INTERNATIONAL LEGAL REGIME ON GENE PATENTING IN PLANTS

Smita Srivastava[*]

I. INTRODUCTION

Under international legal regime there is considerable room for genetic patenting, especially in cases of plants. Due to this flexibility, gene patenting in plants is permitted in many developed countries as biotech industry is dominated by them. Taking the advantage of this legal regime, agro-biotech companies have obtained several patents on genetic inventions relating to plants. They generate huge profits by misappropriating the genetic resources of developing or under-developed countries, which are rich in biodiversity. This free flow of genetic resources and associated knowledge from South to North take place due to concept of "free access" and "common heritage of mankind." Therefore, while accessing the genetic resources consent of country of origin is not obtained. Further, genetic material is taken without compensating and acknowledging the contribution of indigenous communities of provider country. This gives rise to issue of 'bio piracy' and 'cultural piracy'. Convention on Biological Diversity 1992 and Nagoya Protocol 2010 recognize the "sovereign right of state over its natural resources" and address these issues by providing necessary framework for appropriate access to genetic resources and traditional knowledge associated therewith. They also provide for fair and equitable sharing of benefits arising out of them. Purpose of this paper is to make analysis of basis of gene patenting in plants at the international level and to explore the concerns of developing countries in this regard. It further makes critical analysis of present international 'Access and Benefit Sharing regime' in addressing those concerns.

II. GENE PATENTING IN PLANTS AND TRIPS AGREEMENT

At the international level, Article 27 of TRIPS Agreement lays down minimum standards of patent protection that must be met by all WTO members. Article 27.1 provides**:**

> "……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."

With regard to gene patenting the provision is not very clear. However, there is considerable room for gene patenting in plants. It says that patent shall be available for 'anyinvention.'It does not distinguish between inventions having life and inventions not having life, therefore, inventions having life form can be patented. Patent is available for both products and processes. Therefore, patent can be granted on isolated or artificial gene of plant, which is ultimate product. However, with regard to new "uses" of product Article 27.1 is silent. Therefore, member countries are free to allow or disallow the patenting of new use of known substance (e.g. genes).[1] It guarantees patents in all the fields of technology without any discrimination and that off course include the agricultural sector.

[*] Senior Research Fellow, Faculty of Law, Banaras Hindu University, Varanasi, India.

[1] UNCTAD-ICTSD, *Resource Book on TRIPS and Development* 356-357 (Cambridge University Press, New York, 2005).

For patent protection, all inventions including the biotechnological inventions have to fulfill three basic patentability criteria i.e. novelty, inventive step and capability of industrial application. Novelty does not mean that the thing must not exist earlier but it must be "novel in a prior art sense." Therefore, on the date of filing of patent application, invention should not form "part of state of art." In the context of gene patents, the novelty requirement centers around the question whether genes, which already exist in nature can truly be said to new? Naturally occurring gene sequences contain sections that code for proteins and sections that do not. When scientists isolate, purify and amplify gene sequences, they isolate and purify only the protein-coding portions. These purified gene sequences do not occur naturally. Thus, they do not form the part of prior art.[2] Further if a gene can be properly described by its composition, by the process of obtaining it or by its use or other parameters, it is indeed novel item, and therefore merit patent protection.[3] The courts of most jurisdictions have accepted this reasoning, therefore, they have extended patent protection to isolated and purified naturally occurring genes.[4] However, discovery of gene or its known use cannot be accepted as patentable subject matter as it lacks the novelty. Genetic inventions also fulfil the criteria of inventive step as identification or isolation of genes is not an easy task. Individual gene is not obvious but become known only after extensive and sophisticated biochemical and micro-biological research. Further, it also fulfils the requirement of utility as genetically engineered plants, with desired traits such as high yield, resistant to pests, insects, herbicides, weeds and tolerance to drought, flood etc., are useful in serving the needs of society.

However, under Article 27.3(b) of TRIPS Agreement "plants, animals, and essentially biological processes for their production" may be excluded from patentability. But, "microorganisms and microbiological or non-biological processes" must be protected. Micro-organisms may be interpreted to include the genes. Article 27.3(b) of TRIPS requires the member states "to protect the plant varieties either by patent or by effective *sui generis* system or by combination of both." Therefore, TRIPS Agreement leaves considerable room for patenting of genes, plant varieties and microbiological process related therewith. However, it does not require the applicant to disclose the source of origin. Gene patenting is permitted in many jurisdictions like U.S., European Union, Australia, and Canada.

