement with a view to ensure compliance with ABS legislation. The third chapter is dedicated to analyze the positive and negative synergies between the ABS Proclamation on one side and the Proclamation on Inventions and the PBRs Proclamation on the other. The fourth chapter expounds IPR related terms enshrined in the Teff and Vernonia ABS agreements with a view to point out the need to get the support of the IPR system for the implementation of some obligations imposed on users. In fact, the chapter tries to indicate the challenges of implementing ABS agreements from the perspective of the IPR system. Finally, the synopsis of the issues addressed throughout the thesis and recommendations are given, which in the judgment of the writer, are points worth praising.

Chapter One

Conceptual and Theoretical Underpinnings on the Relationship between Access to Genetic Resources and Intellectual Property Rights

1.1. Defining Genetic Resources

As this work dwells on the interface between IPRs and ABS legal regimes, it is quite indispensable to define what GRs are. To begin with, as per Article 2 of the CBD, GRs are defined as: ‘genetic material of actual or potential value.’ Genetic materials, in turn, are defined as: ‘... any material of plant, animal, microbial or other origin containing functional units of heredity.’

More or less similar definition is provided for the ABS Proclamation. The OAU (now called the African Union) Model Law has also enshrined an equivalent definition.²⁹ Article 2(3) of the ABS Proclamation defines GRs as: "...any genetic material of biological resources containing genetic information having actual or potential value for humanity and it includes derivatives." On the same vein, the OAU Model Law defined Biological Resources as: Biological Resource includes genetic resources, organisms or parts thereof, populations, or any other component of ecosystems, including ecosystems themselves, **with actual or potential use or value for humanity.**³⁰ (Emphasis mine)

From these definitions given above, one can discern that genetic material may have any biological origin of plants, animals, microbial or other organisms. And from the wordings of these definitions, there are two elements which require a brief elucidation. These are: functional units of heredity and actual or potential value to humanity.

The first qualifying element in the abovementioned definitions is that genetic material is any material containing ‘functional units of heredity’ which is not further explained in neither of the

²⁹ The African Model Law was developed by the OAU task force in 1997 and adopted in 1998 by the OAU ministerial session and the OAU Summit of Heads of State and Government as Model Legislation on the Protection of the Rights of Local Communities, Farmers, Breeders and the Regulation of Access to Biological Resources to guide the African countries on the issues it has covered. The OAU Heads of State recommended that it become the basis all national laws on the matters across Africa.

³⁰ J.A. Ekpere, An Explanatory Booklet on African Model Law,(2000) ,P.8

instruments cited above. In the English language, the term functional has a broad meaning³¹ which includes the dynamic element as the state of knowledge and technology necessarily develops through history.³² Functionality is used in connection to the term ‘units of heredity’. For the present purpose, units of heredity in the definitions given above for GRs refers to genes found in cells of living organisms. So much so that, if a biological resource contains a gene, it has met one of the elements in the definitions given for GRs. Having said these much on genes as units of heredity, it is appropriate to say a few words on the other important element, i.e., genetic material having actual or potential value.

The wording-actual or potential- refers to an ideal situation where it is possible to recognize and separate GRs from biological resources based on the assumptions of the realization of the value in the inherent hereditary material.³³ To begin with, value is commonly understood as being ‘social, economic, cultural and spiritual in nature’ although economic values of ‘genetic material’ have been identified as relevant to ABS on numerous occasions.³⁴ The focus of this criterion and thus the definition of GRs is at the value that arises from uses capturing the value of the genes.

More often than not, the concept of ‘GRs’ in ABS regimes is closely related to the benefit sharing arising out of the utilization of same. For example, the benefit sharing obligation according to the CBD has focused on sharing ‘the benefits arising out of the utilization of GRs’ and ‘the results of research and development and the benefits arising from the commercial and other utilization of genetic resources’³⁵

The legal concept ‘GRs’ could therefore be understood as including all activities that result in capturing the ‘actual or potential value’ of genetic material by taking advantage of the

³¹ Cambridge International Dictionary of English, Cambridge University Press, (1996), P.574 Functional means relating to or having a function and working or operating. To have a function therefore has a broad meaning which is reflected in the words working or operating.

³² Genetic Resources in the CBD: the Wording, the Past, the Present and the Future, FNI Report, available at [Http://www.fni.no](http://www.fni.no) ; accessed on 22July 2010

³³ Ibid

³⁴G.M. Garitty,L.M. Thompson etal, Studies on Monitoring and Tracking Genetic Resources, 2007, available at:[Http://www.cbd.int/doc/programmes/abs/studies/study-regime-05-en.pdf](http://www.cbd.int/doc/programmes/abs/studies/study-regime-05-en.pdf); accessed on 10 April 2010

³⁵ Ibid

‘functional units of heredity’.³⁶ In consequence, any type of value might be relevant when one is to determine whether something is to be regarded as ‘GRs’ or not.³⁷

All in all, the definition of GRs has based itself on the definition of genetic material. The interrelation between these two elements of the definition can be explained as GRs being material of any biological origin with functional units of heredity which has either an actual or potential value because of them. One can say that all biological material will be covered by this definition when its use captures either the actual or the potential value of the hereditary elements.

Having made this modest attempt to explicate the two elements in the definition given for GRs, it is important to explain other related concepts. And it is believed that understanding these related concepts helps the reader to better understand scope of the concept- GRs. These are, inter alia, derivatives, in situ and ex situ collections.

To begin with Article 2(3) of the ABS Proclamation defines derivatives as: products developed from biological resources which may include products such as plant varieties, oils, resins, gums, chemicals and proteins. This being the definition given to derivatives, analytically difficult issue concerns whether and to what extent derivatives should be covered by ABS regimes. On this issue, the ABS Proclamation is pretty clear in stating that derivatives are considered as GRs as can be read under the provisions of Article 2(6) of same.

Be that as it may, it is equally important to understand how the concept of GRs been understood in relation to in situ and ex situ collections. In situ collections are GRs found in their natural habitat or ecosystem; on the other hand, ex situ collections are GRs found outside of its natural habitat.³⁸ At this juncture, it is good to note that ex situ GRs are within the ambit of the ABS Proclamation while it is not the case under the CBD.

One may consider the term biological resources to be broader, as it might include, apart from GRs, also secondary naturally occurring products such as naturally occurring molecules or

³⁶ FNI Report, Legal Aspects of Exchange, Use and Conservation of Farm Animal Genetic Resources, , available at: <http://www.fni.no/doc&pdf/FNI-Ro107.pdf>; accessed on 26 may 2010

³⁷ Benjamin A. Pierce, Genetics: A Conceptual Approach, (2nd , 2005), P.13

³⁸ Articles 2(4) & (7) of the Proclamation to Provide for Access to Genetic Resources and Community Knowledge and Community Rights, Proclamation No.482/2006, Fed. Neg Gaz, year 13th ,No. 13, hereinafter the ABS Proclamation

combinations of mixtures of molecules including extracts from living or dead naturally occurring organic matter.³⁹ So, in the CBD legal framework, the term biological resource is broader than the term GRs. But then, the thorny question is: is there a biological resource which is not also GRs?

Logically speaking, all GRs are biological resources but also all biological resources are GRs as all contain a unit of heredity. This tells us the importance of searching for a standard in order to make a distinction between the two terms. Since it is not an issue directly relevant to this work, let me wrap it up by indicating the stand of the ABS Proclamation in this regard.

The ABS Proclamation has defined both biological resources and GRs separately. Accordingly, biological resource is defined as which includes GRs, organisms or parts thereof, populations or any other biotic component of ecosystem with actual or potential value for humanity.⁴⁰ Without forgetting that, GRs are defined to include derivatives under the proclamation, what makes biological resources different from GRs then? On its face, the proclamation desires to make a distinction between the two terms. However, it is very difficult to appreciate the functional differences between the definitions given for the two terms under the proclamation.

³⁹ Ibid

⁴⁰ Article 2(2) of the ABS Proclamation

1.2. Access to Genetic Resources, Benefit Sharing and Intellectual Property Rights: Conceptualizing the Linkages

1.2.1. The Notion of Access and Benefit Sharing

Before the coming in to existence of the CBD, GRs in general were considered to be the common heritage of mankind and deemed to belong to everyone.⁴¹ The designation of GRs as the common heritage of mankind reduced national control on GRs and thus made the resources easily available.⁴² States used to allow access to their GRs for the purpose of scientific research, plant breeding and conservation without any payment.⁴³

Later on, some states started to claim that considering GRS as the common heritage of mankind was accelerating the loss of biodiversity and argued that this situation may lead to the 'tragedy of the commons',⁴⁴ where the absence of access regulations of GRs will lead to their depletion because while individuals accrue benefits as they exploit resources, the cost of everybody exploiting the resources at unsustainable levels will have to be met by the community as a whole.⁴⁵

Besides this, the results of technologies and inventions developed on the base of freely accessed GRs have begun to be freely privatized, mainly through IPRs.⁴⁶ As a consequence, developing countries that are rich in GRs have started to voice their resentment towards misappropriation of their GRs and they consider a tighter regulation of access to GRs and fair benefit sharing to be

⁴¹ kwei Jung ni, Legal Aspects of Prior Informed Consent on Access to Genetic Resources: An Analysis of Global and Local Implications Towards an Optimal Normative Construction, available at:<http://www.accessmylibrary.com/.../legal-aspects-prior-informed.html>; accessed on 14 July 2010.

⁴² Atuk Kaushik, the Indian Experience in the fields of IPRs, Access to Biological Resources and Benefit Sharing, in Trading in Knowledge: Development Perspectives on TRIPs, Trade and Sustainability, P.256, Christophe Bellman et al. eds., 2003; see also Sabrina Safrin, Hyper Ownership in a Time of Biotechnology Promises: the International Conflict to Control the Building Blocks of Life,98 Am. J. Int'l Law , (2003) PP. 641

⁴³ Fikremarkos Merse, Challenges and Prospects of Implementing the Access and Benefit Sharing Regime of the Convention of Biological Diversity in Africa: the Case of Ethiopia,(2010), P.250 (on file with the author)

⁴⁴ Aykut Coban, Caught Between State Sovereign Rights and Property Rights: Regulating Biodiversity, 11Review of International Political Economy .4 (2001) ,P.743

⁴⁵ Grahan Dufield, Sharing the Benefits of Biodiversity: Access Regimes and Intellectual Property Rights, available at:<Http://www.cid.harvard.edu/archive/biotech/papers/discussions6.pdf>; accessed on 23 June 2010

⁴⁶ Maria Dolores Pigretti Ohmsn, Access to and Intellectual property Rights over Genetic Resources with a Special Focus on Fair and Equitable Benefit Sharing: International Context and the Argentinian Case, Thesis for the Fulfillment of the Master of Science in Environmental Management and Policy, Lund, Sweden,(2002), p.4 available at : <Http://www.inta.gov.santacruz/informe%20CFI/CD?.../10tesisPigetti.pdf>

essential in preventing the injustice of biopiracy⁴⁷ and to assure equity in bioprospecting.⁴⁸ Ultimately, the CBD was concluded in 1992 which allowed regulation on GRs by conditioning access to the PIC of the provider country and by requiring a fair and equitable sharing of benefits arising from the utilization of GRs as one of its three objectives.⁴⁹

These principles were meant to address the perceived need for bioprospecting activities and GR transfers to be fairer and more equitable; with the assumption that return profit (or other benefit) flows might encourage ongoing conservation and sustainable use of GRs by both national authorities and local communities.⁵⁰ Details will be discussed in the subsequent chapter.

The next important issue that needs to be addressed here is the links between ABS and IPRs. The IP/ABS issues center on the extent to which the IPR system is supportive of or runs counter to the principles contained in international and national ABS regimes concerning the authority of governments to grant access to GRs, subject to PIC and MAT and with fair and equitable benefit.⁵¹

1.2.2. Intellectual Property Rights: General Overview

IP law is that area of the law which concerns legal rights associated with creative efforts or commercial reputation and good will.⁵² The subject matter of IP is very wide and includes literary and artistic works, films, computer programs, inventions, designs and marks used by traders for their goods and services.⁵³ The law basically deters others from copying or taking unfair advantage of the work or reputation of another and provides remedies should this happen. There are different forms of rights or areas of law giving rise to rights that make up IP. Some of the forms currently known of intellectual property protection are: copyright, patent, trademark,

⁴⁷ Ibid

⁴⁸ Jung, Supra Note 41 at 5

⁴⁹ The other objectives of the CBD are conservation and sustainable use of biodiversity which are interdependent with each other.

⁵⁰ Ibid

⁵¹ International Expert Workshop on Access to Genetic Resources and Benefit Sharing: Specific Issues for Consideration in the Elaboration of the International Regime: Interface with existing IP system and limits and opportunities for existing IP rights, available at: [Http://www.cbd.int/doc/meetings/abs/abswg-03/.../abswg-03-inf-06-en.doc](http://www.cbd.int/doc/meetings/abs/abswg-03/.../abswg-03-inf-06-en.doc); accessed on 23 August 2010

⁵² David I Bainbridge, Intellectual property,(6th ed., 2007), P.3

⁵³ Ibid

industrial design, trade secrets and know-how, geographical indications, plant varieties protection, and etc.⁵⁴

It may be mentioning the obvious to state that IP is property in a legal sense that can be owned and dealt with. But then, most forms of IPRs are 'choses in action'⁵⁵ as they are rights that are enforceable only by legal action as opposed to possessory rights.⁵⁶ True, it is in the jurisprudential character of IPRs in that it gives rise to rights and duties.⁵⁷ That is to mean, IPRs establish property rights which give the owner the right to do certain things in relation to the subject matter and it also creates duties.⁵⁸

At this point in time, it is good to note that the rights given to owners of intellectual creations are not absolute as there are limitations imposed on them as IP laws strive to create a justifiable compromise of the conflicting interest that exist between the inventor and the society. Therefore, a duty not to infringe is curtailed by way of exceptions to infringement. For example, it may be possible to obtain a compulsory license to exploit a patent irrespective of the owners' wishes.

The justifications for the existence of IP laws can be broadly categorized in to two: one of them focuses on rewarding an inventor and the other one on recognizing the personality of the creator.⁵⁹ The first argument is that effort deserves reward.⁶⁰ This draws on the long line of political theory starting with John Lock's argument about property rights in previously common land being awarded to the diligent cultivator.⁶¹ It has now become a more general argument that not only should effort be rewarded, but to stimulate useful human activity reward is vital and necessary.⁶² In IP this suggests that only by allowing innovators and creators ownership right over their creations can society stimulate and reward their efforts.

⁵⁴ Ohmsn, Supra Note 46

⁵⁵ 'Choses in action' is a known legal expression used to describe all personal rights which can only be enforced by a legal action and not by taking physical possession.

⁵⁶ Bainbridge, Supra Note 52

⁵⁷ Ibid. In terms of IP, the right is the right to do certain things, such as making copies of a work of copyright, making a product in accordance with a patented invention and the like and the correlative duty is owed by all others not to infringe the rights.

⁵⁸ Ibid

⁵⁹ Ibid

⁶⁰ Alexandra George(ed.), Globalization and Intellectual property Rights, (2006), P.21

⁶¹ Ibid

⁶² Ibid

The other justification is that IPRs reflect the rights of individuals to own the products of their own efforts in that these efforts reflect the expression of an individual's self identity.⁶³ Thus, individuals should be allowed to own IP in the products of their mental activity, because it is their mental work that has produced that which is made property.⁶⁴ This draws on the notion of property as a protection from interference by others as originally set out by George Hegel in the early 19th c.⁶⁵ This has prompted the recognition of the moral rights of creators and authors to ensure that their work remains as they intended even when the economic rights have been transferred.⁶⁶

1.2.3. The Relationship between ABS and IPRs: Introductory Remarks

In order to comprehend the links between regulating access to GRs and ensuring benefit sharing with IPRs, regard may be had to the importance of GRs for the development of biotechnology. This is because the complex legal, political and social links between IPRs and ABS are evident in the biotechnology sector.⁶⁷ GRs provide a store of knowledge and the raw materials for the biotechnology industry.⁶⁸ In particular, GRs can be put to commercial use and companies can use these resources to develop specialty enzymes, enhanced genes, or small molecules.⁶⁹ These can in turn be used in crop protection, drug development, the production of specialized chemicals, or in industrial processing.⁷⁰ It is also possible to insert genes into crops to obtain desirable traits that can enhance their productivity or resilience to disease.⁷¹ That is why; GRs are considered important for industries such as pharmaceuticals, botanical medicines producers, seed industry, ornamental horticulture companies, crop protection products, personal care and cosmetics and others in the field of biotechnology.⁷²

⁶³ Ohmsn, Supra Note 46

⁶⁴ Ibid

⁶⁵ George, Supra Note 60

⁶⁶ Ibid

⁶⁷ Strengthening Research and Policy Making Capacity on Trade and Environment in Developing Countries, THE CBD/TRIPS Relationship, 1999, available at: http://www.unctad.org/trade_envs.docs/cbd-trip.pdf; accessed on 24 July 2010

⁶⁸ Ibid

⁶⁹ The CBD Secretariat, available at <http://www.cbd.int/abs>, accessed on 31 August 2010

⁷⁰ Ibid

⁷¹ Ibid

⁷² Ohmsn, Supra Note 46

True, biotechnology and GRs are interdependent and they can be looked on as biological industry's two legs and none of them can be missing in order to successfully develop inventions made based on GRs.⁷³ Without GRs, biotechnologists have nothing to work on; in the contrast, without biotechnology, GRs cannot effectively be exploited by human beings and cannot serve people's demand.⁷⁴ So, GRs serve as a basis for biotechnological inventions, which may be subject to IPRs, and in particular patents or plant variety rights.⁷⁵

As a result of this, GRs were thus subject to new values and appropriation became a source of economic advantage that gave birth to an international trade in GRs often referred to as bio trade.⁷⁶ In doing so, researchers and companies which are rich in technology use these resources extracted from GRs rich developing countries without appropriate authorization and benefit sharing arrangements in order to obtain new technologies, inventions, techniques and products.⁷⁷ This has been described as biopiracy and this characterization has generated strong public indignation in developing countries.⁷⁸

At this juncture, one may quest what relates then ABS with IPRs. ABS is related with IPRs since biotechnological firms use various forms of IPRs in order to protect their inventions.⁷⁹ And it should not be overlooked that IPRs on biotechnological inventions are meant to be the primary incentive for research initiatives based on GRs.⁸⁰ That is why, pharmaceutical firms mainly rely on patents once the drug is discovered and in case of agricultural varieties, plant variety protection and/or patents are used.⁸¹

Therefore, to the extent that IPRs promote the biotechnological research, they can be linked to the effects, positive or negative, in controlling access and ensuring benefit sharing from the

⁷³ Haoliang Wu and Bing bin Lu, Prior Consents: Preventing Offensive Genetic Engineering Patents Against Indigenous Peoples Rights, *Global Jurist Frontiers*, V.5, Issue 1, (2005), 2005, available at: <http://www.bepress.com/gj/frontiers/vol5/iss1/art3/>; accessed on 21 May 2010

⁷⁴ Ibid

⁷⁵ Ibid

⁷⁶ Siddhartha Prakash, Towards a Synergy between Biodiversity and Intellectual Property Rights, available at: <http://www3.interscience.wiley.com/journal/119099675/articletext?DOI=10->; accessed on 25 April 2010

⁷⁷ Nuno Pires de Carvalho, Requiring Disclosure of Origin of Genetic Resources and Prior Informed Consent in Patent Applications without Infringing the TRIPS Agreement: the Problem and the Solution, *2 Wash .U .J .L.& Policy*, (2000) ,P.375

⁷⁸ Ibid

⁷⁹ Padmashree Gehl Sampath and Richard g. Tarasofsky, Study on the Inter relations between Intellectual property Rights Regimes and the Conservation of Genetic Resources, 2002, available at www.ecologic.de

⁸⁰ Ibid

⁸¹ Ibid

commercial use of products derived from GRs.⁸² Simply put, IPR laws could have a role for the realization of ABS objectives.

A. Patentability of Life Forms

A patent awards an exclusive temporary protection to its holder including the right to exclude others from “making, using, offering for sale, or selling” or “importing” the protected invention into a jurisdiction where the patent protection is in force, or to charge others for any uses or purposes involving the protected invention within such jurisdictions (i.e. through licensing).⁸³ An inventor, however, need to fulfill three requirements which are required in all jurisdictions; and therefore, a person in order to be granted a patent, the invention should be new, involves an inventive step and capable of industrial applicability.⁸⁴

The patent system seeks to simultaneously promote innovation through the provision of an incentive (an exclusive period of monopoly) and to promote the wider use and availability of inventions by requiring that patent applicants disclose their invention within applications.⁸⁵ This is frequently presented in terms of a “bargain” between society and inventors in which society agrees to accept the burden of a limited period of monopoly in return for useful inventions becoming widely available to the public once the period of protection ends.⁸⁶

One of these issues which link patent law with ABS is the issue of patents over GRs or more commonly called patent on life forms. Issues that can be raised in connection with patentability of life forms are extremely complex and it would be a lie if one denies this. Some of these issues will be briefly dealt with to the extent necessary for the present purpose. To begin with, patent on life forms could be on the whole living matter (such as plant, animals and microorganisms); substances extracted from living organisms and the improvements or modifications on the components of living organisms.

⁸² Ibid

⁸³ Paul Oldham, Biodiversity and the Patent System: an Introduction to Research Methods, (2006), available at: <http://www.biopirateria.org/documentos/6-pauloldham.pdf>; accessed on 28 June 2010

⁸⁴ Keith E. Maskus, Intellectual Property Rights in the Global Economy, (2003),P.12

⁸⁵ Ibid

⁸⁶ Ibid

The first issue that needs to be addressed is: are they inventions? Determining what can and cannot be patented rests on the definition given to inventions in national patent laws. It is extremely difficult to define the term 'invention' and distinguish it from discovery. In fact, most patent laws do not even try to define it.⁸⁷ Neither does TRIPs give any definition of what an invention should be.⁸⁸ The debate on the patentability of life forms in relation to the term invention focuses on the difference between invention and discovery. In this regard, there are different approaches and thoughts. According to some, an invention shall offer technical solution to a technical problem and in this perspective life forms and naturally occurring substances are discoveries and therefore excluded from patentability.⁸⁹

On the other hand, the other thought acknowledges that discoveries should not be recognized as inventions.⁹⁰ Nonetheless, it excludes only those freely occurring substances that someone merely found.⁹¹ If, however, the substance had first been isolated from its surroundings and can be properly described, it shall be a patentable invention whether that substance existed in nature before it was recognized.⁹² The idea behind this thinking is that patent should be awarded only for specific expressions of human ingenuity, not for the revelation of something that already exists.⁹³ Of course, allowing patents on materials, for example genes, that are simply discovered unjustly monopolizes material that already exists in nature.⁹⁴

As per this thought, a fortiori, purified hormones, antibiotics, proteins and genes to chemicals synthesized or recombined in the laboratory and improvements of the structural and functional component of a living organism are patentable.⁹⁵ And the principle that natural substances can become inventions when prepared in the form of isolated and purified chemicals is getting

⁸⁷ The Crucible II Group, *Seeding Solutions: Options for National Laws Governing Control Over Genetic Resources and Biological Innovations*, (2001), P.189

⁸⁸ Ibid

⁸⁹ GREENPEACE, *The True Cost of Gene Patents: the Economic and Social Consequences of Patenting Genes and Living Organisms*, available at: <http://www.greenpeace.org/international/en/news/blogs/makingwaves>; accessed on 12 December 2010

⁹⁰ GRAIN, *Patents on Life: the Final Assault on the Commons*, 2000, available at: [http://www.sarai.net/research/...//trips indigenous knowledge and the bio-rush.pdf](http://www.sarai.net/research/...//trips%20indigenous%20knowledge%20and%20the%20bio-rush.pdf); accessed on 10 December 2010

⁹¹ Ibid

⁹² Ibid

⁹³ The Crucible II Group, *Supra note 87* at 190

⁹⁴ Ibid

⁹⁵ Human Genome Project Information, *Genetics and Patenting*, available at: <http://www.genomics.energy.gov>; accessed on 24 November 2010

acceptance in the patent systems of the developed world.⁹⁶ Naturally occurring substances, like cells or genes have become patentable inventions in the US and EU if they have been purified and isolated.⁹⁷ For example, in the US patents were filed and granted for a glandular extractive product claiming purified forms of adrenaline for this compound is a solution with salt and a preservative.⁹⁸ And the line separating invention from discovery has become very thin.⁹⁹ I think, in relative terms, the debate on the distinction between invention and discovery makes sense in case of patents not on the whole life form but the substances extracted from it.

When the distinctions between invention and discovery are considered in case of patent on the whole life form, the question worthy of asking is: is life something to be invented? Is it possible to invent life? Life, even in its tiniest and most primitive state, is complex almost beyond our imagination.¹⁰⁰ What goes on within the walls and membranes of cells and between them and their surroundings are still for the most part a mystery.¹⁰¹ Scientists cannot make life as they can make or invent complex devices like computers, robots or space rockets.¹⁰²

Succinctly speaking, there are arguments forwarded in favor of the idea that life is not something to be invented. First, as it is increasingly evident, all living things seem so far more complicated and creative than any genuinely human artifact.¹⁰³ In this regard, Paul Davies describes beautifully the complexity of life at cellular level in the following words:

As a simple-minded physicist, when I think about life at the molecular level, the question I keep asking is: How do all these mindless atoms know what to do? The complexity of the living cell is immense, resembling a city in the degree of its elaborate activity. Each molecule has a specified function and a designated place in the overall scheme so that the correct objects get manufactured. There is so much commuting going on. Molecules have to travel across the cell to meet others at the right place and the right time in order

⁹⁶ Ibid

⁹⁷ Ibid

⁹⁸ Karl Bozicicevic, Distinguishing Products of Nature from Products Derived from Nature, 68 J.Pat. & Trademark Off. Society, (1987), P.415

⁹⁹ Ibid

¹⁰⁰ Graham Dutfield, Who Invents Life: Intelligent Designers, Blind Watchmakers or Genetic Engineers? 7 Journal of Intellectual Property Law and Practice, 5, (2010), P.6

¹⁰¹ Ibid

¹⁰² Id at 8

¹⁰³ Ibid

*to carry out their jobs properly. This all happens without a boss to order the molecules around and steer them to their appropriate locations.*¹⁰⁴

Second, unlike machines, living things can do without help in carrying out most functions throughout their whole life spans.¹⁰⁵ They are autonomous self creating in terms of how they make, renew and remake themselves.¹⁰⁶ And they are independent from us unlike machines which are assembled and directed to specific tasks by human operators.¹⁰⁷ So, the creativity of life comes within; no amount of human tinkering can change that.¹⁰⁸

Be that as it may, the other technical issue to be raised in relation to biotechnological inventions is: do they fulfill the patentability requirements of newness, inventive step and industrial applicability? Novelty in relation to patenting of inventions relating to naturally occurring substances may be defined in different ways in different jurisdictions. For example, an invention consisting of biological materials is not novel if a patent law considers the material previously existed in nature and they are not patentable.¹⁰⁹ This is of course another way of making discoveries unpatentable.¹¹⁰ To the contrary, an invention consisting of naturally occurring biological material is new if its existence was unknown prior to the application filing date.¹¹¹ In this case, the requirement of novelty excludes only those naturally occurring biological materials whose existence was known before the application filing date. This option reflects the current patent practice of most industrialized countries.¹¹² On the same vein, adapting the requirements of inventive step and industrial applicability to inventions on naturally occurring substances remains controversial.

¹⁰⁴ Ibid

¹⁰⁵ UNESCO, Ethics, Intellectual Property and Genomics, 2001, SHS/HPE/2001/CONF-804/3/REV.1

¹⁰⁶ Ibid

¹⁰⁷ Ibid

¹⁰⁸ Dutfield, Supra Note 100

¹⁰⁹ Intellectual Property Law Policy, A Study on Issues Relating to the Patentability of Biotechnological Subject Matter: Introduction and Overview, available at: [Http://www.ic.gc.ca](http://www.ic.gc.ca); accessed on 25 November 2010

¹¹⁰ Ibid

¹¹¹ Ibid

¹¹² Ibid

In any case, all these issues in relation to patentability of life forms are entertained differently in different jurisdictions; the difference being on its scope.¹¹³ And the issue is under deliberation in the TRIPs Council.

Generally speaking, the patentability or non patentability of GRs as life forms should be seen in line with the abovementioned explanations. In this regard, Graham Dutfield states that all inventions pertaining to GRs cannot be placed under one category as patent can be claimed on the GR itself or on the purified version of the resource and as a result of this it is not easy to give a conclusion to be applicable to all inventions made based on GRs.¹¹⁴ For me, what is clear is that all inventions made based on GRs may not necessarily raise the issues that could be raised in relation to patentability of life forms. Typical of such inventions could be those which make use of the GR as an input. For instance, one can invent the process of producing food and beverage products using the teff GR and claim a patent both on the process and the product. Therefore, the issues on patentability of life forms are more controversial when patent is requested on the GR itself or on its components.

This being so, in the end of the twentieth century, we have witnessed patents being granted on life forms and processes.¹¹⁵ Plant, animals and the process used to introduce novel genetic material into plants or animals have therefore been patented.¹¹⁶ This, in turn, has raised the piquant problem of extending IPRs to products based on GRs.

In fact, up until 1980 when the first patent on a living organism was granted in the United States to a genetically engineered microorganism that could digest and break down crude oil, and

¹¹³ For example, Patentable subject matter is defined very broadly under the U.S. Patent Act which states that: “any process, machine, manufacture, or composition of matter, or an improvement thereof,” can be patented if it satisfies the patentability requirements. The Patent Act does not make any exceptions to the general requirement. In the United States, “everything under the sun that is made by man is patentable.” Comparatively, the scope of patentable subject matter in the EPC is a little narrower, excluding certain types of inventions as not susceptible of industrial application. See *supra* Note 87.

¹¹⁴ Graham Dutfield, *Sharing the Benefits of Biodiversity: Access Regimes and Intellectual Property Rights*, available at: <http://www.cid.harvard.edu/archive/biotech/papers/discussions6.pdf>; accessed on 13 June 2010

¹¹⁵ Dutfield, *Supra* Note 100

¹¹⁶ *Ibid*

through the intervention of the U.S. Supreme Court, the US. Patent and Trademark Office (USPTO) followed the broad principle that products of nature are not patentable.¹¹⁷

Although patents for biological process inventions had been awarded since the 1800s, the USPTO did not permit patents on living products because they were a “product of nature” and not subject to the statutory subject matter defined by the Patent Act.¹¹⁸ In *Diamond II. Chakrabarty*, the Supreme Court determined that a human-made micro-organism is patentable subject matter as a “manufacture” or “composition of matter” and that “anything under the sun that is made by man” could be patented.¹¹⁹ Since then, while the developed world has followed the precedent that was set in the United States in respect of patenting of products of nature, many countries in the developing world remain steadfastly opposed to extending patents to cover “life-forms”.¹²⁰

In this regard, one can mention various examples regarding the grant of patents on inventions made based on GRs in different jurisdictions, commonly in the United States and European countries. Admittedly, it is difficult, if not impossible, to mention all patents granted on products made based on GRs. Therefore, an attempt will be made to mention some of these notorious cases in order to make clear what links the patent law with the notion ABS. To this effect, mention can be made to the Enola Patent¹²¹, Patent on Ayahuasca Plant,¹²² Patent on the

¹¹⁷ Biswajit Dahr and R.V. Anuradha, Access, Benefit Sharing and Intellectual Property Rights, 7 *Journal of World Intellectual Property* 5, (2004) , P.5.

¹¹⁸ *Ibid*

¹¹⁹ *Ibid*

¹²⁰ The African Group has taken a particularly vocal stand against extending patent protection to life-forms during the debate that has taken place in the Council for TRIPS on the issue of review of patentable subject matter.

¹²¹ This patent covered the Enola bean and was strongly challenged for the reason of genetically identical with the mayocoba bean in Mexico and severely damaging indigenous Mexican farmer’s traditional planting. In 1994, Larry Proctor, the patent holder of Enola bean, bought a package of beans in Mexico and brought back to the United States. Mr. Proctor picked up yellow field beans among these beans and planted in his land. He harvested seeds from plants had some abnormal characteristics including small leaves and resistance to pod shattering etc. The beans were planted and self-pollinated repeatedly. A few years later, he applied for a patent for his bean claiming that he created a novel, useful and non-obvious product by breeding a new field bean variety which produced a distinctly yellow-colored seed and the characteristics of the field bean cultivar Enola surpassed original field beans and possessed a unique shade of yellow in Patent 5,894,079. The U.S. administration granted Proctor a utility patent on the “improved” variety of bean and a Plant Variety Protection (PVP) certificate, which gave Proctor and his company, Pod-Ners, the monopoly right to commercialize the Enola bean. See also Erin Donovan, Beans, Beans, the Patented Fruit: see *The Growing International Conflict over the Ownership of Life*, 25 *Loy. L.A. Int'l & Comp. L. Rev.* 117, 121 (2002).

Turmeric Plant,¹²³ Patent on products extracted from the Neem Tree,¹²⁴ Patent on Varieties of the Basmati Rice, Patent on Anti Cancer Extracts and Pharmaceutical Compositions and Methods made from four Ethiopian plants,¹²⁵ a patent on Endod and others.

These and a lot of other similar patents on GRs demonstrate how the attempt to seek patent is highly related with the notion of ABS. This is precisely because the inputs for all these patents are GRs taken from different countries which are believed to be rich in same. That is why; these cases reflect a growing fear in the developing world that multinational corporations and western researchers might use so called patents on life forms to seize control of the potentially lucrative biological resources without any consideration of the concerned local communities consent and interests.

Indeed, patent on GRs from the perspective of ABS raises a multitude of issues; the important queries for the issue at hand are: did inventors who have made use of GRs in coming up with their inventions secured the PIC of the concerned state and/or local communities? Were there benefit sharing arrangements made between the inventors who have made use the GRs and the concerned state and/or local communities?

¹²² In this patent, Mr. Miller claimed a novel variety of the local plant ayahuasca, which is an Amazonian hallucinogenic vine that the industrial use in the main ingredient in a religious ceremonial drink and some samples of this plant was taken by Mr. Miller from an indigenous community in Ecuador. see Ibid

¹²³ “The turmeric plant (an herb) is a native of South Asia, and is cultivated extensively throughout the warmer parts of the world. In Indian systems of medicine, turmeric is used as a tonic and blood purifier. Mixed with warm milk it is said to be beneficial in treating the common cold. The fresh rhizome is used as an anti-parasitic for many skin infections. Externally it is applied to indolent ulcers, and a paste made from the powdered rhizome along with lime forms a remedy for inflamed joints. A decoction of the rhizome is said to relieve the pain of purulent ophthalmia. Oil of turmeric, distilled from the dried rhizomes, has feeble antiseptic properties. Turmeric (rhizomes or powder) is an auspicious article in all religious observances in many Indian households. It is a normal constituent of condiments, curry powders and prepared mustards. See N. Lalitha, Intellectual Property for the Plant Varieties: Issues in Focus, 39 Economic and Political Weekly 19, (2004), P.1921. It is based on this plant the two US based Indian nationals were granted a patent (the turmeric patent) on the use of turmeric in wound healing.

¹²⁴ Neem is a very widely known and long cultivated tree with medicinal and agricultural uses in Asia, especially in India. Today, Neem is almost well known in northern patent offices, where multinationals have filed dozens of patent claims on neem. Most recently, Monsanto has taken out a pair of patents on neem wax and oil and claimed broad fungicidal and insecticidal uses. see Supra Note 116

¹²⁵ A US patent has been granted to Tesfaye Zerihun to this invention and the extracts used for this composition are taken from one or more of *Glinus Lotoides*(Damasciisa „Reta Chalepensis(Tena Adam), *Hegenia Abyssibia*(Kosso), and/or *Milletia Ferruginea*(Birbira).These plants grow in Ethiopia and *Hegenia Abyssinica* is a well known treatment for tape worms in humans and livestock in Ethiopia. Medicinal uses of Reta Chalpensis are also associated with Ethiopia, where it is a household remedy. The plant is believed to have been brought to Americans by Spanish conquistadores. see A Report by Jay Macgown, Out of Africa: Mysteries of Access and Benefit Sharing,(2006) ,PP.7-8

In all the above mentioned patents, inventors who have used GRs as an input in coming up with their inventions did not get the PIC of the concerned state authority and there were no benefit sharing arrangements at all. That is why, in fact, some have succeeded in the revocation of the patents granted on a product made based on GRs without their PIC and without any benefit accruing to them.

At this point in time, it is indispensable to mention some practical cases which indicate the exploitation of GRs using the patent system without securing the PIC of the concerned state and without a benefit sharing arrangement. In this regard, it is notable to note thousands of patents have been filed on inventions made based on GRs originated from African Countries. For example, a report entitled: 'Out of Africa: Mysteries of Access and Benefit Sharing' details 36 brief case studies on medicines, cosmetics and agricultural products originating from GRs in African countries and patented by multinational corporations, without their being evidence of PIC and benefit sharing accruing to the countries of origin.¹²⁶

From the abovementioned discussions, it is easily inferable that the inventor has violated the law in the provider country by failing to agree to share the benefits in accordance with its access legislation. What is more, the country granting the patent may be failing to live up to the expectation of Art.15.7 of the CBD which requires all state parties to: " .. take legislative, administrative or policy measures ...with the aim of sharing in a fair and equitable way the results of research and development and the benefits arising from the commercial and other utilization of GRs with the providing party providing such resource..."

Therefore, when evaluated against this backdrop, is the patent system supportive to the ABS objectives or does it run counter to it? And could there be a role played by the patent system for the realization of ABS objectives? If the patent system did not lend its hands, what was the problem in letting such inventions to pass through it? What is the role that should be played by the patent system? There has been much debate surrounding these questions; but then it is quite clear that the patent system thwarts ABS objectives since patents are granted for inventions

¹²⁶ J. McGown, Out of Africa: Mysteries of Access and Benefit Sharing (2006), available at: <http://www.edmonds-institute.org/outofafrica.pdf>; accessed on 13 August 2010. This Report prepared by Joy McGown, who is considered as the biopiracy hunter by the sponsors of the project, has listed medicines developed from genetic resources, such as drugs for diabetes produced by a microbe, antibiotic from a termite hill, anti fungi from a giraffe, infection fighting amoeba, treatment for impotence, vaccines from microbes, appetite suppressant from hoodia, anti biotic from giant land snails, drug addiction treatment from iboga, to mention some.

involving GRs where PIC has not been obtained and an agreement has not been reached concerning benefit sharing. These issues would be explored in detail in the subsequent chapters.

B. Plant Breeders' Rights Law and ABS

Plant Breeders' Rights laws are a special form of IPRs created to provide incentives for the seed industry.¹²⁷ That is to mean, giving exclusive rights to breeders will provide some sort of assurance to them that they will be able to recoup the risks and costs of a value added innovation that is based up on an underlying GRs.¹²⁸ In fact, in the absence of a grant of exclusive rights to breeders, the danger of free riding by third parties would be considerable as the genetic material within plants that specifies their distinctive and commercially valuable features is naturally self replicating.¹²⁹

It is also believed that the grant of exclusive rights to plant breeders is designed to benefit the society granting the rights since it provides an incentive for private research and development and development in to new breeding techniques, thereby reducing the need for government funding to subsidize those activities.¹³⁰ Besides these, it also encourages the development of new and beneficial plant varieties for use by farmers and consumers.¹³¹ This legal regime which is believed to have such purposes came in to existence as a result of efforts made by breeders.

Breeders led the move to evolve plant breeders' rights as an alternative to patents, which is the main form of IPRs for industrial innovation, because of the potential opposition to extending patent protection to plants and the complexities of defining plant varieties.¹³² This is because patent protection was generally considered not appropriate for plant GRs on different counts.

Some critics on the application of patents to plant varieties included the lack of efficacy owing to the difficulty of reporting unlawful propagation, the delay of dissemination of new varieties, the difficulties to satisfy patent requirements such as novelty – especially for the case of discoveries of new varieties - and the description of the invention “in such a way that any person

¹²⁷ Anitha Ramanna, India's Plant Variety and Farmers' Rights Legislation: Potential Impacts on Stakeholder Access to Genetic Resources, Discussion Paper, 2002, available at: [Http://www.ifpri.org](http://www.ifpri.org); accessed on 10 august 2010

¹²⁸ Ibid

¹²⁹ Phundan Singh, Intellectual Property and Plant Breeders Rights, (2009), P. 34

¹³⁰ Ibid

¹³¹ Ibid

¹³² Ibid

having skill in the art can carry it out”¹³³ as some of the reasons which make patent laws inappropriate for the protection of plant varieties.¹³⁴ The main problem was that many patent laws prohibit the patenting of “products of nature”.¹³⁵

PBR is a patent-like system that allows the plant breeder to prohibit specific unauthorized uses of the variety.¹³⁶ The legal regime for PBRs is not uniform as some countries have modeled their legislations on the UPOV and others have enacted a legislation of their own and still some others have enacted their laws basing some aspect of it on the UPOV convention and making the others their own. Such a divergence of approach in legislating PBRs laws resulted from what has been provided by the TRIPs agreement in this regard. PBR under the TRIPS Agreement is a component of the WTO. Although the TRIPs text is quite exhaustive in most regards, only a single sentence refers to PBR.

Article 27.3(b) reads, in part, that WTO members must provide plant variety protection using patents, “an effective sui generis system,” or both. PBR is clearly a sui generis system, but what constitutes “effective” is less clear.¹³⁷ In fact, analyzing what constitutes an effective sui generis system under TRIPs is out of the scope of this paper.

Identifying what can be protected as a sui generis system, protection is limited to plant “varieties,” but this term lacks a standard definition. The definition in the 1991 Act (Article 1(vi)) of the UPOV Convention reads in part: a plant grouping defined by the expression of the characteristics; distinguished by the expression of at least one of the said characteristics; and having suitability for being propagated unchanged.¹³⁸ Plant varieties can only be protected by PBRs if they fulfill the four basic criteria of novelty,¹³⁹ distinctness,¹⁴⁰ stability¹⁴¹ and uniformity or homogeneity.¹⁴²

¹³³ Ohmsn, Supra Note 46

¹³⁴ Ibid

¹³⁵ Ramanna, Supra Note 127

¹³⁶ N. Lalitha, Intellectual Property Protection for Plant Varieties: Issues in Focus, 39 Economic and Political Weekly, 19, (2004), P.1921

¹³⁷ Ibid

¹³⁸ Ibid

¹³⁹ The concept of novelty requires further elaboration because it differs from its use under patent law. Under UPOV, a variety is novel if it has not been sold or otherwise disposed of to others, by or with the consent of the breeder, for purposes of exploitation of the variety. Novelty is thus defined entirely by commercialization and not by the fact that the variety did not previously exist. UPOV gives a specific time frame for the application of novelty. To

From these, it is easily discernable that protectable subject matters in PBR are GRs which are also at the heart of ABS notions. So much so that, the manner of devising plant breeders' laws has an effect on the realization of ABS objectives.

The rights conferred to plant breeders differ from patent rights insofar as they provide much more extensive exceptions to the rights conferred than patents.¹⁴³ Breeders have exclusive rights to produce or reproduce protected varieties, to condition them for the purpose of propagation, to offer them for sale, to commercialize them, including exporting and importing them, and to stock them in view of production or commercialization.¹⁴⁴

These rights are restricted by a number of exceptions that are compulsory in the UPOV context. The rights of breeders do not extend to acts done privately and for non-commercial purposes, to acts done for experimental purposes, to the use of the protected variety for the purpose of breeding other varieties and the right to commercialize such other varieties as long as they are not essentially derived from the protected variety.¹⁴⁵ While the previous exceptions are compulsory, there exists a set of further exceptions which have been progressively reduced over time.¹⁴⁶ The so-called farmer's privilege falls into this category. In fact, Under UPOV-1991, the rights of breeders have been extended to the harvested material of the protected variety and the farmer's privilege has been made optional.¹⁴⁷

From the discussions made above, the important point to be noted is that plant varieties are not built from the scratch; rather they are developed from existing varieties in particular and from existing GRs in general. So, it raises the concern of whether the variety used as an input has been

be novel, a variety must not have been commercialized in the country where the application is filed more than a year before the application and in other member countries more than four years (six years in the case of trees and vines).

¹⁴⁰ The criterion of distinctness requires that the protected variety should be clearly distinguishable from any other variety whose existence is a matter of common knowledge at the time of the filing of the application.

¹⁴¹ Stability is obtained if the variety remains true to its description after repeated reproduction or propagation.

¹⁴² Philippe Cullet, Plant Variety Protection, available at: <http://www.ielrc.org/content/f0303.htm>; accessed on 21 May 2010. Finally, uniformity implies that the variety remains true to the original in its relevant characteristics when propagated.

¹⁴³ Mathew Rimmer, Patent Law and Plant Breeders Rights, 10 Murdoch University Journal of Law, 4, (2003) ,P.1,

¹⁴⁴ Ibid

¹⁴⁵ Ibid

¹⁴⁶ Ibid

¹⁴⁷ Bill Whitmore, Intellectual Property Rights and Plant Variety Protection in Relation to Demands of the World Trade Organization and Farmers in Asia and Pacific, available at: <http://www.fao.org/ag/AGP/agps/bangkok/paper10.html>; accessed on 27 May 2010

accessed as per the access legislation of the concerned state and whether there are benefit sharing arrangements.

To put it differently, there is a possibility of misappropriation of GRs using plant breeders' rights laws if access is made without securing PIC and without any benefit sharing arrangement. For example, a variety of teff which is believed to be originated from Ethiopia and widely grown in the country mainly to make injera, a flat bread staple food in Ethiopia, has been taken from the country and protected by the plant variety right in the US by the teff company without their being any benefit sharing to the country and the communities that have conserved and preserved the GRs.¹⁴⁸

Therefore, since plant varieties are developed based on underlying GRs, plant variety protection regimes have a strong link with ABS. The need for benefit sharing arises, for example, when commercial plant breeders get exclusive rights while farmers' varieties are held to be in the public domain. In this situation, benefit sharing schemes are put in place as a form of compensation for the absence of property rights.¹⁴⁹

At any rate, the concerns we raised in relation to patent law vis-à-vis ABS can also be raised in relation to plant breeders' laws. For example, one can raise questions like what are the things that need to be considered by plant breeders' rights laws in order to avert any possible misappropriation of GRs and ensuring benefit sharing arising out of their utilization. Hopefully, these things will be clear when we discuss the Ethiopian Plant Breeders' Rights Proclamation in this regard.

1.3. Positive and Negative Linkages between ABS and IPRs

Discussions related to IPRs and biodiversity can be organized in to two fundamental issues: the impacts of IPRs on the conservation and sustainable use of GRs and the impacts of IPRs on ABS. Capturing all these complex relationships is out of the scope of this work and emphasis will be given to the linkages between ABS and IPRs.

¹⁴⁸ Supra Note 51

¹⁴⁹ Ibid

At the very outset, it is good to make it clear that most of the arguments forwarded on the negative and positive linkages between ABS and IPRs are speculative for most of the arguments are not supported by empirical evidence. There are claims and counterclaims on the positive and negative impacts of IPRs on ABS. To begin from the positive one, some claim that IPRs are important instruments for the realization of benefit sharing arising out of the utilization of GRs as they are the major incentives for biotechnological research.¹⁵⁰ That means biotechnological companies would not get a benefit had there not been IPR regimes and as a result of this it is difficult to imagine them sharing benefits with the providers of GRs. In simple parlance, if there are no IPR regimes, there would not be benefits accruing to biotechnological industries and; if they do not get a benefit, there is nothing to be shared with the providers of GRs.

Interestingly enough, Gupta has given us some case studies in order to substantiate such a line of argument. To this effect, he studies three cases in order to support the idea that the role of IPRs is crucial in generating benefits from commercializable technologies which utilize GRs.¹⁵¹ From these case studies, the subject of the first one is the role of IPRs in the benefit-sharing arrangements surrounding the gene Xa21 of *Oryza longistaminata*,¹⁵² a wild rice from Mali, which was isolated, cloned and patented at the University of California at Davis.¹⁵³

The identification, cloning and patenting of this gene has involved several processes. A specimen of *Oryza longistaminata* was originally accessed in Mali and transferred to a rice research program in India, where its resistance to bacterial rice blight, one of the most serious rice diseases, was identified.¹⁵⁴ The blight resistant specimen was transferred to the International Rice Research Institute (IRRI) in the Philippines, which determined that the resistance was coded by a single locus called Xa21 and bred the resistance into cultivated rice varieties by conventional breeding methods.¹⁵⁵

¹⁵⁰ Ibid

¹⁵¹ Anil K. Gupta, WIPO UNEP Study on the Role of Intellectual Property Rights in the Sharing of Benefits Arising from the use of Biological Resources and Associated Traditional Knowledge, available at: <http://www.wipo.int/about-ip/en/studies/.../genetic-resources.html>; accessed on 4 June 2010

¹⁵² *Oryza Longistaminata* or Kamlo in local language implying rice from the river is a wild rice which was considered by some farmers as a weed. But, it is now a donor of a unique of gene which now confers resistance against bacterial diseases throughout the world.

¹⁵³ Ibid

¹⁵⁴ Ibid

¹⁵⁵ Prabuddha Sangal, Intellectual Property Right Protection and Location of R&D by Multinational Enterprises, 5 *Journal of Intellectual Capital* 1, (2004), P. 64

One such variety was then acquired by the University of California at Davis, where gene Xa21 was mapped, sequenced and cloned.¹⁵⁶ After a patent application was filed and granted for the cloned gene, a Genetic Resource Recognition Fund (GRRF) was established at UC Davis to share with the stakeholders in Mali and other developing countries the benefits arising from the commercial utilization of the patented gene.¹⁵⁷ This intellectual property-based benefit-sharing mechanism provides that the licensee of the patent over Xa21 shall annually pay a certain percentage of sales of products and derivatives of Xa21 into the GRRF for a specified number of years following the first year of commercialization.¹⁵⁸

So much so that, IPRs which were granted over this invention provides an important mechanism for sharing of monetary and non monetary benefits arising from the use of the GRs.¹⁵⁹ Putting it differently, patenting and licensing of the cloned gene help in generating benefits with the communities in Mali. However, such arguments make sense in a situation where there are benefit sharing arrangements made between providers and recipients of GRs.

At this juncture, one may quest that what are the grounds for believing that IPRs are necessary to ensure commercial benefits made based on GRs that can be shared with the providers of the resource? The precise answer is IPRs-like other property rights-provide exclusive rights that allow markets for certain things- in this case valuable information in the form of inventions- to operate where they otherwise could not do so.¹⁶⁰ So much so that, it is possible to get benefits by the successful appropriation of the particular intellectual property's market value, either by developing a product or selling or licensing the property to someone else interested in it.

In contrast, it should not be forgotten that there are some who opine that IPRs are not and cannot be important instruments for the effective implementation of ABS.¹⁶¹ They are rather instruments used for the misappropriation of GRs without any benefit accruing to the providers of the resources.¹⁶² But then, IPRs could encourage ABS if application for such rights requires

¹⁵⁶ Ibid

¹⁵⁷ Ibid

¹⁵⁸ Richard Tarasofsky, Report on Trade, Environment and Intellectual Property Rights, available at: [Http://www.cathamhouse.org.uk/files/3270-r-iprs.pdf](http://www.cathamhouse.org.uk/files/3270-r-iprs.pdf); accessed on 25 December 2010

¹⁵⁹ Ibid

¹⁶⁰ P.Geroski, Markets for Ethnology: Knowledge, Innovation and Appropriability, in P.Stoneman (ed.), Handbook of the Economics of Innovation and Technological Change, (1995), P.97

¹⁶¹ Ibid

¹⁶² Ibid

identification of the source of GRs used in the development of the subject matter which is to be protected by IPRs and proof of the PIC of the competent national authority of the provider country. The paramount importance of these requirements lies in the fact that once the origin of the GRs utilized in the patents technology (or other IPRs for that matter), the country in which the resource originates can claim benefits arising out of the exploitation of the invention.

Chapter Two

International Legal Regimes on Access and Benefit Sharing and Intellectual Property Rights

There are numerous international agreements on Access and Benefit Sharing (ABS) and Intellectual Property Rights (IPRs) which have a direct or indirect bearing on the issue at hand; i.e., the role of IPRs in the implementation of ABS objectives. From these, mention can be made to the CBD, the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA)¹⁶³, TRIPs, and UPOV. However, this chapter will basically focus on the CBD and TRIPs for different reasons. In the first place, it is difficult if not impossible to deal with ABS and IPR issues in relation to all these instruments. Besides this, the two are the most relevant instruments on the issue at hand and they have their own important implications on Ethiopia's legal regime on ABS and IPRs as the country is a member to the CBD and it is in the process of accession to the WTO. What is more, discussion on the relationships between ABS and IPRs under the CBD and TRIPs can be applied to the other instruments, *mutantis mutandis*. The discussions on synergies between ABS and IPRs under the CBD and TRIPs are at order in what follows.

¹⁶³ It is a treaty adopted in 2001 and in to force since 2004 with the aim of conservation and sustainable use of plant genetic resources for food and agriculture and the fair and equitable sharing of the benefits arising out of their utilization. see FNI Report, International Agreements and Processes Affecting an International Regime on Access and Benefit Sharing Under the CBD: Implications for its Scope and Possibilities of a Sectoral Approach, 2010, available at: [Http://www.fni.no/ABS/publication-41.html](http://www.fni.no/ABS/publication-41.html); accessed on 1 October 2010

2.1. The Convention on Biological Diversity on ABS and IPRs

2.1.1. Introduction

Before going in to the discussions on the important principles incorporated under the CBD¹⁶⁴ relevant to the issue at hand, it is important to say a few words about its background. Negotiations on the CBD signed by over 150 nations in Rio De Janeiro, Brazil, in 1992, often revolved around the allocation of perceived economic benefits from biotechnological exploitation of GRs.¹⁶⁵ The debate centered on what can be called the international bio trade which raises several issues linking GRs and ABS.¹⁶⁶ The most important one for this context raises the question: how should the economic benefits of GRs be distributed among nations? In particular, how should biotechnology based on GRs be transferred or shared between the countries in which the biotechnology is developed and the countries from which the GRs are taken? And the relationship between these issues and IPRs was one of the most divisive issues in the treaty negotiations.¹⁶⁷

GRs have traditionally been considered as the common heritage of mankind and as such have been treated as an unregulated and freely accessible good.¹⁶⁸ Consequently, prior to the CBD there existed no requirement that the benefits derived from the use of these resources be shared

¹⁶⁴ The origin of the negotiations for the Convention on Biological Diversity lies in the 1987 Governing Council decision 14/26 of the United Nations Environment Programme (UNEP), which called upon UNEP to convene an Ad Hoc Working Group of Experts on Biological Diversity for the harmonization of existing conventions related to biological diversity. At its first meeting, the Group of Experts agreed on the need to elaborate an internationally binding instrument on biological diversity. In May 1989, another Ad Hoc Working Group of Experts on Biological Diversity was established to prepare an international legal instrument for the conservation and sustainable use of biological diversity, taking into account the need to share costs and benefits between developed and developing countries and the ways and means to support innovation by local people. The Ad Hoc Working Group, which in February 1991 became the Intergovernmental Negotiating Committee (INC), held seven working sessions (five negotiating) which culminated in the adoption of an agreed text of the Convention on Biological Diversity through the Nairobi Final Act of the Conference for the Adoption of the Agreed Text of the Convention on Biological Diversity. The Convention was opened for signature at the United Nations Conference on Environment and Development (UNCED) in Rio de Janeiro in June 1992. It entered into force on 29 December 1993. See Secretariat of the CBD, Handbook of the Convention on Biological Diversity including its Cartagena Protocol on Biosafety, (3rd. 2000), P.15.

¹⁶⁵ David R. Downes, New Diplomacy for the Biodiversity Trade: Biodiversity, Biotechnology and Intellectual Property in the Convention on Biological Diversity, 4 *Toure Journal of Transnational Law*, (1993) ,P.3

¹⁶⁶ Ibid

¹⁶⁷ Ibid

¹⁶⁸ Michael Jeffrey, Bioprospecting: Access and Benefit Sharing under the Convention on Biodiversity and the Bonn Guidelines, 6 *Singapore Journal of International and Comparative Law*, (2002) ,P.747

with the country of origin.¹⁶⁹ These industries have long relied on IPR regimes to establish monopoly rights that aim to provide fair reward to industries for their investment in research and product development.¹⁷⁰ Thus, most of the benefits derived from GRs have accrued in the developed countries which are rich in biotechnological industries.¹⁷¹

Many developing countries with significant GRs complained that for too long the developed countries located in the northern hemisphere- the North- had used these resources to improve crop varieties and otherwise add value to agriculture and industries without paying compensation to the countries from which the resources came.¹⁷² They argued that they deserved to share in the rewards that biotechnology promised to reap from the manipulation of GRs.¹⁷³ This is because as a matter of fact the wealth of the world's GRs is located in the developing countries while the biotechnology to exploit these resources belongs primarily to institutions of the developed countries.¹⁷⁴ As a result of all these, the ownership and control of GRs became an intensely debated issue in the negotiations leading up to the CBD.

Generally speaking, developing countries have perceived a great inequity in the accumulation of wealth by companies in the north as a result of the use of GRs freely obtained from their borders.¹⁷⁵ They thus came to reject the common heritage doctrine and maintaining that they had the right to benefit from their own resources and they sought to affirm that GRs fall within their national sovereignty to regulate and manage and thus afforded the right to control access to their GRs. In return for allowing northern industry to bioprospect within their borders, countries in the south demanded more of the benefits from products developed as a result.¹⁷⁶

Ultimately, the final text of the CBD was adopted in 1992 and entered in to force as an international legal framework that has sought to encourage the formation of mutually beneficial relationships between providers and users of GRs based on a concept of bilateral agreement.¹⁷⁷

¹⁶⁹ Ibid

¹⁷⁰ Lyle Glowka, A Guide to Designing Legal Frameworks to determine Access to Genetic Resources ,(1998) ,P.1.

¹⁷¹ Ibid

¹⁷² Oldham, Supra Note 2

¹⁷³ Ibid

¹⁷⁴ Ibid

¹⁷⁵ John Ntambirweki, Biotechnology and International Law within the North South Context, 14 Transnational Law, (2001) , P.103

¹⁷⁶ Ibid

¹⁷⁷ Ibid

In ratifying the CBD, countries have committed themselves in general terms to undertake national and international measures aimed at achieving three explicit objectives: the conservation of biological diversity; the sustainable use of its components; and the equitable sharing of the benefits arising out of the utilization of GRs which is at the heart of this thesis.¹⁷⁸ It provides the general contours of the new relationship between users and provider countries, so to speak.¹⁷⁹

Thanks to the CBD, GRs are no longer the common heritage of mankind and they are no more freely accessible commodities. The CBD recognized the sovereign rights of countries to control the use of their GRs and it stresses that the authority to determine access to GRs rests with national governments and subject to national policies.¹⁸⁰ That is why; it is believed that the coming in to existence of the CBD has brought a shift in thinking on the regulation of GRs.

2.1.2. Access and Benefit Sharing under the CBD

The CBD basing itself on the principle of national sovereignty of states over their natural resources aims to create a framework for access to GRs and equitable benefit sharing.¹⁸¹ The sovereign rights of states over their GRs are recognized and mentioned in the preamble and in Arts.3 and 15.1., which specifically recognize the authority of the state to control access to their GRs through national legislation.¹⁸² Access to GRs requires the PIC of the providing country and where granted will be on MAT.¹⁸³ Thus, nation states may condition access to their GRs on informed consent and other terms which provides the potential for capturing most aspects of bioprospecting within enforceable and bilateral agreements.¹⁸⁴

This is a definitive move away from the common heritage doctrine; however, it should also be noted that the CBD sets certain legal limits on sovereign rights.¹⁸⁵ That means, the convention does not create property rights like any other natural resource and national control over GRs is limited by the obligation to facilitate access by other contracting parties and not to impose

¹⁷⁸ CBD, Article 1

¹⁷⁹ Biodiversity: Opportunities and Obligations, 28 Vandebilt Journal of Transnational Law 4,(1995) ,P.613

¹⁸⁰ Santiago Carrizosa, Stephen B. Brush, and etal(eds.,) Accessing Biodiversity and Sharing the Benefits: Lessons from Implementing the CBD,IUNC, Environmental Policy and Law Paper No.54,(2004) ,P.1

¹⁸¹ CISDEL Legal Brief, A New Regime on Access to Genetic Resources and Benefit Sharing,(2003), P.23

¹⁸² CBD, Articles 3 and 15.1.

¹⁸³ CBD, Article 15(4)&(5)

¹⁸⁴ Michael Gollin and Sarah Laird, Global Policies, Local Actions: The Role of National Legislation in Sustainable Biodiversity Prospecting,, 2 B.U.J. Sci.Tech.I., (1996) P.16

¹⁸⁵ Ibid

restrictions that run counter to the convention's objectives.¹⁸⁶ In fact, the emphasis placed on national sovereignty is offset by recognition that the conservation of biological diversity is a common concern of humankind.¹⁸⁷

Furthermore, the sovereign rights to GRs are limited to those collected after the convention's entry in to force and therefore plants, animals or microorganisms that have been removed to ex situ collection prior to this date are exempt from the CBD and cannot be protected through access control.¹⁸⁸

Be that as it may, Articles 8 and 15 are particularly important in laying the foundation for ABS. Article 15.1 recognizes state sovereignty over natural resources in the context of access to these resources, allowing for the possibility of profiting from providing access and under the provisions of Article 15, access to GRs is to be on MAT subject to PIC.¹⁸⁹

In addition to these, the principal provisions of the CBD relating to benefit sharing are to be found in Articles 8(J), 15.6, 15.7, 16 and 19.1. & 2. While it is beyond the scope of this thesis to explain Articles 16 to 21 in detail, it is good to note that they relate to ABS. Indeed the articles on access and transfer of technology and the handling of biotechnology and the distribution of its benefits affect the interface between ABS and IPRs.

The principal provision relevant for the present purpose is Article 15.7., which provides a framework for the implementation of the third objective of the convention, namely fair and equitable sharing of the benefits. In accordance with Art.15.7 of the CBD, the contracting parties shall take legislative, administrative or policy measures for sharing in a fair and equitable manner the results of R&D and the benefits arising from the commercial and other utilization of

¹⁸⁶ Jeffrey, *Supra* Note 168 at 762

¹⁸⁷ CBD, preamble

¹⁸⁸ CBD, Article 4

¹⁸⁹ CBD, Articles 15 (4) &(5). The CBD as a general framework as opposed to defining the term of PIC seems simply to declare its intention to mandate PIC in the access process. In effect, A GR user is required to obtain PIC before accessing GR in providing nations. Relatively, GRs providers are entitled to grant consent upon such applications. But the CBD itself does not articulate substantial content about the requirement. The absence of both a clear definition of the term and detailed configuration of the PIC system sustain it leaves much room to be filled in. The single provision of the CBD alone cannot provide resolution for a variety of issues that may be of critical importance. See Laurel A. Firestone, *You Say Yes, I Say No: Defining Community Prior Informed Consent Under the Convention on Biological Diversity*, 16 *GEO.INT'L L.REV.*, (2003), P.185

GRs with the contracting party providing such resources. Such sharing shall be based upon MAT.

According to Article 15(7) of the CBD, benefits to be shared on MAT are not only research and development results, but also the commercial or other benefits derived from the utilization of GRs provided. These benefits include access to transfer of technology using the GRs; participating in biotechnological research activities and priority access to the results and benefits arising from biotechnological uses of the GRs.¹⁹⁰ And a specific form of benefit sharing, Article 15(6), requires parties to promote collaborative scientific research between provider and user parties.

To implement the benefit sharing requirement, countries that have or may have users within their jurisdiction need to adopt legislative, administrative or policy measures. as noted by Tvedt and Young, this means that there are at least two distinct national legislative components to every ABS situation; source country measures, including provisions clarifying each countries sovereign rights over GRs and the identification of access procedures and requirements; and user country measures, by which each country addresses the responsibility of users under their jurisdiction who are utilizing GRs from other countries.¹⁹¹

The general understanding being all countries have the potential to be users and providers of GRs; all parties are required to adopt national legislation to implement the CBD benefit sharing requirements in interstate relations.¹⁹² However, the CBD does not provide guidance on the measures that can be or should be taken by parties for the implementation of the benefit sharing requirements as set out in Article 15(7).

Of course, as will be discussed in the subsequent sections of this chapter, the Bonn Guidelines provide a list of measures that countries with users in their jurisdictions could consider including measures to encourage the disclosure of the country of origin of GRs in IPR applications, among others. On its part, the newly enacted Nagoya protocol has incorporated provisions on compliance measures.

¹⁹⁰ CBD, Articles 16 & 19

¹⁹¹ M.W. Tvedt and T. Young, *Beyond Access: Exploring Implementation of Fair and Equitable Sharing Commitments in the CBD*, IUCN ABS series No.2, (2007), P.76

¹⁹² *Id* at 78

The point I am trying to make is that Article 15(7) is important in recognizing the fact that access legislations in provider countries are not sufficient to achieve fair and equitable benefit sharing. Achieving benefit sharing would further require enactment of supportive legislation in countries with users in their territories in order to secure compliance. This provision therefore links IPRs with ABS since member states can require IPR applicants for inventions made based on GRs acquired in other countries prove that the resources were acquired in compliance with the CBD or national laws in the source country as one measure which may even be considered as an effective one.

From the provisions expounded above, we can discern that the CBD is a convention which outlines a general framework on ABS and the specific rules are supposed to be elaborated, negotiated and implemented through the decision of the COP, additional protocols, specific multilateral regimes and national legislation.¹⁹³ As will be discussed in the upcoming parts of the paper, the COP (conference of the parties)¹⁹⁴ has already passed several decisions on specific provisions of the CBD and on the same vein a Protocol on ABS is recently adopted in the COP 10 at Nagoya.¹⁹⁵ Therefore, under the CBD framework, access is possible with the PIC of the concerned state authority and with benefit sharing arrangements which are supposed to be made based on the mutual agreement between the provider and user parties.

2.1.3. ABS and IPRs under the CBD

It is generally recognized - particularly by developing countries - that it has not yet been possible to fully achieve the ABS objective of the CBD, i.e., the fair and equitable sharing of benefits arising from the use GRs.¹⁹⁶ That is why it is conceded that, identifying the fundamental factors hindering the effective achievement of this objective of the CBD has a paramount importance as it is a one step ahead to the solution.

¹⁹³ Merso, Supra Note 43 at .252

¹⁹⁴ It is the governing body of the convention established under Article 23. Its key functions are to keep under review the implementation of the convention and to steer its development. Other important functions of the COP include the adoption of budget, the consideration of national reports, the adoption of protocols or annexes and the development of guidance to the financial mechanism. A list of the functions of the COP under the convention is set out in Art.23.

¹⁹⁵ Tvedt and Young, Supra Note 190

¹⁹⁶ Jorge Cabrera Medaglia, The Political Economy of the International ABS Regime Negotiations: Options and Synergies with relevant IPR Instruments and Processes, , Available at [Http:// www. lctsd. org/i/ news/ bioresreview /8087/1](http://www.lctsd.org/i/news/bioresreview/8087/1); accessed on 26 September 2010

One commentator stated three factors in this regard. First, the limited nature of the economic and non-economic benefits that appear to have been derived from different bioprospecting activities and, in general, from the application of ABS frameworks, has led to substantial frustration for the actors involved; second, there have been cases of illegal access, misappropriation or “biopiracy” that have occurred in countries and communities, especially in Africa, Asia and Latin America.¹⁹⁷ These cases have been difficult to address with cost-effective legal solutions within the framework of national ABS legislation.¹⁹⁸ Third, although the CBD requires the Parties to take measures to ensure fair and equitable benefit sharing, it has mostly been developing countries that have issued regulations on ABS.¹⁹⁹ Thus, the nations where agricultural, biotechnological and pharmaceutical companies have their headquarters - mostly developed countries - have not put in place corresponding regulations that would ensure benefit sharing, and as a result compliance with their legally binding international obligations.²⁰⁰

Indeed, the absence or limited presence of so-called “user country measures” has been criticized as one of the causes of high transaction costs and the highly controlling nature of current access laws.²⁰¹ The need for “user country measures” has been stressed by those who have noted the transboundary nature of ABS in trade relations as well as the inadequacy of local regulations to effectively monitor samples or information on GRs, once they have left the country that provided them.²⁰² In this context, it is clear that the ABS provisions in the countries of origin are markedly inadequate for creating an ABS system that is functional and consistent at the international level.²⁰³

The present work is concerned with misappropriation as one of the stumbling blocks for the implementation of ABS objectives, which links IPRs with ABS. The CBD being cognizant of the

¹⁹⁷ Ibid

¹⁹⁸ Ibid

¹⁹⁹ G. Kirstin Rosendal, *Balancing Access and Benefit Sharing and Legal Protection of Innovations from Bioprospecting: Impacts on Conservation of Biodiversity*, 15 *the Journal of Environmental Development*, (2006), P. 430

²⁰⁰ Ibid

²⁰¹ Anchim Seiler and Graham Dutfield, *Regulating Access and Benefit Sharing: Basic Issues, Legal Instruments and Policy Proposals*, 2001, available at: <http://www.neobiota.net/fileadmin/MDB/documents/access.pdf>; accessed on 21 June 2010

²⁰² Ibid

²⁰³ Ibid

fact that IPRs have an impact on the realization of ABS objectives devotes a provision which directly deals with same. Article 16(5) states as follows:

*The 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 law in order to ensure that such rights are **supportive of and do not run counter to its objectives**.* (Emphasis added)

From this provision, one can dissect some important elements which need to be expounded. To begin with, the caveat "national legislation and international law" in regard to IPRs raises a question: which set of international law? In this regard, the reference can be construed as the call for cooperation between parties is subject to the WIPO administered IP treaties and the TRIPs agreement.²⁰⁴ This shows the convention's recognition of the IP system both at national and international level since IP rights remain the key outstanding consideration in the negotiation.²⁰⁵

This, in turn, raises another question: which one is to prevail if there is a conflict between IP protection and the objectives of the CBD? Would non compliance with IPR obligations be justified if they are not supportive to the objectives of the CBD? When the phrase which calls for the parties to ensure that principles of IPRs are supportive of and do not run counter to the CBD objectives seen; it seems that in case of conflict, IPRs must give way. And one may persuasively argue that the ecological objectives of the CBD should indeed take precedence over IPRs.²⁰⁶

True, Article 16 (5) is ambiguous whose imprecise text reflects the complexity of the political debate and the subsequent compromise reached during the negotiation.²⁰⁷ What is pretty clear is that the provision emphasizes on the need to take positive action in developing positive synergies between IPRs and the ABS objectives of the CBD. The Convention concedes that the exclusive effects of the instruments to protect IP can have an influence on the implementation of the CBD's objectives and establishes that the contracting parties should cooperate on this point.

²⁰⁴ David Hurblet, Fixing the Biodiversity Convention: Towards a Special Protocol for Related Intellectual Property, 34 Natural Resource Journal 2, (1994), P.385

²⁰⁵ The Crucible Group, People, Plants and Patents: The Impacts of Intellectual Property on Trade, Plant Biodiversity and Rural Society, (1994) ,P.35

²⁰⁶ Hurblet, Supra Note 204

²⁰⁷Crucible II Group, Seeding Solutions: Policy Options for Genetic Resources: People, Plants, and Patents Revisited , (2000), P.42

The other important element of this provision is contained in the phrase that calls for the parties to ensure that principles of IPRs are supportive of and do not run counter to the convention's objectives. Succinctly speaking, it requires contracting parties to ensure that IPR regimes are supportive of and do not run counter to the CBD's objectives and these rights will be subject to national legislation and international law. The placement of this provision implies that IPRs have an impact on the convention's objectives in general and on the fulfillment of ABS requirements in particular. It also implies the possibility that parties will need to take steps cooperatively to manage the influence of IPRs to ensure that its impact is positive on the CBD objectives.

But then, it is difficult to hold that the parties to the convention have taken a position as to the impacts of IPRs on the convention's objectives. This is because the term 'may' implies that the negotiators could not agree whether IPRs have a positive or negative effect on the achievement of the convention's objectives.²⁰⁸

In any case, at this juncture, one will be compelled to raise a nettlesome question: do available forms of IPRs support the goals of the CBD in regard to ABS? Though it is an area that is complex, technical and controversial, the first chapter of the paper has made a modest attempt to review the range of viewpoints that have been expressed on the impacts of IPRs on ABS.

The complex debate on IPRs and their relationship with the Convention's objectives has often been hampered by a lack of specific factual grouping.²⁰⁹ For example, there has been little empirical study of the impacts of specific types of IPRs on the specific objectives of the Convention.²¹⁰ The truth remains that the impacts of IPRs on CBD objectives are still controversial though it is pretty clear that IPRs are linked to important ways to the many provisions of the Convention in addition to the one discussed above.²¹¹ This partly stems from the underlying fact that the convention focuses on the value of biological diversity as a source of

²⁰⁸ The Impacts of IPRs on the Conservation and Sustainable Use of Biological Diversity and on the Equitable Sharing of Benefits from its Use: a Preliminary Study, UNEP/CBD/COP/3/22 available at: http://www.iisd.ca/biodiv/cop3_22_vfinal.htm, accessed on 25 September 2010

²⁰⁹ Ibid

²¹⁰ Ibid

²¹¹ In this regard, one can have a look at Art.8 (j) on traditional knowledge; Art.11 which requires parties to create economically and socially sound incentives for the conservation and sustainable use of the components of biological diversity; Art.12 which requires parties to promote and cooperate in the use of scientific advances in biological diversity research...; Art.19 which demand parties to take measures to provide for effective participation in biotechnological research. In these provisions, IPRs are considered relevant for implementation.

GRs which are valuable as source of information, which in turn, is valuable to humanity in many ways.²¹²

This being so, it is believed that IPRs can be important instruments in order to do away with one of the challenges for the implementation of ABS objectives, i.e., misappropriation of GRs and the breaches of ABS requirements. Unfortunately, however, the present IPR regime as it stands now does not serve this purpose, to say the least. That is why, the CBD is grappling with the challenge of coming up with measures in order to make use of the IPR system to prevent misappropriation of GRs and promote compliance with CBD ABS requirements.

Without losing sight of the purpose of this section, generally speaking, it has not been easy to determine the role of IPRs in the application of ABS provisions of the CBD. In this regard, the challenge has been to determine the role of IP in the mutually agreeable terms of access and their place in sharing the benefits from that access.²¹³ To date, the major areas where IP has been actively considered by the COP under the CBD are access to genetic resources and benefit sharing; and the issue of IPRs has been reviewed in the context of the CBD in regard to how IPRs can assist in monitoring compliance with ABS.²¹⁴ Even then, there seems to be a consensus amongst developing countries rich in GRs in that IPRs could have a role for the implementation of ABS requirements if they are designed to this effect. This takes us to the discussions on the developments in the CBD on the issue at hand.

2.1.4. ABS and IPRs: Developments under the CBD

Being cognizant of the fact that IPRs can be used as an important instruments to ensure compliance with ABS requirements, the third COP decided to seek further information about existing mechanisms both addressing ABS, and sought to extend co-operation with other institutions dealing with IP, notably the WIPO and the WTO.²¹⁵ Building on what has been done at the 3rd COP, the 4th COP after considering the various materials before the meeting, decided

²¹² Medaglia, Supra Note 196

²¹³ Charles Lawson, Implementing an Objective of the CBD- Intellectual Property, Access to Genetic Resources and Benefit Sharing in Australia, 22 EPLJ, (2005), P.5

²¹⁴ Ibid

²¹⁵ Report of the Third Meeting of the Conference of the Parties on Biological Diversity, 1997, UNEP/CBD/COP/3/38

to convene a Panel of Experts on Access to and Benefit-Sharing (hereinafter the Panel). The purpose was:

*to draw upon all relevant sources, including legislative, policy and administrative measures, best practices and case studies on access to genetic resources and benefit sharing arising from the use of those genetic resources, including the whole range of biotechnology, in the development of a common understanding of basic concepts and to explore all options for access and benefit sharing on mutually agreed terms including guiding principles, guidelines, and codes of best practice for access and benefit sharing arrangements.*²¹⁶

The focus was to be on legislative, administrative and policy measures for PIC, references to the country of origin in relevant publications and patent applications, MAT including on benefit sharing and IPRs and technology transfer, and incentive measures to encourage the conclusion of "contractual partnerships".²¹⁷

The subsequent report of the Panel reached a broad consensus about the principles that should govern ABS arrangements and a common understanding of the key concepts such as PIC, MAT, and fair and equitable benefit sharing, together with important information and capacity-building needs associated with ABS arrangements.²¹⁸ The key recommendation of the Panel was the need to develop guidelines about PIC and MAT.²¹⁹

At this early stage, the Panel considered IP might provide an incentive to comply with the CBD's PIC requirements by a requirement to provide evidence of satisfactory consent on applying for IP presumably this was addressed to Patents and Plant Breeder's Rights that require formal registration.²²⁰

²¹⁶ See Report of the Fourth Meeting of the Conference of the Parties to the Convention on Biological Diversity, 1998, UNEP/CBD/COP/4/27

²¹⁷ Ibid

²¹⁸ Ibid

²¹⁹ Ibid

²²⁰ Ibid

Significantly, the Panel considered the COP needed to explore IP issues in greater depth recognizing that it was a component of other domestic and international legal instruments.²²¹ However, in dealing with IP, the Panel acknowledged that it may have an influence on the implementation of ABS arrangements and may have a role in providing incentives for users to seek PIC.²²² However, the Panel was not able to come to any conclusions about these issues, and therefore suggests that the COP consider these matters further.²²³

To this effect, the Panel identified a number of issues that required further study, including that IP application procedures require that the applicant submit evidence of PIC, the guiding parameters for contractual arrangements, application of the formal IP threshold standards and the resulting scope, and an assessment of the effect of IP as an incentive to ABS.²²⁴

In parallel with the Panel's work, the 4th COP had also decided to convene an Inter-Sessional Meeting on the Operations of the Convention (ISOC) as a preparatory discussion on access to GRs.²²⁵ The ISOC began assessing the relationship between IP and the relevant provisions of the TRIPs and the CBD,²²⁶ ex situ collections made before 29 December 1993,²²⁷ and a number of other matters that the Panel should consider²²⁸ without formally making any firm conclusions about the place on IP in ABS arrangements.

The 5th COP took note of the Panel's report and the ISOC report, and then decided, in dealing with access to GRs, to establish an Ad Hoc Open-Ended Working Group on Access and Benefit-Sharing with the mandate to develop guidelines and other approaches to ABS.²²⁹ The outcome of this decision was the Ad Hoc Open-Ended Working Group's report that recommended the

²²¹ Supra Note 206

²²² Ibid

²²³ Ibid

²²⁴ Report of the Fifth Meeting of the Conference of the Parties, UNEP/CBD/COP/5/8, No 75, PP.23-26

²²⁵ Supra Note 209 at 132

²²⁶ Conference of the Parties to the Convention on Biological Diversity, Report of the Inter sessional Meeting on the Operations of the Convention(1999) ,UNEP/CBD/COP/5/4,PP.30-31

²²⁷ Id at 31-32

²²⁸ Id at 28-30

²²⁹ Supra Note 218 at 21, 25, and 197-198

adoption of the Draft Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization.²³⁰

The key objective of the guidelines was to assist Parties in developing an overall ABS strategy and in identifying the steps involved in the process of obtaining ABS.²³¹ In addressing the role of IP in implementing ABS arrangements the Ad Hoc Open-Ended Working Group recommended that the COP invite countries to disclose the country of origin of GRs in applications for IP as a possible contribution to tracking compliance with the obligations under the CBD of PIC and the MAT to access GRs.²³²

As merely the first step on a long and complex process to secure ABS under the CBD, the 6th COP adopted the Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization (Bonn Guidelines) as voluntary guidelines that apply to all GRs covered by the CBD except human GRs, in a manner that is coherent and mutually supportive of the work of relevant international agreements.²³³

While the Bonn Guidelines do not appear to favour a specific approach to IPRs, they contemplate private contracts addressing IPRs and other matters between the resource holder and the user dealing with the ABS arrangements. However, the Bonn Guidelines deal at some length with the various methods by which benefits might be shared identifying those involved in the resource management, scientific and commercial process and the various kinds of monetary and non-monetary benefits.²³⁴

A. Disclosure Requirements under the Bonn Guidelines

As mention has already been made, in 2002, the COP at its Sixth Meeting adopted the Bonn Guidelines to address ABS arising from use of those resources. In the Bonn Guidelines, the CBD COP invited Parties and governments to encourage disclosure of the country of origin of GRs in

²³⁰ See Report of the Sixth Meeting of the Conference of the Parties on the Convention on Biological Diversity, UNEP/CBD/COP/6/6, PP.14 and 15

²³¹ Id at 16

²³² Id at 36-38

²³³ See Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of Benefits Arising out of their Utilization, Report of the Sixth Meeting of the Conference of the Parties to the Convention on Biological Diversity, 2002, UNEP/CBD/COP/6/20

²³⁴ Ibid

applications for IP where the subject matter of the application concerns or makes use of such knowledge in its development.²³⁵ This is proposed in order to make use of the IPR regime to make sure that ABS requirements are complied with when one uses a GR in developing an invention.

The Bonn Guidelines set up a voluntary framework for legislative, administrative or policy measures on ABS as well as ABS contracts and agreements.²³⁶ Due to this broad approach and their non binding nature, the guidelines represent recommendations which leave room for choice and interpretations.²³⁷ On the other hand, it has been pointed out that the Bonn Guidelines further harmonized the steps for adequate ABS and clarified and complemented existing obligations under the CBD.²³⁸ The Guidelines substantiate Art. 15 (2), (5) and (7) of the CBD as well as Arts. 16 to 19 of the CBD.²³⁹

The Bonn Guidelines contain five chapters. The General Provisions (chapter I) includes objectives, the scope and definitions. The core of the Guidelines is contained in chapter II, which clarifies roles and responsibilities of the different stakeholders. The participation of stakeholders is detailed in chapter III. Part IV describes the steps of the ABS process. The Other Provisions are followed by two appendices that suggest elements for material transfer Agreements and exemplify monetary and non monetary benefits. It is not in the interest of this author to discuss the provisions of Bonn guidelines; the purpose here is to discuss provisions of the guidelines which are related to ABS-IPR issues.

Interestingly enough, the relationship between IPRs and ABs has been set out in a number of provisions of the Bonn Guidelines. Parties concluding contracts with users of GRs under their jurisdiction should consider measures to encourage the disclosure of origin of the resources in

²³⁵ Josua D. Sarnoff and Carlos M. Corea, Analysis of Options for Implementing Disclosure of Origin Requirements in Intellectual Property Applications, UNCTAD/DITC/TED/2005.