III. ISSUE OF BIO PIRACY

Issue of bio piracy arises out of concept of bioprospecting. According to Phillipe Cullet, "bioprospecting covers all activities related to the search and collection of biological resources, the use of information regarding traditional uses of biological resources as well as research towards commercial exploitation."[5] For, bioprospecting major mega diverse countries are Brazil, Columbia, South Africa, Philippines, Australia, Indonesia, China, Mexico, Venezuela, Ecuador, Peru, Mexico, India, Madagascar. Most of them are developing countries located in tropical and sub-tropical region and contain 70 percent of the world's biodiversity.In order to find out the desired genes traditional knowledge-based bioprospecting is more profitable than conventional screening system. But the controversy arises when

[2] Eike-Henner W. Kluge, "Res nullius, Res communis and Res propria: Patenting Genes and Patenting Life-Forms" 13*Annual Review of Law and Ethics (JRE)* 543, 549 (2005), *available at*: https://www.jstor.org/stable/43593718 (last visited on July 4, 2018).
[3] P. K. Vasudeva, "Patenting Biotech Products: Complex Issues" 35(42) *Economic & Political Weekly* 3726-3727 (October 14-20, 2000), *available at*: https://www.jstor.org/stable/4409857 (last visited on May 20, 2018).
[4] *Supra* note 2 at 549.
[5]Philippe Cullet, *Intellectual Property Protection And Sustainable Development* 157 (Lexis Nexis Butterworths, New Delhi, 2005).

without any consideration and acknowledgement of contribution of indigenous communities of developing countries, patent is granted to bio prospectors or their licensees on final product.[6] Therefore, demand of developing countries is that if profits are gained through bioprospecting based genetic engineering, there should be sharing of benefits and technology involved with original contributors of genetic material or traditional knowledge.

A.Bio piracy Episodes

(i) Enola Beans

Enola Beans is an alleged case of bio piracy, in which, PODNERS L.L.C., a small American seed company, studied the genes of traditional Mexican Beans through selection techniques and developed new variety of same beans with better yellow color and a more consistent shape. It obtained a US patent (No.5,894,079) and a US Plant Variety Protection Certificate (No. 9700027) on that bean.[7] Now the Mexican Beans were either prohibited from being imported to the USor subject to payment of royalties when sold. This had resulted in a sharp decline in exports of this bean from Mexico to USdriving many Mexican farmers out of the market.[8]

(ii) Sweet Berry

This case involves the patent over "brazzien" a "sweet berry" of a West African plant "pentadiplandra brazzeana," which was discovered by team of University of Wisconsin with the help of local community of Gabon. But people of Gabon were never compensated for that.[9]

(iii) Australian Bio piracy Episode

In 1998, two organizations "Agricultural Western Australia" and the "Grains Research Development Corporation" applied for Plant Breeder's Right under the Australian Plant Breeder's Rights Act, 1994, for two varieties of "chickpea" developed from genetic material obtained from the "International Crop Research Institute for the Semi-Arid Tropics (ICRISAT)." Chickpeas are generally grown by subsistence farmer in India and Iran. However, before the determination of issue by the Australian Plant Breeder's Rights Office, application was withdrawn due to public anger.[10]

(iv) Nuna Beans

In this case patent was obtained by US Corporation on a "bean-nut popping bean" onMarch 21, 2000. This variety was developed by selection and crossing of thirty-three "Andean nuna bean species" of Bolivia, Peru, Colombia and Ecuador.[11]

---

[6] Jaishree Watal, *Intellectual Property Rights In WTO & Developing Countries* 170-171 (Oxford India Paperbacks, Oxford University Press, 3rd edn., 2009).
[7] Srividhya Ragavan, *Patent And Trade Disparities In Developing Countries* 340 (Oxford University Press, New Delhi, 2012).
[8] Tilahun Weldie, "The Impact of the Trade Related Aspects of Intellectual Property Rights Agreement (TRIPS Agreement) on the Realization of the Right to Food" 1(1) *Bahir Dar University Journal of Law* 97, 123 (2010).
[9] *Supra* note 7 at 340, 341.
[10] Michael Blankeney, "Regulating Access to Genetic Resources", in S.K. Verma & Raman Mittal (eds.), *Intellectual Property Rights: A Global Vision* 4 (The Indian Law Institute, New Delhi, 2008).
[11] *Id.* at 9.

IV. ACCESS TOGENETIC RESOURCES AND BENEFIT SHARING REGIME

A. Convention on Biological Diversity 1992

Convention on Biological Diversity was adopted in 1992 at the United Nation's Conference on Environment and Development. It became effective on December 29, 1993. It has a near universal participation with 196-member states, the main exception being the United States.[12] Apart from conservation and sustainable use of biodiversity, its main focus is on fair and equitable sharing of benefits derived from the use of genetic resources.

(i) Sovereign Right of State over its Natural Resources

Preamble and Article 3 of CBD reaffirms the sovereign right of states over their natural resources. Article 15, which deals with access to genetic resources, reflects this sentiment by emphasizing again on sovereign rights of States over their natural resources and provides that "the authority to determine access to genetic resources rests with the national governments and is subject to national legislation". However, Article 15(2) requires contracting parties "to endeavor to create conditions to facilitate access to genetic resources and not to impose restrictions that run counter to the objectives of the Convention."