²³⁶ Mariam Dross and Franziska Wolff, New Elements of the International Regime on Access and Benefit Sharing of Genetic Resources - the Role of Certificate of Origin, 2005, available at: www.dnl-online.de; accessed on 5 April 2010

²³⁷ Ibid

²³⁸ Secretariat of the CBD, Bonn Guidelines on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising out of their Utilization, 2002, available at: [Http://www.cbd.int/doc/publications/cbd-bonn-ed/s-en.pdf](http://www.cbd.int/doc/publications/cbd-bonn-ed/s-en.pdf); accessed on 26 July 2010

²³⁹ Ibid

applications for IPRs. In addition, the joint ownership of IPRs is considered a basic requirement of contractual agreements.

In adopting the Bonn Guidelines, the CBD COP noted that disclosure of origin requirements could contribute to tracking compliance with PIC and the MAT (including provisions for equitable sharing of the benefits of research and commercialization) on which access to those resources was granted.²⁴⁰

It is worth reiterating that in the Bonn Guidelines, the CBD COP also urged consideration of measures aimed at preventing the misappropriation of GRs obtained without the PIC of the contracting party providing such resources.²⁴¹ Specifically, it suggested measures to support compliance with ABS requirements, including disclosure of the country of origin of GRs, and measures to prevent use of GRs obtained without prior informed consent.²⁴² The CBD COP further suggested that national governments monitor applications for IP relating to the material supplied, recognized that verification of compliance with ABS requirements may involve systems of voluntary certification, and authorized parties to adopt appropriate, effective and proportional measures to address violations of national requirements for implementing the CBD.²⁴³

B. Disclosure Requirements and the Nagoya Protocol on ABS: A Possible Measure Left to Members

After seven years of negotiation, COP 10 of the CBD held from October 18-29 2010, in Nagoya, Japan, adopted a protocol on Access and Benefit Sharing.²⁴⁴ In this meeting, one of the sticking points was related to compliance measures on checkpoints in general and disclosure requirements as a compliance measure to be used by IP offices in particular.²⁴⁵ Compliance measures were addressed throughout the meeting under the representatives of Namibia and

²⁴⁰ Supra Note 226

²⁴¹ Ibid

²⁴² Ibid

²⁴³ Ibid

²⁴⁴ State of ABS Negotiations from Third World Network, available at: <http://www.twinside.org.sg/>; accessed on 21 November 2010

²⁴⁵ Summary of the Tenth Conference of the Parties to the Convention on Biological Diversity: 18-29 October 2010, Earth Negotiations Bulletin, available at: <http://www.iisd.ca/biodiv/cop10/>; accessed on 6 November 2010

Spain, in a contact group, a closed group consisting of parties only and bilateral confessional meetings.²⁴⁶

In particular, with regard to disclosure requirements, delegates debated on the inclusion of this measure, its mandatory nature and consequences of non compliance; and with regard to checkpoints, negotiations focused on whether establishment should be mandatory; whether an indicative list of checkpoints should be included; as well what kind of information they would manage.²⁴⁷ As to the international certificate of compliance, discussions basically focused on requirements for minimum information to be included in such certificate.²⁴⁸ Delegates also debated whether the provision aims exclusively at supporting compliance, as suggested by developing countries or also at enhancing transparency as promoted by developed countries.²⁴⁹

Before going to the discussions on the relevant Articles of this protocol, it is important to give the snapshot of the arguments forwarded by developed and developing countries on DRs which show their deep rooted divisions and which in fact ended up in rejecting mandatory DRs.

The long awaited discussions on DRs at specific checkpoints²⁵⁰ - prominent of which are IP offices - showed an unwillingness of developed countries to consider mandatory DRs and even mandatory checkpoints.²⁵¹ The reasons forwarded by developed countries in doing so includes weary of administrative procedures that would be created by adopting mandatory DRs and they were not convinced of the need for an obligation to disclose information on PIC and benefit sharing on GRs being utilized in their jurisdiction.²⁵² Instead, they argued for flexible compliance measures and checkpoints which give the option of choosing the appropriate measure and checkpoint to national governments. On this issue, Japan said that the important

²⁴⁶ Ibid

²⁴⁷ Ibid

²⁴⁸ CBD COP 10 Highlights: 18 October 2010, Earth Negotiation Bulletin, available at: [Http:// www.iisd. ca/biodiv/ cop10/](http://www.iisd.ca/biodiv/cop10/); accessed on 17 November 2010

²⁴⁹ Ibid

²⁵⁰ Apart from intellectual property examination offices, checkpoints such as entities publishing research results relating to the utilization of GRs; research institutions subject to public funding; authorities providing regulatory or marketing approval of products derived from the use of GRs.

²⁵¹ TWN Info Service on Intellectual Property Issues, Developed Countries Rejected Mandatory Disclosure, 2010, available at: [Http://www.twinside.org.sg/title2/intellectual; property/info.service/2010/ipr.inf.101005.htm](http://www.twinside.org.sg/title2/intellectual;property/info.service/2010/ipr.inf.101005.htm); accessed on 16 December 2010

²⁵² Ibid

thing to do is to examine each checkpoint to see if it is feasible and implementable.²⁵³ It goes on stating that its government found it especially difficult to implement DRs at IP offices, research institutions subject to public funding and entities publishing research results.²⁵⁴ So, according to Japan, what is important is flexibility of the measures and checkpoints at the national level to find where these checkpoints may be set up.

On the same vein, Canada expressed its extreme position by stating that a list of checkpoints is not needed and that it wanted flexibility and nothing mandatory.²⁵⁵ It emphasized that we should try to build in flexibility in putting in place the necessary measures and checkpoints in national jurisdiction.²⁵⁶ On its part, EU said that what we ultimately may need is experience on how these measures will work and what we may be able to do in ensuring compliance with ABS laws of provider countries in their jurisdictions.²⁵⁷ And it underscored the importance of flexibility in adopting these measures and designating the checkpoints.²⁵⁸

In sum, developed countries are of the view that it is easier if the measures that can be taken to ensure compliance with ABS regulatory frameworks of GR provider countries are left to member states; and IP offices should not be taken as mandatory checkpoints.

On the other side of the spectrum, developing countries argued that the criterion is to choose "effective" measures and checkpoints and DRs at IP offices is no doubt an appropriate effective measure.²⁵⁹ Adding on this argument, India believed that there is a need to look for several measures and checkpoints; but then, DRs and patent offices are the most appropriate ones and they should be mandatory.²⁶⁰ True, the appropriateness of patent offices in particular and IP offices in general for the implementation of DRs is basically because patent are at the point of direct transition in to commercialization and benefit generation.²⁶¹

²⁵³ Ibid

²⁵⁴ Ibid

²⁵⁵ Supra Note 248

²⁵⁶ Ibid

²⁵⁷ IUCN, Access and Benefit Sharing: Position Paper,(2010), available at: [Http://www.iucn.org](http://www.iucn.org) ; accessed on 13 December 2010

²⁵⁸ Ibid

²⁵⁹ Supra Note 244

²⁶⁰ Ibid

²⁶¹ Hodges T.J. and Daniel A., Promises and Pitfalls: First Steps on the Road to the International ABS Regime, 14 Review of European Community and Environmental Law 2, (2005), P.149

No one denies that the objective of the Protocol is ensuring the fair and equitable sharing of the benefits arising from the utilization of GRs. It is also believed that this is possible when developed countries where GRs are used are legally bound to implement ABS laws of provider countries. Therefore, if developed countries believe in the objectives of the Protocol and at the same time if they are not in favor of adopting DRs at IP offices; that means, they are not serious about compliance and it shows the hard fact that they lack the political commitment to do so.

In any case, in the presence of this entrenched positions between developed and developing countries on this critical issue, the Protocol was adopted²⁶² having two interrelated provisions on compliance which is considered as a masterpiece in creating ambiguities.

For the effective implementation of ABS objectives, parties are obliged to take appropriate, effective and proportionate legislative, administrative or policy measures in order to ensure compliance with domestic legislation or regulatory requirements on ABS.²⁶³ These measures need to be taken by member states to provide that GRs utilized within their jurisdiction have been accessed in accordance with PIC and MAT have been established as required by the domestic ABS legislation.²⁶⁴

In addition to these, with a view to ensure compliance with the measures adopted, parties are supposed to take measures, as appropriate to monitor and to enhance transparency about the utilization of GR which includes the designation of one or more checkpoints.²⁶⁵ Of course, these designated checkpoints would collect or receive relevant information related to PIC, to the source of the GR, to the establishment of MAT and/or the utilization of GR as appropriate.²⁶⁶ To this effect, each party requires users of GRs to provide the information provided above at a

²⁶² In fact, until the very end, it appeared unlikely that agreement would be reached on the most contentious issues relating to compliance in general and disclosure requirements in particular. For this to happen, it is believed that the secret meeting between the EU, the African group, Norway and Brazil by the Japanese COP presidency in order to produce the draft for the informal ministerial consultation has contributed a lot. But, this move is criticized by many for its lack of transparency. The procedure also enraged many regions in particular the like minded Asia Pacific and Latin American and Caribbean group members who felt excluded from the key meeting in the process. I think behind the scene deals cannot be the standard for negotiating such important issues which are at the core of the protocol.

²⁶³ The Advanced Unedited Text of the Nagoya Protocol, Article 12

²⁶⁴ Ibid

²⁶⁵ The Advanced Unedited Text of the Nagoya Protocol, Article 13

²⁶⁶ Ibid

designated checkpoint as appropriate.²⁶⁷ What is more, a duty is imposed on members to cooperate in case of non compliance with domestic ABS legislation by taking appropriate, effective and proportionate measures to address the situation.²⁶⁸

Laconically speaking, from the relevant provisions of the Protocol on compliance measures, we can discern that parties shall take effective and proportional measures to ensure compliance with ABS requirements as prescribed in domestic ABS legislation and to address situations of non compliance. Nonetheless, there is no indication given to what these measures may be. This shows the success of developed countries in having a protocol which gives the liberty to parties to take the measure they consider appropriate in order to ensure compliance with national ABS laws of provider countries.

The Protocol allows flexibility for countries to choose their own menu for implementation based on their own needs and experiences. And the measures that would be taken by member states can be inferred from the positions expressed in the negotiation. For example, developing countries will take DRs to be implemented by IP offices as an appropriate and effective measure to ensure compliance with ABS requirements. As will incidentally be indicated in the forthcoming chapter, some developing countries have already adopted DRs in their IP and/or ABS laws. On the other hand, the measures that would be taken by developed countries in this regard remains to be seen. At any rate, due to the flexibility of the Protocol, we will inevitably witness different interpretations to the 'appropriate and effective measures' that would be taken at national level which would, in turn, create legal uncertainty.

This being so, the Protocol in general and the provisions under consideration are flooded with vague expressions such as, 'appropriate', 'effective', 'proportionate' and the like. When do we consider a compliance measure appropriate, effective and proportionate? Very difficult to answer and that is why; one negotiator lauded the vagueness of these provisions as they will provide lots of work for lawyers who will be tasked with sorting out how to operationalize them.²⁶⁹ The point worth reiterating is that operationalizing these terms in the measures that would be taken is left to member states. Even then, one can easily guess that the effectiveness of these measures will be

²⁶⁷ Ibid

²⁶⁸ Ibid

²⁶⁹ Supra Note 245

an issue to be tabled by developing countries if developed countries fail to adopt effective measures in this regard.

Generally speaking, when the Protocol is seen from the expectation of developing countries in incorporating DRs as one of the measures for compliance to combat misappropriation and ensure benefit sharing, it is far from perfect. One of the focuses of the negotiation on the Protocol was that there have been cases of illegitimate access or misappropriation that have occurred in countries, especially in Africa and Latin America. The problem is it may be difficult to address these cases if parties are not specifically required to ensure that users of GRs in their jurisdictions proved that they received PIC from the provider in registering patents or other IP rights.

Even then, the adoption of the Protocol can be celebrated as a success for developing countries as it obliges developed countries to take effective and appropriate measures in order to ensure compliance with ABS laws of providers. Not only this, interestingly enough, it has envisaged an assessment and review mechanism on its implementation in general and compliance measures in particular.²⁷⁰ So, if developed countries are not going to take any measure at all or if the measures taken are not effective, developing countries will obviously have the chance to present this failure on the part of developed countries for evaluation. In any case, the effectiveness of the Protocol in ensuring compliance with ABS requirements in national ABS laws depends on its implementation at national level, particularly in developed countries.

What will happen next? The protocol will be open for signatures at the United Nations headquarter in New York from 2 February 2011 to 1 February 2012.²⁷¹ And the protocol shall enter in to force on the 90th day after the date of the deposit of 50th instrument of ratification. Therefore, the impact of this protocol in ensuring compliance with ABS requirements as stipulated in the CBD and ABS legislations of provider countries remains to be seen in the years to come after its effectiveness.

2.2. The TRIPs Agreement and ABS Requirements

The TRIPs Agreement is the first international treaty that links IPR to trade issues. The TRIPs Agreement requires that WTO Members ensure that their laws meet the minimum standards of

²⁷⁰ The Advanced Unedited Text of the Nagoya Protocol, Article 25

²⁷¹ The Advanced Unedited Text of the Nagoya protocol, Article 26

IP protection that it contains. Although differences exist among domestic regulations on IPRs, TRIPs allowed developed countries to universalize the core of their own IPR systems, which are generally stronger than those of developing countries.²⁷²

The Agreement , inter alia, contains minimum standards that will contribute to certain harmonization but leave some space for member states to determine aspects of IPR protection that are not dealt with in it and to make interpretations of the provisions, especially the exceptions. Even then, the TRIPs Agreement does not include any provision directly related to the CBD requirements on ABS. If that is so, one may question the need to discuss about this regime.

This being an appropriate concern, discussions on the TRIPs Agreement in line with the issues at hand can be justified as the agreement incorporates provisions which have a repercussion on the fulfillment of ABS requirements and also it is an agreement which is considered an appropriate regime to enshrine DRs. So, it is meaningful to discuss the provisions of the agreement which have an impact on ABS before dealing with the relationship the agreement has with CBD on the issue of DRs.

The relevant rules, in this regard, are: Article 27(which establishes what can be patented and the scope of the exceptions from patentability), Article 29(on conditions on patent applicants), Article 62(on acquisition and maintenance of intellectual property rights and related inter parties procedures) and Article 32(on revocation and forfeiture of patents).

To begin with, Article 27 states that:

1. Subject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application. ... patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.
2. Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect order public or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment,

²⁷² Ibid

provided that such exclusion is not made merely because the exploitation is prohibited by their law.

3. Members may also exclude from patentability... (b) Plants and animals other than microorganisms, and essentially biological processes for the production of plants or animals other than non biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof. The provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement.

This provision replicated above contains several elements. The first is the presumption that patents are to be available for any invention meeting the substantive conditions of patentability. Secondly, patent rights are to be enjoyed without discrimination between technologies. Thirdly, a general exception to this presumption is provided for inventions whose commercial exploitation would violate *ordre public*, public morality or would seriously prejudice the environment. Fourthly, a set of specific exceptions from patentability is provided: plants, animals and essentially biological processes. So, a country may exclude from patentability plants, animals and essentially biological processes for the production of plants and animals. But, a country must allow patents for microorganisms and non biological and microbiological processes for production of plants and animals. From this component of the provision, one can infer that a country is obliged to provide protection for plant varieties either by patents or by an "effective" *sui generis* system or a combination thereof. No definition of "effective" is provided, and some commentators have suggested that to meet this threshold, the minimum principles of the TRIPS Agreement must be respected. Finally, the provision stipulates that the WTO was to review Article 27.3(b) in 1999.²⁷³

Patent on life forms in the TRIPs Agreement has been and remains to be a contentious issue starting from its negotiation.²⁷⁴ This is precisely because it is an issue that divides developed and

²⁷³ Begona Venero Aguirre, Addressing the Disclosure Requirement at the International Level- the Role of the TRIPs Agreement , ICTSD/CIEL/IDDRI/IUCN/QUNO,2005

²⁷⁴ Ibid

developing countries.²⁷⁵ In fact, that is why, negotiators of TRIPs Agreement agreed to review the provision four years after it was concluded as a means to reach sufficient consensus.²⁷⁶

The point is although members may exclude from patentability plants and animals, and essentially-biological processes for their production; they must, however, grant patents on microorganisms, as well as non-biological and micro-biological processes, including those for the production of plants or animals.²⁷⁷ One of the issues related to this article is that the logic used to make a distinction between microorganisms on one side and plants and animals on the other side is not clear. The agreement singled out microorganisms and the processes for their making and made them a patentable subject matter. But, the rationale for the artificial distinction between patentable and non patentable subject matter is difficult to understand.

That being said, Article 27 (3) (b) of the TRIPs Agreement blurs the distinction between inventions which are patentable under the traditional patent law and discoveries which are not. It is a well established principle in patent law that substances which exist in nature are simply a discovery and not an invention. On this basis, plants, animals, genes and for that matter any GR found in nature, should be deemed non patentable. That is why, developing countries in the WTO have already made their opposition to the patenting of life forms and they are pressing for the revision of this provision so as to prohibit the patenting of plants and animals including their parts. In particular, the African Group in the WTO has made a proposal in that plants and animals as well as microorganisms and all other living organisms and their parts including the natural processes for their making shall not be patentable.²⁷⁸

In any case, a lot of concern has been expressed especially by developing countries in respect of these provisions and they are among the most contentious currently under debate at WTO meetings. Principal among the concerns are: the fact that it requires or allows the patenting of life forms which is believed to affect food security and development prospects of developing countries by paving the way for multinationals to control nature and distribution of new life

²⁷⁵ Ibid

²⁷⁶ Ibid

²⁷⁷ Joseph Straus, Biodiversity and Intellectual Property Rights, available at: [Http://www.estig.ipbeja-pt/~ac_direito/straus.pdf](http://www.estig.ipbeja-pt/~ac_direito/straus.pdf); accessed on 27 July 2010

²⁷⁸ Jonathan Curci, The Protection of Biodiversity and Traditional Knowledge in International Law of Intellectual Property, (2005), P.91

forms.²⁷⁹ It had previously been thought that private monopolistic rights could not and should not be imposed over GRs which are the sources for the basic food and medicine requirements of human life.²⁸⁰ The other concern is that, in the TRIPs Agreement, there is no mechanism for sharing equitably the benefits arising from the utilization or exploitation of genetic materials in the development of new varieties or novel products.²⁸¹ Their major concern as regards to the TRIPs Agreement is that it allows the granting of patents for inventions that use GRs without requiring compliance with the provisions of the CBD.²⁸²

As a result of this, therefore, ABS under the CBD may be affected by the IPR systems required by the TRIPs Agreement. IPRs are often granted to individuals of one country over GRs obtained from another country.²⁸³ Consequently, if the ABS objectives of the CBD are to be achieved, IPR holders should have gained access to GRs with PIC, on MAT, and with provisions to guarantee fair and equitable sharing of benefits. This, however, is not always the case. IPRs required or permitted by the TRIPs Agreement may in certain circumstances undermine efforts to ensure equitable benefit sharing – in both countries that use GRs and that provide access to GRs.²⁸⁴ At this juncture, one may question the legal basis for using the TRIPs Agreement to ensure compliance with the CBD.

Admittedly, there are differences in rationale, origins and overall framework of the CBD and the TRIPs Agreement. TRIPs is a trade agreement with commercial objectives.²⁸⁵ On the other hand, the establishment of CBD was prompted mainly by the growing concern over the rapid worldwide loss of biodiversity and the need to regulate ABS and the conservation and

²⁷⁹ Ibid

²⁸⁰ Ibid

²⁸¹ Kent Nnadozie, the Emergence of IPRs in the field of Access to Genetic Resources and Benefit sharing, available at: <http://www.ppl.nl/bibliographies/wto/files/2186.pdf>; accessed on 14 July 2010

²⁸² CIEL, Intellectual Property and Development: Overview of Developments in Multilateral, Plurilateral and Bilateral for a, 2005, available at: <Http://www.ciel.org/publications/pubipqu.html>; accessed on 11 October 2010

²⁸³ CIEL, Biodiversity and Intellectual Property Rights: Reviewing Intellectual Property in light of the Objectives of the Convention on Biological Diversity, Discussion Paper, 2001, , available at: <Http://www.ciel.org/publications/tripsmay01.PDF>; accessed on 23 June 2010

²⁸⁴ Cynthia M. Ho, Disclosure of Origin and Prior Informed Consent for Applications of Intellectual Property Rights based on Genetic Resources: a Technical Study for Implementation Issues, Final Report to the CBD, 2003, UNEP/CBD/WG-ABS2/INF/2

²⁸⁵ Darrell A. Posey and Graham Dutfield, Beyond Intellectual Property: Toward Traditional Resource Rights for Indigenous Peoples and Local Communities, (1996), P. 180

sustainable use of biodiversity.²⁸⁶ But then, there are inherent tensions between the granting of IPRs under the TRIPs Agreement with the objectives of the CBD. In fact, Article 16(5) of the CBD recognizes that international IPRs can have an effect on the implementation of its provisions. Therefore, the interconnectedness between the two treaties is not as such controversial. The problem in this regard is their relationship- the treaty which prevails up on the other in case of conflict- is clearly spelt out neither in the CBD nor in the TRIPs Agreement. And that is why; this is under deliberation in the TRIPs Council as will be fairly discussed in the forthcoming sub sections.

The point I am trying to make is that if developing countries will succeed in incorporating a provision which requires patent applicants to prove their compliance with ABS requirements in the TRIPs Agreement, it is an important and effective instrument to make sure that patents or other IP rights for that matter claimed on inventions made based on GRs are granted in compliance with ABS requirements of the CBD and the concerned nation's access legislation. This is precisely because TRIPs is enforceable under the WTO dispute settlement proceeding which is regarded as one of the most effective means of enforcing international law.²⁸⁷

Actually, developed countries that use GRs in a process of formal innovation have an incentive to limit efforts to promote benefit sharing.²⁸⁸ In some of these countries, IPRs have provided a tool for individuals and corporations to gain access to the GRs of others without sharing the benefits.²⁸⁹ As noted in the previous chapter, patent offices in some developed countries have granted patents over GRs – from the developing world – without the consent of their custodians, and without any benefits flowing to them.

Claims of these types are clearly inconsistent with the CBD's objectives, and should be the subject of international cooperation to bring them into conformity with the CBD, as required by Article 16(5) of same. In these countries, at a minimum, patent applications should be considered only where evidence of PIC and the arrangements made for benefit sharing are provided.²⁹⁰

²⁸⁶ Id at 183

²⁸⁷ Ibid

²⁸⁸ Ibid

²⁸⁹ Marthin Khor, *Intellectual Property, Biodiversity and Sustainable Development: Resolving the Difficult Issues*, (2002), P. 89

²⁹⁰ Id at 92

On the other hand, developing countries that provide access to GRs have an incentive to seek strong benefit sharing measures.²⁹¹ In these countries, however, the TRIPS Agreement may be used to undermine attempts to develop and use benefit-sharing measures such as national legislation to require patent holders to share their profits with the providers of GRs, or to provide licenses for the use and development of the patented product or process.²⁹²

Being cognizant of the fact that IPRs may, in certain cases, undermine efforts to implement the CBD's ABS objectives, they are increasingly turning to the TRIPS Agreement to enforce their ABS regimes.²⁹³ In conformity with their own practice of linking the IP system with compliance with their ABS regimes, developing countries have proposed amendments to the TRIPS agreement to require as a condition of patent acquisition:

1. The disclosure of the source and the country of origin of GRs used in the invention;
2. Evidence that the country of origin had consented to its extraction and use; and
3. Evidence of fair and equitable benefit sharing under the relevant national regime.²⁹⁴

They further proposed that failure by the applicant to provide this information should render the patent unenforceable. They argued that these amendments were imperative to implement the TRIPS agreement and the CBD in mutually supportive and complementary way.²⁹⁵ This takes us to the analysis on the relationship between the two agreements on the issue of implementing ABS requirements based on the proposed disclosure requirement.

2.3. The Relationship between the TRIPs and the CBD

Perhaps no other subject has in recent times generated as much controversy as the interface between CBD and TRIPs. Shortly after the CBD and TRIPs were adopted, several ideas surfaced regarding the incompatibility of the two international agreements. The arguments surrounding the conflict or harmony between the CBD and TRIPs have a real significance since there are over

²⁹¹ Graeme Laurie, Should there be an Obligation of Disclosure of Origin of Genetic Resources in Patent Applications? Learning Lessons from Developing Countries, 2005, available at: [Http://www.law.ed.ac.uk/ahrel/script-ed/vol12-2/laurie.asp](http://www.law.ed.ac.uk/ahrel/script-ed/vol12-2/laurie.asp); accessed on 8 December 2010

²⁹² Ibid

²⁹³ Sabrina Safrin, Hyper ownership in a Time of Biotechnological Promise: the International Conflict to Control the Building Blocks of Life, 98 AM.J. INT.L., (2004), p. 666

²⁹⁴ Ibid

²⁹⁵ Ibid

130 countries which adhere to both treaties.²⁹⁶ One side of the argument is that the two agreements embody and promote conflicting objectives, systems of rights and obligations and as a result of this, the argument runs, the TRIPs agreement threatens to make the CBD impossible to implement.²⁹⁷

In particular, in terms of objective, the CBD is intended to ensure conservation and sustainable use of biodiversity and the fair and equitable share of benefits arising out of the utilization of GRs. To this effect, the CBD has empowered the developing south to regulate access to GR by making it conditional on PIC and benefit sharing. On the other hand, TRIPs is intended to provide private property rights over products and processes, be they are GR based or not, in order to ensure that corporate interest are safeguarded equally worldwide.²⁹⁸ The uniform legal regime which TRIPs aims to achieve would provide monopoly control to those who claim to have 'invented' new plants, animals, microorganisms or uses thereof.²⁹⁹ Therefore, the conclusion drawn is the two treaties have conflicting objectives.³⁰⁰

TRIPs is considered in conflict with the CBD not only in its objectives; the system of rights embodied in these instruments are also believed to be in conflict.³⁰¹ That is to mean, TRIPs recognizes private rights which bases itself on the requirements of novelty, among others. To the contrary, community rights under the CBD are founded on the basis of preexisting rights to GRs and associated TK.³⁰² And therefore, the implementation of the TRIPs will systematically negate the wider historical contribution made by communities in the conservation of GRs.³⁰³

²⁹⁶ GRAIN briefing, TRIPs versus CBD: Conflict between the WTO Regime of Intellectual Property Rights and Sustainable Biodiversity Management, 1998, available at: [Http://www.grain.org/briefings/?id=24](http://www.grain.org/briefings/?id=24); accessed on 13 June 2010.

²⁹⁷ Ibid

²⁹⁸ Ibid

²⁹⁹ Ibid

³⁰⁰ GRAIN Briefing, TRIPs versus Biodiversity: What to do with the 1999 Review of Article 27.3 (b), available at: [Http://www.grain.org/publications/report/tripsmay99.htm](http://www.grain.org/publications/report/tripsmay99.htm); accessed on 10 June 2010.

³⁰¹ Ibid

³⁰² Ibid

³⁰³ Ibid

What is more, the CBD and TRIPs have imposed conflicting obligations on member states.³⁰⁴ All member states of the CBD and TRIPs face an inescapable problem as the obligations imposed by these instruments pull them in different directions.³⁰⁵ For example, a country which in all good faith seeks to implement ABS objectives and does so by requiring a mandatory DRs, it could find itself in contravention of the TRIPs agreement, though arguable.

Admittedly, it is difficult to exhaustively deal with all the expositions on the conflict or harmony between these instruments. But, when the issue is seen from the perspective of fulfilling ABS objectives in the CBD, the main point of controversy is that TRIPs does not allow countries to seek a share of profits obtained from inventions made based on GRs.³⁰⁶ This is precisely because, in the TRIPs Agreement, there is no provision requiring the patentees to disclose the country of origin of GRs and fulfillment of access obligations towards GRs; and as a result, no claim can effectively be made by the provider countries.³⁰⁷

This being so, a strange event at UN meeting demonstrated these divergent views. At the opening of the Ad Hoc Open-Ended Working Group on ABS meeting, a statement favoring amendment to TRIPs was presented on behalf of United Nations Environment Program (UNEP) Executive Director Klaus Töpfer.³⁰⁸ Specifically, the statement argued that TRIPs and the CBD were inconsistent and that TRIPs must be amended to promote ABS.³⁰⁹ Australia, the European Union, Switzerland, New Zealand and the United States strongly opposed the statement, arguing instead that the two agreements are compatible as they address different topics- TRIPs sets norms for IPRs and the CBD addresses GR governance.³¹⁰ After hearing the objections from these countries, the UNEP Secretary General stated that the previous Statement did not reflect the position of the UNEP Executive Director.³¹¹

³⁰⁴ GRAIN Briefing, Intellectual Property Rights: Ultimate Control of Agricultural R&D in Asia, 2001, available at: [Http://www.grain.org/publications/asiaipr-en-cfm](http://www.grain.org/publications/asiaipr-en-cfm); accessed on 13 June 2010

³⁰⁵ Ibid

³⁰⁶ GRAIN Briefing, IPRs and Biodiversity: The Economic Myths, 1998, available at: [Http:// www. grain.org/brifings/?id= 14](http://www.grain.org/brifings/?id=14); accessed on 20 June 2010.

³⁰⁷ Ibid

³⁰⁸ Report of the Ad Hoc Open-Ended Working Group on Access and Benefit-Sharing on the Work of its Third Meeting, UNEP/CBD/WG-ABS/3/7, (2005)

³⁰⁹ Ibid

³¹⁰ Supra Note 226

³¹¹ Ibid

Generally speaking, the overriding question is whether there is any conflict at all between the CBD and TRIPs Agreement. If yes, then the question is whether TRIPs must be amended to resolve the conflict between the two documents.³¹² More specifically, there are four categories of views expressed by Member States regarding the conflict issue: (1) there is no conflict and national governments can implement the two in a mutually supportive way; (2) there is no conflict, yet further study regarding the patent system is required; (3) there is no inherent conflict; however, international intervention is needed in order to ensure the two Agreements are mutually supportive; (4) there is inherent conflict, thus requiring an amendment to TRIPs to resolve the conflict.³¹³

The truth remains conflicting regulations in any legal system are problematic because they are a threat to the coherence and effectiveness of the law. In the field of international law, normative conflicts are more likely to occur than in national legal order due to the absence of a well established hierarchical normative structure.³¹⁴ This is even more complicated by the formally equal validity of all international norms which poses a danger of uncertainty as to the interpretation and application of overlapping treaty provisions.³¹⁵ Meanwhile, the issue of resolving conflicts between treaties in international law has not been dealt with international law.³¹⁶ Understandably, it is not within the scope of this paper to deal with all the issues revolving around overlapping treaties.

The point that needs to be underscored is that TRIPs and CBD can be considered as overlapping regimes since both have their own bearing on GRs- the principal one being the CBD. Not only this, many countries are parties to both. Agreeably, therefore, this overlap and the consequent conflict between these treaties can be solved through consultation and cooperation between the bodies associated with the two agreements. And this seems to be the preferred method taken to

³¹² Ibid

³¹³ Ibid

³¹⁴ Brown-Weiss, E. (1993). International Environmental Law: Contemporary Issues and the Emergence of a New Order, 81 Georgetown Law Journal, (1993) , P.675

³¹⁵ Id at 678

³¹⁶ Id at 690

resolve the conflict when the ongoing consultations in the CBD COP and the TRIPs Council are seen.

In any case, at the center of the debate, Article 27 specifically calls for the review of the TRIPS Agreement itself, four years after its entry into force. Interestingly enough, Ethiopia was one of the first members of the CBD to propose that the CBD “examine the relationship between TRIPS and the CBD.”³¹⁷ Specifically, Ethiopia recommended that the secretariat of the CBD:

*[r]equest the WTO/TRIPS Council to take into account and accommodate the concerns of the Contracting Parties to the CBD before taking any decisions or measures in relation with the TRIPS Agreement that may affect biological diversity and the protection of knowledge, innovations, and practices of local and indigenous communities.*³¹⁸

But, India takes the lions share in this regard. In 1996, India became the first country to formally propose, directly to the WTO, that the Committee on Trade and the Environment (CTE) review the consistency between the CBD and TRIPS.³¹⁹ India’s argument was based upon the premise that the TRIPS Agreement would cause limited competition for environmentally sound technologies and products, driving up prices and reducing supplies of such technologies.³²⁰ This led to India’s proposal that the CBD and TRIPS Agreement could be reconciled through DRs in patent applications, effectuated by means of an amendment to TRIPS.³²¹ This proposal sparked ongoing international discussions regarding the controversial DR issue.

As it was believed that there is a need to scrutinize the relationship between these instruments, the Doha Declaration adopted in November/2001 mandated further review of Article 27, which states that:

³¹⁷ Dominic Keating, Access to Genetic Resources and Equitable Benefit Sharing Through a New Disclosure Requirement in the Patent System: An Issue in Search of a Forum, 87 J. PAT. & TRADEMARK OFF. SOC’Y, (2005), P.530

³¹⁸ Ibid

³¹⁹ Id at 531

³²⁰ Lara Ewens, Seed Wars: Biotechnology, Intellectual Property, and the Quest for High Yield Seeds, 23 B.C. INT’L & COMP. L. REV., (2000), P.305

³²¹ Ibid

*We instruct the Council for TRIPS, in pursuing its work programme including under the review of Article 27.3(b), the review of the implementation of the TRIPS Agreement under Article 71.1 and the work foreseen pursuant to paragraph 12 of this declaration, to examine, inter alia, the relationship between the TRIPS Agreement and the CBD, the protection of traditional knowledge and folklore, and other relevant new developments raised by members pursuant to Article 71.1. In undertaking this work, the TRIPS Council shall be guided by the objectives and principles set out in Articles 7 and 8 of the TRIPS Agreement and shall take fully into account the development dimension.*³²²

Since then, many countries have subsequently submitted proposals and responses about how TRIPs can be reconciled with the CBD.³²³ In general, the suggested amendment to TRIPs incorporates certain requirements of the CBD, such as: (1) patent applicants disclose the source and country of origin of any GR used in inventions, and (2) the applicants both obtain PIC from the appropriate authority and enter into a fair and equitable benefit-sharing arrangement.³²⁴ The United States and other developed countries oppose the proposal, while developing countries such as Bolivia, Brazil, Columbia, Cuba, India, and Pakistan strongly support the TRIPs amendment.³²⁵

2.3.1. The TRIPs Disclosure Proposal

The mandated review of Article 27.3 (b) to be undertaken in 1999, which is still pending in 2010, opened the door for requests by a number of developing countries to revise said article, inter alia, to make it compatible with the CBD.³²⁶ During the 1990s, and in the light of the access and benefit sharing framework established by the CBD, a number of cases of misappropriation of GRs were reported, such as in relation to quinoa, ayahuasca, the neem tree, kava, barbasco, endod and turmeric, to mention some.³²⁷

³²² World Trade Organization, Ministerial Declaration of 14 November 2001, Art. 19, WT/MIN (01)/DEC/1, 41 I.L.M. 746, 749 (2002).

³²³ Council for Trade-Related Aspects of Intellectual Property Rights, Note by the Secretariat: The Relationship Between the TRIPS Agreement and the Convention on Biological Diversity, 3, IP/C/W/368/Rev.1 (Feb. 8, 2006).

³²⁴ Ibid

³²⁵ CIEL, Supra Note at 283

³²⁶ South Face, Disclosure of Origin at the CBD, WIPO and the WTO: Conflict, Coherence or Complementarity? Innovation and Access to Knowledge Programme, (2008), P.40

³²⁷ Ibid

Therefore, it is no surprise that proponents of the proposed amendment are developing countries, whose GRs are diverse and generally used by commercial enterprises of more industrialized, developed countries.³²⁸ Also, the developed countries are typically more likely to afford IPRs to organic innovations than the developing countries. Brazil, the most biodiverse country on the planet and the first signatory to the CBD, has been a strong proponent of the amendment. Proposals from developing countries, it is believed, will address the problem of biopiracy. And the hypocrisy of western demand for IP protections is twofold: not only do developing countries pay a high premium for the patented products that are reintroduced in their countries (yet made from local resources), but developing countries are unable to use the IP framework to protect against the piracy of their own GRs.³²⁹

Therefore, the specific proposals for amendment to the TRIPs Agreement have come from the African Group, the Andean Community, Bolivia, Brazil, China, Columbia, Cuba, Ecuador, India, Indonesia, Kenya, Pakistan, Peru, Thailand, Venezuela, and Zimbabwe.³³⁰ Along with Bolivia, Columbia, Cuba, India, and Pakistan, Brazil submitted a paper to the WTO in 2005 regarding the relationship between the TRIPs Agreement and the CBD.³³¹ The countries summarize the three types of disclosure requirements: “(1) disclosure of source and country of origin of the genetic materials used in developing the invention claimed in the patent application; (2) disclosure of the evidence of prior informed consent; and (3) disclosure of the evidence of a benefit-sharing agreement.”³³² The Source is defined as the country from where the applicant received the genetic material, while country of origin is the country to which the GR is indigenous.³³³

In a broader perspective, the paper claims that the intent of the DR is to prevent the grant of "bad patents" and promote greater legal certainty³³⁴ as the revocation of an erroneously granted patent is more expensive and burdensome than DRs.³³⁵ Besides, the DR would act as a crucial factor in

³²⁸ Ibid

³²⁹ Ibid

³³⁰ CIEL, Supra Note 283

³³¹ Council for Trade-Related Aspects of Intellectual Property Rights, Communication from Bolivia, Brazil, Colombia, Cuba, India and Pakistan: The Relationship Between the TRIPS Agreement and the Convention on Biological Diversity (CBD) and the Protection of Traditional Knowledge, IP/C/W/459 (Nov. 18, 2005)

³³²The World Trade Review, Reconciling the TRIPs and CBD Through Disclosure Requirement, 2005, available at: [Http://www.worldtradereview.com/news.asp?pType=N&iType...](http://www.worldtradereview.com/news.asp?pType=N&iType...); accessed on 17 November 2010

³³³ Ibid

³³⁴ Ibid

³³⁵ Fleur Claessens, Negotiations on Disclosure of Origin Requirements under Scrutiny, 2008, available at: [Http://www.ictsd.org/i/environment/31514/](http://www.ictsd.org/i/environment/31514/); accessed on 15 November 2010

the determination of the patentability of biotechnological inventions, according to the proponents.³³⁶ The paper also contends that DRs would help build databases to aid in the prior art information available to patent examiners and the general public.³³⁷ The amendment would make inclusion of the DR mandatory in national laws and regulations.³³⁸

Two proposed amendments to the TRIPs Agreements have been suggested as regards to the legal form that such an amendment to the TRIPs agreement might take, each with unique wording. First, an amendment to Article 27 itself has been suggested, adding an exception to patentability:

*Members may also exclude from patentability: (c) products or processes which directly or indirectly include genetic resources or ... obtained in the absence of compliance with international and national legislation on the subject, including failure to obtain the prior informed consent of the country of origin or the community concerned and failure to reach agreement on conditions for the fair and equitable sharing 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 CBD.*³³⁹

The second method is an amendment to Article 29, including one of the following wordings: "(1) Members shall require an applicant for a patent to disclose the country and area of origin of any biological resources and.... used or involved in the invention, and to provide confirmation of compliance with all access regulations in the country of origin."³⁴⁰

(2) Where appropriate, Members shall require the disclosure of origin and legal provenance in the patent applications to be submitted."³⁴¹

³³⁶ Ibid

³³⁷ Ibid

³³⁸ CIEL, Supra Note 282

³³⁹ Council for Trade-Related Aspects of Intellectual Property Rights, Communication from Peru: Article 27.3(B), Relationship Between the TRIPS Agreement and the CBD and Protection of Traditional Knowledge and Folklore, pt. VII, IP/C/W/447 (June 8, 2005)

³⁴⁰ Council for Trade-Related Aspects of Intellectual Property Rights, Joint Communication from the African Group: Taking Forward the Review of Article 27.3(b) of the TRIPS Agreement, 6, IP/C/W/404 (June 26, 2003).

³⁴¹ Supra Note 202

In general, the proposals are an attempt to alleviate the developing countries' fear of continued biopiracy by increasing transparency regarding the use of GRs and responsibility to share benefits of their use.

2.3.2. The Proposed Disclosure Requirement: the Debate

In strongly opposing the proposal for the TRIPS amendment the USA comes at the forefront. In 2001, the U.S. submitted one of its first papers to the WTO stating its position that the U.S. sees no conflict between the TRIPS Agreement and the CBD.³⁴² The U.S. reasoned that the WTO review called for under Article 27(b) (3) should be limited to its own subparagraph and not encompass other international treaties.³⁴³ However, the U.S. stated that a “serious discussion of the provisions of both agreements, rather than negative rhetoric” would be helpful in understanding the issue.³⁴⁴ The paper thoroughly discussed particular sections of the CBD and concluded that it and the TRIPS Agreement are mutually supportive, not conflicting.³⁴⁵ For example, the U.S. argues that the absence of provisions regarding theft and misappropriation of GRs in the TRIPS Agreement is not a conflict, but rather evidence that such issues are not within the purview of the TRIPS Agreement and “are appropriately the domain of a separate regulatory system.”³⁴⁶

A theme throughout the U.S. arguments is that member countries must enact national access and benefit sharing systems and that any DR in TRIPS would create “legal un-certainty and other negative consequences.”³⁴⁷ The U.S. supports and has proposed national contract-based systems to deal with issues of PIC and ABS.³⁴⁸ Throughout its papers submitted to the WTO, the U.S.

³⁴² Council for Trade-Related Aspects of Intellectual Property Rights, Communication from the United States: Views of the United States on the Relationship Between the Convention on Biological Diversity and the TRIPS Agreement, IP/C/W/257 (June 13, 2001).

³⁴³ Ibid

³⁴⁴ Ibid

³⁴⁵ Ibid

³⁴⁶ Council for Trade-Related Aspects of Intellectual Property Rights, Communication from the United States: Article 27.3(B), Relationship Between the TRIPS Agreement and the CBD, and the Protection of Traditional Knowledge and Folklore, para. 4, IP/C/W/469 (Mar. 13, 2006)

³⁴⁷ Ibid

³⁴⁸ Ibid

argues for a fact-based discussion, centered on an analysis of national experiences regarding ABS systems already in place.³⁴⁹

In its most recent submission, the U.S. responds to specific assertions made by developing countries-particularly Peru-and papers submitted to the WTO which list “bad patents” and claim benefits of the TRIPS amendment proposal.³⁵⁰ The US perceives that other countries assume that because an applicant got a GR from a foreign country, the resource must have been obtained “illegally, irregularly, or questionably.”³⁵¹ Of course, the U.S. views this assumption by developing countries as illogical.³⁵² The U.S. also addresses the difficulty of determining the exact origin or source of genetic material. For example, many biological resources are sold throughout the world for purposes of industrial processing, which even Peru recognizes as making it difficult to assess source and origin, thus identifying illegal access.³⁵³ This raises the question of whether “commercial channels” are a legitimate way of procuring GRs.³⁵⁴

The “bad patents” that Peru cited in an earlier submission are found to have actually contained disclosures of genetic source and origin and therefore the U.S. claims that such a DR would have had no effect or benefit.³⁵⁵ A vital issue to the debate is whether extracts or other products isolated from large quantities of raw material, legitimately exported from foreign countries that have traveled through the normal channels of commerce are exempt from ABS agreements and DRs. The U.S. suggests that this issue would not be covered by the current proposed TRIPS amendment.³⁵⁶ The U.S. repeatedly argues that source and origin rarely are relevant to patentability and would not prevent the issuance of what India calls “bad patents,” such as in the turmeric case.³⁵⁷

³⁴⁹ United States, Article 27.3(b), Relationship between the TRIPs Agreement and the CBD and the Protection of Traditional Knowledge and Folklore,2004, WTO,IP/C/W/443

³⁵⁰ Ibid

³⁵¹ Ibid

³⁵² Ibid

³⁵³ Ibid

³⁵⁴ Ibid

³⁵⁵ Peru, article 27.3(b), Relationship between the TRIPs Agreement and the CBD and Protection of Traditional Knowledge and Folklore,2005,WTO,IP/C/W/447

³⁵⁶ Ibid

³⁵⁷ Ibid. Turmeric (*curcuma longa*), a plant found in India, is well known there for both culinary use and as a traditional medicine. Apparently, the plant was also used medicinally by Greeks and Romans. Two expatriate Indian scientists at the University of Mississippi patented turmeric, in 1995, for use in wound healing. The patent was then challenged by the Council of Scientific and Industrial Research in India and subsequently invalidated by the United

The turmeric case is the first instance where the USPTO invalidated a patent based on GRs and related traditional knowledge.³⁵⁸ The U.S., in its paper to the WTO, claims that any DRs would not have remedied the problem of the erroneously granted turmeric patent, given that the country of origin was identified in the patent application.³⁵⁹ According to the U.S., origin had little to do with patentability in the turmeric case.³⁶⁰ In place of a specific GR source and origin DR in the patent application, the U.S. argues for improvement upon existing procedures, such as post-grant opposition and re-examination practices, along with a general requirement that the applicant disclose all information relevant to patentability.³⁶¹

The U.S. emphasizes that what is known about a GR before the invention occurs is not typically relevant to the reasoning behind using that resource in the invention.³⁶² The U.S. claims that mandatory “disclosure requirements . . . may upset the careful balance created by the patent system to promote innovation.”³⁶³ The U.S. fears that developing countries are overlooking the massive risk of investing in research and development activities, where commercialization of products as a result of research is arguably uncommon.³⁶⁴

The U.S. claims that the TRIPs Agreement proposal completely ignores the risks involved in developing a commercially successful product.³⁶⁵ Contracts between countries and national ABS systems appear to be the solution, according to the U.S. Merck Sharp and Dome (Merck) and the National Institute of Biodiversity of Costa Rica (InBio) entered into a contract agreement where

States Patent and Trademark Office (USPTO) for lack of novelty due to prior art in Indian traditional knowledge. Besides, the extract from the Pacific Yew, originally found in Washington State, was determined to have the needed anti-cancer properties, which were entirely unknown before the research and trial-and-error type testing had begun. See Murray Lee Eiland, *Patenting Traditional Medicine*, 89 J. PAT. & TRADEMARK OFF. SOC'Y, (2007), p.61

³⁵⁸ R.A. Mashelkar, *Intellectual Property Rights and the Third World*, 81 CURRENT SCI., (2001), P.960

³⁵⁹ Supra Note 346

³⁶⁰ Ibid

³⁶¹ Ibid

³⁶² Ibid

³⁶³ Ibid

³⁶⁴ Ibid. To demonstrate this principle, the United States cites the development of the anti-cancer drug TAXOL, a story well known to many at Florida State University, where the final stages of the research took place. Bristol-Meyers Squibb (BMS) reportedly invested more than \$1 billion USD over 30 years, using the results of a mass-screening program of more than 100,000 plant and 16,000 animal extracts. See Frank Stephenson, *A Tale of Taxol*, FLA. ST. U. RES. IN REV., (2002), available at <http://www.rinr.fsu.edu/fall2002/taxol.html>.; accessed on 10 April 2010

³⁶⁵ Supra Note 346

InBio supplied 10,000 samples of plants, animals, and soil to Merck in exchange for \$1 million USD up front.³⁶⁶

The agreement also gave Merck receiving rights to research the samples for two years with retention rights to any resulting patents and Merck agreed to pay royalties to BIO for any products commercialized from the samples.³⁶⁷ InBio has since claimed significant benefits from this original agreement and the two subsequent extension agreements between Merck and InBio.³⁶⁸ The U.S. views such international contract agreements as the ultimate way to trace an intangible asset, such as the intellectual contribution of a GRs.³⁶⁹ Noting that the Merck and InBio agreement has not yet produced any patentable inventions, the U.S. claims that such contracts created under ABS systems are effective in producing all the benefits sought by developing countries (prior informed consent, equitable sharing of benefits, and monitoring of the use of the resource) even absent a patentable invention.³⁷⁰ It is worth pondering why the US becomes a hard liner on this issue. Perhaps, it wants to make sure that patents on biotechnological inventions will not be affected as a result of the inclusion of DRs in the TRIPs Agreement.

On the same vein, the European Communities have argued that it would not be feasible for a patent office to verify evidence of PIC, especially since terms and conditions of a contract often remain confidential.³⁷¹ Japan has argued that a DR would violate multiple provisions of the TRIPs Agreement.³⁷² Specifically, the DR is proposed to be applicable to only particular fields of technology, violating Article 27.1, which provides for non-discrimination in patent availability between fields of technology.³⁷³ Japan also argues that the proposed amendment would violate

³⁶⁶ Michael D. Coughlin, Jr., Recent Development, Using the Merck-INBio Agreement to Clarify the Convention on Biological Diversity, 31 COLUM. J. TRANSNAT'L L., (1993), P.345

³⁶⁷ Ibid

³⁶⁸ Ibid

³⁶⁹ Ibid

³⁷⁰ Supra Note 346

³⁷¹ See Council for Trade-Related Aspects of Intellectual Property Rights, Minutes of Meeting, para. 34, IP/C/M/44 (July 19, 2004).

³⁷² Council for Trade-Related Aspects of Intellectual Property Rights, Minutes of Meeting, para. 155, IP/C/M/29 (Mar. 6, 2001).

³⁷³ Ibid

Article 62.1 of the Agreement since only reasonable procedures and formalities are provided for under TRIPS.³⁷⁴

However, this strong opposition to the proposed TRIPS amendment from developed countries such as the U.S. and Japan has been met with equally powerful support for the amendment from Bolivia, Brazil, Columbia, Cuba, India, Pakistan, and other developing countries.³⁷⁵ In a paper submitted to the WTO in 2005, developing countries in favor of the proposed TRIPS amendment argued that the nation-based contract systems proposed by the U.S. is by no means sufficient to deal with the problems of misappropriation, bad patents, and illegitimate bioprospecting.³⁷⁶ Referring to the original claim of conflict between the CBD and TRIPS, the countries argue that the current TRIPS Agreement treats all GRs as if they are part of the public domain and open to appropriation by anyone.³⁷⁷ Bolivia and fellow proponents reason that the U.S. is misguided in its view of the burden of the proposal.³⁷⁸

A DR would only require “reasonable efforts on the part of patent applicants” to acquire the source and origin information, which would already be a component of a larger set of information submitted by the applicant.³⁷⁹ Without specifically addressing the turmeric case, Bolivia and other developing countries argue that a new DR is essential to determination of the novelty and inventive step and would prevent patent offices from issuing patents, like the US turmeric patent, erroneously.³⁸⁰ Also, as countries build databases about origin, source, and perhaps agreements between countries, the burden on patent offices regarding verification will lighten.³⁸¹ Developing countries counter the U.S. argument about confusion of goods that have traveled through the normal channels of commerce by stating that the source is simply the country from where the applicant received the genetic material and the country of origin is the country to which the genetic resource is indigenous.³⁸² After the patent office has received the

³⁷⁴ Ibid

³⁷⁵ Supra Note 277 at 148

³⁷⁶ Ibid

³⁷⁷ ICTSD, WTO Disclosure Talks try to Clarify CBD-TRIPS Relationship, 2006, available at: [Http://www.ictsd.org/i/news/biores/9025/](http://www.ictsd.org/i/news/biores/9025/); accessed on 12 December 2010

³⁷⁸ Ibid

³⁷⁹ Ibid

³⁸⁰ Patent Disclosure Requirements relating to Genetic Resources and Traditional Knowledge, 2004, WIPO/ GRTKF /IC /7/ 10

³⁸¹ Ibid

³⁸² Perrault Anne and Olina Marria, On Disclosure Requirements: Incorporating the CBD principles in the TRIPS Agreement on the Road to Hong Kong, ICSTD/CIEL/IDDRI/IUCN/QUNO,2005

origin and source information from the applicant, it may request further information from the source or origin countries and the applicant to ensure that bad patents are not granted.³⁸³

As far as contracts and national ABS systems, the developing countries defend the proposed TRIPs amendment by arguing that a contract-based system will not ensure international enforcement and a binding international obligation is necessary.³⁸⁴ Also, proponents of the proposal offer reassurance that the requirement is not overly burdensome, since a simple statement by the patent applicant of compliance with PIC and benefit sharing requirements will serve as prima facie evidence of compliance with the requirement.³⁸⁵

This debate on the establishment of DRs at the WTO in the context of examining the relationship between the TRIPs agreement and the CBD is still ongoing. Since it is a debate which is an integral part of the outcome of the Doha Round of Multilateral Trade Negotiations, an ending in this regard may not be expected before negotiations under Doha Development Agenda are over. Therefore, the time when these debates surrounding DRs will come to a conclusion and what will be the final result; all remains to be seen.

But then, it is natural to ask: is a compromise deal possible at the WTO? To be honest, the success of developing countries in amending the TRIPs agreement for the inclusion of DRs will be a great success because we are witnessing the rejection of agendas which do not involve the interests of developed countries being rejected in such forums. One does not need to go too far; in the recently adopted Nagoya Protocol, developed countries- in particular the EU- have successfully blocked the inclusion of mandatory DRs in the protocol without having good reasons.

The DRs proposal in the TRIPs Agreement does not get the support of the most influential figure- the US and it is not an issue which elicits western support in general. Of course, among developed countries, Switzerland and the EU have accepted the principle but they differ with regard to the nature of the requirement or the effects of non compliance. In particular, they disagree about the possibility pursued by developing countries that a patent be revoked or

³⁸³ Ibid

³⁸⁴ Ibid

³⁸⁵ Ibid

otherwise limited in its effects if obtained in breach of disclosure obligations regarding the origin of GRs.³⁸⁶

In addition to this, a proposal of Draft TRIPs modalities, submitted by around 110 developed and developing countries at the WTO attempts to link amendments to the TRIPs Agreement on three issues: creation of registry for geographical indications, establishment of disclosure obligation and extension of geographical indication protection.³⁸⁷ The proposal suggests the inclusion of these issues as part of the horizontal process in order to develop and elaborate final draft legal text with respect to each of these issues as part of the "single undertaking."³⁸⁸ The linkage made in the draft between these issues may be seen as a technical move to obtain the support to the proposed DRs from the EU whose interest in enhancing the international protection of GIs is notorious. Seen from this perspective, effectuating amendments within the TRIPs Agreement seems likely. However, one may see a bleak prospect for any amendment in the TRIPs when it is noted that the DR proposal directly contradict with deeply held western beliefs concerning the appropriate realm of patent law as the proposal in effect suggests that TRIPs should accommodate and promote social norms outside the patent system.

In any case, let us hope that things may not always go the usual way and be optimistic about the incorporation of DRs in the TRIPs agreement. If that happens, it would allow a member to trigger the application of a WTO dispute settlement system in case of non compliance which would constitute a distinct achievement for the proponents of the proposal.

But then, since it is an issue under way, before wrapping up discussions on this chapter, it is worthwhile to deal with the issue of compatibility of DR as a proposed measure with the TRIPs agreement and options of analysis for its incorporation in the forthcoming sub sections.

2.3.3. Disclosure Requirement: Does it infringe the TRIPs Agreement?

The issue is whether the requirement described above with all the debates surrounding it is compatible with the standards concerning the availability of patent rights established by the TRIPs agreement. In this framework, the relevant provisions are: Articles 27.1, 29, and 62 of the

³⁸⁶ Face, Supra Note 326

³⁸⁷ Ibid

³⁸⁸ Ibid

TRIPs Agreement. When seen in line with Art.27.1. (Which lists the substantive conditions of patentability), DR is seen by many as incompatible as the manner of obtaining GRs used in the development of an invention is external condition.³⁸⁹ In other words, the outcome of the inventive activity is indeed independent of the ways and means employed to reach it.³⁹⁰

By the same token, though Art.29 of the TRIPs Agreement contains disclosure conditions, it is not an appropriate framework since the purpose of disclosure under the abovementioned provision is to enable a person skilled in the art to carry out the invention. As a matter of course, the indication of the origin of the GRs 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.³⁹¹

The other provision important for the issue at hand is Art.62 which authorizes members to require compliance with reasonable procedures as a condition of acquisition or maintenance of patents. In fact, the agreement does not clarify what a reasonable measure is but it provides few elements that may help to clarify it.³⁹² In the first place, Art. 62.1 establish that such procedures and formalities shall be consistent with the provisions of the agreement which creates a link between the reasonable procedure admitted by this provision and the conditions of patentability establish in arts 27.1 and 29.³⁹³ Therefore Carvalho opines that reasonable procedures are those that assist the patent administrations to assess whether the substantive conditions have been met by the invention.³⁹⁴

So much so that, requiring patent applicants identify the source of the GRs and give evidence of PIC and benefit sharing as a condition of patentability conflict with the TRIPs Agreement. However, it does not mean that the TRIPs Agreement prohibits WTO members from adopting patent law provisions intended to secure compliance with ABS requirements as far as such

³⁸⁹ Carvalho N.P., *Requiring Disclosure of Origin of Genetic Resources and Prior Informed Consent in Patent Applications without Infringing the TRIPs Agreement: the Problem and the Solution*, Washington University Journal of Law and Policy,(2000), P.379

³⁹⁰ Ibid

³⁹¹ In this regard, it is good to note that where the biotechnological invention does require the use of natural resources to be carried out, the knowledge of where to obtain the resource may be relevant for the practical exploitation of the invention. For example, where the source of the resource is unique, it must be disclosed under Art.29 of the TRIPs agreement. The argument here is that the scope of Art.29 does not reach beyond the obligation to explain how the invention works and therefore the agreement does not require disclosure of the material source where knowledge of that source is not essential to reduce the invention in to practice. see Ibid

³⁹² Carvalho, *Supra* Note 389

³⁹³ Id at 381

³⁹⁴ Ibid

provision does not lead to the rejection of patent application or the revocation of patents.³⁹⁵ That is why, I think, proponents of DRs are proposing the amendment of the TRIPs Agreement being aware of the fact that the introducing the requirement in to the TRIPs Agreement as it stands now is not compatible. But some commentators believe that it is possible for members of the WTO to introduce the requirement in their laws by making refusal to enforce as a measure of failure to disclose by patent applicants.³⁹⁶

2.3.4. Disclosure Requirements: Analysis of Options for Implementation

As stated elsewhere, an international system of mandatory DR is needed to prevent misappropriation, promote compliance with CBD ABS requirements, and prevent misuse of the IP system. As one possible compliance measure that can be taken by members as per the Nagoya Protocol and as an issue under deliberation in the TRIPs Council, many important issues are open for further discussions. For example, in the TRIPs Council proponents of the draft have apparently agreed to include a mandatory DR. This means that the TRIPs Agreement if amended would include an obligation applicable to all WTO members not to process patent applications when this disclosure has not been met. But then, the nature and extent of a reference to PIC and ABS are qualified as additional elements and are still to be defined. In addition, no agreement is reached about the possibility of imposing post grant sanctions demanded by developing countries, such as revocation of patent or declaring it non enforceable when it was found that false or incomplete information has been provided by the patent applicant. The following discussions are made having in mind these and other related issues outlined above.

The point is IP applicants should not be rewarded with rights or privileges that convey commercial benefits, when the subject matter of the applications was obtained or derived from GRs acquired in violation of CBD PIC requirements and conditions of access for GRs. Similarly, IP owners should not retain such commercial benefits in violation of CBD benefit-sharing requirements.

³⁹⁵ Ibid. If one follows such a line of argument, rejecting patent application for failure to disclose will be incompatible with the TRIPs agreement.

³⁹⁶ Ibid

However, when introducing a DR in IP laws, a number of issues arise, including the following: Is the requirement of a formal or of a substantive nature? What information needs to be disclosed in the IPR application? Is it the source or the country of origin of the GRs used that needs to be disclosed? What mechanism triggers the requirement? Are there any exceptions to the requirement? Should the wrongful disclosure or failure to disclose carry any sanctions and, if so, what kind?

A. Nature of Disclosure Requirements

In general terms, two different sets of issues exist for adopting model provisions of an international regime to implement DRs. The first set relates to whether to impose DRs as mandatory treaty obligations or just facilitate such disclosures within the existing IP law system.³⁹⁷ The second set relates to the nature of the disclosure obligations and the mandatory or facultative consequences to be prescribed for failures of applicants or parties to comply with requirements or obligations.³⁹⁸

Voluntary disclosure is the least burdensome type of DR which encourage the disclosure of origin/source of GRs relevant to an invention being protected by IP law.³⁹⁹ That means, its omission would not disqualify the application from being, accepted, being granted or being subsequently enforced.⁴⁰⁰ On the other hand, in case of mandatory disclosure, failure to disclose or dishonest disclosure will have the following consequences: the application would not be accepted, it would be rejected during the prosecution stage, if granted, it would not be enforceable or it would be revoked.⁴⁰¹

As there is no coherent international system in place to assure that either of such requirements are effectuated on a worldwide basis, concerns have been raised that adoption of proposed mandatory requirements in new international treaty provisions or other agreements directly addressing DRs would lead to significant uncertainties.

³⁹⁷ Analysis of options for Implementing Disclosure of Origin Requirements in Intellectual Property Applications, UNEP/CBD/WG-ABS4/INF/2,2005

³⁹⁸ Ibid

³⁹⁹ Graham Dutfield, Thinking Aloud on Disclosure of Origin, QUNO, available at: www.quno.org; accessed on 16 April 2010

⁴⁰⁰ Ibid

⁴⁰¹ Ibid

The concern is that imposing mandatory DRs will create significant uncertainties within the IP system and reduce investment in biotechnological and biopharmaceutical companies.⁴⁰² Besides this, it is argued that DRs will not necessarily prevent misappropriation.⁴⁰³ Additional objections are based on concerns that invalidation of IP will not necessarily assure, and may even prevent, equitable benefit-sharing.⁴⁰⁴ In response, it has been noted that DRs seek not to replace but to supplement other methods for enforcing PIC and benefit-sharing regimes.⁴⁰⁵ On the contrary, developing countries argued that, proposals made in relation to voluntary DRs would provide no guarantee that it will be considered in order to prevent the improper issuance of IPRs and they are unlikely to deter biopiracy and prevent misappropriation.⁴⁰⁶

When seen from the perspective of developing countries, mandatory DRs in IP applications are useful enforcement mechanisms after the application stage compared with enforcement mechanisms external to the IP system or reliance on contractual measures.⁴⁰⁷ This is precisely because the later measures are inadequate as there is no obligation on other states to legislate for such measures or to enforce such contracts.⁴⁰⁸ On the other hand, mandatory DR would reduce the need for costly administrative or judicial challenges to the validity of the patent or the entitlement of the applicant or owner.⁴⁰⁹

Generally speaking, numerous benefits from adopting mandatory disclosure obligations have been identified for both the CBD regime and the IP system itself. These include: improving the substantive examination of applications; providing greater certainty regarding the validity of granted rights and privileges; reducing the need for revocation of improperly granted IP; improving identification of possible cases of misappropriation; facilitating actions to challenge the validity of wrongly issued IP; improving determinations of inventorship or other relationship to the subject matter, thereby assisting identification of persons who should participate in equitable benefit-sharing; facilitating abilities to use the subject matter of the IP; promoting compliance with ABS legislation; and tracking commercialization to promote more effective

⁴⁰² Ibid

⁴⁰³ TRIPs Issues: Article 27.3(b), Traditional Knowledge, WTO,IP/C/W/434,p.7

⁴⁰⁴ Ibid

⁴⁰⁵ Michel Blakney, Proposals for Disclosure of Origin of Genetic Resources in Patent Applications, WIPO/IP/GR/05/01

⁴⁰⁶ Ibid

⁴⁰⁷ Ibid

⁴⁰⁸ Ibid

⁴⁰⁹ Ibid

benefit-sharing.⁴¹⁰ But then, disclosure obligations should be seen as only one of many elements of an international system to prevent biopiracy and misappropriation.

B. Elements of Disclosure Requirements

When specifying what DRs to mandate by treaty, consideration should be given to what information⁴¹¹ must be disclosed during the application process, what evaluations⁴¹² should be made of the information, and how the information may otherwise be used, and whether and when information should be supplemented or corrected. Basically, the applicant should be obligated to disclose the source and country of origin of the GRs used in the invention, evidence of prior informed consent and evidence of fair and equitable benefit sharing.⁴¹³

In relation to the first element, it is good to note the distinctions between origin of GR and source of GR. According to the CBD, the country providing GRs-source country- is the country supplying GRs collected from ex situ sources, including wild and domesticated species which may or may not have originated in that country.⁴¹⁴ On the other hand, the country of origin of GRs is the country which possesses those GRs in in situ conditions.⁴¹⁵ That means, since the source country may be different from the country of origin, the distinction between the two is significant. And since it is practically difficult and sometimes impossible to know the country to

⁴¹⁰ Blakney, Supra Note 405

⁴¹¹ There are also numerous options regarding what information and documentation should be disclosed by applicants, and whether and when it should be supplemented or corrected at a later period. These include: disclosures of information only (which may be required in prescribed forms or content); disclosures of information accompanied by various declarations by applicants (e.g. declarations of adequate investigation, declarations of the accuracy of submitted information, and declarations of compliance with access and benefit-sharing requirements); disclosures of information accompanied by documentary information regarding access and benefit-sharing (e.g. submission of contracts providing conditions for access and benefit-sharing; evidence of compliance with contractual requirements); and disclosures of information accompanied by international certificates of origin. See Ibid

⁴¹² The scope of evaluations of information submitted pursuant to mandatory disclosure obligations could include: evaluations for completeness of submitted information, declarations and documents; evaluations for substantive adequacy of disclosed information; evaluations of relevance and accuracy of declarations; evaluations of relevance and accuracy of documentary information regarding access and benefit-sharing; and evaluations of validity of international certificates of origin. See Supra Note 399

⁴¹³ Supra Note 403

⁴¹⁴ Queen Mary Intellectual Property Research Institute, Report on Disclosure of Origin in Patent Applications, 2004, retrieved on September 10/2010., available at:[Http://www.trade.ec.europa.eu/doclib/html/123533.htm](http://www.trade.ec.europa.eu/doclib/html/123533.htm)

⁴¹⁵ Ibid

which the GRs used in the invention is indigenous- country of origin-, the country of source seems to be clearly in the foreground to be used in the context of DRs.

The mandatory furnishing of evidence of PIC by patent applicants would facilitate the monitoring and enforcement of Article 15 of the CBD and it, therefore, aims at ensuring that GRs used in an invention for which a patent is being sought was legally and legitimately accessed.⁴¹⁶ On the same vein, the disclosure of evidence of benefit sharing arising out of the utilization of GRs in inventions is aimed at not only ensuring that there is benefit sharing per se but that sharing of benefits is fair and equitable among the parties taking in to account the circumstances of each particular case.⁴¹⁷ The provision of evidence of benefit sharing will therefore include evidence that there was sharing arising out of the utilization of the GRs used in the invention and that the sharing of the benefits that accrued to the source and country of origin was equitable and fair in the circumstances.⁴¹⁸

C. What Would Trigger Disclosure Requirements?

One of the basic issues for disclosure obligations is when the subject matter of the application for IP is sufficiently related to GRs in order to require the disclosure of relevant information. In this regard, numerous proposals have been made to require disclosures of origin in regard to GRs under various conditions.⁴¹⁹

The important considerations on the possible linkages between GRs and the subject of IP protection include whether the relationship was necessary or contingent, and whether the GR was

⁴¹⁶ Supra Note 403

⁴¹⁷ Ibid

⁴¹⁸ Ibid. In fact, it has never been an easy task to determine the fairness and equitability of benefits but, in the very least there are a number of factors that could be used to make this determination. These include, among others: assuming that there was sufficient PIC, that the sharing of benefits or an arrangement for future sharing of benefits premised upon Article 15.7 of the CBD, mutually agreed terms generally cover elements relating to the conditions, obligations, procedures, types, timing, distribution and mechanisms of the benefits shared; and there is reporting obligation on issues relating to patenting or commercialization especially where future benefit sharing is contemplated. See *ibid*.

⁴¹⁹ For the sake of comparison, for example, the Bonn Guidelines suggest the need for such disclosures when “the subject matter of the application concerns or makes use of genetic resources in its development”; the Swiss proposal would require disclosures only when the subject matter of the patent application is “directly based” on genetic resources, by making immediate use of the genetic resources ; and various national or regional laws, such as those of the Andean Community, require extensive disclosures (including contracts for access and documentary information on legal provenance for access to GRs) based on much broader relationships to the subject matter of the applications (e.g. for products or processes that are developed or obtained from genetic resources). see *Ibid*

actually part of the process that led to the invention, or is necessary for understanding or carrying out the invention after the invention has been attained.⁴²⁰

For instance, the requirement may relate to: GR that is used during the steps that led to the claimed invention; GR that is necessary to assess, understand, replicate or carry out the invention once the invention has already been achieved -in this case, it might refer to material that would be necessary to implement the invention-; GR that was a necessary prerequisite for the invention, in that without access to this material, the inventor would not have been able to achieve the invention; GR facilitated the invention in the sense that it did in fact make it easier to develop the invention and it did practically help the inventor to conceive the invention, but it was not necessary for the inventor to have made the invention ; for instance, the invention relates to a genetic transformation, and the transformation is applied to a range of different GR after the essential invention has been conceived, in order to demonstrate its widespread application, as the basis for a broadly-drafted claim for the invention.⁴²¹

According to some commentators, the appropriate linkage for DRs of GRs to the subject matter of an IP application will depend on the reasons for making the disclosures and on the types of information to be disclosed and evaluated.⁴²² Broader reasons for making disclosures entail correspondingly broader substantive relations between the subject matter and the applicant on one hand and the kinds of information that may become relevant for disclosure on the other.⁴²³

The purpose of disclosure could be directly related to IP laws,⁴²⁴ determination of entitlements and equity under other laws;⁴²⁵ and determination of compliance with ABS requirements. In the latter case, the purpose of disclosure is ensuring implementation of CBD ABS obligations, and contracts adopted pursuant to such legislation or to effectuate ABS requirements. Disclosing the

⁴²⁰ Supra Note 397

⁴²¹ Ibid

⁴²² Ibid

⁴²³ Ibid

⁴²⁴ Though existing requirements for disclosure of origin in IP applications vary as national IP laws differ, disclosure is required to achieve different purposes. For example, in patent applications, GRs are required to be disclosed to the extent that they constitute a known prior art relevant to examination or when they are needed to enable those skilled in the art to practice the claimed subject matter.

⁴²⁵ Laws addressing entitlements and equity may require disclosure of the authority or the source to provide access for GRs for the uses leading to the IP application. And failure to disclose such information may affect the enforceability of the IP. For example, failure to disclose unauthorized acquisition of GRs might qualify as inequitable conduct or unclean hands, which would prevent enforceability of patents. See Supra Note 391

source or country providing GRs and the country of origin may assist countries to identify unauthorized access or use and inequitable benefit-sharing. What should be the relationship required between the GR and the subject of the IP to require DRs for this purpose? In this regard, some opine that an invention should be directly based on a GR to which the inventor has had access in order for the DR to apply.⁴²⁶ Accordingly, the invention must make immediate use of the GR, that is, dependent on the specific properties of this resource, and the inventor must have had physical access to this resource, that is, at least sufficient enough contact to identify the properties of the GR relevant for the invention.⁴²⁷

⁴²⁶ Martin A. Girsberger, Disclosure of the Source of Genetic Resources and Traditional Knowledge in Patent Applications, 2004, available at: [Http://www.ciel.org/publications/iprights.pdf](http://www.ciel.org/publications/iprights.pdf); accessed on 4 September 2010

⁴²⁷ Ibid

Chapter Three

Access to Genetic Resources, Benefit Sharing and Intellectual Property Rights in Ethiopia: Analysis of the ABS Proclamation vis-à-vis the Patent and Plant Breeder's Right Legal Regimes

3.1. The Legal Regime on Access and Benefit Sharing in Ethiopia

Ethiopia is rich in GRs which is resulted from its wide ranging agro climatic conditions.⁴²⁸ With endemism and diversity, Ethiopia is identified as one of the major vavlovian⁴²⁹ centers of origin and diversity for a number of domesticated plants and their wild and weedy relatives.⁴³⁰ Crop plants, such as coffee, teff, noog and anchote are known to have originated in Ethiopia.⁴³¹ Farmers' varieties of several major crops, namely, wheat, barley, sorghum, field pea, and fava bean, which are relatives of some of the world's important crops are claimed to be widely found in Ethiopia.⁴³²

Though there is no formalized study on how much of the countries GRs have been taken out and commercially utilized, it is a hard fact that there have been an unconstrained access to Ethiopia's GRs.⁴³³ As a result of this, genetic materials have been harvested and exported to R&D nodes abroad, for innovative value addition and off shore financial benefits.⁴³⁴ The consequence being the country has not been benefitted equitably with the concerned stakeholders from the commercial gains derived from GR commercialization.

⁴²⁸ kent Nnadozie, Robert Lettington and etel (eds.), African Perspectives on Genetic Resources: A Handbook on Laws, Policies and Institutions Governing Access and Benefit Sharing, Environmental Law Institute,(2003),P.106

⁴²⁹ Nikolai Vavilov (1887-1943) was a Soviet plant geneticist. Through his extensive botanical expeditions, he identified 12 different geographical areas of the world, which he believed to be significant plant genetic origin and represent enormous diversity. And accordingly, the first formal GRs collection had taken place where the country's GRs were catalogued during an expedition led by this Russian professor who is renowned pioneer of GRs conservationist laboring under the conviction that "time is short, we must hurry". Ethiopia is identified as one of the centers of crop diversity on the basis of its ancient agricultural civilization and the diversity of cultivated species. see Eshetayehu Tefera, Global Potentials and challenges of some of Ethiopian Germplasm, the Plant Genetic Resources Review, (on file with the author)

⁴³⁰ Ibid

⁴³¹ Ibid

⁴³² Ibid

⁴³³ Ibid

⁴³⁴ A Study by Rural Advancement Fund International- RAFI- now Action Group on Erosion, Technology and Concentration ETC and the Report entitled: Out of Africa, Mysteries of Access and Benefit Sharing, show that Ethiopian barely, sorghum and varieties were used in the US generating US \$150 million and 12 million respectively. In addition to this, Endod, known as the African soapberry plant and which has been identified by the Ethiopian communities as a laundry soap and shampoo. The University of Toledo has applied for a patent on the use of Endod to control zebra mussels which is expected to generate millions of dollars. see Tefera, Supra Note 423

To begin with, the GR capable of resisting the gene of the Barley Yellow Dwarf Virus (BYDV) is thought to have been taken from the Ethiopian barley collection and introduced in to the genetic material of the Californian barley in the 1960s.⁴³⁵ It was stated that this BYDV resistant gene has saved California from a yearly expenditure of USD 160 million for pest control.⁴³⁶ Ottawa based Ethiopian scientist Awugachew Teshome states that Ethiopian barley contribution may in fact be worth as much as USD 600 million, not only to California but also to all of the US, Canada, Australia and many other countries.⁴³⁷

In addition to this, teff GR is believed to have been taken by Wayne Carlos who had worked in Ethiopia in 1970s.⁴³⁸ Based on this, he has developed a variety named Dessie teff variety for which he had been granted a Plant Variety Protection in 1996 by the US Plant Variety Protection Office.⁴³⁹ Though there is no information on how he accessed the teff GR, this might be because prior to the adoption of the CBD, access to GRs was unregulated.

The complex reality does not end here; Endod which is a perennial plant which has been selected and cultivated by Ethiopian woman is used as bedrock for the patents granted to the University of Toledo.⁴⁴⁰ Ethiopian biologist Aklilu Lemma discovered that the sun dried and crushed Endod berries are lethal to all major species of snails and may be effective in controlling schistosomiasis.⁴⁴¹ After Aklilu demonstrated Endod's potency to a scientist in the University of Toledo, they took out patents hoping to sell Endod as a biological control for the zebra mussle, a costly pest in the great lakes of the US and Canada.⁴⁴² In this point, it is difficult to imagine these are the only GRs taken out of the country in different ways and the discussion made here cannot be considered as exhaustive.

⁴³⁵ Tefera, Supra Note 429

⁴³⁶ Ibid

⁴³⁷ Ghelawdewes Aria, the Paradox of the Breadbasket Starving Ethiopia, 2002, available at [Http://www.tisid.net/paradox.htm](http://www.tisid.net/paradox.htm).; accessed on October 10/2010. Ghelawdewes reviewed the fact that US farmers already earned \$150 million annually by growing varieties of barley developed from the Ethiopian strains. It is a public knowledge that the unique Ethiopian barley was benefitting many nations, although Ethiopians were kept in the dark about their own resources. In 2001, the Pan African news agency from Dakar told the world " seeds from starving Ethiopia give America abundant yields" what a paradox!!

⁴³⁸ Tefera, Supra Note 429

⁴³⁹ Ibid

⁴⁴⁰ Ibid

⁴⁴¹ Ibid

⁴⁴² Ibid

Since lack of legislation on ABS was considered as one of the factors for such free access, two of the major GR related issues, namely access to GRs and the fair and equitable sharing of benefits derived from the use of GRs have been widely discussed in Ethiopia since the ratification of the CBD in 1994.⁴⁴³ These discussions have culminated in the enactment of the Proclamation on Access to Genetic Resources and Community Knowledge and Community Rights- Proclamation No.482/2006. The Proclamation has seven different parts dealing with general provisions; protection of community rights; conditions of access, follow up and compliance measures; exploration of GRs; administration of access and miscellaneous provisions. For this thesis, the most important parts are those which deal with access conditions, benefit sharing and compliance measures.

The ABS Proclamation has sought to redress the disparities in the sharing of benefits derived from the commercialization of GRs as can be inferred from its objectives. Article 3 of the ABS Proclamation states that: "the objective of this proclamation is to ensure that the country and its communities obtain fair and equitable share from the benefits arising out of the use of genetic resources so as to promote the conservation and sustainable utilization of the country's biodiversity resources." In this regard, one should not forget the fact that this same objective is enshrined in the CBD which shows that the proclamation is informed by the CBD as it is stated in the preamble.⁴⁴⁴

For the realization of its ABS objectives, the proclamation has put in place different provisions which deal with conditions of access and modalities of benefit sharing. To begin with, access to and exploration of GRs is possible with the possession of an access permit. Therefore, any person is not allowed to access GRs unless he/she/it is in possession of the written access permit granted by the Institute of Biodiversity Conservation- the Institute hereinafter.⁴⁴⁵

⁴⁴³ Nnadozie and Lettington, Supra Note 428

⁴⁴⁴ The third paragraph of the preambular statement states the country's being a member to the CBD as one of the reasons for the promulgation of the law as it requires the enactment of the access legislation.

⁴⁴⁵ See Article 11(1) of the ABS Proclamation. The Institute of Biodiversity Conservation is a government institution established under Proclamation No.120/1998(as amended) in order to administer the access proclamation. See a Proclamation to Provide for the Establishment of Biodiversity Conservation and Research, Proclamation No. 120/1998, Establishment of Biodiversity Conservation Proclamation, and A Proclamation to Amend the Institute of Biodiversity Conservation Research Establishment Proclamation No.381/2004, Fed. Neg. Gaz., 10th year No.16- hereinafter the Proclamation to Reestablish the Institute of Biodiversity Conservation.

However, this is not without exception as the proclamation excludes the customary use and exchange of GRs by and among local communities as can be seen under the provisions of Article 4(2) of same. In addition to this, national public research and higher learning institutions as well as intergovernmental institutions based in the country may get a special access permit for facilitated access without the need to strictly follow the standards access procedures, provided that the purpose is only for development and academic research and that such activities are undertaken in the country.⁴⁴⁶

The Council of Ministers Regulation to provide for Access to Genetic Resources and Community Knowledge and Community Rights- ABS Regulation hereinafter- has envisaged special procedures for non commercial access.⁴⁴⁷ Ethiopian higher learning and research institutions as well as inter governmental institutions based in Ethiopia shall present an application to access GRs and/or community knowledge for the purpose of their institutional activities.⁴⁴⁸ Upon receiving the access application, the Institute shall after determining the obligation the applicant shall have while having access and upon signing of the access agreement to this effect, grant access to the applicant.⁴⁴⁹ One obligation imposed by the law on these institutions that have accessed GRs in accordance with the special procedure is that they are not allowed to export GRs out of Ethiopia unless they are given explicit permit to this effect.⁴⁵⁰ But then, where the Institute ascertains that they cannot undertake the research in Ethiopia, it may allow them to export GRs out of Ethiopia.⁴⁵¹

Where the Institute grants permit to export GRs, it shall cause that an access agreement be concluded that enable to protect the interest of the country over the GRs in question and shall also bind the foreign institution where the research is intended to take place and follow up and monitor the observance of such agreement.⁴⁵² All these show us that it is difficult to track compliance with ABS agreements once the GRs have taken out of Ethiopia.

⁴⁴⁶ Merso, Supra Note 43 at 257

⁴⁴⁷ See Articles 11-13 of the Council of Ministers Regulation to Provide for Access to Genetic Resources and Community Knowledge and Community Rights, Fed. Neg.Gaz., 15th year No.67-hereinafter the ABS Regulation

⁴⁴⁸ See Article 11 of the ABS Regulation

⁴⁴⁹ See Article 12 of the ABS Regulation

⁴⁵⁰ See Article 13 of the ABS Regulation

⁴⁵¹ Ibid

⁴⁵² Ibid

At this juncture, it is worth noting that issuing access permit should be based on the PIC of the Institute and the concerned local communities. This is the first crucial condition for access to GRs. PIC is defined as: " the consent given by the Institute and the concerned local community based on access application containing complete and accurate access information to a person seeking GR or community knowledge."⁴⁵³ PIC is a manifestation of the states sovereign rights over its GRs and that is why it is clearly stipulated that the ownership of GRs is vested in the state and the Ethiopian people.⁴⁵⁴

This being as it may, one thing is pretty clear, i.e., the definition does not tell us the kind of information that should be provided by the applicant in order to satisfy the PIC requirement. Honor to the ABS Regulation; typical of the requirements for the information to be contained in the access application so that consent granted by the state can be informed are general information on the name, address and qualification of the applicant; financial details on the budget of the project; details of the GRs to be accessed; details of the planned collection mission; details of the proposed use of the genetic resource; and benefit sharing information.⁴⁵⁵

As incidental it may be, at this point in time, it is worthwhile to raise an issue in relation to role of local communities in giving PIC for access to be granted. The question is: is the PIC of local communities required to grant access to GRs? One can get the answer from the cumulative reading of Articles 11(1)(3), 13(2),14(2) of the ABS proclamation which more or less made it clear that the PIC of local communities is not required to permit access to GRs. This can be more clear when one recognizes that the PIC of local communities is required in case of access to community knowledge as can be discerned from the cumulative reading of Articles 6(10), 7(1)(a)(b) &(c) of the ABS proclamation; but not in case of access to GRs.

Coming to the procedures of PIC, the access application to the Institute is the triggering factor for the access determination process. In this regard, as a special condition of access, expatriate

⁴⁵³ See Article 2(11) of the ABS Proclamation. This being how PIC is defined in the proclamation, some commentators have identified the key elements of PIC as prior- before access takes place; informed- based on truthful information about the use that will be made of the genetic resources that is adequate for the authority to understand the implications; and consent- the explicit consent of the concerned government organ of a country providing GRs. See Kerry Ten Kate and Sarah A Laird, the Commercial Use of Biodiversity: Access to Genetic Resources and Benefit Sharing, (1999) ,P.27

⁴⁵⁴ See Article 5(1) of the ABS Proclamation.

⁴⁵⁵ For the details on the information required to be included in the access application, see Annex I of the ABS Regulation

applicants are required to submit a letter of guarantee that they should obtain from their respective competent authorities hosting the research ensuring their compliance with the conditions and terms of the ABS agreement.⁴⁵⁶ Interestingly enough, this additional requirement shows that the law maker is fully aware of the fact that it is not easy to enforce conditions of access once the GRs is accessed and taken abroad.

So, it is a requirement which attempts to ensure that the applicant will comply with the ABS agreement and the ABS proclamation in general even he/she/it is not conducting the research in Ethiopia by involving the state to which the applicant is a citizen in the process. Interestingly enough, therefore, it is one of the implementation tools incorporated in the proclamation as it stipulates one of the basic preconditions for access that the applicant must present to the Institute a letter from the competent authority of his home state stating that the authority shall uphold and enforce the access obligation of the user.

Even then, the Proclamation does not make it clear who would be the competent authority and how this authority enforces the obligations assumed by the applicant. Besides this, in case of foreigner applicants, collection is supposed to be accompanied by the personnel of the Institute or another institution designated by the same.⁴⁵⁷ Of an equal importance is the other precondition stipulated under Article 12 of the ABS proclamation. According to Article 12 of the ABS proclamation, the access applicant accessing the GR must carry out the research in Ethiopia and exporting the GR from Ethiopia is not allowed. The principle is therefore that the user must carry out the research in Ethiopia and the user is exceptionally allowed to export the GR when conducting the research in Ethiopia is impossible.⁴⁵⁸

This precondition has different policy rationales; one of this is related with ensuring compliance. That means, if the research is required to be carried out in Ethiopia, obviously, it makes the enforcement of access conditions relatively easy as enforcing an obligation in ones jurisdiction is easier that doing it in an another jurisdiction. If the research is allowed to be carried out of Ethiopia, the institution hosting or sponsoring the research shall give a guarantee that it shall observe its access obligations and to this effect the user is required to present a letter of

⁴⁵⁶ See Article 12(4) of the ABS Proclamation

⁴⁵⁷ See Article 12(5) of the ABS Proclamation

⁴⁵⁸ See Article 12(6) of the ABS Proclamation

assurance from the institution that hosts or sponsors the research.⁴⁵⁹ Though its implementation seems to be unrealistic, the inclusion of such provision in the ABS proclamation is very important. The truism being once GRs have left their source, it is very complicated and it may be impossible to control their dissemination. Hence, others may be able to use these resources without the permission of the source country. As a consequence, the country may not be able to benefit from the exploitation of its GRs.

The other condition for access to GRs in Ethiopia is benefit sharing. As can be discerned from Article 12(3) of the ABS Proclamation, obtaining fair and equitable benefit from the commercialization of GRs by the state and the concerned local communities is mentioned as one precondition. And the proclamation lists modes of benefits which includes, license fee, upfront payment, milestone payment, royalty, research funding, joint intellectual property, employment opportunity, among others.⁴⁶⁰ By the way, it is good to note that the modes of benefits listed under Article 19 of the proclamation are not exhaustive and any appropriate benefit can be agreed.

3.2. The Legal Regime on Patentability of Inventions made based on GRs in Ethiopia

One may raise a multitude of issues related to the Proclamation Concerning Inventions, Minor Inventions and Industrial Design- the Proclamation on Inventions. However, for this work, two aspects of the law are important: patentability or non patentability of life forms and DRs in connection with inventions made based on GRs. This section is ordained to discuss the first aspect and the other one will be discussed under sub sections 3.4. and 3.5.

In considering whether biotechnological inventions are patentable or not, the relevant parts of the law are the ones which deal with the definition of an invention, non patentable subject matters and conditions of patentability. To begin with, one of the problems of biotechnological patenting is related with patent eligibility. A subject matter for which a patent is sought should fall within

⁴⁵⁹ See Article 12(7) of the ABS Proclamation

⁴⁶⁰ The other modes of benefits are employment opportunity, participation of Ethiopian nationals from either the institute or from another relevant institution in the research made based on the GRs accessed; priority to supply the raw materials of GRs required for producing products therefrom; access to products and technologies developed from the use of GRs accessed; training to enhance skills in the conservation, evaluation, development, propagation and use of GRs at institutional and local level; provision of equipment, infrastructure and technology support and any other benefit. See Article 19 of the ABS proclamation.

the scope of the subject matter that patent law prima facie exists to protect.⁴⁶¹ It thus precedes as a matter of logic the determination of substantive principles of patentability and constitutes the linchpin of the patent system.⁴⁶² This requirement is the inevitable point of initial intersection between new technologies and the patent system. And the line between eligible and ineligible subject matters rests on a fundamental distinction between patentable inventions and non patentable discoveries.⁴⁶³

The principle of eligibility is explicated differently in different jurisdictions.⁴⁶⁴ With a view to identify eligible subject matters for patentability, the Proclamation Concerning Inventions defines an invention as: "an idea of an inventor which permits in practice the solution to a specific problem in the field of technology" which could be a product or a process.⁴⁶⁵ This definition does not seem to exclude biotechnological inventions from being considered as patentable subject matters when compared with the classical definition given to the term as an idea which gives a technical solution to a technical problem. The point is that if the term invention is construed as an idea which offers a technical solution to a technical problem; this might exclude biotechnological inventions from patentability. As contradistinguished with such understanding of the term, the definition given in the Proclamation Concerning Inventions does require neither the solution nor the problem to be technical. Besides this, the word technology is stated without any qualification and therefore the definition can be construed to envisage

⁴⁶¹ Justine Pila, Bound Futures: Patent Law and Modern Biotechnology, available at: [Http://www. works. bepress/Justine_pila/4/](http://www.works.bepress.com/Justine_pila/4/); accessed on 14 December 2010

⁴⁶² Ibid

⁴⁶³ Andre Heitz, Intellectual Property in New Plant Varieties and Biotechnological Inventions, 10 European Intellectual Property Review, (1998), P.297.

⁴⁶⁴ In the US, eligibility is defined in positive terms to mean any new and useful process, machine, manufacture or composition of matter and any new and useful improvement thereof. And the distinction between invention and discovery is not fundamental under US law; that is why, the US patent law is considered to follow a liberal approach towards biotechnological patents. The US Supreme Court decision in *Diamond V. Chakraborty* opened the way for inventions relating to genetic engineering and living organisms declaring them as inventible. In Australia, eligibility is defined as any manner of new manufacture the subject of letter patent and grant of privileges and including an alleged invention. The Australian approach to biotechnological patent is considered the most liberal as the Australian Patent Act contains no express prohibition against the patenting of life forms aside from human beings; and all living organisms excluding human beings as potentially patentable subject matters. In Europe, in contrast, eligibility is defined in negative term to exclude discoveries, animal and plant varieties, essentially biological processes for the production of plants and animals. The EPC definition of eligibility has recently been explicated in the specific context of modern biotechnology. By express provision, the EU directive requires contracting states to provide national patent protection for biotechnological inventions including products consisting of or containing biological material. But to support a patent, a naturally occurring biological material must be isolated from its natural environment or produced by means of a technical process. See Pila, *Supra* Note 455

⁴⁶⁵ Article 2 (3)&(5) of the Proclamation on Inventions

biotechnology as one field of technology. Thus, it is within the bounds of reason to opine that biotechnological inventions can be regarded as inventions pursuant to the definition given to the term in this proclamation.

The other important consideration is whether biotechnological inventions are excluded from the ambit of patentable subject matters. Article 4 of the Proclamation on Inventions is entitled: **non patentable inventions**; which seemingly implies that those matters listed in it are inventions. By the way, technically speaking, one can argue that this article implies that even living matters excluded in there can be considered as inventions because what are excluded under this article are patentable inventions. How can it make sense to consider what have been listed under this article are inventions while it includes discoveries, mathematical methods and the like which are obviously not inventions. As a result, the technical argument may not take too far as it is difficult to consider, for example, discoveries, scientific theories and mathematical methods as inventions.

Be that as it may, Article 4(1) (b) of the Proclamation on Inventions, which is directly relevant to the issue at hand, excludes **plant and animal varieties, and essentially biological processes** for their production from patentability even when these subject matters fulfill the requirements for patentability. **(Emphasis added)**. And from this provision, we can infer that microorganisms, the essentially biological processes for the production of microorganisms, parts of plant and animals, such as, cell lines, genes, and the like are not explicitly excluded from patentability. Therefore, microorganisms and the biological processes for their production can be patented as per the Proclamation on Inventions, to say the least. In particular, when this provision which deals with non patentability subject matters is closely seen, it raises the issue of whether all plants and animals are excluded. This is because the Proclamation on Inventions uses the terminology "plant and animal varieties" instead of the simple words "plants and animals" which in turn makes the distinction between plants and plant varieties as an issue in order to understand what is excluded from patentability.

Though the Proclamation on Inventions does not define what plant varieties are, the Plant Breeder's Right Proclamation has defined it for the purpose of protection. The definition reads: "variety means a plant grouping within a single botanical taxon of the lowest known rank which can be defined by the expression of the characteristics resulting from a given genotype or a

combination of genotypes; distinguished from any other plant grouping by the expression of at least one of the said characteristics and considered as a unit for being propagated unchanged."⁴⁶⁶ On the other hand, plant is defined as a living organism which is not an animal and which can reproduce itself naturally.⁴⁶⁷

For the present work, it does not seem to be relevant to delve in to the notoriously contentious definition of plant and plant varieties beyond this. What is worth noting here is that all plants and plant groupings beyond plant varieties shall be patentable provided that the invention upon them meets the requirements of patentability. This is precisely because plant varieties have a narrow scope when compared with plants and the Plant Breeder's Right Proclamation complemented the Proclamation on Inventions by providing IPRs for those excluded from patentability.⁴⁶⁸ The broadness or narrowness of the definition of plant variety will determine what scope is left for patents on plants and when the Patent and Plant Breeder's Right laws are cumulatively seen, it gives rise to a recognition of IPRs for all life forms which, according to a researcher in the area, is unplanned and unwanted.⁴⁶⁹

The other important exclusion under Article 4(1) (a) is the one which deals with inventions contrary to public order⁴⁷⁰ or morality.⁴⁷¹ This is because an invention related to a particular living organism may be considered as contrary to public order or morality. Such inventions concerning directly human beings may be generally prevented from being patented based on public order or morality considerations.⁴⁷² For example, patenting humans as a product or even of processes for cloning human beings and its genetic identity can be envisaged as inventions to be made based on GRs and which could be excluded based on public order or morality

⁴⁶⁶ See Article 8 of the Proclamation to Provide for Plant Breeders' Right, Proclamation No 481/2006, Fed. Neg. Gaz., 12th year No.12- hereinafter the PBRs Proclamation

⁴⁶⁷ See Article 6 of the PBRs Proclamation.

⁴⁶⁸ Gizachew Sileshi, the Ethiopian Legal Regime on Plant Variety Protection: Assessment of Its Compatibility with TRIPs Agreement, Implications and the Way Forward, LL.M Thesis, AAU, Law Faculty,(2010),P.67, Unpublished

⁴⁶⁹ Ibid

⁴⁷⁰ It is not an easy task to define the term public order. But then, its essence concerns matters threatening the social structure of the society.

⁴⁷¹ Morality is the degree of conformity to moral principles. The concept of morality is relative to the values prevailing in one society. Such values are not the same in different cultures and countries.

⁴⁷² Gerd Winter, Patent Law Policy in Biotechnology, 4 Journal of Environmental Law, (1992), P.167

reasons.⁴⁷³ This is the extreme case scenario and other invention made based on living organism could also be excluded from patentability based on these considerations.

The other door inventions in the field of biotechnology need to pass are fulfilling patentability requirements. Principally, an invention to be granted a patent, the requirements of novelty, inventive step and industrial applicability need to be satisfied. These requirements set the basic standards of patentability by ensuring that inventions were not previously available to the public; are sufficiently different from what was previously available to the public and are capable of industrial applicability.⁴⁷⁴ Undeniably, the development of biotechnology challenged the traditional norms of the patent system and as a result it is not easy to determine the fulfillment or otherwise of these requirements in biotechnological inventions.

As every patent law does, as per the Proclamation on Inventions, an invention is patentable if it is new, involves an inventive step and is industrially applicable.⁴⁷⁵ As said before, applying these requirements to the patenting of inventions relating to life forms may pose a problem. For example, is an invention consisting of a GR new if the material existed in nature? Or would an invention consisting of a GR new if its existence was unknown prior to the application? Under the Proclamation on Inventions, an invention is considered new if it is not anticipated by a prior art; which consists of everything disclosed to the public either in writing, orally or in any other way before the filing date of the application.⁴⁷⁶ So, the newness of biotechnological inventions is subject to interpretation. Though the current trend of developed countries seems to support excluding only naturally occurring living organism or the substances extracted therefrom whose existence was known before the application filing date, it is difficult to consider an invention made based on life forms as new for the mere fact that its existence was not known before the application date for a patent.⁴⁷⁷ If it is a naturally occurring biological material existing in nature, it is not after all an invention rather a discovery and should not be considered for patentability.⁴⁷⁸

⁴⁷³ Ibid

⁴⁷⁴ Ibid

⁴⁷⁵ Article 3(1) of the Proclamation Concerning Inventions, Minor Inventions and Industrial Designs, Proclamation No. 123/1995, Neg. Gaz., the Proclamation on Inventions.

⁴⁷⁶ Article 3(2) of the Proclamation on Inventions

⁴⁷⁷ Rainer Moufang, Patentability of Genetic Inventions in Animals, 20 Intl Review of Industrial Property and Copyright, (1989), P.823

⁴⁷⁸ Ibid

The other patentability criterion is inventive step. The idea behind this requirement is that if every technical advance could be patented, innovation would come to a halt.⁴⁷⁹ So, an invention must go beyond the routine -it must be inventive or non obvious and it should not be obvious to a person skilled in that particular art. When this requirement is adapted to biotechnological inventions, the question is: when do we consider an invention on biological resources as involving an inventive step? Admittedly, it is easy to state this requirement but it is difficult to define it. And when this requirement is to be applied on biotechnological inventions, defining it would be more difficult. In any case, it is not palatable to consider life forms and naturally occurring substances as involving an inventive step if there is no intervention of human ingenuity at all.

The patentability requirement of industrial applicability seems to be less controversial and it is not difficult to determine whether a certain invention made based on GRs is industrially applicable or not. This is because with all its problems it is believed that biotechnology is relevant in agriculture and other sectors.

At this point in time, it is appropriate to consider whether the issue under discussion is entertained by the ABS Proclamation. The Proclamation does not rule out the possibility of patent on inventions based on GRs accessed; rather it makes acquiring IPRs over the GRs accessed or parts thereof contingent up on negotiating a new agreement with the Institute. This point will be discussed later; what is worthy to note at this juncture is that the Proclamation does not ban patent on inventions made based on GRs.

Laconically speaking, with all the complexities, biotechnological inventions can be considered as patentable subject matters under Ethiopian legal regime. True, the non patentability of all life forms and processes thereto is not the principle under the Proclamation concerning Inventions. For me, the proclamation seems to be a little bit liberal and disregard some of the arguments forwarded against the patentability of life forms as it fails to explicitly exclude microorganisms and the biological processes for their making; and plants in their broader sense from patentable subject matter. There is an explanation for this.

⁴⁷⁹ Ibid

The patenting of life forms has become the subject of worldwide campaign by environmentalists, farmers' organizations, lawyers and religious leaders, mostly from developing countries.⁴⁸⁰ This is because patent on life forms is considered unethical and it goes against the economic and social interests of developing countries.⁴⁸¹ As a result of this, they have directed a barrage of criticisms against the granting of IPRs on life forms and processes.

To begin with, according to the views of the opponents, life forms and processes do not qualify the term invention and hence may not be patented.⁴⁸² They corroborate their argument by saying that such processes and activities are tantamount to discovery and not inventions.⁴⁸³ Besides this, it is strongly argued that granting IPRs on life forms and processes frustrate the idea that they are sacred, as individuals claim the role of the creator.⁴⁸⁴

The other argument is forwarded based on an economic point of view. Based on this, developing countries vehemently argue that granting IPRs on life forms and processes and thereby allowing monopolization will give rise to greater economic dependency on the big multinational companies who more often than not are guided only by business interest.⁴⁸⁵ Thus, once an IP granted to such a company, for instance on a certain modified crop, free exchange of this crop among farmers will be impaired as they are supposed to seek authorization from the right holder upon payment of a royalty.⁴⁸⁶

More importantly, at least for this work, developing countries fervently argues that IPRs on life forms and processes facilitate the hijack of their GRs by multinational companies who have sought IPRs on same.⁴⁸⁷ This opposition is caused due to the fact that companies are being granted IPRs for products and technologies that make use of GRs that have long been identified,

⁴⁸⁰ Martin Khor, Why Life Forms Should not be Patented? Available at: <http://www.twinside.org.sg/title/2103.htm>; accessed on 23 October 2010.

⁴⁸¹ Ibid

⁴⁸² An Explanatory Booklet on the OAU's Model Law on the Protection of the Rights of Local Communities, Farmers and Breeders and for the Regulation of Access to Biological Resources, OAU Scientific, Technical and Research Commission, (2000), P.30,

⁴⁸³ Ibid

⁴⁸⁴ Graham Dutfield, Who Invents Life: Intelligent Designers, Blind Watchmakers or Genetic Engineers? 7 Journal of Intellectual Property Law and Practice 5, (2010), P. 3

⁴⁸⁵ Martin Khor, A Worldwide Fight Against Biopiracy and Patents on Life Forms, Available at <Http://www.twinside.org.sg/title/pat-ch-htm>; Accessed on September 25/2010

⁴⁸⁶ Ibid

⁴⁸⁷ Ibid

developed and used by local communities, mainly from developing countries rich in GRs.⁴⁸⁸ Consequently, opposition against IPRs on life forms and processes is rapidly building up to prevent the massive biopiracy that potentially occurs in developing countries.⁴⁸⁹ All these have caused debates on the issue in different foras, basically in the TRIPs council as highlighted in the previous chapter.

At this juncture, it is worthwhile to mention that the African Group in the TRIPs Council is arguing for the inclusion of the prohibition of patents on plants, animals as well as microorganisms and all other living organisms and their parts. This group believes that natural processes that produce plants, animals and other living organisms should not be patented. Is this not puzzling therefore that the Proclamation concerning Inventions does not unequivocally exclude microorganisms, the natural processes for their making and all plants and animals from patentability? Do the arguments forwarded by developing countries work for Ethiopia? For me they do and that is why plant and animal varieties and the natural processes of their production are excluded from being considered as a patentable subject matter.

I opine that it is within the bounds of reason to argue that making microorganisms, plants other than plant varieties and the biological processes thereof patentable subject matters is not made by the lawmaker with full knowledge of its ramifications when seen in line with the abovementioned arguments. And truly speaking, it is difficult to imagine that Ethiopia's position would be different from other similarly situated African Countries. This is without forgetting the fact that Ethiopia is not a member to the WTO and the position taken by the African Group in the TRIPs Council does not reflect the country's position in this regard. But then, paradoxical as it seems, Ethiopia has adopted the African Model Law which fully agrees with the proposals made by the African Group and which is very clear in making the motto- no patent on all life forms- as can be seen in its preamble and Article 9(1).⁴⁹⁰

⁴⁸⁸ Tewelde Birhan G/Egziabher, the Inappropriateness of the Patent System for Life Forms and Processes, available at: [Http://www.twinside.org.sg/title/gebte.htm](http://www.twinside.org.sg/title/gebte.htm); accessed on 23 September 2010

⁴⁸⁹ Ibid

⁴⁹⁰ The African Model Law in its preamble states that all life forms are the basis for human survival and therefore, the patenting of life, or the exclusive appropriation of any life form or part or derivative thereof violates the fundamental rights of life. On the same vein, Article 9(1) states that: patents over life forms and biological processes are not recognized and cannot be applied for.

Researchers in this area tipped us that the position taken by the Proclamation on Inventions on the issue at hand is mostly compatible with Article 27 .3. (b) of the TRIPs Agreement which allows members to exclude plants and animals from patentability.⁴⁹¹ Even then, it is hard to imagine that the law maker designed this provision having in mind making it compatible with the TRIPs Agreement and there is nothing mentioned in the preamble. Regardless of how the legislature is far sighted, I do not think that making the Proclamation on Inventions compatible with the TRIPs Agreement justifies the non exclusion of microorganisms and the biological processes thereto from patentability. Unluckily, we have not seen this provision tested in practice as there has never been an application for patent on an invention made based on microorganisms, plants and microbiological processes to the EIPO.

The legal, ethical, moral and economic issues highlighted in relation to biotechnological inventions are a bird's eye view. Seen in the context under consideration, what is worth noting is that the Proclamation on Inventions embraces inventions made based on GRs and there is a strong cause to deal with its interface with the ABS Proclamation. This is because there could be a possibility of patenting an invention which used GRs without fulfilling the conditions of access stipulated in the ABS Proclamation.

Besides this, the liberality of the Proclamation on Inventions does not seem to support the ABS objectives as it does not make all life forms non patentable. This is true when seen in line with the understanding that making all life forms non patentable has the purpose of curbing misappropriation; especially when DRs are not incorporated in patent laws. But then, one can raise a practical issue in this regard? If patent on life forms in general and on GRs in particular is excluded, what would motivate researchers or multinational corporations to seek access to GRs since access in most cases is driven by the incentive inherent in the possibility of gaining a monopoly right? One needs to beware that it is difficult to imagine benefit sharing being accrued to local communities and the concerned state without access to its GRs. This being an appropriate concern, the idea is 'inventions' on GRs or on their parts and inventions made based on GRs are different admittedly though it is not always easy to make such a distinction.

⁴⁹¹ Fikremarkos Merso and Imiru Tamrat, Ethiopia's Experience in Access to Genetic Resources and Benefit Sharing: the Hope for Economic Benefits and the Risks for Research and Innovation, available at: [Http://www.yaleisp.org/wp-content/uploads/2009/10/Merso-Tamrat-GRs.doc](http://www.yaleisp.org/wp-content/uploads/2009/10/Merso-Tamrat-GRs.doc); accessed on 10 June 2010

Therefore, in most cases, the outright exclusion of patents for inventions based on GRs is not the concern of patent claimed on inventions which used GRs as an input.

All in all, the country needs to adopt a cautious approach in dealing with biotechnological inventions. In particular; the technical, ethical, moral, economic, health and environmental issues that can be raised in relation to biotechnological inventions needs to taken in to account in adopting policy and regulatory frameworks on the matter.

3.3. IPRs and Disclosure Requirements under the ABS Proclamation

As enforcement is critical to any ABS legislation, the ABS Proclamation in its part has imposed some obligations on the access permit holder in order to make sure that the ABS objectives of the law are changed in to a reality. In this regard, a reference can be made to Article 17 of the proclamation entitled: obligations of the access permit holder. But, this section discusses those obligations which are important in indicating the place given to IPRs for the implementation of the ABS Proclamation.

To begin with, the access permit holder is not at liberty to apply for IPRs on inventions made based on the GRs accessed and on the accessed GRs unless a new agreement is negotiated with the Institute.⁴⁹² That means, the access agreement concluded to get access to GRs does not entitle the access permit holder to seek for IPRs on inventions made using the GRs accessed or the GR itself or parts thereof. So much so that, if the access permit holder wants to obtain IP protection, he/she/it is required to conclude a separate agreement.

At this point in time, one may quest why the law has imposed such an obligation on the access permit holder. It can be conjectured that such imposition on the access permit holder gives an option to the Institute to negotiate a new benefit sharing arrangement as it is not always easy to determine the benefits that would be accrued as a result of the commercialization of GRs at the time of concluding the ABS agreement. In relative terms, the time of application for IPRs on inventions made utilizing the GRs accessed can be considered as an appropriate time to negotiate a new benefit sharing arrangement. It also gives an option to the Institute to negotiate a new benefit sharing arrangement when it thinks that the benefit determined in the access agreement was not appropriate for different reasons.

⁴⁹² See Article 17(12) of the ABS Proclamation

In addition to this, it can be guessed that such an obligation imposed on the access permit holder helps the Institute to negotiate as to the jurisdiction to which the application for IPRs should be made. Choosing a jurisdiction has a paramount importance since it gives an opportunity to the Institute to determine a country whose IP law adopts DRs or a jurisdiction easy for enforcement may be because the country has a bilateral or regional agreement. Not only these, one can also guess that the rationale behind this obligation is to give an option for the Institute to negotiate as to the specific kind of IPR to be requested by the access permit holder. It goes without saying that, IPRs in this context refers to those which require registration to acquire an IP right. This basically includes the Patent and Plant Breeder's Right Laws. Therefore, taking in to account the distinctions between the Patent and Plant Breeder's Right law, the Institute would be well placed to negotiate for which of these rights the access permit holder should apply.

These reasons can be considered as good reasons in case of application of IPRs on inventions made based on the accessed GRs. But, would it hold the same in case when the access permit holder seeks to apply for an IP protection on the accessed GRs itself or on its parts? The law as it stands now seems to legitimize patent on life forms because had the purpose been prohibition of patent on accessed GRs, negotiating a new agreement would not have been a condition for the access permit holder to seek an IPR on same. Of course, in case of IPRs on the accessed GRs itself or on its parts, this condition will enable the Institute to evaluate the IP claim on that particular life form in line with the issues to be raised in relation to the patentability of life forms; such as ethics, morality, its impact on human and animal health, environmental well being and the like. And such an agreement is supposed to be made in accordance with the relevant laws of Ethiopia though to what the phrase 'relevant laws of Ethiopia' refers to is not clear. Perhaps, the Institute may resort to IP laws including the Proclamation on Inventions to determine whether the subject matter for which an IPR is claimed is patentable or not in negotiating the agreement. For example, if it is considered an invention against the morality of the Ethiopian people, the request may be rejected.

To the contrary, it can be argued that the language used in the ABS Proclamation in this regard implies that IPRs could be claimed on the GRs as they are or on the parts such as isolated or purified genes from the accessed GRs.⁴⁹³ Even then, it is difficult to imagine that the law is

⁴⁹³ Merso and Tamrat, *Supra* Note 491

allowing IPR over the accessed GRs as they are since there is no reason for IPR claim on the GRs or parts thereof without the involvement of human creative efforts. In any case, when one considers the fact that the ABS is modeled on the African Model Law, which has unequivocally banned patents on life forms and biological processes, he/she may expect the law to provide clear rules on what should and should not be patentable. Unfortunately, however, that is not the case.

Be that as it may, one important question that needs to be raised is: how would the Institute know that the access permit holder has made an application to get IP protections for the invention developed based on the GRs accessed from Ethiopia if the holder wishes to do so by breaching the obligation imposed on him? What would be the fate of the IP granted to the access permit holder by breaching the obligation to negotiate a new agreement before doing so? Do IP laws- Patent and Plant Breeder's Right in particular- have a role for the enforcement of this obligation? These and other related questions would be addressed in the subsequent sub sections of this chapter. What is worth noting, at this juncture, is the place given to IPRs as a tool for the implementation of ABS objectives in the ABS Proclamation.

In addition to the obligation expounded above, the ABS Proclamation obligates the access permit holder to recognize the locality where the GR accessed from as origin in the application for IP protection on the products developed therefrom.⁴⁹⁴ It should not be overlooked that this is an obligation imposed on the access permit holder even after successfully negotiating a new agreement as to the application of the IPR. Can it be considered as an adoption of disclosure requirements as discussed in the preceding chapter? I would say the answer to this question is yes with a reservation. This is because this sub Article which requires disclosure does not obligate the access permit holder to disclosure evidence as to PIC given and the fair and equitable benefit sharing shared or to be shared. That is to mean, the latter two elements of DRs are not enshrined in the ABS Proclamation. With all its limitations, therefore, the access proclamation can be considered as a legal basis for disclosure of origin requirement.

For the sake clarity, let us take the following scenario. Habesha pharmaceutical company which has been registered as per the Commercial Code of Ethiopia has concluded an ABS agreement with the Institute in 1998E.C. According to the agreement, the company is allowed to access

⁴⁹⁴ See Article 17(14) of the ABS Proclamation

'Dama Kese' for the purpose of developing a medicine. After conducting a research for three years relentlessly, the company has successfully developed the medicine using the GR accessed. In order to ensure its commercial exploitation, it has decided to apply for a patent to the EIPO. In such an application, the company is required to disclose the locality where it has accessed 'Dama Kese' as per the Article 17(14) of the ABS Proclamation.

This scenario begs the question: is the ABS Proclamation binding on the EIPO? If so, should the patent examiner take in to account what is stipulated under the ABS Proclamation in applications for patents on inventions made based on GRs? In the ABS Proclamation, there is no provision which imposes an obligation on the EIPO to make sure that applicants for patent in case of inventions made on GRs have complied with the ABS Law. But, as per Article 6 (1) of the Ethiopian Intellectual Property Office Establishment Proclamation, the office is duty bound to receive applications for patent and give appropriate decisions after undertaking the necessary examination in accordance with **the relevant law. (Emphasis added)** For me, in case of applications for patent on inventions made based on GRs, the ABS Proclamation is a relevant law to be taken in to account in undertaking the examination. That means, the EIPO is supposed to make sure that the applicant has complied with the obligations imposed on him before granting the right. Needless to say, patent examiners are required to make sure that applicants have complied with what has been provided in the ABS proclamation before granting the right. But it is difficult to consider this as a law which creates a linkage between the ABS Proclamation and IPR laws.

Indeed, requesting access permit holders to disclose the origin of GRs is extremely important as mentioning the locality in IPR applications would give the Institute a legal basis for demanding benefit sharing and the fulfillment of other obligations set in ABS agreements. And logically, monitoring IPR applications can be considered as a possible check point or 'kella' in order to trace the commercialization of GRs and ensure benefit sharing. But this sub provision of the ABS Proclamation which attempts to incorporate DRs Leaves many questions an unanswered. For example, it does not tell us what would trigger DRs, the nature of DRs and the consequences of failure to disclose origin to an already granted IPR, among others. To be more specific, is DR a patentability requirement under Ethiopian law? This being the deficiency of the law, one

would be compelled to raise another cross cutting issue when one he/she thinks of the enforcement of DR as enshrined in the ABS Proclamation.

At issue here is: is enforcement of this obligation possible if the relevant IPR laws do not lend their hands to this effect? In fact, the legal basis for DRs could be the ABS Proclamation or IPR laws; it is a matter of approach; but in my opinion, as mention has already been made, IPRs are the appropriate instruments to incorporate DRs as it is appropriate to deal with the details of DRs- issues of the relationship between the GR and the invention to trigger disclosure and consequences of non compliance in the relevant IPR laws. Besides these, it is relatively easy for patent examiners to make sure that the applicant has complied with this obligation when such obligations are specified in IPR laws.

Taking in to account the problems pin pointed above, I think, it is preferable to implement DRs in the relevant IP laws. This is important for ensuring legal certainty as incorporating DRs in Proclamation on Inventions and PBRs Proclamation would help to clarify the consequence for lack of fulfillment and to ensure its implementation.

In this regard, we are unfortunate to evaluate how the practice entertained these issues as there has never been a patent granted on an invention made based on GRs in Ethiopia.⁴⁹⁵ In fact, let alone inventions made based on GRs, the patents granted on other inventions are not significant.⁴⁹⁶ But then, the place given to IPRs for the enforcement of ABS objectives is pretty clear and whether they are designed in a manner to help the ABS Proclamation is an issue that remains to be addressed in the coming sub sections of this chapter.

Mention is also made to IPRs as a mode of benefit sharing. Under Article 19(6) of the ABS Proclamation, joint ownership of IP is stated as one form of benefit sharing. As can be seen from the last limb of the above-mentioned provision, joint ownership of IP may not always be considered as a mode of benefit sharing as it is not a mandatory form of benefit sharing. As a result, it all depends on the negotiation made by the Institute with the applicant. At any rate, joint ownership of IPRs can be considered as one mode of benefit sharing and may be preferred as one way of ensuring that the provider retains a distinct stake in the outcomes resulting from the

⁴⁹⁵ Getachew Mengistie, The Impacts of the International Patent System on Developing Countries,2003, WIPO/A/39/13

⁴⁹⁶Ibid

access.⁴⁹⁷ Ownership can provide reassurance to the resource providers that they will retain a say over how the resources are developed and used, and how any new technology derived from the GRs are developed, used and disseminated.⁴⁹⁸ This could be realized in jurisdictions which require the consent of the other owner(s) for an assignment or license; i.e. the agreement of all owners is required for effective development and exploitation of the patent if there is more than one owner of IP.⁴⁹⁹

However, undeniably, these all is possible when the ABS Proclamation has got the support of the relevant IP laws in this regard. This takes us to the discussions on the relationship between the ABS Proclamation and IP laws- the Proclamation on Inventions and Plant Breeder's Right Proclamation- on the realization of ABS objectives enshrined in the ABS Proclamation. The question in simple terms is: do these IP laws support the ABS objectives of the ABS Proclamation and are they designed in a manner to lend their hands for the effective realization of ABS objectives? The forthcoming discussions are ordained to answer these and other related questions.

3.4. The Proclamation on Inventions, Minor Inventions and Industrial Designs and ABS

The other issue that can be raised in relation to the Proclamation on Inventions is whether it has incorporated DRs in connection with inventions made based on GRs. The discussion in this regard seeks to answer this question: does the Proclamation on Inventions adopt DRs in order to ensure that the rules regarding GRs enshrined in the ABS Proclamation are effective?

3.4.1. Conventional Disclosure under the Proclamation on Inventions and ABS

Since disclosure is part of the core rationale of patent laws, the Proclamation on Inventions require applicants for patent to include in their application the description of the invention, one or more claims,⁵⁰⁰ an abstract and drawings,⁵⁰¹ where necessary.⁵⁰² The description shall disclose

⁴⁹⁷ UNU-IAS Report, Benefit Sharing in ABS: Options and Elaborations, available at: [Http://www.ias.unu.edu](http://www.ias.unu.edu); accessed on 12 September 2010.

⁴⁹⁸ Ibid

⁴⁹⁹ Ibid

⁵⁰⁰ It is an information requirement for patent applications that defines the matter for which protection is sought.

⁵⁰¹ It is an information requirement in patent law which is important to elucidate the invention.

the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art and the applicant, shall in particular indicate one mode known to him or her for carrying out the invention.⁵⁰³ So, it is believed that such information will enable a person skilled in the art to carry out the claimed invention.

There are also other information requirements relevant to the determination of the novelty, inventive step and capability of industrial application or utility of the claimed invention, including search reports and other known prior arts. Besides, there are other administrative or bibliographic information relevant to the claimed patent right, such as the name of the inventor, address for service, details of priority documents etc.⁵⁰⁴ Succinctly speaking, the requirements to disclose information under the Proclamation on Inventions can be broadly categorized as: an indication that the grant of the patent is sought, the name and address of the applicants, inventors and/or patent agents, the title of the invention, one or more claims, information relevant to the assertion of claims of priority, an abstract and a description of the invention and drawings if necessary.⁵⁰⁵

These requirements are generally characterized as formal or substantive. Formality requirements may apply to the need to disclose information, such as the names of the inventor and addresses or the need to submit certain documents like priority documents(copies and translation of foreign patent applications that form the basis of a claim to priority) and formality requirements may also refer to the physical format- layout on the page, size of the paper etc.⁵⁰⁶ On the other hand, substantive requirements generally refers to the actual nature of the invention as such and whether it meets the standards set forth for patentability.⁵⁰⁷ The distinction between substantive and formal requirements is often considered in terms of consequence of non compliance, in particular, failure to comply with substantive requirements such as novelty renders a patent invalid, and on the other hand, failure to meet certain formality requirements may be fatal for a patent application, especially if it is not rectified in time.

⁵⁰² Article 9(3) of the Proclamation on Inventions

⁵⁰³ Article 9(4)(b) of the Proclamation on Inventions

⁵⁰⁴ Edmund W. Kitch, The Nature and Function of the Patent System, 20 J.L&Econ., (1977), P.286

⁵⁰⁵ Suzanne Scotchmer & Jerry Green, Novelty and Disclosure in Patent Law, 21 Rand J.Econ., (1990), P.135

⁵⁰⁶ Ibid

⁵⁰⁷ Ibid

The obligation of an applicant to provide information can therefore be considered under two aspects- compliance with formal requirements and compliance with substantive requirements.⁵⁰⁸ For example, where a patent application is required to identify the inventor or inventors, this may be considered as a formality requirement in that an application will generally not be accepted if there is no mention of the claimed inventor.⁵⁰⁹ An incorrect or incomplete indication of the inventor may lead to transfer or invalidation of the patent right. Similarly, it is also a formality requirement that a patent application should include a description of the invention, but this description must also meet specific substantive standards if the application is to be accepted or if a granted patent is to be valid.⁵¹⁰

The substantive requirements for disclosure can be generally characterized by a reference to some objectives. To begin with, patent disclosure is considered essential as it encourages cumulative innovation both by dangling the patent before the inventor as an incentive in the first instance and by requiring him to disclose to the public his invention so that science can progress by building on the divulged knowledge.⁵¹¹ It indirectly stimulates others' future innovation by revealing to them the invention so that they can use it fruitfully when the patent term expires and so that they can design around, improve upon or be inspired by the invention both during and after the patent term.⁵¹²

That being said, the crux of the matter is: do information required to be disclosed under the Proclamation on Inventions, as it stands now, have any hand to lend in disclosing the source and/or origin of GRs, evidence of PIC and benefit sharing? It is a hard fact that this proclamation does not stipulate the fulfillment of DRs (source and/or origin of GRs, evidence of PIC and benefit sharing) by patent applicants in relations to inventions made based on GRs.

But, is it not necessary to disclose the source of the GRs when doing so is extremely important for a person skilled in the art to carry out the invention? In order to achieve the objectives of disclosure under patent law in relation to inventions involving the use of GRs, some countries

⁵⁰⁸ Douglas Lichtman, Scott baker and Kate Krans, Strategic Disclosure in the Patent System,53 Vand. L.Rev., (2000),P.218

⁵⁰⁹ Ibid

⁵¹⁰ Guang Ming Whitely, a Patent Doctrine without Bounds: The Extended Written Description Requirement,71 University of Chicago Law Review,(2004),P.629

⁵¹¹ Ibid

⁵¹² Ibid

have a system for the GRs to be deposited for the purpose of patent procedures, dealing with the situation where a GR cannot be fully described.⁵¹³ To this effect, many referred to specific disclosure obligation concerning either microorganisms only or GRs more broadly.⁵¹⁴ The requirement is that details be provided of the deposit of a sample of a microorganism or biological material required to implement the invention when it cannot be described in writing or related to specific requirements for the identification or description of biological material.⁵¹⁵

For example, in France, when the invention concerns the use of a microorganism to which the public does not have access, the description is not considered as disclosing the invention sufficiently if a sample of the microorganism has not been the object of deposit with a designated body.⁵¹⁶ On the same vein, the EPC Rule 28 states that: " if an invention involves the use of or concerns biological materials and this biological material is not available to the public and cannot be described in such a manner as to enable the invention to be carried out by a person skilled in the art, reference needs to be made to the deposit of this biological material."⁵¹⁷ Interestingly enough, in Australia too, if the starting point of an invention is a biological material, disclosure requirement could be met when a full description of the material in the words including where to find the material and how to recognize it are made.⁵¹⁸ These are some of the countries⁵¹⁹ which make a reference to disclosure obligations in relation to GRs for the realization of objectives of disclosure within the ambit of the patent law.

⁵¹³ Technical study on disclosure requirements related to genetic resources and traditional knowledge, WO/GA/30/7 Add.1 (2003)

⁵¹⁴ Ibid

⁵¹⁵ Ibid

⁵¹⁶ Ibid

⁵¹⁷ Ibid

⁵¹⁸ Ibid

⁵¹⁹ There are also other countries which stipulate more or less the same disclosure requirement, in this regard, mention can be made to the Republic of Korea which require that a patent application of an invention relating to microorganisms shall provide a detailed information about any microbial material used in the development of the invention so that the person skilled in the art could easily carry the invention. By the same token, the Russian Federation, in a claim characterizing the strains of microorganisms, the cell cultures of plants and animals shall comprise the generic and specific name of the biological subject in Latin with an indication of the surnames of the inventor of the type and, if the strain has been deposited, the name or abbreviation of the collection depository, registration number attributed by the collection to the deposited subject and the designation of the strain. Moldova requires the applicant to disclose in an application referring to a biological material the information concerning the cultural morphological, physiological-biochemical, hemo and geno taxonomical, carpological and biotechnological characteristics of the material; the characteristics of the pattern material; the hybridization principle; the genealogy of colonies; the conditions of cultivation and other characteristics, as well as the process of production of the said material. In China too, where a patent application contains disclosure of one or more nucleoside and/or amino acid sequences, the description shall contain a sequence listing in compliance with the standard prescribed by the state

when seen in comparative perspective, neither deposit of the GRs nor specific disclosure obligation are mentioned in the Proclamation on Inventions and one can say that there is no special disclosure obligation imposed on patent applicants in relation to invention involving GRs to disclose the source of the GR or deposit the GR or other relevant information to enable the person skilled in the art to successfully carry out the invention. The importance of such a requirement under patent law is pretty clear. But, in this regard, one may raise a question on the relevance of such a requirement for the effectiveness of ABS rules; cases in point are PIC and benefit sharing arrangement. For me, it is an appropriate concern and the relevance of such requirements for the implementation of ABS objectives is incidental, so to speak. This is because the argument goes when an applicant is required to disclose the source of the GR in order to enable the person skilled in the art, providers of GRs can track its compliance with the particular access legislation and material transfer agreement using mention of the source in the patent application as a legal basis.

Even then, one may question whether the conventional disclosure requirements enshrined in the Proclamation on Inventions has the potential to oblige patent applicants to disclose the source of the GR. Though arguable, as a general rule, when a GR is well known and widespread, the place of the locality where the applicant has accessed may not be required, but when the object of the patent application is a rare or exotic GR extract, the applicant is required to provide an information relating to the country of origin in the description of the invention.⁵²⁰ Simply put, the argument is disclosure requirement may entail disclosing the source of the GR when that is endemic to a specific location.

In my opinion, if the GR used in an invention occurs in a particular location, its source and other relevant information about the GR need to be disclosed in order for the person skilled in the art to carry it out. This is precisely because it may not be possible for others to carry out an invention made based on GRs without making use of the GRs as an input. This, in turn, is possible when they have got a GR deposited or when the origin of that GR is disclosed in the patent application. This is an interpretation of the patent law in this regard which is shared by many countries as can be discerned in their positions expressed in different foras. For instance, in

intellectual property office. The sequence listing shall be submitted as a separated part of the description and a copy of the said sequence in machine readable form shall also be submitted. see Ibid

⁵²⁰ Lichtman, Supra Note 508

a report submitted upon WIPO's request on the matter, Germany noted that in general an indication of the source is not necessary to enable a person skilled in the art to carry out the invention but this might be different where the source is unique and essential to put the invention to put in practice.⁵²¹ Burundi confirmed that such information was required in the case of an invention on traditional medicine by citing the case of a traditional healer who had submitted a patent application to protect his knowledge.⁵²² Similarly, the US reported that based on experience, the USPTO is aware that patent applicants, at times, provide information about the GR used in the invention including the source of origin in order to meet the written description, enablement or best mode requirement.⁵²³

In connection to this, the Proclamation on Inventions requires the applicant for a patent to disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person having ordinary skill in the art.⁵²⁴ Arguably, the applicant may be required to disclose the place where he accessed the GRs which is used in the invention if it is not easy for other persons to know the origin of the GR. The thing is if it is not possible under the circumstances to access that particular GR, others would not be in a position to carry the invention out perhaps because the invention is not fully described as required by the law.

From the preceding discussions, one can appreciate the fact that disclosure requirement is not recognized as a measure in order to make use of the patent system as a check point to ensure that the applicant has complied with the ABS Proclamation before granting patent. As I have

⁵²¹ Ibid

⁵²² Ibid

⁵²³ In the US, there are three substantive disclosure requirements. In case of written description requirement, the basic inquiry is whether one skilled in the art would reasonably conclude that the inventor was in possession of the claimed invention at the time of the application was filed. If a skilled artisan would have understood the invention at the time of filing, even if every nuance of the claim is not explicitly described in the specification, then the requirement for an adequate written description is met. An invention is considered enabled if the specification teaches one skilled in the art how to make and how to use the invention without undue experimentation. Undue experimentation is determined based on a weighting of several factors. these are: the nature of the invention, the breadth of the claims, the state of the art, the amount of the direction, predictability or unpredictability of the art, the amount of direction or guidance provided in the specification, the presence or absence of working examples provided in the specification and the quantity of experimentation necessary to make the claimed invention. And for the requirement of the best mode to be met, the description of an invention must set forth the best mode of the invention. It is a safeguard against the desire on the part of some people to obtain a patent protection without making a full disclosure as required by the statute. See D.L. Carlson et al, Patent Linchpin for the 21st Century – Best Mode Revisited, 87 J. Pat. & Trademark Off.

Soc'y, (1989), P. 92. It is good to note that the best mode disclosure requirement has got a place under the Ethiopian patent proclamation.

⁵²⁴ See Article 9(4)(b) of the Proclamation on Inventions

attempted to show, there is a very little room to use the patent law as it stands now to require disclosure of source of GRs when such a resource is unique to a certain locality and important for a person skilled in the art to carry out the invention.

3.4.2. Disclosure Requirements under the Proclamation on Inventions

The Proclamation on Inventions does not incorporate DRs in relation to applications for inventions derived from GRs. Since access to GRs and benefit sharing is a recent theme with a new perspective, it may not be surprising that the Proclamation does not recognize DRs as a measure to ensure that ABS requirements are fulfilled. As it has already been mentioned, DR is considered as an important measure as it requires any applicant for a patent to prove that the process of innovation was undertaken in compliance with the ABS Proclamation before granting the right.

In discussions of such a nature, the issue that comes at the very outset is: is it legitimate to use the patent system to achieve non IP related goals? The argument forwarded against the use of the IP system to identify possible misappropriation of GRs and to demonstrate compliance with national ABS laws is considered a wrongful use of the system.⁵²⁵ This is because, the argument runs that the patent system is designed to promote innovation and to provide economic development incentives.⁵²⁶ It is not designed to regulate or enforce rules relating to ABS.⁵²⁷

This argument begs the question: what is the purpose of the patent system? True, at its simplest, the patent system exists for public benefit of supporting innovation through the disclosure of the nature of new invention in return for a time limited right of monopoly use by the inventor.⁵²⁸ However, it is argued that while this philosophy may underlie the system, over the years its application has also served other purposes including protection of national industry, prevention of technical transfer and economic welfare.⁵²⁹

⁵²⁵ Oldham Paul and Burton Geoff, Defusing Disclosure in Patent Applications, 2010, available at: [Http://ssrn.com/abstract=1694899](http://ssrn.com/abstract=1694899); accessed on 2 November 2010

⁵²⁶ Ibid

⁵²⁷ Ibid

⁵²⁸ Ibid

⁵²⁹ Alison Hoare and Richard Tarasfosky, Patenting Genetic Resources: Striving for the Right Balance, (2007),P.46

In addition to this, a proposal on the incorporation of DRs in the patent system seeks to achieve its public policy ends through transparency.⁵³⁰ The public policy ends is the demonstration of compliance with applicable ABS laws and prevent the misappropriation of GRs through deterrence.⁵³¹

After all, is it necessary to incorporate DRs in the Proclamation on Inventions for the implementation of ABS requirements enshrined in the ABS Proclamation? If one answers this question in the affirmative, the question that follows is related with addressing on how to incorporate the requirement. Admittedly, it is not an easy task to give an automatic answer to these and other related questions. In answering these questions, regard should be given to the importance of the connections between the ABS and the patent system in particular and the IP system in general. For all the theoretical underpinnings and how the issue is being addressed in its international dimension, the reader is advised to refer to the two preceding chapters as the discussions in the sub section builds on the discussions made in there.

The focus here is on the appropriateness of enshrining DRs under the Proclamation on Inventions for the implementation of the ABS proclamation in Ethiopia. The nettlesome question I am trying to raise is: would the inclusion of DRs in this proclamation bring any tangible significance? one of the basic nature of IP in general and the patent system in particular is territoriality which implies that the issue of granting patents would be the concern of the country where protection is sought.

Therefore, in the absence of an International ABS Regime which incorporates the principle of DRs, it does seem difficult to comprehend the significance of envisaging same requirements in national patent laws when the access permit holder makes an application for IP in another jurisdiction. Ensuring compliance using IP laws in these cases depend on the good will of this particular state to which an application is made. This is an important question that needs to be raised in the context of a country like ours where innovation is at its infant stage let alone inventions to be made based on GRs, which presupposes the existence of biotechnology.

⁵³⁰ Ibid

⁵³¹ Ibid

On this issue, one can argue that it is appropriate and the time is ripe now to recognize DRs in the Proclamation on Inventions for the following reasons. To begin with, Ethiopia is a party to the CBD which requires members to make their patent and other IP laws to be supportive to its objectives, one of them being ABS. Even though, the exact role of IPRs in achieving these objectives still remains uncertain and possibly controversial, Ethiopia's progress in implementing the ABS framework required by the CBD provides some insight in to the place of IP.

This can, in particular, be evidenced from the references made to IP in the ABS Proclamation which makes it vivid that the support of the IP system in general and the patent system in particular is needed for its implementation. At this point in time, it is worth reiterating that according to the ABS Proclamation, seeking to acquire IP over GRs accessed and inventions made based on GRs is contingent upon the negotiation of a new agreement. In addition to this, any applicant for a patent or other IPR on products developed from accessed GRs is required to disclose the locality where the GR is accessed. So much so that, when these references are closely seen, incorporating DRs in the Proclamation on Inventions is important to make sure that it is supportive to the fulfillment of these rules in the ABS Proclamation.

Furthermore, when such a measure is seen in line with the recently adopted Nagoya Protocol on ABS, it can be considered as an appropriate and effective compliance measure to ensure the effective implementation of ABS Proclamation. Though, the Protocol does not say anything about the measures that can be taken by member states in this regard, DRs would be one of the measures to be taken by developing countries since they were fighting hard for its incorporation in the Protocol as a mandatory compliance measure to be adopted by member states. Hence, including DRs in the Proclamation on Inventions can be considered as one measure to be taken by the country in order to carry out the obligation imposed on it by this protocol.

Undeniably, one can counter argue based on the fact that the country does not have the required biotechnology and as a result of this it is difficult to imagine inventions made based on GRs and applications for IPRs made thereto. For instance, Ato Tamire, the Legal Officer in the EIPO does not see any significance in incorporating DRs in the Proclamation on Inventions for the reason mentioned above.⁵³² Instead, he underlines the importance of an International Regime for

⁵³² Discussions Held with Ato Tamire, The Legal Officer in the Ethiopian Intellectual property Office(EIPO), on 9 October 2010

effective use of DRs in order to track compliance with ABS requirements.⁵³³ I do not have any point of disagreement with the latter statement; even then, incorporating such a requirement in the Proclamation on Inventions has a paramount importance in showing that the country has a real commitment on its position expressed in the CBD COP on the relationship between TRIPs and the CBD which obviously has a bearing on DRs.

True, Ethiopia is not yet a member of the WTO and hence not formally bound by the TRIPs Agreement but the country has been active in uncovering the alleged adverse implications of Article 27.3(b) of the TRIPs Agreement in other foras.⁵³⁴ That is why, it has submitted an agenda item and a paper on the relationship between the TRIPs Agreement and the CBD with recommendations to the 4th meeting of the COP.⁵³⁵ It should not be unnoticed that Ethiopia was one of the pioneers from the members of the CBD to propose that the CBD examine the relationship between TRIPs and the CBD and of course DRs is one of the measures proposed to make the two instruments mutually supportive.

Therefore, it is within the bounds of reason to argue that the country needs to adopt DRs in its Proclamation on Inventions and harmonize the ABS and the patent system in order to support its effort in advocating the necessity of making the CBD and TRIPs mutually supportive. If the country remains reluctant in doing so, would it not be difficult to request other countries to require disclosure when patent applications are made on inventions made based on GRs accessed from Ethiopia as user measures. I believe, it is a wise move to incorporate DRs in the Proclamation on Inventions though it may not have a real effect in inventions to be applied in the country, in order to request other jurisdictions to ensure users compliance with the ABS Proclamation and the respective ABS agreements when an application for IP is made in their IP offices.

What is more, one can see the real significance of incorporating DRs when ABS agreements make the laws of Ethiopia as applicable laws in governing the agreement and in resolving disputes that would arise thereon. Technically speaking, the importance of including this requirement in the Proclamation on Inventions is evident when there is a term in the ABS

⁵³³ Ibid

⁵³⁴ Ibid

⁵³⁵ Nnadozie and Lettington, Supra Note 428 at 134

agreements which make the laws of the country the applicable laws. By the way, appreciably, this is what we can see in the Vernonia ABS agreement as will be discussed in its appropriate place. In this connection, Dr. Gemedo Dalle, emphatically states that until the controversies in relation to this issue at the international level will be settled, incorporating DRs in the Proclamation on Inventions can be considered as one magic bullet in ensuring compliance with ABS requirements.⁵³⁶ Though, undeniably, his office has done nothing in this regard.

Not only these, taking such a measure is crucial by its own as some national laws make the request of legitimate access by the applicant for IP dependent upon what has been provided in the state laws where the GR is accessed. For example, in Norway, patent applications require evidence of PIC if the state law of origin of the GR deems it necessary.⁵³⁷ All in all, for the good reasons mentioned above, incorporating DRs in the Proclamation on Inventions has its own significance in ensuring compliance with the ABS Proclamation.

Moreover, in the long run, when the time comes for the development of biotechnological inventions in the country, incorporating DRs in the Proclamation on Inventions would no more be contentious. The current biotechnological activities in Ethiopia are limited in scope and number as it requires a huge amount of capital; and the human and infrastructural capabilities are lacking.⁵³⁸ If biotechnology is used smartly, the country can benefit out of it as it along with other efforts such as changing the backward farming system, reducing land degradation etc can take the country one step forward in increasing production and productivity.⁵³⁹ There were efforts in the country to use biotechnology for improving the poor performance of agricultural sector using biotechnologies such as bio fertilizers though the country is not able to scale up such resource outputs partly due to lack of policy and strategy.⁵⁴⁰ Being cognizant of all these facts, the draft biotechnology policy prepared by the Ministry of Science and Technology has

⁵³⁶ Discussions held with Dr. Gemedo Dalle, Director, Genetic Resources Transfer and Regulation Directorate, Institute of Biodiversity Conservation, on 4 November 2010

⁵³⁷ Jess Nierenberg and Alejandro Garcia Alvarez (eds.), *Triggering the Synergies between Intellectual Property Rights and Biodiversity*, available at: [Http://www2.gtz.de.../search.aspx?...%20triggering%20the%20synergies%20between%20intellectual%20](http://www2.gtz.de.../search.aspx?...%20triggering%20the%20synergies%20between%20intellectual%20), accessed on 20 November 2010

⁵³⁸ Kidanemariam Jembere and Wondwossen Belete, *A Paper Prepared for Biotechnology and the Public Policy Training Course under the BIO-EARN Programme, 1999*, available at: [Http://www.bioearn.org/content/policies-and-strategies.htm](http://www.bioearn.org/content/policies-and-strategies.htm); accessed on September 20 2010

⁵³⁹ Ibid

⁵⁴⁰ Ibid

been sent to the Council of Ministers for deliberation and Ato Firew, the Legal Officer in the Ministry of Science and Technology, is optimistic that the policy will get the blessing of the Council in the near future.⁵⁴¹

This move in putting in place the biotechnology policy coupled with other activities such as the establishment of the National Agricultural Biotechnologies Research at Holleta Research Center show the fact that the country understands that it cannot afford ignoring biotechnology in this globalized world. Expectedly, this thesis does not delve in to the intricate issues that can be raised in relation to biotechnology; the purpose is to show that it will not be an unreasonable optimism to think that the EIPO will entertain patent applications made based on GRs when biotechnology develops in the country and the significance of enshrining DRs in the patent law will not be subject to argument; though it may not be in the near future.

At this juncture, it is worth noting that the ABS Proclamation encourages and even it makes it mandatory the conduct of research based on the GR accessed to be carried out in Ethiopia unless doing so is impossible.⁵⁴² As a corollary of this, therefore, when the necessary infrastructures are fulfilled for the conduct of a research based on GRs, applications of patents on inventions made based on accessed GRs will be a reality. And of course, it is appreciable to devise laws taking in to account future circumstances. This takes us to the discussions on how to incorporate DRs in the Proclamation on Inventions. Proposing the stands that should be taken by the country in incorporating DRs will be made with the simultaneous discussions on the experiences of some countries in DRs, albeit briefly. So much so that; opinions expressed are made based on the experiences of some selected countries.

⁵⁴¹ Discussions held with Ato Firew, the Legal officer in the Ministry of Science and Technology, on 10 November 2010

⁵⁴² See Article 12(6) of the ABS Proclamation

3.4.3. Options in Adopting Disclosure Requirements: Taking Lessons from the Experiences of Some Countries

Discussions in relation to the adoption of DRs without including further analysis of their binding nature, scope or consequences for lack of fulfillment could paint a false picture. Therefore, in this sub section, a modest attempt will be made to propose the specific positions that need to be taken in adopting DRs in the patent law. In doing so, I opine that it is important to have a brief overview of the national laws of some countries so much so that it would serve as an instructive example in outlining the options for the future development of this measure in the patent law.

Several countries and regions have applied DRs in relation to IPR applications for inventions derived from GRs.⁵⁴³ These national and regional experiences can be clustered as weak, medium and strong disclosure requirements. A disclosure requirement is considered weak if it is not obligatory and compliance does not affect the granting of patent. To the contrary, in case of strong disclosure requirements, the requirement is mandatory and non compliance affects the granting of patent. The middle one is that which puts the consequences of failure of non compliance outside the patent law. Therefore, failure to comply with does not entail the invalidation of the patent but it is considered as a violation of an obligation to provide correct information and it is punishable.⁵⁴⁴

From countries or regions that have adopted weak disclosure requirements, mention can be made to Egypt,⁵⁴⁵ European Union,⁵⁴⁶ Romania,⁵⁴⁷ Spain,⁵⁴⁸ and Sweden.⁵⁴⁹ In the middle are countries

⁵⁴³ United Nations University Institute of Advanced Studies, UNU-IAS Report: User Measures: Options for Developing Measures in User Countries to Implement the Access and Benefit-Sharing Provisions of the Convention on Biological Diversity (2nd ed., 2003), P.35

⁵⁴⁴ Ibid

⁵⁴⁵ Article 13 of the Egyptian Law No. 8 of 2002 on the Protection of Intellectual Property Rights states that: where an invention involves biological, plant or animal products or traditional medicine, agricultural, industrial or handicraft knowledge, cultural or environmental heritage, the inventor should have acquired the sources in a legitimate manner. See the full text available at:http://www.egypo.gov.eg/inner/English/laws_0html.

⁵⁴⁶ Weak disclosure was adopted by the European Union through the directive on the legal protection of biological inventions which states that if an invention is based on biological material of plant or animal origin or if it uses such material, the patent application should, where appropriate, include information on the geographical origin of such material, if known; whereas this is without prejudice to the processing of the patent application or the validity of rights arising from granted patents. See UNEP/CBD/WG-ABS/2/3/2003

⁵⁴⁷ Implementing Regulation of the Patent Law 64/1991, Rule 14, point1(c) states that: " when the state of the art includes GRs, they shall be clearly indicated in the description including their source, when known." See UNEP/CBD/WG-ABS/2/INF/4,2003

⁵⁴⁸ Spanish Patent Law allows for voluntary disclosure of origin of biological resources upon which an invention is based.

that have adopted medium disclosure requirements. In this category, countries like Denmark,⁵⁵⁰ Norway,⁵⁵¹ and New Zealand⁵⁵² can be included.

There are countries and regions which have adopted mandatory DRs in their national laws. The pioneer in this regard is the Andean community and DRs become an issue in international forums and national laws after its inclusion in the decision of the same and the idea quickly attracted proponents around the world.⁵⁵³ It is worth reiterating that the proposal to amend patent legislations arose to answer to the charge that misappropriation of GRs are permitted or even encouraged by this legislation. The remedy to this injustice is believed by proponents of mandatory DRs to lie partly in requiring patent applicants to disclose certain information about the GRs used in their invention.

The purpose of this kind of disclosure would be to help ensure that no patent was granted in cases where the invention was linked to GRs that had been improperly acquired or utilized. Accordingly, at the regional and national level, several jurisdictions have enacted legislation mandating or requiring disclosure. A case in point in this regard at the regional level is decision 391 of the Andean Community-Common Regime on Access to Genetic Resources- signed in 1996 which requires consent for the actual and potential uses of a resource and it also states that IPRs for GRs that were obtained without compliance with the decision shall not be recognized

⁵⁴⁹ Rule 5(a) of the Patent Regulation states that: "if an invention concerns biological material of plant or animal origin, or if it uses such material, the patent application shall include information on the geographical origin of such material, if known. If the origin is unknown, this shall be said. Lack of information on the geographical origin or the knowledge of the applicant regarding the origin is without prejudice to the processing of the patent application or the validity of rights arising from a granted patent. See Ibid

⁵⁵⁰ According to the Ministerial Regulation enacted based on the patent act, if an invention concerns or makes use of biological material of vegetable or animal origin, the patent application shall include information on the geographical origin of the material, if known. If the applicant does not know the geographic origin of the material, this shall be indicated in that application. Lack of information on the geographical origin of the material or on the ignorance hereon does not affect the assessment of the patent application or the validity of the rights resulting from the granted patent. See UNEP/CBD/WG-ABS2/INF/1,2003

⁵⁵¹ Paragraph 8(b) of the Norwegian Patent Act reads: "if an invention concerns or uses biological material, the inventor shall disclose in the patent application the country providing such material. If national legislation in the providing country requires PIC before providing such material, the application shall include information on whether such consent has been sought. In cases where the providing country is different from the country of origin of the biological material, the country of origin shall also be disclosed." And violations of the requirements to disclose information is punishable under paragraph 166 of the Penal Code. The requirement to disclose information does not affect the handling of a patent application or the validity of the patent. See UNEP/CBD/WG-ABS/2/3,2003

⁵⁵² Under the Patent Act of New Zealand, where an invention relates to an indigenous flora or fauna or products extracted therefrom, applicants are asked to provide an indication or evidence of PIC consent being given by a relevant Maori group. See UNEP/CBD/WG-ABS/2/INF4,2003

⁵⁵³ Alison L. Hoare and Richard G. Tarasofsky, Asking and Telling: Can Disclosure of Origin Requirements in Patent Applications Make a Difference? 10 *Journal of World Intellectual Property* 2, (2007), P.149

by member countries.⁵⁵⁴ Following this, Decision 486 was in adopted in 2000 which is considered as Common Regime on Intellectual Property.⁵⁵⁵

In particular, Article 26 of the Andean Community Decision 486 states that: application for patents shall be filed with the national competent authority and shall contain: a copy of the contract for access, if the products or processes for which a patent application is being filed were obtained or developed from GRs or byproducts originating in one of the member states.⁵⁵⁶ In the Andean community therefore patent applicants are required to disclose the access contract, PIC of indigenous and local communities and evidence that material was accessed in accordance with national, Andean community and international law. Moreover, the laws of Brazil,⁵⁵⁷ Costa Rica,⁵⁵⁸ India, Peru,⁵⁵⁹ China⁵⁶⁰, Panama⁵⁶¹ and South Africa⁵⁶² have incorporated more or less

⁵⁵⁴ Ibid

⁵⁵⁵ Ibid

⁵⁵⁶ Article 3 of Andean Community Decision 486 On the Biological and Genetic Heritage and Traditional Knowledge states that: "The Member Countries shall ensure that the protection granted to intellectual property elements shall be accorded while safeguarding and respecting their biological and genetic heritage, together with the traditional knowledge of their indigenous, African American, or local communities. As a result, the granting of patents on inventions that have been developed on the basis of material obtained from that heritage or that knowledge shall be subordinated to the acquisition of that material in accordance with international, Andean Community, and national law..." On the same vein, Article 26: "Applications for patents shall be filed with the competent national office and shall contain: "h) a copy of the contract for access, if the products or processes for which a patent application is being filed were obtained or developed from genetic resources or byproducts originating in one of the Member Countries; "i) if applicable, a copy of the document that certifies the license or authorization to use the traditional knowledge of indigenous, African American, or local communities in the Member Countries where the products or processes whose protection is being requested was obtained or developed on the basis of the knowledge originating in any one of the Member Countries, pursuant to the provisions of Decision 391 and its effective amendments and regulations;" available at: [Http://www.wipo.int/tk/en/documents/word/brazil-provisional-measures.doc](http://www.wipo.int/tk/en/documents/word/brazil-provisional-measures.doc)

⁵⁵⁷ In Brazil, a disclosure requirement is a condition of patentability and to this effect Article 31 of the Provisional Measure stipulates that: the grant of industrial property rights by the competent bodies for a process or product obtained using samples of components of the generic heritage is contingent upon the observance of the provisional measure, the applicant being obliged to specify the origin of the genetic material and the associated traditional knowledge as the case may be. The provisional measure regulates the Access to Genetic Resources, Protection and Access to Traditional Knowledge, Sharing of Benefits and Access to and Transfer of Technology for its conservation and use. See WIPO/GTRK/IC/5/9,2003

⁵⁵⁸ The 1998 Biodiversity Law of Costa Rica requires a certificate of origin to accompany applications for intellectual property rights pursuant to articles which refer to innovations involving elements of biodiversity. This law requires that the patent office must consult with the technical office of the commission responsible for managing biodiversity and provide a certificate of origin and PIC. Opposition from the technical office will prohibit registration of a patent. See UNEP/CBD/WG-ABS/2/3,2003

⁵⁵⁹ As a member of the Andean community, Peru is a signatory to the community decisions, under which patent applications are required to disclose the access contract and evidence of PIC for genetic resources. Peruvian Law No. 29811- a law introducing a protection regime for the collective knowledge of indigenous peoples derived from biological resources was published in 2002. On patents, the law states that: where a patent is applied in respect of goods or processes produced or developed on the basis of collective knowledge, the applicant shall be obliged to submit a copy of the license contract as PIC for the grant of the rights concerned. Failure to comply with this obligation shall be a cause of refusal or invalidation as the case may be of the patent concerned. See Ibid

similar mandatory disclosure requirements as a condition of patentability and revocability is envisaged for failure to disclose or false disclosure.

From all these, we can discern that different legislations contain DRs which are different in terms of their consequences. In most cases, the European laws that have introduced this requirement have referred only to the obligation to disclose origin and/or source and to prove the existence of PIC.⁵⁶³ However, these laws do not affect the existence of IP rights as such. On the other hand, in the laws of countries which are rich in GRs and which have considered enforcement of ABS laws as their policy priorities have included mandatory DRs.⁵⁶⁴

On the information that needs to be disclosed for the fulfillment of DRs, there are divergences among the IP laws of the abovementioned countries. As can be seen from the relevant laws of these countries, some of them such as the Andean community, Brazil and India have adopted a DR which requires the applicant to disclose information on source/origin, PIC and benefit sharing. On the other hand, the IP laws of European countries- Switzerland, Spain, and Sweden- do not introduce a DR for evidence of PIC and benefit sharing.

Categorically speaking, therefore, most of the countries which have adopted voluntary and intermediate DRs are developed countries; on the other hand, mandatory DRs are recognized in developing countries which are rich in GRs. What is more, though there are exceptions, most of the developing countries mentioned above have adopted a DR which require disclosure of origin/source, evidence of PIC and benefit sharing. Based on this, Ethiopia as a country rich in GRs need to follow the footsteps of developing countries by recognizing mandatory DR and a disclosure requirement which not only require disclosure of origin/source but also evidence of PIC and benefit sharing in its patent law. Not only this, applicants for patent do not have an incentive to comply with the requirement unless it has a teeth for its enforcement. The teeth in this case is making DRs conditions of patentability and the consequence of failure being revocation of the patent granted.

⁵⁶⁰ See Articles 5(2) and 26(5) of the Patent Law Amendment Act, 2008

⁵⁶¹ see Law No 20/2000, a Special IP Law for Rights of Industrial Property and Traditional Knowledge and Executive Decree 257/2006

⁵⁶² See the Patent Amendment Act 20/2005 and Section 82 of the 2004 Biodiversity Act.

⁵⁶³ Sarnoff, J., Compatibility with Existing International Property Agreements of Requirements for Patent Applications to Disclose the Origins of Genetic Resources and Traditional Knowledge and Evidence of Legal Access and Benefit Sharing. Available at: <http://www.piipa.org>; accessed on 23 October 2010

⁵⁶⁴ Ibid

At this point in time, what one can do is giving a general direction; and the details on the stand that should be taken by Ethiopia in adopting DRs in the Proclamation on Inventions should be guided by the objective it seeks to address; i.e., using the Proclamation on Inventions for the enforcement of ABS requirements. The details on how to incorporate DRs is an issue of its own which needs to take in to account the following:

1. What should be the nature of the requirement? Should it be mandatory or permissive?
2. What information should be divulged?
3. How should the relationship between the GR and the actual invention be determined?
4. What should the consequence be for non compliance?

Generally speaking, as Correa stated consideration of these issues in introducing DRs should be consistent with its purpose, taking care not to impose a disproportionate burden on applicants for patent and the institutions in charge of their applications.⁵⁶⁵

Before winding up the discussions under this sub section, it is important to quest whether incorporating DRs would be incompatible with the TRIPs Agreement. It is, of course, an appropriate concern that needs to be addressed as the country is in the process of accession to the WTO. As discussed in chapter two, in the WTO, the issue of DRs is being debated as part of the Doha Round of Trade Negotiations. Since the debate is under way, it is difficult to say for sure that adopting DRs in our Proclamation on Inventions is or is not compatible with the TRIPs Agreement. In fact, incorporating voluntary DRs which does not affect the handling of the patent application and the validity of the granted patent does not seem to contradict with the TRIPs agreement. This is not true in case of mandatory DRs which are proposed as conditions of patentability.

Therefore, if the country adopts a mandatory DR and faces a challenge in the process of its accession, the country should argue by reiterating the importance of the requirement in creating mutual supportiveness between the TRIPs and the CBD and for the effective realization of the ABS objectives enshrined both in the CBD and in its ABS Proclamation. If the debate on the issue in the TRIPs Council continues until its accession, such an argument can be raised to

⁵⁶⁵ Jorge Cabrera Medaglia, the Disclosure of Origin Requirements in Central America, ICTSD,2010. available at: [Http/www.ictsd.org](http://www.ictsd.org); accessed on 5 July 2010

defend its position. In addition to this, another more pragmatic reason can be forwarded as a justification for the adoption of mandatory DRs in the Proclamation on Inventions. These days, there are countries which have adopted mandatory DRs in their patent laws and which are at the same time members of the WTO. In this regard, mention can be made to India, China, Brazil, South Africa, Peru and Switzerland,⁵⁶⁶ to mention some. Therefore, it can be argued that Ethiopia has done something which other members of the WTO did.

3.5. The Plant Breeders' Right Proclamation and ABS: Introductory Remarks

In 2006, Ethiopia brought in to place IP protection for plant breeders under the legislation- Plant Breeders' Right Proclamation No 481/2006- PBRs Proclamation for short. This law has six parts and 35 Articles. Scrutiny on the structure and content of the legislation shows that it has modeled itself on the OAU Model Law for the Protection of the Rights of Local Communities, Farmers and Breeders and the Regulation of Access to Biological Resources.

The grounds of the introduction of plant breeders' right are indicated in the statement of purpose of the PBR Proclamation. Among others, the law maker was convinced that the new plant varieties developed through research would have a significant role for improving agricultural production and productivity; and development of new plant varieties requires considerable effort and investment.⁵⁶⁷ Being cognizant of these facts, the legislature concluded that the recognition and economic reward for those involved in the sector should be accorded IP protection with the belief that it is possible to achieve this by granting plant breeders' right. In fact, in the course of doing so, the legislature claimed to have full consideration of the need to protect the interest of the farming and a pastoral community of Ethiopia, whose interest often goes in variance with PBRs.

3.5.1. The Connections between ABS and PBR Laws

As a matter of fact, traditional varieties which have been conserved and preserved by farmers and local communities are the backbones for commercial breeding. And as a result of the introduction of IPRs in plant varieties, the misappropriation nature of commercial breeders utilizing traditional varieties may raise equity concerns which might perhaps have a discouraging

⁵⁶⁶ Supra Note 497

⁵⁶⁷ See the preamble of the PBRs Proclamation

effect on the future conservation efforts of these communities. Due to this, there appears to be a general understanding that farmers have to be rewarded for the use of these varieties by commercial breeders in the process of developing new varieties. In fact, this has been progressively advocated as 'farmers' rights' though its precise scope and content as well as the right course of achieving that remains as a problem.

The PBRs Proclamation provides for farmers' rights in recognition of their role in the conservation of their varieties. But, it does not mention on how they are supported and recognized for the role they play in conserving and developing crop genetic diversity and on how to ensure their rights to share benefits derived from their varieties. Therefore, in order to know about the further scope of farmers rights, regard may be had to the ABS Proclamation. Though the ABS Proclamation does not make a clear reference to farmers and their role within the local community structure, they can be recognized as a local community which is defined as human population living in a distinct geographical area in Ethiopia as a custodian of a given GR. Thus, farmers as a concerned local community in case of ABS made in relation to traditional varieties, they are entitled to the benefits that accrued to the state in the utilization of GRs.

The crux of the matter is that since farmers are the concerned local communities in case of ABS made in relation to traditional varieties, the PBRs Proclamation is considered as an appropriate check point in order to make sure that access to these resources by commercial breeders is made in compliance with the ABS Proclamation. This takes us to the task of scrutinizing whether DRs are adopted in the PBRs Proclamation to this effect.

3.5.2. Disclosure Requirement as a Precondition for Protection

The PBRs Proclamation stipulates that PBRs shall be granted if 'the breeder has a proof that he has obtained the genetic resource used to develop the variety in accordance with the relevant laws on access to genetic resources.⁵⁶⁸ What is pretty clear from the reading of this is that the PBRs Proclamation has attempted to create a connection with the relevant legislations on ABS. The correlation of the PBRs Proclamation with the ABS Proclamation is fully recognized starting from its inception and that is why the draft version of the law had been referred to the

⁵⁶⁸ Article 14(3) of the PBRs Proclamation

Institute.⁵⁶⁹ And the Institute was tasked to evaluate the congruence of this law with the ABS Proclamation.⁵⁷⁰ To this effect, it had evaluated the draft and made sure that the PBRs Proclamation is supportive to the objectives of the ABS Proclamation by proposing proof of lawful access as a precondition for the grant of plant breeder's right.⁵⁷¹ Interestingly enough, therefore, under this law, the applicant for PBRs is obligated to prove the fact that he/she/it has accessed GRs which are the subject of protection. Now let us probe in to the task of analyzing the relevant part of this law in line with the notorious issues that are raised in relation to DRs.

To begin with, this requirement is imposed on breeders as a condition for the grant of plant breeder right as can be discerned by reading the full text of Article 14 of the PBRs Proclamation. Article 14 of same deals with the eligibility requirements for the protection of plant varieties.⁵⁷² And proof of legal access is vibrantly mentioned as a precondition for the grant of plant breeders' right. So much so that, proof of lawful access to GRs is a mandatory requirement for the grant of PBRs. On the same vein, under the Malaysian PVP Act, applicants for plant breeder's right are required to include in their application an indication on the source of the genetic material or the immediate parental lines of the plant variety; accompanying their application with the PIC of the authority representing local communities where the plant variety is developed from traditional varieties and support their applications with documents relating to the compliance of any law regulating access to genetic or biological resources.⁵⁷³ Registration of new plant varieties and grant of breeder's right in Malaysia are subject to the fulfillment of the abovementioned conditions in addition to the conventional conditions of newness, uniformity and stability of the variety. And this puts the Ethiopian PBRs Proclamation in the same position with the Malaysian PVP Act since both laws make lawful access as a condition for the grant of a right.

⁵⁶⁹ 3/.. 1 1998 ./..
.....1998.....

⁵⁷⁰ Ibid

⁵⁷¹ Ibid

⁵⁷² It in particular states that the Ministry shall grant plant breeders' right if it is satisfied that the plant variety is new; there is no ground to refuse the grant of the right as provided in the proclamation; the breeder has proof that he obtained the GRs to develop the variety lawfully; a PBRs has not been granted to another person in same variety; there has not been earlier application which has not been withdrawn or rejected in respect of the new variety under consideration and all fees in relation to the grant of the PBRs have been made.

⁵⁷³ See Section 12(1)(e)(f)(g) of the Malaysian Plant variety Act No.634/2004

As contradistinguished with what has been provided hereinabove, the PVP Acts of India,⁵⁷⁴ Thailand,⁵⁷⁵ Indonesia⁵⁷⁶ and the Philippines⁵⁷⁷ do not make lawful access to GRs as a condition for the grant of plant breeder's right though both have adopted DR in their respective PVP Acts. From the relevant provisions of these PVP acts indicated in the footnote, one can understand that DR is not considered as a substantive condition for the grant of plant breeder's right; rather it is considered as a formality requirement.

The other important point worthy of consideration is the specific information which needs to be divulged in order to prove the fact that access was lawful. In this regard, one can construe that the breeder is required to prove that access is made based on the PIC of the Institute and with benefit sharing arrangement as these are the basic preconditions for access, to say the least. Is disclosure of source or origin a requirement under Article 14 of the PBRs Proclamation? Obviously, disclosure of origin or source is not a requirement for lawful access as it is a requirement which comes in to the scene when one applies for IP protection and therefore it is difficult to construe the provision to include disclosure of origin or source as a requirement for a grant of a right. Why the law maker failed to so? I suspect that the lawmaker did not include disclosure of origin or source as a requirement in this provision knowing full well that the ABS Proclamation requires applicants for IPRs on inventions made based on GRs to disclose the locality where the GR is accessed.

⁵⁷⁴ Section 18(1) of the Indian PVP Act states that every application for registration shall contain a complete passport data of the parental lines from which the variety has been derived along with the geographical location in India from where the genetic material has been taken and all such information in relation to the contribution, if any, of any farmer, village community, institution, or organization in breeding, evolution or developing the variety; and contain a declaration that the genetic material or parental material acquired for breeding, evolving or developing the variety has been lawfully acquired.

⁵⁷⁵ Section 19 of the Thai PVP Act prescribes that an application for the registration of a new plant variety shall include the following particulars: details showing the origin of the new plant variety or the genetic material used in the breeding of the variety or in the development of the new plant variety, including its breeding process, provided that the details enabling clear comprehension of such process shall also be included; a statement that the propagating material of the new plant variety in respect of which the application for registration has been filed and the genetic material used in the breeding or in the development of the new plant variety will be furnished to the competent official for the purpose of examination thereof within the time specified; and a profit sharing arrangement in the case where a general domestic plant variety or wild plant variety or any part thereof has been used in the breeding of the variety for a commercial purpose.

⁵⁷⁶ Pursuant to Article 11(2) of the Indonesian PVP Act, a letter of application for a right for PVP is required to contain the description of the variety including the origin or pedigree, morphological characters and other important characters.

⁵⁷⁷ In the Philippines PVP Act, the application must include exhibits of the detailed origin and breeding history of the variety, including the source of the germplasm and the results of other plant variety tests or trials that have already been done on the variety.

In this regard, all the above mentioned five countries have provided that information on the source or origin of the GR must be included in the application for PVP.⁵⁷⁸ Not only this, the Malaysian PVP act has provided that the application for PVP must be accompanied by PIC of the authority representing the concerned local community and the Thai PVP act has provided benefit sharing as an element of DR. By the way, the Thai PVP act is one of the few PVP acts including the Ethiopian PBRs Proclamation which provide for a DR which require evidence of benefit sharing arrangement. The act applies where genetic material from local plant varieties has been used in the breeding of new plant varieties for commercial purposes. And where a general domestic plant variety or a wild plant variety is to be used for a commercial purpose, the application for PVP requires that a profit sharing agreement is entered in to.⁵⁷⁹ To the contrary, Indian PVP act borders the obligation to mere declaration so that it would provide information for concerned stakeholders to desiring to claim and negotiate benefit sharing without guaranteeing that there shall be benefit sharing.

DRs to be successfully used as a measure to ensure that the parties involved or contributing to the development of a new variety have an opportunity to claim their share in the benefits reaped from the new plant variety and to show where the GR originates from a particular community, and to make sure that the concerned authority has consented to the access; it should be accompanied by disclosure of origin or source, PIC and benefit sharing arrangement.

This being so, to what the phrase 'relevant laws on access to genetic resources' refers to is not clear. This is because one can opine that it signifies access legislation of other countries as there is no qualification to limit it to the Ethiopian ABS Proclamation. If one follows this line of argument, this obligation applies on breeders though the GR used in the development of the variety has been accessed somewhere else out of Ethiopia.

This argument makes more sense when seen in line with Article 10(1) of the PBRs Proclamation which states that: "a breeder shall be entitled to a plant breeders' right in respect of his new plant variety, whether or not the breeder is an Ethiopian national or a foreigner, or is an Ethiopian resident or not and whether the variety has been bred locally or abroad." Hence, when the

⁵⁷⁸ Rajeswari Kanial, Plant Variety Protection in Indonesia, Malaysia, the Philippines and Thailand, 8 Journal of World Intellectual Property 3, (2005), P. 301

⁵⁷⁹ Ibid

persons entitled to plant breeders' rights in the proclamation are seen, one may surmise that the lawmaker has included the phrase 'relevant laws on access to GRs' in order to make the requirement applicable in case when the GR used in the development of the variety is accessed from another country. It should not be overlooked that such a measure is appreciated and even expected from members of the CBD as it requires parties to it to take user measures in order to facilitate the enforcement of ABS requirements.

However, this would be a rather an extraordinary tendency of unilateral commitment to protect the rights of another state by making the law as a possible check point and therefore it should be interpreted to imply the access legislations of Ethiopia. And in such cases, the applicant need not prove anything except a mere declaration to the effect that the GR used in the development of the variety has not been accessed in Ethiopia. A related issue is would the obligation be applicable when the GRs of Ethiopia have been accessed in accordance with a multilateral system established by the treaties to which the country is a party- a case in point in this regard is the ITPGRFA? Since there were not detailed rules on the procedures for multilateral system of access before the coming in to existence of the ABS regulation, the issue was a little bit hazy.

The above-mentioned regulation has devoted section three to deal with procedures for multilateral system of access and therefore in case of multilateral access to Ethiopian GRs and when it is used for the development of plant varieties, the applicant has the duty to proof that he has accessed the GRs in accordance with this regulation as it is included in the reference to relevant laws on access to GRs in the PBRs Proclamation.

As per this regulation, access to GRs in accordance with the multilateral system of access shall be granted if and only if the GR requested is the one listed in Annex I of the ITPGRFA; and the intended use is exclusively for the purpose of utilization and conservation for research, breeding and training for food and agriculture provided that such use does not include chemical, pharmaceutical and/ or other non food or feed industrial uses.⁵⁸⁰

Moreover, access is conditioned on the fact that the access applicant is a citizen of a country that is party to the ITPGRFA; and the GR used is found in the ex situ and in situ management and control of the Ethiopian government organs and the possessor has given its consent to the

⁵⁸⁰ See Article 14(1) of the ABS Regulation

conduct of multilateral system of access.⁵⁸¹ At any rate, the applicant for plant breeders rights who has made use of GRs in accordance with the multilateral access procure is required to prove the fact that access is made in compliance with the regulation which can be evidenced by presenting the material transfer agreement to the concerned authority mandated to grant plant breeder's right.

A related issue that can be raised at this juncture is: is this obligation imposed on breeders to prove lawful access applicable in case of GRs taken out of Ethiopia through different channels and preserved in the different ex situ collections which have been used in the development of plant varieties? In answering this question, regard may be had to the scope of application of the ABS Proclamation which claims sovereignty on both in situ and ex situ GRs and therefore the applicant should adduce the same proof as he does in case GRs accessed inside the country.⁵⁸²

On the kind of documentation or information needed to be submitted by the breeder to prove lawful access, the law lacks articulacy. Is it the ABS agreement and/or the access permit or another document required from the breeder? Since there is no specific requirement in this regard, it can be conjectured that the breeder is at liberty to prove lawful access using any document. Undoubtedly, however, the ABS agreement and/or access permit are the most important documents to prove lawful access.

What is more, the law does not seem to be clear on the consequences of failure to fulfill this requirement. Save for, one can opine that the PBR is susceptible to revocation as can be implied from the provisions of Article 22(1)(a) of the law which partly states that ...the Ministry shall revoke a plant breeders' right if... facts exist which, if known before the granting of the right, would have resulted in the refusal of the right. As stated elsewhere, lawful access is considered a requirement for the grant of PBRs and hence if the applicant fails to prove lawful access, the grant of the right will be rejected. As a corollary of this, if the right is granted without the fulfillment of this requirement, revocation will be the consequence.

These being so, a somehow associated issue that can be raised at this juncture is the compatibility or incompatibility of the requirement with the TRIPs Agreement. This is a question

⁵⁸¹ See Article 14(2)&(3) of the ABS Regulation

⁵⁸² Merso and Tamrat, Supra Note 491

that needs to be seen in line with the broader argument on the compatibility or otherwise of DRs with the TRIPs Agreement as painted in the preceding chapter. In any case, there appears to be a growing consensus for legitimizing DRs albeit divergence as to its effect. In their concerted effort to curb misappropriation and ensure benefit sharing, developing countries are demanding DRs to form part of patentability requirement. Developed countries- the EU in particular- seems to be pro to the inclusion of the requirement in the TRIPs Agreement but insisted that it should not constitute patentability criterion. Instead, EU demanded that legal consequences of failure to disclose, insufficient disclosure or wrong disclosure should lie outside patent law.

It goes without saying that, this trend will have important ramifications to PBR as well. In this stare, a researcher in the area states that given TRIPs silence on requirements of sui generis option, coupled with the growing emphasis on harmonization of TRIPs and the CBD, it is unlikely that making access requirement a precondition in PBR, which is weaker than patent, would be held incompatible with TRIPs.⁵⁸³ Moreover, it can be argued that the flexibility of the TRIPs in allowing member states to adopt sui generis laws for the protection of plant varieties gives an option for them to envisage DRs in such laws.

After appraising all these expositions in relation to Article 14 of the PBRs Proclamation, a reader may question what the real impact this requirement brought about in the process of implementation. Nearly five years have been counted since the adoption of the PBRs Proclamation; but then, there has never been an application made to the concerned office in the Ministry of Agriculture and Rural Development so far and the regulation for its implementation has not been enacted. As a result, it is difficult to assess the real impact of this requirement for the enforcement of ABS requirements as enshrined in the ABS Proclamation. In this regard, one may raise a host of issues on the reasons why this law has never been tested in practice. Though legitimate to raise issues in connection to this, it is not within the scope of this thesis to deal with this and it is an agenda of its own.

Even then, it can be said that the private sector has failed to engage in breeding perhaps because the investment requires a huge amount of capital or may be because it is not profitable. On the issue at hand, W/ro Misa Demissie and Ato Daniel Assefa- Variety Release and Registration

⁵⁸³ Sileshi, *Supra* Note 468 at 74

Experts in the Ministry of Agriculture and Rural Development are of the opinion that the law itself does not encourage the private sector as it is in favor of farmers and as a result of this it is under revision.⁵⁸⁴ For me, it is a little bit surprising and unusual to revise a law without testing it in practice and the reasons forwarded by these officials for doing so seem to be one sided and it sparks a fear that the law under revision will be pro the private sector. This is because from the discussions I had with them, the aim seems to enact a law which favors the private sector at the cost of farmers. In any case, incorporating DRs in the PBRs Law being one significant step in ensuring compliance with ABS requirements and making it supportive to the ABS Proclamation and the CBD; its real impact remains to be seen in the years to come.

⁵⁸⁴ Discussions held with W/ro Misa Demissie(Variety Release and Registration Expert) and Ato Daniel Assefa (Variety Release and Registration Performer) in the Ministry of Agriculture and Rural Development, on 12 November 2010

Chapter Four

Ethiopia's Experience in the ABS Agreements on Teff and Vernonia: the Role of IPRs for Implementation

4.1. Background of the ABS Agreements on Teff and Vernonia

Before the conclusion of the ABS agreement on Teff⁵⁸⁵ in 2005, there was a Memorandum of Understanding (MoU) signed between EARO (Ethiopian Agricultural Research Organization) now called the Ethiopian Institute for Agricultural Research (EIAR) from Ethiopia and the Larenstein University and Soil and Crop Improvement Co. (hereinafter referred to as the company) from the Netherlands in 2003.⁵⁸⁶ Among others, the MoU focuses on the registration and utilization of teff varieties, research on teff and establishment of teff fund.⁵⁸⁷

After a long protracted negotiation in 2005, a ten year ABS Agreement was concluded for the breeding and development of teff (*eragrostis teff*) between the Institute in Ethiopia and EARO and the small Netherlands based Soil and Crop Improvement Co.⁵⁸⁸

The other ABS agreement is made between the Institute and the Vernique Biotech Ltd on Vernonia.⁵⁸⁹ Vernonia (*Vernonia galamensis*) is a tall plant with shiny black seeds originated in Ethiopia which is identified by Robert E Perdue near the old city of Harar in Eastern Ethiopia.⁵⁹⁰ Vernonia is a semi arid plant which is suitable for dry land farming and requires

⁵⁸⁵ Teff which is originated and domesticated in Ethiopia is an important cereal crop and Ethiopia is the sole country that is the source of genetic diversity for teff. As contradistinguished with other grains such as wheat, barley and maize, teff has more food value and it is gluten free which makes it the best grain for the preparation of foods for gluten intolerant individuals. Gluten intolerance (celiac disease or gluten sensitivity) is a lifelong autoimmune disorder in which a person's body cannot tolerate a group of grain proteins known as gluten. Traditionally, teff grain is ground in to flour and fermented for the preparation of teff based foods, such as injera- a traditional gluten free pancake, teff bread and pudding (genfo). The traditional use of teff flour also includes the preparation of local alcoholic drinks-tella and katicalla. see Abeba Tadesse, Material Transfer Agreements on Teff and Vernonia-Ethiopian Plant Genetic Resources, 2 Journal of Politics and Law 4, (2009), available at: [Http://www.doaj.org/doaj?func=openurl&genere=journal&issn=19139047&volume=2&date=2009](http://www.doaj.org/doaj?func=openurl&genere=journal&issn=19139047&volume=2&date=2009); accessed on 17 November 2010

⁵⁸⁶ Gemedo Dalle, Access and Benefit Sharing Agreement on Teff(*Eragrostis Teff*) and its Implementation Challenges, 2010 (on file with the author)

⁵⁸⁷ Ibid. The objectives of the MoU were strengthening the position of Ethiopia as a leading producer of teff and teff based gluten free products in the international market and assisting research and production in relation to the project in Ethiopia. See Ibid

⁵⁸⁸ Sarah Laird and Rachel Waynberg, Access and Benefit Sharing in Practice: Trends in Partnership Across Sectors, A Study Commissioned by the CBD,(2008),P.64

⁵⁸⁹ Tadesse, Supra Note 585

⁵⁹⁰ Tesfaye Baye and Sileshi Gudeta, Pest Survey of Vernonia Galamensis in Ethiopia,(1996), P.219

drained soil and low rainfall.⁵⁹¹ The plant has unique properties which makes it interesting economically and ecologically.⁵⁹² The seed of Vernonia contains 42% of oil which in turn contains vernolic acid which is a useful input for the manufacturing of adhesive, varnishes, paints and coatings.⁵⁹³ Vernonia plant grows in most parts of Ethiopia and it is traditionally considered by local communities as indigenous weed.⁵⁹⁴ As a consequence, they tended to eradicate it in order to free their land for other crops.⁵⁹⁵ But now, it is considered as a potential crop to be included in the agricultural system of the country as a result of the increased awareness on its importance.⁵⁹⁶

4.2. Scope of Access and Benefit sharing under the Teff and Vernonia ABS Agreements

As per the Teff ABS Agreement, the company was entitled to access and use 20 teff varieties which are specified and annexed to the agreement.⁵⁹⁷ The purpose of the access by the company was to use the GR for the development of non- traditional food and beverage products which are listed in annex III of the agreement.⁵⁹⁸ The central focus of the company was to develop teff products for western markets in forms such as bread, sports bars and beer.⁵⁹⁹ That means, the company is not allowed to use teff for any other purposes such as chemical and pharmaceuticals under this agreement unless explicit written consent is given by the Institute to this effect.⁶⁰⁰

On the same vein, the company is not permitted to access TK of the Ethiopian communities on the conservation, cultivation and use of teff GR.⁶⁰¹ It was explicitly pointed out that the company shall not claim any rights over such TK nor make commercial benefits out of such TK unless

⁵⁹¹ Ibid

⁵⁹² Ibid. By the way, knowing full well the significance of this GR, in the 1970s, the United States Department of Agriculture carried out extensive research in to vernonia as a potentially important industrial crop for US farmers, as the oil is the potential source of plastic compounds currently made only from petrochemicals. And more than 50 US patent applications were filed; however, efforts were abandoned when the department of agriculture concluded that vernonia would not thrive in the US. see Secretariat of the CBD, Action for Biodiversity: Towards a Society in Harmony with Nature, available at: [Http://www.cbd.int](http://www.cbd.int); accessed on 25 November 2010

⁵⁹³ Tesfaye Baye, Genotypic and Phenotypic Variability in Vernonia Galamensis Collected from Eastern Ethiopia, 139 Journal of Agricultural Science 2, V.139, (2002), P.161

⁵⁹⁴ Ibid

⁵⁹⁵ Ibid

⁵⁹⁶ Ibid

⁵⁹⁷ See Annex I of the Teff ABS Agreement

⁵⁹⁸ See Annex III of the Teff ABS Agreement

⁵⁹⁹ See Article 4(3) of the Teff ABS Agreement

⁶⁰⁰ Ibid

⁶⁰¹ See Article 4(5) of the Teff ABS Agreement

written agreement to that effect is given by Institute. And the company is prohibited from transferring teff seed samples or any component of the teff GR to third parties without first obtaining explicit written consent from the Institute.⁶⁰² But then, the company is permitted to develop new varieties of teff in a manner suitable for its business.⁶⁰³

Besides these, the company has undertaken to share the following monetary and non monetary benefits arising out of the utilization of teff GRs:

- To pay 1% of the average gross net income of the years 2007-2009;
- Annually royalty of 30% of the net profit from sale of basic and certified seeds of Teff varieties specified in the agreement;
- To contribute 5% of its net profit to the Financial Resource Support for Teff (FiRST) that aimed at improving the living conditions of local farming communities and developing Teff business in Ethiopia. This contribution was agreed not to be less than 20,000 Euro per year;
- To share research results, knowledge or technologies with IBC and EARO, except when those are identified to be undisclosed information;
- To involve Ethiopian scientists in Teff research; and
- To establish profitable Teff businesses in Ethiopia (Teff farming, cleaning, milling enterprises, bakeries, etc) so that access to Teff genetic resources can be linked to improvement of local economy and poverty eradication.⁶⁰⁴

From this benefit sharing arrangement, we can discern that both monetary and non monetary benefits are included. From the monetary benefits, mention can be made to the upfront payment in lump sum, annual royalty, annual license fee, annual contribution to a fund to be used for the improving the living conditions of local communities for the development of teff business in Ethiopia. In addition to the monetary benefits, the company has promised to share its knowledge and technologies that may be generated using teff to Ethiopian communities. However, the company does not have such an obligation when either of this information to be shared constitutes undisclosed information.

⁶⁰² See Article 6(1) of the Teff ABS Agreement

⁶⁰³ See Article 5(1) of the Teff ABS Agreement

⁶⁰⁴ See Article 8 of the Teff ABS Agreement

Coming to the ABS Agreement on Vernonia, Vernique is allowed to access Vernonia seed to export and use for developing and commercializing the vernonia seed oil products specified and annexed in the agreement.⁶⁰⁵ If Vernique wants to use vernonia seed for other purposes and applications which are not stipulated in the list of 27 products, the company is required to get the written consent of the Institute.

As can be seen from the benefit sharing arrangement, Vernique agreed to pay upfront payment of Euro 35,000 up on signing the agreement as a monetary benefit.⁶⁰⁶ By stipulating such a mode of benefit sharing arrangement, the country can obtain a payment even when the company does not use the vernonia GR.; and compared with other modes of benefit sharing which are dependent upon the company's income from the exploitation of the resources, an upfront payment will help the country obtain something from the agreement. This would be even the case when the company does not produce anything using the GR and it does not affect the country's right to freely give access permit to other companies when the party holding access permit failed to utilize the accessed GR.⁶⁰⁷

In addition to this, Vernique has also agreed to share non monetary benefits. To this effect, it has agreed to source at least 75% of its annual demand for vernonia seed by producing it and/or by buying it from contract growers or local communities in Ethiopia.⁶⁰⁸ Such term in ABS agreements has the purpose of ensuring that local communities benefit from the agreement through job opportunities and developing the required skills to grow vernonia. Nonetheless, the company is free to produce vernonia seed outside Ethiopia if it is prevented to do so in Ethiopia due to force majeure.⁶⁰⁹ For the fulfillment of the other 25% vernonia requirement, it is stated that the company can produce vernonia seed in Zambia and Australia.⁶¹⁰ And as part of the non monetary benefits, Veronique has promised to train local communities.⁶¹¹ So much so that, the company shares its research results and technologies with the provider country provided that it does not affect the commercial advantage of the company.

⁶⁰⁵ The Annex lists 27 products and applications of vernonia seed, such as adhesive, cosmetics, pharmaceuticals, paper and wood products, lubricants, waxes, polishes and etc

⁶⁰⁶ See Section 7 of the Vernonia ABS Agreement

⁶⁰⁷ Tadesse, Supra Note 585

⁶⁰⁸ Dalle, Supra Note 586

⁶⁰⁹ Ibid

⁶¹⁰ Ibid

⁶¹¹ Ibid

4.3. IPR Related Provisions in the Teff and Vernonia ABS Agreements

In order to appraise the place given to IPRs and their supportiveness for the implementation of some of the obligations imposed on the user companies; it is worthwhile to discuss IPR related provisions incorporated in the agreements. Mention is made to IPRs in the Teff ABS Agreement as one mode of benefit sharing, which it is not the case in the Vernonia ABS agreement. To be more specific, since it is possible for countries to negotiate the possibility of joint ownership of IPRs as part of the non monetary benefits, the Ethiopian Government and the company agreed to jointly own teff varieties that will be developed by the user company.⁶¹² The relevant part of the agreement in this regard states that: "the plant variety protection rights over new teff varieties the company will develop shall be co owned by the company and EARO."⁶¹³ Such varieties shall be used by EARO and the company in such a way as not to damage the business interests of the company over the products listed in annex III or the interest of EARO or the provider."⁶¹⁴

From this one can recognize that the principle being making new varieties developed under the joint ownership of EARO and the company, use of such jointly owned varieties is expected not to affect the business interests of the company and of course the interest of EARO and the provider. Consequently, this can be considered as a limitation imposed on the parties in exercising their joint ownership right. In any case, the most important point to note is that joint ownership is included as one modality of benefit sharing which, as discussed in the preceding chapter, has its own role in the enforcement of ABS provisions enshrined in the agreement.

However, such a stipulation in the teff agreement does not have a counterpart in the Vernonia ABS Agreement. That means joint ownership of IPRs on inventions and products from the utilization of the vernolic oil are not included in the agreement as one mode of benefit sharing. This may be because there is no much research on vernonia in Ethiopia as compared with teff which is an important cereal at national level and EARO has doing research on teff GR which has developed many teff varieties.⁶¹⁵

⁶¹² See Article 5(2) of the Teff ABS Agreement

⁶¹³ Ibid

⁶¹⁴ Article 5(2) of the Teff ABS Agreement

⁶¹⁵ Tadesse, Supra Note 585

Besides this, in both agreements the companies are not allowed to obtain IPRs over the GRs (teff and vernonia) or over their parts. Such stipulations in the agreements are significant in clarifying what should or should not be done with the accessed GR which is vaguely stated in the ABS Proclamation. On this issue, the ABS Proclamation instead of making IPRs on accessed GRs more clear by stating that IPRs may not be claimed on the accessed GRs or parts thereof; it makes acquiring IPRs over same conditional upon the negotiation of a new agreement with the Institute. The language used in the proclamation seemingly implies that IPRs could be claimed on accessed GRs as they are or on their parts such as the isolated or purified genes from the GR.⁶¹⁶ Nonetheless, it is difficult to envisage that the law is allowing IPRs over the GRs as they are without their being any creative intervention by human beings.⁶¹⁷ Tribute to the terms of the ABS agreements which made it clear that the user companies are not allowed to claim IPRs over the GRs or their parts ; which in effect give a panacea to the problems which may be encountered due to the vagueness of the ABS proclamation in this regard.

Succinctly speaking, GRs and derivatives as defined in the ABS Proclamation cannot be a subject for IPR protection in both agreements. Even then, under the Teff ABS Agreement, the company is allowed to gain plant variety right for new varieties of teff and under the vernonia agreement, the company can obtain IPRs relating to inventions, products or applications developed from the utilization of vernonia oil.⁶¹⁸

What is more, in both agreements, the user companies are obliged to acknowledge in their relevant publications and applications for IPRs protection over varieties or products developed from these GRs that Ethiopia is the country of origin/source of teff and vernonia as the case may be. There is a difference between the two agreements on the use of the terms 'source' and 'origin'. In the Vernonia ABS Agreement, the term source is used while the Teff ABS Agreement uses the term origin. In fact, the Teff ABS Agreement imposes an obligation on the user company in cases when Ethiopia is not the source of the teff GR. That means, this obligation will be maintained when Ethiopia is not the provider of the GR and this makes clear the distinction between the two terms-source and origin. As discussed elsewhere, the two terms are believed to be different as source refers to the country which provides the GRs and origin refers to the

⁶¹⁶ Merso and Tamrat, Supra Note 491

⁶¹⁷ Ibid

⁶¹⁸ See Article 5(1) of the Teff ABS Agreement

country to which the GR is indigenous. But then, the Vernonia ABS Agreement does not use the term origin though vernonia is believed to be indigenous to Ethiopia. Therefore, it is good to be curious in the use of these terms in concluding ABS agreements.

On the same issue, a similar obligation is imposed on users of GRs in the ABS Proclamation but in the proclamation the obligation is to recognize the locality where the GR is accessed. However, as can easily be inferred, in the agreements under consideration, the obligation is to acknowledge Ethiopia as a source/origin of GRs as a country not to recognize a specific locality. Technically, the two are different with different ramifications. For me, in enshrining such a provision in the ABS Proclamation, the lawmaker had in mind the fact that there could be a community which has conserved the GR for long and which is entitled to share the benefits arising from the utilization of the GR.

Thus, obliging the user to recognize the specific locality has the effect of identifying the particular local community which has the right to share benefits. But, more often than not, it is difficult to identify a specific locality as a place where the GR is accessed when the particular GR is to be found in the different parts of the country. In such cases, Ethiopia as a country can be considered as source or origin and Ethiopian communities are considered as those entitled to share the benefits. This being the case, the ABS Proclamation lacks clarity in making such a distinction.

On the other hand, terms on the same issue in the ABS agreements seem to be realistic in the sense that it will be burdensome on users to require them to recognize a specific locality as the origin/source of the GR accessed as it is not always easy to identify a certain locality as such. In my view, one needs to consider the matter on case by cases basis before rushing to conclude that the terms in the ABS agreements violate what has been provided in the ABS Proclamation on the issue at hand. This is precisely because sometimes Ethiopia as a country may be considered as a country of origin/source if that GR is found in most parts of the country and identifying a specific locality would be almost impossible.

But then, the ABS Proclamation should have made it clearer by making a distinction between the situations which make recognition of the specific locality or the country as a source or origin of the GR under consideration appropriate.

At any rate, the interesting point to note is that both agreements have adopted disclosure of origin/source requirements as an obligation imposed on users. As it has been stated now and then, such requirements stipulated in ABS agreements are indispensable for ensuring compliance with ABS requirements using IPRs as a tool since disclosure of origin/source helps provider countries to track the commercialization of their GRs and compliance with ABS conditions.

Though not explicit, it is within the bounds of reason to opine that, a reference is made to IPRs in both agreements in relation to terms of the agreements on applicable laws. In both ABS agreements, there are laws which meant to govern and interpret the agreements. In this regard, the Teff ABS Agreement mentions the UPOV, and the CBD from international treaties and the relevant Ethiopian and Dutch laws as applicable laws.⁶¹⁹ In particular, Article 15(2) of the agreement, besides listing the relevant laws, states that the CBD shall prevail over the UPOV in case of disagreement between the two treaties. This term of the agreement gives prevalence to the treaty which governs access and benefit sharing if in case it contradicts with the UPOV which governs IPRs. Moreover, it gives a right to each party to use the relevant laws of Ethiopia or the Netherlands as it sees fit to enforce their rights in line with the agreement.⁶²⁰

Undeniably, this section of the agreement which deals with applicable laws raises a host of issues. To begin with, a researcher in the area expressed his concern on the issue at hand by stating that it is not clear why the provision of UPOV convention should at all be applicable to interpret the agreement while the country intentionally prefers not to be a member to the convention.⁶²¹ He goes on mentioning that such a stipulation may amount to an attempt to enforce an international treaty which has not been ratified by the lawmaking organ which has the authority to do so.⁶²² And true, such terms in ABS agreements raise constitutional law issues.

A related issue is that the reference to Ethiopian laws is too general and it is perplexing why the agreement fails to list down some relevant laws of Ethiopia. As a consequence, one will be compelled to ask what these relevant Ethiopian laws are. As to me, among others, Access and Benefit Sharing Laws, IPR Laws, and other basic laws important to interpret the ABS agreement such as Property and Contract laws can be considered as relevant laws.

⁶¹⁹ See Article 15(1) of the Teff ABS Agreement

⁶²⁰ See Article 15(3) of the Teff ABS Agreement

⁶²¹ Merso, Supra Note 43

⁶²² Ibid

Be that as it may, the agreement is vague and as a result complicates things by making a reference to both Ethiopian and Dutch laws as relevant laws and by giving the liberty to the parties to resort to the laws of either country which they deem is appropriate to enforce their rights. As a result of this term in the agreement, there would inevitably be a situation where one party considers Ethiopian law as a relevant law and the other party considers Dutch law as relevant law which raises the issue of conflict of laws.

At this juncture, one may quest whether there could be another option in framing provisions of ABS agreements which deal with applicable laws. Without going too far, what has been provided in the Vernonia ABS Agreement on the issue at hand is far better than what has been stipulated in the Teff ABS Agreement as discussed above. Interestingly enough, Section 13 of the Vernonia ABS Agreement which deals with governing laws states that this agreement shall be interpreted in accordance with and governed **in all respects by the laws of Ethiopia** (Emphasis added). It goes on stating that where applicable, by international treaties to which Ethiopia is a party, and in particular the CBD and any other international law emanating from it. This agreement is far more better than its counterpart partly because it does make UPOV and other international treaties to which Ethiopia is not a party applicable laws and partly because it makes Ethiopian laws as applicable laws in all circumstances and it is not left to the parties to chose a relevant law unlike what has been provided in the teff ABS agreement.

Even then this agreement shares the blame with the teff agreement as it does not specifically mention the relevant Ethiopian laws to govern and interpret the agreement. But then, similar interpretation given to the term on the teff agreement in this regard can be applied to this term of the vernonia agreement. So much so that, one can include in the reference to relevant law, inter alia, access and benefit sharing, IPR, property and contract laws.

The crux of the matter in this regard is that IPR laws being one of the relevant laws, they can be used as an important instrument for the enforcement of provisions of the ABS agreements if they are designed with a view to have such an effect. For instance, some have reservations on the importance of incorporating DRs in the Proclamation on Inventions as things stand now since there have never been applications for patent for inventions which are made using GRs and they are pessimistic about the development of biotechnology in the country. Though difficult to close eyes to the truism in this regard, incorporating DRs in the Proclamation on Inventions will be

indispensable in cases when there are terms in ABS agreements which make Ethiopian laws relevant to govern the agreement. In other words, even when the patent is granted outside Ethiopia and if a controversy arises in relation to the granted patent, the issue will be resolved as per the Proclamation on Inventions of Ethiopia.

In sum, it is worthwhile to note that IPR related provisions stipulated in the ABS agreements and the ABS Proclamation indicate the place given to IPR Laws for the realization of ABS objectives though they are not magic bullets by their own. In this respect, one may reiterate IPR related provisions which deal with joint ownership, which require negotiation of a new agreement with the institute before the grant of IPRs, disclosure of origin/source and the like. As a consequence, support of the relevant IPRs laws is needed for the enforcement of these obligations and for changing the ABS objectives in to a reality in general.

Even then, the questions one will be compelled to ask at this juncture are: are IPR related provisions in the ABS agreements and the ABS proclamation complied with by the user company in securing IPRs on teff varieties and the processing of teff flour? Were the relevant European IP laws supportive in this regard? These issues are addressed below, albeit briefly.

4.4. IPRs over Teff Varieties and the Processing of Teff Flour

The purpose of this sub section is not to probe in to the discussions of all issues surrounding the IPRs granted to Health and Performance Food International over the three teff varieties and the processing of teff flour. The forthcoming discussions are made with a view to show the extent to which IPR laws are supportive in enforcing the obligations imposed on the user company in the agreement and the terms of the ABS agreement breached in the process. Discussions of this sort are relevant in showing the real impacts of IPRs on the implementation of ABS requirements in practice.

To begin with, on 21 April 2008, STICHING (foundation) SCEAR has been granted a Community Plant Variety Right for three teff varieties which are denominated as ADINA, AYANA and TESFAYA by the European Plant Variety Office.⁶²³ The names of the teff varieties are taken from Ethiopian maiden names having the following meaning: AYANA:

⁶²³ European Union Plant Variety Office, Application for Community Plant Variety Right to the Community Plant Variety Office on AYANA Teff variety, CPVO File No. 2004/2698,(2004) (on file with the author)

beautiful flower; TESFAYA: my future; and ADINA: saves people.⁶²⁴ The Community Plant Variety Office in its decision (decision No EU22115) acknowledges the grant of the rights to SCEAR, which is considered as the holder of the right.⁶²⁵ In fact, originally, the application for Community Plant Variety Rights for these varieties was submitted by Soil and Crop Improvement Co. and EARO.⁶²⁶ This application filed on 8 December 2004 is the continuation of the prior application made in June/2004. In the application filed on December 2004, the applicant is SCEAR, an organization set up to be the legal owner of the teff varieties.⁶²⁷ In this organization, based in Assen, the Netherlands, both soil and crop Improvement Co. as the Dutch counterpart and EARO as a representative of Ethiopian government participate.⁶²⁸

The most puzzling fact is that the organization- SCEAR- has never been mentioned in the ABS Agreement made on 05 April 2005; and the application is made before the conclusion of the agreement. What is the mystery? As stated somewhere else, the company had a memorandum understanding with EARO and it has accessed the GR before formally concluding the Teff ABS Agreement with the Institute. I opine that the company has not concluded the ABS Agreement with a real motive to be governed by the relevant ABS laws. As mention has already been made, the truth is that the company misusing the MoU it signed with the EARO, applied for IPR protection for products developed form teff in order to gain sufficient returns on its research investment in to improvements and potential uses of teff.

As a result of this, in March, 2004, the Wageningen University science magazine reported that a Canadian non-profit organization has charged the soil and crop improvement company with biopiracy as a result of its act of unilateral application for patent.⁶²⁹ Mr. Hans Turkensteen, Financial Director of the company, explained in this report that the unilateral measure his company took for the patent application was right because negotiations with the Ethiopian government authorities were taking much longer.⁶³⁰

⁶²⁴ Ibid

⁶²⁵ Ibid

⁶²⁶ Ibid

⁶²⁷ Ibid

⁶²⁸ European Union Community Plant Variety Office, Application for Community Plant Variety Right to the Community Plant Variety Office on TESFAYA Teff Variety, CPVO File No.2004/2697,(2004) (on file with the author)

⁶²⁹ Dalle, Supra Not 586

⁶³⁰ Ibid

But then, this cannot be a justification as there is no provision in the MoU that gives the company the mandate of unilaterally applying for patent. In the same report, it was mentioned that the Dutch focal point on ABS for the CBD had asked the company to proceed carefully with the sharing of advantages of potential patents with Ethiopia which the company did not want to accept and implement.⁶³¹

So much so that, the hard fact worthy of reiterating is that the company did not come to the negotiation table in good faith. Rather, the company's motive was to pretend that it has concluded ABS Agreement with the Ethiopian government with a view to avert all these pressures and to pave the way for its planned actions. This is true when one considers all these facts coupled with the fact that the company has already the necessary access from EARO and gene banks around the world.⁶³²

Be that as it may, all these facts cannot be taken as a justification for encroaching the Teff ABS Agreement signed on 5 April 2005 with the Institute. Therefore, the following discussions are designed to see to it whether the IPRs granted are in line with the agreement and the role played by EU IPR laws in facilitating compliance with ABS requirements.

As it has been explained in the preceding sub section, one of the provisions of the Teff ABS Agreement which deals with IPRs is Article 5.2 which stipulates that all teff varieties developed by the company are required to be co owned by the company and EARO. The question that comes is: are the teff varieties developed by the company co owned with EARO? As far as my scrutiny of the three applications for the three teff varieties goes on, I have not seen any mention to the EARO as a joint owner of the teff varieties developed except that EARO is mentioned as a participant in the foundation to hold the plant variety rights. This foundation is established with the unilateral action of the company whose objective is not as such clear. Therefore, mentioning EARO as one participant in the foundation is not the right thing to do to ensure joint ownership of the varieties developed as it is not made as per the spirit of the agreement.

This being what we can discern from these documents, Dr.Gemedo told us that in the email communication the Institute had with the officials of the company, they have made it clear that

⁶³¹ Ibid

⁶³² Ibid

the teff varieties have been registered in the name of the Financial Resource Support for Teff - FiRST for short, which even is not made as per the agreement.⁶³³ I think all these show the fact that the company does not have the little motivation to comply with the terms of the agreement.

The other obligation imposed on the company in relation to IPR application is the obligation to recognize Ethiopia as origin of the teff GR; even irrespective the source from which the company has acquired the GR. In this regard, the company has disclosed Ethiopia as the origin of the teff varieties in all the three applications. In particular, it has mentioned the vicinity of Mekelle as origin of the TESFAYA and ADINA teff varieties and Addis Ababa as origin of the AYANA teff variety.⁶³⁴ Interestingly enough, in the applications, the company has mentioned EARO as a provider of the varieties which are used as an input for the development of the three varieties on which a request has been submitted for protection.⁶³⁵ In fact, as per the Teff ABS Agreement, the provider of the teff GR is the Institute; not EARO.

But then, the part of the application which deals with the geographical origin of the varieties, it has been stated that the varieties for the applications for protection has been selected from a landrace in the North East of the Netherlands in an experiment field trial of research and breeding to select for lines, of the original short day and at high altitudes grown teff, adapted to long day growing conditions of North Western Europe; which is considered as the geographic origin of the varieties.⁶³⁶ This is an attempt made to make a distinction between origin of the varieties themselves and origin of the varieties used as an input for their development.

In any case, this fact of mentioning Ethiopia as origin of the three teff varieties developed by the company coupled with mentioning EARO as a provider will help the country to request the benefit it deserved to get pursuant to the agreement and it is also important to enforce any claim the country has against the company. From all these, one can discern that there are some acts made by the company which are contrary to the Teff ABS Agreement in the process of securing a plant variety right for the three denominated varieties.

⁶³³ Dalle, Supra Note 536

⁶³⁴ European Union Community Plant Variety Office, Application for Community Plant Variety Right to the Community Plant Variety Office on ADINA Teff Variety, CPVO File No. 2004/2699,(2004) (on file with the author)

⁶³⁵ Ibid

⁶³⁶ Ibid

Besides these, the company did not attempt to negotiate an agreement with the Institute when it sought a plant variety protection for the abovementioned three varieties developed as requested by the ABS Proclamation. Surprisingly, the company let alone negotiating with the Institute, it has not made a response to all the official requests of the Institute on problems in relation to the implementation of the agreement.⁶³⁷

Be that as it may, it is quite important to give the full picture to readers in order to help them pass a judgment on the supportiveness of relevant EU IP laws for the enforcement of the obligations imposed on the company. To this effect, let us see the relevant provisions of the EC Regulation on Community Plant Variety Rights.

Article 6 of the EC Regulation No.2100/94 on Community Plant Variety Rights states that community plant variety rights shall be granted for varieties that are distinct;⁶³⁸ uniform;⁶³⁹ stable⁶⁴⁰, new and the variety must be designated by a denomination.⁶⁴¹ Moreover, Article 50 of the Regulation seems to foresee a disclosure requirement which requires the applicant for a Community Plant Variety Rights to state the geographical origin of the variety. However, this disclosure is limited to the variety and does not cover the parent material from which the new variety was developed. Therefore one can say that DR in the sense discussed so far in the thesis is mentioned nowhere as a user country measure in order to ensure compliance with ABS requirements. Of course, without their being a law which requires the company to do so, in the application documents, Mekelle and Addis Ababa are mentioned as origin of the parent material

⁶³⁷ Dalle, Supra Note 536

⁶³⁸ A variety shall be deemed to be distinct if it is clearly distinguishable by reference to the expression of the characteristics that results from a particular genotype combination of genotypes, from any other variety whose existence is a matter of common knowledge on the date of application. A variety shall in particular be deemed to a matter of common knowledge if on the date of application, it was the object of a plant variety right or entered in to an official register of plant varieties, in the community or any state or in any intergovernmental organization with relevant competence; and an application for the granting of a plant variety in its respect or for its entering in such an official register was filed.

⁶³⁹ A variety shall be deemed to uniform if, subject to the variation that may be expected from the particular features of its propagation, it is sufficiently uniform in the expression of those characteristics which are included in the examination for distinctness, as well as any other used for the variety description. See Article 7 of the EC Council Regulation No 2100/94 on Community Plant Variety Rights, EC Regulation hereinafter

⁶⁴⁰ A variety is considered stable if the expressions of the characteristics which are included in the examination for distinctness as well as any others used for the variety description remain unchanged after repeated propagation or in the case of a particular cycle of propagation, at the end of each cycle. See Article 8 of the EC Regulation

⁶⁴¹ A variety is new if, at the date of application, variety constituents or harvested material of the variety have not been sold or otherwise disposed of to others, by or with the consent of the breeder for purposes of exploitation of the variety: earlier than one year before the date of application within the territory of the community; or earlier than four years outside the territory of the community. See Article 9 of the EC Regulation

from which the three teff varieties were developed. As mention has already been made, this by itself is important for any possible measure the country would take in relation to the plant variety rights granted contrary to the ABS agreement.

Though hard to pass a judgment in this regard, one can at least say that had DR been included in the Regulation on Community Plant Variety Rights, it would have contributed in preventing the use of GRs without PIC and benefit sharing arrangement for the enforcement of IPR related obligations imposed on the company. This is in particular true when seen alongside with the fact that the applications for these rights were made before the conclusion of the ABS agreement. Admittedly, however, it is difficult to attribute all the problems encountered in the implementation of the agreement to the absence of DRs in the regulation mentioned above.

The other IPR granted by the European Patent Office to the company is a patent on the processing of teff flour in 2007.⁶⁴² The invention relates to the flour of teff and products comprising this flour. It in particular relates to flour of teff which can well be processed in to inter alia gluten free food products and to methods for preparing these food products.⁶⁴³ By the way, it has already been known for many years that gluten in the food coming from flour of wheat, barley, oat and spelt, which covers the large portion of the typical western diet, is not suitable for a large number of people who are patients of gluten intolerance or celiac disease.⁶⁴⁴ And there is no medicine for gluten intolerance; the only way for celiac disease patients being to prevent or treat symptoms by following strict gluten free diet.⁶⁴⁵

Teff crop which has been cultivated for human consumption mainly in Ethiopia and Eritrea for more than 5,000 years, is considered as one of the sources for a naturally gluten free products.⁶⁴⁶ Teff flour is traditionally used for preparing injera, a spongelike, gray pan cake with somewhat

⁶⁴² European Patent Office, a Patent on the Processing of Teff Flour, European Patent Specification, EP 1646287B1, 2004, available at: [Http://www.freepatentonline.com/EP1646287.html](http://www.freepatentonline.com/EP1646287.html); accessed on 16 November 2010

⁶⁴³ Ibid

⁶⁴⁴ Celiac disease is caused by hypersensitivity to gluten. When a celiac disease patient eats or drinks something which has been prepared from or with one or more gluten containing types of grain or has been in contact therewith, the mucous membrane of the small intestine will be affected. A healthy small intestine has a large number of intestinal villi on the inside which together form an enormous surface for food intake. The intestinal villi of celiac disease patients cannot tolerate gluten. As a result of an immune response initiated by gluten, the intestinal villi are affected.

⁶⁴⁵ Ibid

⁶⁴⁶ Ibid

sourish taste as mentioned in the description part of the invention.⁶⁴⁷ It is usually made from a flour mixture consisting of equal parts of teff flour and wheat flour diluted with water and yeast.⁶⁴⁸ Then after, the diluted flour mixture is usually fermented for three to four days before it is baked. In any case, though teff is believed to offer an attractive source of gluten free flour, it has been found that the preparation of a food product with traditional teff flour, for instance, teff flour which is mixed with wheat flour for preparing injera, often causes problems.⁶⁴⁹ As a result of such traditional way of processing teff flour, one of the problems identified by the company is the instability of baked products and an unattractive taste and/ or structure of products.

The essence of the invention is, therefore, to provide the insight that the abovementioned problems do not occur if teff flour with a particular falling number is used. To this effect, the invention provides for teff flour characterized in that the flour comprises grain whose falling number at the moment of grinding is at least 250, preferably at least 300, more preferably at least 340, most preferably at least 380.⁶⁵⁰ A great advantage of flour with such a falling number resides in the fact that it can, virtually without any problem, be processed in to a stable, gluten free product with an attractive taste and structure. In this connection, the invention demonstrates that the traditional teff flour which is obtained by grinding the grain after harvest causes a problem with the processing thereof and it has low falling number to be processed in to an attractive product.⁶⁵¹

Moreover, it is generally known that grain goes through an after ripening process after harvesting, in which the falling number increases preferably, a flour according to the invention is obtained by storing the harvested grain in kernel and/or having it after ripen for some time and

⁶⁴⁷ Seifu K., Studies on Lodging, Floral Biology and Breeding Techniques in Teff, PhD Thesis, University of London, UK,(1983), P.67

⁶⁴⁸ Ibid

⁶⁴⁹ Supra Note 636

⁶⁵⁰ Technically speaking, the falling number of a grain is usually determined according to the Hagberg method. This method gives a measure for the activity of the enzyme alpha amylase. This enzyme degrades starch to sugar. The falling number obtained relates to the amount of undigested sugars in the starch. The higher the falling number then, the lower the alpha amylase activity in the grain and the fewer digested sugars are present in the grain. In the Hyber analysis method, usually, exactly, 7 grams of starch with a moisture content of 14% are brought in to a tube with 25 ml of water. After vigorous shaking, an agitator is brought in to the tube and the whole is placed in a boiling water bath. After this, the agitator is moved up and down 55 times, then to be released in the highest position. Due to its own weight, the agitator falls down through the firm mixture and the duration thereof, measured with the aid of a second counter, determines the falling number. see Supra Note 190

⁶⁵¹ Ibid

only grinding the grain after the falling number has reached a value of at least 250.⁶⁵² As a solution, the invention provides flour of teff grain with the grain having been ground at least 4, preferably at least 5 and more preferably at least 8 weeks after harvesting. Such a period is sufficient to obtain grain which has after ripened sufficiently and has a falling number which meets the abovementioned conditions.⁶⁵³

Of course, for making a gluten free product adequate precaution needs to be taken in the process of harvesting, drying, transport, storage, grinding, mixing and packaging in order to prevent any mixture of teff grain with non gluten free grain and/ flour.⁶⁵⁴ To this effect, it is preferable to use equipments and materials which do not come in to contact with gluten containing crops. Furthermore, in order to be able to store⁶⁵⁵ grain so as to be free from decay, the grain preferably has a moisture content of at most 12 %. It is therefore advisable to dry the teff for a few days before storage.⁶⁵⁶

The invention further provides the insight that traditional teff flour does not only have a low or too high falling numbers to be processed in to a good baking product, but that, in addition, is not ground fine enough.⁶⁵⁷ The truth being the finer the flour, the better the flour can be baked. Flour according to the invention is preferably ground so fine that an essential part of the flour can pass through a sieve with a pore size of at most 100 microns, preferably at most 120 microns, more preferably at most 100 microns.⁶⁵⁸ Therefore, the grinding of teff grain to flour according to the invention can be carried out according to the standard procedure for the preparation of flour to get fine flour suitable for processing in to a baking product.⁶⁵⁹

⁶⁵² United States Patent Application Publication, Publication No. US 2006/0286240A1, 2006, available at: [Http://www.freepatentonline.com/y2006/0286240.html](http://www.freepatentonline.com/y2006/0286240.html); accessed on 10 November 2010

⁶⁵³ Ibid

⁶⁵⁴ Ibid

⁶⁵⁵ The teff grain is preferably stored in a closed storage room free from vermin. During after ripening of teff grain in cold areas, the falling number goes from an average of 230 immediately after harvesting to 260 after four to five weeks to 330 two to three months after harvesting. See Ibid

⁶⁵⁶ Ibid

⁶⁵⁷ Ibid

⁶⁵⁸ So that minimally 70 % of the teff flour according to the invention passes a sieve with a pore size of 100 microns. Such fine flour has been found to be particularly suitable for processing in to a baking product. without wishing to be bound by theory, it is conceivable that the good baking qualities of such finely ground teff flour are related to the fact that due to the fine grinding, a relatively large surface is available for the absorption of water or a different liquid used for the preparation of a dough. See Ibid

⁶⁵⁹ Ibid

This being so, as regards to the embodiment of the invention, it is preferable if at least two batches of different lots of teff with different falling number are mixed and ground to obtain a flour with falling number in an optimal range, for example with a falling number of at least 380-390 for preparing a backed product in accordance with the market standard.⁶⁶⁰ Furthermore, flour according to the invention may consist of a mixture of teff flour with flour of a different gluten free crop or grain, such as potato, rice, corn, arrowroot, buckwheat, or quinoa.⁶⁶¹

What is more, the invention also provides a method for baking a product comprising the steps of preparing a dough⁶⁶² or batter⁶⁶³ by mixing flour according to the invention with a liquid; kneading this dough in a desired shape and heating this dough for some time.⁶⁶⁴ And based on the invention described above, the patent has 29 claims granted to the proprietor. The prime aim of this author being evaluating whether this patent granted to the company is in line with the teff ABS agreement; it is difficult to give a blind eye and a deaf ear to the issues that can be raised in relation to patentability requirements.

As can be extrapolated from Articles 52 to 57 and 83 of the EPC (European Patent Convention), the basic requirements for patentability are: there must be an invention; the invention must be susceptible of industrial application; the invention must be new; the invention must involve an inventive step and the invention must be disclosed. To be more specific, an invention is considered new if it does not form part of the prior art and Article 54(2) of the EPC goes on to define "state of the art" as everything made available to the public, whether written, oral, in use, or any other way before the date of filing of the European patent application.

Under the EPC, European patents shall be granted for inventions which, inter alia, involve an inventive step and the central provision- Article 56 of the EPC-provides that an invention having regard to the state of the art must not be obvious to a person skilled in the art. In order to assess

⁶⁶⁰ The grain is preferably mixed such that it comprises different after ripening stages, while, with material which has after ripened for a long time, some addition of material which has after ripened for a short time results in a better baking quality. Flour according to the invention can be obtained by grinding a mixture of grains with different falling numbers.

⁶⁶¹ The mixture can be obtained by grinding a grain mixture or by mixing flours of different, already ground grains or crops.

⁶⁶² It is a kneaded mixture of flour and a liquid, such as water, milk, beer or olive oil, optionally other ingredient such as eggs and salt.

⁶⁶³ It is a mixture of flour and liquid.

⁶⁶⁴ Supra Note 642

and decide whether an invention involves an inventive step, the problem solution approach has been predominantly applied. This approach consists in: identifying the closest prior art; determining the objective technical problem (determining in view of the closest prior art, the technical problem which the claimed invention addresses and successfully solves); and examining whether or not the claimed solution to the objective technical problem is obvious for the skilled person in view of the state of the art in general.

In addition to this, an invention is considered as susceptible of industrial application if it can be made or used in any kind of industry, including agriculture. The last but not the least basic requirement of patentability is disclosure. Article 83 of the EPC relates to the disclosure of the invention which prescribes that a European patent application must disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art. In order to meet the requirement of this article, a European patent applicant must therefore contain sufficient information to allow a person skilled in the art, using his common general knowledge, to perceive the technical teaching inherent in the claimed invention and to put it in to effect accordingly.

In other words, the disclosure of the invention must be reducible without undue burden. That means, the invention as claimed should be disclosed in such a way that the technical problem or problems with which it deals can be appreciated and the solution can be understood. And the applicant has to mention any background art of which the applicant is aware and which can be regarded as useful for understanding the invention and its relationship with the prior art.⁶⁶⁵

As I have made it clear at the very outset, it is not the agenda of the thesis to exhaustively evaluate the fulfillment or the non fulfillment of the above-mentioned patentability requirements in the patent granted to the company under consideration. Even then, let us illustrate the requirements of novelty and disclosure in line with the patent granted on the processing of teff flour and the products thereto in order to spark a light for further research in the area.

Is the requirement of novelty fulfilled in the patent under consideration? In the application, the company claimed high falling number (better flour quality) grain stored for longer time than

⁶⁶⁵ Abeba Tadesse, In Favour of the CBD: Patent or Breeder's Right? Network Seminar of IPR Researchers, Finland, 2010

recently harvested as a new invention. This, in my opinion, is not a new idea for this is an idea our mothers well know and mention the qualities of such grain for making injera and the traditional teff consumers accordingly prefer the teff grain stored for long time and they pay a higher price for it. It is a common knowledge for us that Teff grain is mostly consumed after being stored for several months and only a rare case that it could be used immediately after harvest. For every good reason, I believe that this traditional knowledge which has already been gained by Ethiopian communities due to their long experience with the crop was totally ignored in the patent application. Surprisingly enough, the company wrongly stated the fact that consuming teff immediately after harvest was usual among Ethiopian traditional communities. In so doing, isn't the company claiming over TK of the Ethiopian community?

As incidental it may be, the company in its patent application has misinformed the other world in stating that injera is usually made from a flour mixture of equal parts of teff and wheat flour. Is that the case? As far as I know, the common and best quality injera known to most Ethiopian communities is the one made from pure teff flour and wheat in particular is mixed with teff very rarely. Of course, mixing teff flour with the flour of sorghum, millet, maize, barley and recently rice is fairly common.

This being as it may, in the email exchange I had with Demissew Sertse- a researcher in the area, informed me that results of recent experiment determination of falling numbers of 19 Ethiopian teff varieties indicated that the falling number records claimed by the company are attributable to the inherent genetic quality of the genetic resource. Consequently, falling numbers for flour passed through 132 micron sieve ranged from 223 for a variety names D2-01-99 to remarkably above 400 for four varieties. This fact speaks for itself that the above claimed falling numbers most likely are attributable to the inherent genetic quality of the resource; not the creative intervention of the employees of the company.

If one subscribes to this technical explanation, he/she ends up by concluding that the company has claimed and secured an IP right over the teff GR of Ethiopia which is in fact prohibited from doing so in the teff ABS agreement as GR belongs to the state and local communities who have preserved and maneuvered the crop for millennia. Therefore, the company appears to be illegitimately claimed the genetic qualities of the crop or any quality products attributable to the

inherent potential of the crop and the TK of the Ethiopian communities; which in fact goes beyond the non fulfillment of the conventional novelty requirement.

Apart from these, when disclosure requirement is illustrated with the patent on the processing of teff flour, in the application mention has been made to the fact that the Ethiopian way of processing teff grain immediately after harvest, the absence of a time gap to gain appropriate level of dryness and the unattractiveness of the baked products as a result of these as a technical problem. As a technical solution to this problem, the invention identified the appropriate level of dryness of the grain before processing the products and methods of the invention make it possible to provide food products with an eating value acceptable in the western world which can be used as functional food.

In this regard, the question needs to be asked is: is teff grain processed immediately after harvest in the traditional way of processing teff flour? Absolutely not; as mention has already been made, usually teff grain is not processed immediately after harvest and it can be stored for longer periods of time. And as regards to better level of dryness, the traditional method may have the same result as the invention. Is it not therefore a wrong disclosure of technical problem of the prior art in the application?

Coming to the heart of the matter, there are some of the terms of the agreement which are violated by the company in the process of securing a patent right on the processing of teff flour. To begin with, according to the agreement, the company is supposed to acknowledge Ethiopia as the origin of the crop in all its publications and applications for IPRs. Instead, it mentioned other nations as teff growers which seems an attempt to distance teff from Ethiopia.

Apart from this, the company should have submitted its proposal to the Institute to avoid confusion between its finding and the TK of the Ethiopian communities. Rather, it tried to make a deliberate confusion by discrediting the most commonly known TK and the experiences of the Ethiopian communities in its application; and it has got IP right on this already existing knowledge. What is more, in the part of the application which exemplifies composition after ripening and baking behavior of flour mixtures, it has listed 21 teff varieties though according to the agreement, it was allowed to access 20 varieties. So, where did the company bring the extra one variety?

As a final remark, one can say that disclosure requirements enshrined in IP laws which oblige applicants to provide information on the origin/source, evidence of PIC and benefit sharing are important to ensure compliance with ABS requirements. This is in fact true when IP laws are designed to be supportive for the enforcement of obligations imposed on users in ABS agreements for the realization of ABS objectives. When the EU IP laws are seen in line with this, one would get Directive 98/44/EC on Biotechnological Inventions. Under this legislation, disclosure by the patent applicant is encouraged, but it is not mandatory.

In particular, the preamble states that: " whereas if an invention is based on biological materials of plant or animal origin or if it uses such material, the patent application should, where appropriate, include information on the geographical origin of such material, if known, whereas this is without prejudice to the processing of patent application or the validity of rights arising from granted patents."⁶⁶⁶ From this, one can discern that the requirement is purely voluntary. Other than the inclusion of this voluntary disclosure of origin requirement in this directive, neither the European Patent Convention nor the Plant Variety Protection has adopted disclosure requirement. And this lack of integrating disclosure requirement in these IP laws, I think, has contributed its own for the breach of IPR related terms in the Teff ABS Agreement by the company. The European community is a member of the CBD and it is bound by the mandatory ABS requirements and it is expected to take measures for the enforcement of these requirements. But, as can be witnessed from what happened in the Teff ABS Agreement, the EC did nothing in this regard.

Most important of all, the action the Ethiopian government will take with regard to the IP rights granted to the company in violation of the ABS agreement remains to be seen. Requesting revocation of the rights granted to the company using the EPC itself or the laws of the member states can be contemplated as one measure.

⁶⁶⁶ See Recital 27 of the EC Directive

4.5. Implementation Challenges Beyond Access: Final Remarks and Lessons to be Learned

From the analysis made in the preceding sub sections of this chapter, one can draw some conclusions and pin down lessons to be learnt for future action to be taken in concluding ABS agreements. To begin with, the relationship between ABS and IPRs is evident in the Teff and Vernonia ABS agreements. This is because the Health and Food International Company has used the IP system to get the proprietary protection for the inventions made based on Teff GR. In addition to this, Vernique has applied a patent on an invention which relates to the use of epixodized compounds such as oils, esters and waxes which are made based on the vernolic acid.⁶⁶⁷ The application is pending at the European Patent Office and in Japan.⁶⁶⁸ However, the IP system in the EU did not support the Teff ABS Agreement in particular and the ABS Proclamation and the CBD in general. Hence, there is a strong cause to exert every effort at national and international level to create positive synergies between the ABS and IPR systems.

Additionally, Ethiopia's experience has proved that it is difficult to ensure compliance with ABS agreements once the GR accessed crossed border. True, no country may legitimately control any person's actions under the jurisdiction of another country. Due to its trans- national nature, at least two countries are involved in every ABS transaction: a source country from which the GRs are obtained and a user country which has a jurisdiction over the user.⁶⁶⁹ As a corollary of this, the ABS objective is made nearly impossible by the lack of user measures;⁶⁷⁰ one of which could be DRs. Until user country measures are adopted, ensuring the fulfillment of ABS conditions cannot ultimately be effective.

Hence, an international regime which requires states to take user country measures in general and DRs in particular is exceedingly important in order to enable the source country to assert its

⁶⁶⁷ Dross, M. and F. Wolff, *New Elements of the International Regime on Access and Benefit Sharing of Genetic Resources – the Role of Certificates of Origin*, (2005), P.56.

⁶⁶⁸ Ibid

⁶⁶⁹ Hirsch, L., *Provider and User Country Measures – Do Two Wrongs Ever Make a Right?* Paper presented at the International Expert Workshop on Access to Genetic Resources and Benefit Sharing, (2005), P.34.

⁶⁷⁰ Bin Osman, M., *Issues of Bioprospecting and Implementation of ABS Legislation at National and Regional Levels*, Paper presented at the International Expert Workshop on Access to Genetic Resources and Benefit Sharing, (2005), P.56

sovereign rights over GRs in the place in which those rights are infringed.⁶⁷¹ Ethiopia's experience shows that the unfilled gap in the current ABS regime is much more serious. If countries remain reluctant in adopting user measures by requiring users of GRs in their jurisdictions to comply with source country ABS requirements, provisions incorporated in ABS agreements remain frail. This is because if such measures are lacking, users are not directly bound by the ABS regime except when they are in direct contact with the source country.⁶⁷² This omission creates a large loophole in ABS essentially freeing all users in jurisdiction out of the source country from any legal obligation of ABS compliance.

In this regard, the Nagoya Protocol adopted recently at COP 10 can be considered as one positive step since it requires member states to take appropriate and effective measures to ensure compliance with ABS conditions by users of GRs in their jurisdictions. The problem is that it does not specifically mention what measures could be taken and countries are at liberty to choose a measure which they deem is appropriate and effective. The good thing is if implementation challenges remain as a problem after the effectiveness of the protocol, it will pave the way for developing countries to demand mandatory disclosure requirements as a compliance measure to be adopted by member states.

From all these, there are some lessons to be learned. First, since it is practically difficult to monitor compliance with ABS conditions, it is a wise move to require users to conduct the research on the GR accessed in Ethiopia. Exporting GRs should be the exception and be allowed when conducting the research in Ethiopia is impossible. Second, before rushing to conclude ABS Agreements, it is good to pore over the background of the access applicant as compliance most of the times is dependent upon the sympathy of the user.

Third, concluding an ABS agreement is not an end by itself for the realization of ABS objectives and therefore to the extent possible it is extremely important to follow up the user as to its progress in relation to the utilization of the accessed GRs. Sometimes, if information relevant to take an action is known lately, it would be a bar for any possible measure that would have been taken. For example, the EPC gives nine months for any interested party to object a patent

⁶⁷¹ UNU-IAS, User Measures – Options for Developing Measures in User Countries to Implement the Access and Benefit-Sharing Provisions of the Convention on Biological Diversity,(2003), P.145

⁶⁷² Ibid

granted. There was no any objection made to the patent granted to Health and Performance International on the processing of Teff flour in this time gap perhaps because the concerned authorities do not have this information.

Fourth, to the extent possible every effort should be made to engage the government of the country to which the access applicant is a citizen. In other words, an attempt should be made to operationalize the condition stipulated by the ABS Proclamation on foreign applicants to present a letter from the competent national authority of his national state or that of his domicile assuring that it shall uphold and enforce the access applicant.

Conclusions and the Way Forward

Genetic Resources provide a huge wealth of resources for the development of biotechnology as a basis of innovation. In particular, the advances made in biotechnology by developed countries enabled them to exploit GRs mainly accessed from the developing south to build up new products of commercial value. More often than not, these products developed from the utilization of GRs are protected through IPRs which in turn gave them an economic value with commercial benefits accruing to the industries in developed countries but with no benefits shared with developing countries which have conserved such resources for millennia. This inequity is exacerbated by the fact that developed countries, who have misappropriated GRs as they were freely accessible before the CBD era, required users in developing countries to purchase the secondary products which are subjected to intellectual property protection.

As a result of this situation, voices have been expressed by developing countries on the need to regulate access and benefit sharing at the international level; and they have succeeded in bringing this topic to the attention of global political decision makers in 1992 when the CBD was adopted.⁶⁷³ Consequently, the sharing of fair and equitable benefits arising out of the utilization of GRs is included as one objective in this convention. Following the adoption of the CBD, many developing countries have put in place their own regulatory framework for the realization of fair and equitable benefit sharing from the utilization of GRs.

However, even after putting in place ABS regulatory framework, they have recognized the limitation of national ABS legislations in guaranteeing minimum levels of control and the realization of fair and equitable distribution of benefits.⁶⁷⁴ The truth remains that countries, on their own and ABS laws as a standalone legal regime are unable to verify the destination of their GRs once these resources leave their jurisdictions. Besides this, they are not able to verify compliance with clauses or obligations established in ABS agreements and unable to monitor how these resources are being used during the different stages of R & D process.⁶⁷⁵ Therefore, they cannot

⁶⁷³ Couchena R.M., Ruiz Muller M, Vicas D and S Winkler, Disclosure Requirements: Ensuring Mutual Supportiveness between the WTO TRIPs and the CBD, 2005, IUCN and ICTSD

⁶⁷⁴ Ibid

⁶⁷⁵ Ibid

guarantee that benefits generated are distributed in a fair and equitable manner. Of course, this inability is partly the result of the physical and informational nature of GRs.

The limitations of the standalone ABS legislation coupled with the fact that products developed from misappropriated GRs are protected by IPRs, the idea of creating synergies between ABS and IPR legal regimes comes in to the scene. In this context, the IPR regimes- Patent and Plant Breeders' Right in particular- are believed to offer an important measure to verify compliance with ABS conditions. IPRs can also serve to determine and trigger the sharing of benefits and identify advances in the R&D process. To operationalize this idea of creating positive synergies between the two legal regimes, the incorporation of disclosure requirements in IP laws has been proposed as a measure for such link to happen.

Since then, the incorporation of disclosure requirements in IPR applications to achieve the synergistic relationships between ABS and IPRs have been a bone of contention in international foras and national law making processes. At the international level, much of the debate in this regard has been played out in the CBD and WTO.

In the CBD, disclosure of origin is encouraged by the Bonn Guidelines as a mechanism to track compliance with ABS requirements. Apart from this, with a view to put in place an internationally agreed mechanism in order to monitor the utilization of GRs even when they are transferred to user countries, the World Summit on Sustainable Development held in Johannesburg, South Africa, 2002, gave the ABS topic in general and disclosure requirements in particular, a boost when political leaders requested the negotiation of an international regime on ABS to safeguard the implementation of the CBD.⁶⁷⁶ Unfortunately, however, after several rounds of protracted negotiations, COP 10 recently held in Japan has adopted a protocol without incorporating disclosure requirements as a compliance measure.

In the WTO, discussions on the incorporation of disclosure requirements in the TRIPs agreement have taken place and it is under way. The TRIPs agreement guarantees patent protection for microorganisms as well as non biological and microbiological processes. As a result, it encourages research institutions and producers in the biotechnology sector to undertake

⁶⁷⁶ Brendan T, Cunningham D and K Watanbe, The Feasibility, Practicality and Cost of Certificate of Origin for Genetic Resources, 2004, available at: [Http://www.ias.unu.edu.biparies2/abswg-03-inf-05-en-revised%202.pdf](http://www.ias.unu.edu.biparies2/abswg-03-inf-05-en-revised%202.pdf); accessed on October 12 2010.

bioprospecting for research and new product development.⁶⁷⁷ However, it does not require disclosure of origin/ source of GRs used in the invention and proof of PIC from providers of GRs and benefit sharing arrangement thereof. Thus, CBD non conform patents are granted; and developing countries have started raising concerns on the misappropriation of GRs through the patent system.⁶⁷⁸ This compelled them to make strong calls to reform the TRIPs agreement in making mandatory disclosure requirement as part of WTO rules and align it better with ABS objectives of the CBD.⁶⁷⁹ They argue that such a requirement would be necessary to ensure that the TRIPs agreement did not undermine the objectives of the CBD. This in turn, raises the discussions on the relationships between the TRIPs agreement and the CBD in the TRIPs Council.

In any case, during the last decade, discussions on the relationship between the TRIPs agreement and the CBD have taken place in the WTO. At the center of this discussions has been the question of how to develop an inbuilt mechanism as part of the patent application system to reduce/avoid further misappropriation of GRs.⁶⁸⁰ While many WTO members recognize the need to create synergies between the TRIPs agreement and the CBD, incorporating a requirement to disclose the origin/source of the GRs used in an invention and evidence of PIC and benefit sharing in patent applications in dealing with the implementation of CBD objectives is still controversial. The main positions expressed by members on the proposal to amend the TRIPs agreement are:

1. Japan and the US are against to any amendment to the TRIP agreement to require patent applications to include disclosure of origin of GRs alongside with evidence of PIC and benefit sharing.⁶⁸¹ This is because they believe that there is no relationship between access and benefit sharing regimes and IPRs as each system has a purpose of its own.

⁶⁷⁷ Ibid

⁶⁷⁸ Abbott F, Post Mortem for the Geneva Mini Ministerial: Where Does TRIPs go from Here? Information Note No 7, ITSCD, available at: [Http://www.itscd.org/i/publications/16949/](http://www.itscd.org/i/publications/16949/); accessed on 24 October 2010

⁶⁷⁹ Cabrera Medaglia, the Relationship between the International Regime, the World Trade Organization, the World Intellectual Property Organization and the Convention for the Protection of New Varieties of Plants, Document Prepared for the CBD Secretariat,2009, available at: [Http://www.biodiv.org](http://www.biodiv.org); accessed on 14 September 2010

⁶⁸⁰ Ibid

⁶⁸¹ Ibid

2. Almost all developing countries, Norway and the EU have supported the proposed disclosure requirement.⁶⁸² But Norway and the EU differ with the others in that Norway does not agree in sanctioning patent applicants who fail to meet disclosure requirements within the patent system, for example by revoking the patent.⁶⁸³ The EU, on its part, is in favour of negotiating this proposal outside the WTO and preferably in the WIPO.⁶⁸⁴ At any rate, they all believe that there is a certain level of overlap in the subject matter of both agreements since the material subject to access under the CBD and the material used in a particular invention subject to a potential patent are GRs. Therefore, there is a need to take an international measure so as to avoid cases where the GRs being used in inventions without respecting national access laws.

Given that the TRIPs agreement is broadly recognized as the most important international instrument on intellectual property which establishes a set of minimum principles which all WTO members are required to implement and having a relatively effective enforcement mechanism, it is logical to think that modifying the instrument in order to include the disclosure requirements will facilitate coherence with the CBD and will have a significant role in ensuring compliance with ABS requirements.

In any case, the issue of disclosure requirements has been raised in the different TRIPs Council Meetings since 2001- the time when it has got the mandate by the Doha Declaration- which launched the current round of trade negotiations. The declaration adopted in 2005 at the Ministerial Summit in Hong Kong provides that note be taken of the work carried out by the TRIPs Council in accordance with the Doha Declaration and agreed that work will continue based on paragraph 39 of the declaration.⁶⁸⁵ After this, at the mini-ministerial conference held in 2008, not much changed. The issue was also raised at the several TRIPs Council Meetings in

⁶⁸² Brendan T, Burton G, and J.C. Fernandez Ugalde, certificates of Clarity and Confusion? the Search for a Practical, Feasible and Cost Effective System for Ensuring Compliance with PIC and MAT, 2008, UNI-AIS, available at: [Http://www.ias.unu.edu/sub_page.aspx?catID=7&ddID=682](http://www.ias.unu.edu/sub_page.aspx?catID=7&ddID=682)

⁶⁸³ Ibid

⁶⁸⁴ Ibid

⁶⁸⁵ Young T, An Analysis of Claims of Unauthorized Access and Misappropriation of Genetic Resources and Associated Traditional Knowledge, 2006, UNEP/CBD/WG-ABS/4/INF/6, SCBD.

2009 and 2010 with similar results.⁶⁸⁶ In essence, countries reiterated known positions on the issue of disclosure requirements and the future of the issue remains to be seen.

Although discussions on the introduction of disclosure requirements in the different international foras with a view to create positive synergies between ABS and IPR systems have never achieved consensus, many countries have attempted to incorporate disclosure requirements in the areas of patent and plant breeders' rights laws to ensure that the rules regarding ABS are effective. In this regard, the reader is advised to refer to chapter three of the thesis since the laws of some countries in this regard are pointed out in an attempt to look the issue in a comparative perspective.

Since the prime aim of this thesis is to discuss the synergetic relationships between the legal regimes governing ABS and IPRs (the Proclamation on Inventions and PBRs Proclamation in particular), a modest attempt is made to evaluate this relationships in the third chapter. Summarily speaking, Ethiopia has put in place ABS regulatory regime on ABS following the basic principles of the CBD and it has also enacted IPR laws in order to encourage innovation by rewarding inventors. As it has been stated time and again, if IPRs are designed with a view to have positive synergies with ABS laws, they could play an important role towards the achievement of ABS objectives.

The synergy between ABS and IPRs could be viewed from different angles with the aim of using IPR laws as a tool for the achievement of ABS objectives. As can be inferred from the body part of the thesis, the author has made a modest attempt to show the relationship between the ABS Proclamation on one side and the Proclamation on Inventions and PBRs Proclamation on the other. In fact, an effort is also exerted to extrapolate how the Teff and Vernonia ABS agreements have tried to create a link with the IP system to get its support for the enforcement of some of the obligations enshrined within them.

To begin with, when seen from this perspective, the ABS Proclamation has made IPR claims on accessed GRs conditional upon the negotiation of a new agreement with the Institute. Actually, the law could have made it more clear by prohibiting IPRs such as patents on the accessed GRs. Making negotiation of a new agreement a condition for acquisition of IPRs on the accessed GRs

⁶⁸⁶ Ibid

raises some questions: does it mean that there is a possibility to allow patent on GRs? If not, what is the rationale for putting such a condition?

In my opinion, such vagueness should not take us to the conclusion that the law has envisaged the possibility of allowing patent on life forms. This is precisely because the law has relied and modeled on the African Model Law, which has unequivocally banned patents on life forms and processes. Though it is worth pondering why the law maker has preferred to use such a prescription, in the discussions held on the draft version of the proclamation, the consensus as between the participants was to make all life forms and processes non patentable. Even then, I never dare to say that the proclamation does not have a problem in providing the rules on what should and should not be done with the accessed GRs.

Besides this, the ABS Proclamation expressly demands the access permit holder to disclose the locality where the GR is accessed as origin. Such a disclosure requirement of origin aims at identifying the geographical origin of the resource. Since the disclosure requirement does not extend to the other elements of disclosure requirement- providing proof of PIC of the providers and benefit sharing arrangement- it is not helpful in verifying compliance with ABS requirements.

Undoubtedly, incorporating disclosure of origin in the ABS Proclamation is one step forward in creating linkages between ABS and IPRs. Nonetheless, the proclamation has some deficiencies which in turn will be stumbling blocks for the full realization of the objectives desired to be achieved by enshrining disclosure requirements. Firstly, as indicated above, the disclosure of origin requirements in the proclamation does not contain the other two elements of disclosure requirements. Secondly, the ABS Proclamation requires recognition the locality where the GRs were accessed. The truth is that it is not always possible to identify a certain locality as origin of a particular GR. That is why, both the Teff and Vernonia ABS Agreements required the respective companies to disclose Ethiopia as a country of origin in the former and as a country of source in the latter. Thirdly, the ABS Proclamation does not tell us what the consequence of non compliance should be. For instance, does it entail the revocation of the patent granted? If it is before the grant of the right, is it a condition of patentability or for the grant of plant breeder right?

This being so, implementation of disclosure of origin requirements as stipulated in the ABS Proclamation is almost impossible without integrating it with the rules of the relevant IPR laws- the Proclamation on Inventions and PBRs Proclamation. Here comes the importance of positive synergies between ABS and IPRs legal regimes. At this juncture, it should be noted that the whole thinking of ABS has been built on the supposition that GRs would be accessed and commercialized where IPRs could play an important role towards its achievement. Does it hold true for the Patent and Plant Breeders' Right Legal Regimes?

The Proclamation on Inventions is not supportive to the objectives of the ABS Proclamation. This is because the law as it stands now, patent may be granted for an invention made based on GRs even when the access to such GR is in violation of the ABS Proclamation and the Regulation thereon. Simply put, disclosure requirements as an important measure to ensure compliance with ABS conditions are not incorporated in the Proclamation on Inventions. Not only this, the Proclamation on Inventions may be sued as an instrument for the misappropriation of GRs as it does not exclude all life forms and processes from patentability. The proclamation excludes only plant and animal varieties and essentially biological processes for the production of plants and animals from patentability. That means, plants other than plant varieties (the term plant is broader than plant varieties), microorganisms and microbiological processes could be patentable so long as they qualify as 'invention' and fulfill the requirements of patentability pursuant to the proclamation. Truly speaking, it is the most puzzling aspect of the law as it seems to provide more extensive patent protection on life forms than the TRIPs agreement requires. And it does not live up to the expectations of the African Model Law which clearly excludes all life forms and processes from patentability.

Coming to the PBRs Proclamation, interestingly enough, it has made lawful access of GRs used as an input in the process of developing a variety as a condition for the grant of the rights of plant breeders. That is to mean, proof of the fact that GRs were accessed after the fulfillment of ABS conditions- PIC and benefit sharing- as required by the ABS proclamation is a precondition for the grant of the right. For me, this is a glimpse of hope for the development of the jurisprudence in creating positive synergies between ABS and IPR Legal Regimes in Ethiopia. However, from a technical point of view, the law is not sufficiently clear on the following points:

1. On the kinds of information or documentation that should be submitted; for example, is mere declaration of information sufficient to comply with the requirement or should the application be accompanied by a declaration from the applicant or some form of documented evidence to prove compliance with ABS laws, such as copy of the ABS agreement, the access permit and/or another authorizing document.
2. How should the relationship between the GR and the actual plant variety be determined? For example, do they form part of the material for which the right is requested; have they been used in the process of developing the variety; have they been used to facilitate the development of the material to be protected; do they constitute the necessary antecedent for that material?
3. What should be the consequence for non compliance? Should these involve the suspension of application processing; revocation or annulment of rights when the submitted information is insufficient or false?

But then, it is worth reiterating that the PBRs Proclamation is supportive to the ABS objectives of the ABS Proclamation as it can be used as a checking point in order to ensure that the GR used as a raw material for the development of a variety is accessed after fulfilling the conditions stipulated in the ABS Proclamation with all its deficiencies.

These being so, the Teff and Vernonia ABS Agreements concluded so far have included terms on IPRs. Most of these terms are stated in a manner to impose an obligation on user companies. And admittedly, the effective enforcement of these IPR related obligations imposed on users is dependent up on the supportiveness of IP laws in the jurisdiction where the rights are claimed.

In any case, both ABS agreements have made it clear that IPRs may not be claimed on the GRs (teff and vernonia) or any components thereof. Nonetheless, IPRs can be claimed over teff varieties in the case of the Teff ABS Agreement and on inventions made based on the vernonia GRs in case of the Vernonia ABS Agreement. Compared with the ABS Proclamation, the terms in these agreements are pretty clear in providing what should be or should not be subjected to IPR protection.

Apart from this, in both agreements, disclosure of origin (in the Teff ABS Agreement) and source (in the Vernonia ABS Agreement) in all publications and applications for IPRs is one of

the obligations imposed on the user companies. Unlike the ABS Proclamation which requires disclosure of a specific locality, both agreements require acknowledgement or recognition of Ethiopia as origin.

What is more, in the Teff ABS Agreement, joint ownership of teff varieties to be developed by the company is enshrined as one mode of benefit sharing which allows the country to share in the benefits that arise out of the use of teff GR. This is not the case in the Vernonia ABS Agreement as the company has retained IP rights over products to be developed based on Vernonia. Even though not explicitly stated, the reference to IPRs can be implied from the terms of the agreements which deal with applicable laws to govern the agreements and settle disputes that would arise between the parties.

Despite the existence of these terms, the company did not recognize Ethiopia as a country of origin of teff GR in the patent application on the processing of teff flour. In the applications for community plant varieties, however, Ethiopia is disclosed as the country of origin of teff GR. Though arguable, the patent claimed by the company on the processing of teff flour is believed to be a patent claimed on the TK of Ethiopian communities as the invention is not new. In addition to these, the company has made the application for the three teff varieties in the name of a foundation which is the owner of the rights though it is nowhere mentioned in the agreement. The simplest and the appropriate way to effect this term of the agreement could be listing the company and EARO as co owners of the varieties. Therefore, it is an act made in clear contravention of the agreement which establishes joint ownership between the company and EARO in the varieties to be developed by the former.

Surprisingly enough, as expounded in chapter four of the thesis, the company made the application for patent on the processing of teff flour and plant variety rights on the three varieties developed are made before the conclusion of the ABS agreement. So, the company has sought these claims without lawfully accessing the teff GRs which is used as an input for the development of the invention and the varieties; and without having any benefit sharing arrangement. Of course, it is difficult to appreciate the relationships between ABS and IPRs in this regard as the EPC does not conditioned the patentability of inventions made based on GRs on compliance with ABS conditions as required in the ABS laws of the provider country. The point I am trying to make is that had disclosure requirements been included in the EPC and the

EC Plant Variety Regulation, we could have witnessed IP laws playing a role in ensuring compliance with ABS conditions. Even then, technically speaking, it is difficult to argue that the patent and plant variety rights granted to the company should not be seen under the preview of the ABS agreement as the rights are granted after the conclusion of the contract.

At any rate, from the breaches of IPR related terms of the Teff ABS Agreement made by the company in the process of securing these rights, we can depict that compliance with ABS agreements in general still remains as a challenge if there is no an international agreement which require users to incorporate disclosure requirements in their IP laws to this effect. Once GRs leave a territory that is it; especially as those providing the resources are weakest members and poor, it is very expensive to hire lawyers and ensuring compliance with ABS agreements is almost impossible. In short, monitoring and tracking compliance with ABS agreements is a costly process that would severely stretch the financial resources of a country.

Form this case, the other interesting point to emerge is that some of the terms in the ABS agreements and the ABS Proclamation in general may not be implemented by users without putting in place disclosure requirement in IPR laws. Emphatically speaking, making sure that the user has complied with any relevant access related requirements and that he has fairly and equitably shared the benefits with the source and other complementary terms in ABS agreements may not be complied by users if the IP system is not supportive in this regard. I consider this case as a good example which underpins the belief that an answer to such non compliance needs to be found in the IP system. And without this, the IPR related terms and other ABS terms in ABS agreements for that matter remain feeble.

The analysis made on the relationship between ABS and IPR laws under the Ethiopian Legal System in the body part of the paper and the findings pin down above will lead us to advance the following recommendations: .

- ♣ Though as a matter of approach disclosure requirements could be included either in the ABS or IPR laws; it is recommendable to enshrine these requirements in IPR laws. This is precisely because the implementation of disclosure requirements in IPR laws is more systematic and provides legal certainty on the nature of the requirement and on the consequences of non compliance with the requirement. And it is easier for IP offices to

execute the requirements if they are included in IPR laws. Should disclosure requirements included in the ABS Proclamation be maintained, they need to be reconsidered with a view to include the two elements of disclosure requirements-evidence of PIC and benefit sharing arrangement- so much so that the requirements would be effectual in ensuring compliance with ABS conditions. Besides this, since disclosing a certain locality as origin of a GR is not always possible, the law needs to be revisited to clarify the situations which justify disclosure of locality and disclosure of country as origin.

- ♣ Regarding the Proclamation on Inventions, there is a strong cause to incorporate appropriate provisions for disclosure requirements as a condition for the grant of a patent to make it supportive to the ABS objectives of the ABS Proclamation. This is true as incorporating such a requirement is basic to make sure that the applicant for patent on inventions made based on GRs have complied with ABS requirements. Moreover, the liberality of the law in making microorganisms, microbiological processes, and plants other than plant varieties needs to be critically reexamined. Seen from the perspective of ABS, such a law is believed to facilitate misappropriation of GRs which are not accessed in compliance with ABS legislations and therefore, this reason coupled with the other reasons forwarded against patentability of life forms as expounded in the thesis, will lead us to recommend for the revision of the law in this regard for every good reasons. Of course, revising the law to the extent of making all life forms and processes non patentable raises concerns of its incompatibility with the TRIPs Agreement as the country is in the process of accession to the WTO. It is an appropriate concern; even then, it is possible to do so using the room given by TRIPs for countries to follow their own course on the matter.

- ♣ As one noticeable step in creating positive synergies between ABS and IPR Legal Regimes, the PBRs Proclamation has adopted disclosure requirements as a condition for the grant of plant breeders' right. The PBRs Proclamation, however, does not include one pillar of disclosure requirements-disclosure of origin. In addition to this, the provision which deals with disclosure requirements does not have a panacea to the possible problems that would arise in implementing the requirement. Hence, future revision of the law or the regulation to be enacted for the enforcement of the proclamation needs to specify many details, including the circumstances leading to a requirement for disclosure; the timing; the

content, format, and the level of details required from the applicant; and the consequence of failure to disclose. And disclosure of origin/source as one element of disclosure requirements needs to be integrated in the law.

This being so, as incidental it may be, if this additional requirement included in the PBRs proclamation raises the issue of its incompatibility with the TRIPs Agreement in the process of Ethiopia's accession to the WTO, it should be argued that it is a measure necessary to change ABS objectives enshrined in the CBD and the ABS Proclamation in to a reality and the sui generis option envisaged in the TRIPs Agreement for the protection of plant varieties allows countries to include such additional requirements in addition to the conventional ones.

- ♣ In negotiating and concluding ABS agreements, a reasonable care should be given to IPR related terms as creation of IPRs is the usual method for crystallizing the economic values of R&D made based on GRs. In particular, the following are recommendable:
 - Including joint ownership of IPRs as one mode of benefit sharing since it can provide a reassurance to the country in that it will retain a say over how the resources are developed and used and how a new invention derived from the GRs are developed, used and disseminated. Of course, this can be realized in jurisdictions which require the consent of the joint owners of the IP for effective development and exploitation of the patent or another IP right.
 - Incorporating disclosure requirements as a contractual obligation in ABS agreements;
 - Including terms which mandate the applicability of IPR laws of the country to govern the agreement and to settle disputes that would arise;
 - Taking the necessary care in using the terms 'origin' and 'source'; that means, if the GR which is the subject of the ABS agreement is indigenous to Ethiopia and at the same time it is the provider, the terms 'origin' and 'source' should be used in stipulating terms which impose an obligation of disclosure on users. So much so that, the user will be duty bound to disclose Ethiopia as origin of the GR irrespective of where it is sourced.

On the other hand, if the country is a provider of the GRs only, it suffices to use the term 'source' in obliging the user to recognize Ethiopia as a country of source.

- ♣ Finally, for all these to happen, the coordination between government institutions working on the management and governance of GRs and IPRs both at the process of lawmaking and enforcement has a paramount importance. In this regard, developing the culture of working together in a coordinated manner between the Institute of Biodiversity Conservation, the EIPO and the Ministry of Agriculture is quite indispensable in harmonizing ABS and IPR Legal Regimes in the process of lawmaking (as these institutions are the places where laws in the areas of ABS and IPRs to be initiated) and keeping this harmony at the time of implementation.

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Discussions

A discussion held with Ato Tamire, the Legal Officer in the EIPO, on 9 October 2010

A discussion held with Dr. Gemedo Dalle, Director, Genetic Resources Transfer and Regulation Directorate, Institute of Biodiversity Conservation, on 4 November 2010

A discussion held with W/ro Misa Demissie, Variety Release and Registration Expert in the Ministry of Agriculture, on 12 November 2010

A discussion held with Ato Daniel Assefa, Variety Release and Registration Performer, on 12 November 2010

A discussion held with Ato Firew, the Legal Officer in the Ministry of Science and Technology, on 10 November 2010