(ii) Appropriate Access: Prior informed Consent, Mutually Agreed Terms and Benefit Sharing

In order to facilitate appropriate access to genetic resources CBD provides that access is subject to the 'prior informed consent'[13] of supplier country of genetic resources. It should be on 'mutually agreed terms.'[14]Most importantly, "each Contracting Party is bound 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 genetic resources with the Contracting Party providing such resources. Such sharing shall be upon mutually agreed terms."[15] At international level, benefit-sharing is well recognized compensation mechanism. Objective is to compensate the holders of biological resources and traditional knowledge for their contribution to the evolution of plant varieties.[16] Sharing of benefit should be fair and equitable.

Transfer of technology may be means of benefit sharing. Therefore, Article 16 of CBD specifically requires the contracting parties to facilitate the transfer of technologies, that are relevant to the conservation and sustainable use of biological diversity or make use of genetic resources, on 'fair and most favorable terms, including on concessional and preferential terms' to the countries providing the genetic resources. It specifically indicates that genetic engineering is one of those technologies. Article 16(3) requires the "transfer of technology on mutually agreed terms."

(iii) Recognition of Traditional Knowledge

---

[12] List of Parties, CBD, *available at*: https://www.cbd.int/information/parties.shtml (last visited on January 04, 2019).
[13] Convention on Biological Diversity, 1992, art. 15.5.
[14] *Id*., art. 15.4.
[15] *Id*., art. 15.7.
[16] *Supra* note 5 at 164.

Since traditional knowledge provides a significant basis for obtaining patent, therefore. Article8(j) of the CBD requires the member states to respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities, promote their wider application and encourage the equitable sharing of the benefits arising from the utilization of such knowledge, innovations and practices.

(iv) Critical Analysis

CBD provides merely general framework for access and benefit sharing. It does not provide implementation mechanism for the same. Though, it recognizes the principle of "sovereign rights of state over its natural resources" and requires the access to genetic resources subject to prior informed consent, and benefit sharing on mutually agreed terms, but in case of conflict, it does not have overriding effect on TRIPS. TRIPS does not require the patent applicant whose inventions incorporate or use the genetic material or associated knowledge to comply with these obligations. TRIPS also does not require to disclose the source of origin. Further, language of provisions of CBD is not sufficiently strong to enforce these obligations. Most of the provisions use words like 'endeavor to fulfil', 'as appropriate', 'as for as possible', 'subject to national legislation and international law.' Further, it lacks effective enforcement mechanism. All dispute concerning the interpretation or application of Convention is to be settled by "negotiation, mediation, conciliation, arbitration or submission to the International Court of Justice."[17]

B. Nagoya Protocol: An Effective Implementation Mechanism?

(i) Background

For further implementation of the third objective of CBD, onOctober 29, 2010, CBD Conference of Parties, at its 10th session in Nagoya, Japan, adopted "Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity". It came into force on October 12, 2014, 90 days after its 50th ratification. Presently, it has 111 parties. Not all the parties of CBD have ratified the Nagoya Protocol.[18]

The Nagoya Protocol is a legally binding, ancillary agreement to the CBD.[19] It provides implementation mechanism for access and benefit sharing principle enshrined under Convention. It consists of 27 preambular paragraphs, 36Articles and one annexure having a "non-exhaustive list of monetary and non-monetary benefits."[20]

---

[17] *Supra* note 13, art. 27.

[18] Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization, CBD (2010), *available at*: https://www.cbd.int/abs/doc/protocol/nagoya-protocol-en.pdf (last visited on January 04, 2019).

[19] Most of the provisions of Protocol have been borrowed from the "Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization", a set of voluntary non-binding guidelines on access and benefit sharing endorsed by the CBD Conference of the Parties (COP) at its 6th Session in 2002. *See* UNCTAD, *The Convention On Biological Diversity And Nagoya Protocol: Intellectual Property Implications* 11 (UNCTAD, Geneva, 2014).

[20] IUCN, "An Explanatory Guide to the Nagoya Protocol on Access and Benefit-Sharing" *IUCN Environmental Policy and Law Paper No. 83, available at*: https://cmsdata.iucn.org/downloads/an_explanatory_guide_to_the_nagoya_protocol.pdf (last visited on November 25, 2018).

(ii) Objective

Article 1 of Nagoya Protocol reiterates the third objective of the CBD by referring to "the fair and equitable sharing of the benefits arising from the utilization of genetic resources" as the fundamental aim of the Protocol. It makes clear that benefit sharing includes "appropriate access to genetic resources, appropriate transfer of relevant technologies, and appropriate funding."

(iii) Scope

Protocol applies to "genetic resources and benefit arising from utilization of such resources." It also extends to "traditional knowledge associated with genetic resources and benefit arising from utilization of such knowledge."[21]

(iv) Access Mechanism

The issue of "access to genetic resources and traditional knowledge associated therewith" is fundamental to Nagoya Protocol. Different part of Protocol addresses this issue. Reiterating the "sovereign rights of States over their natural resources", Article 6 specify once more that "access to genetic resources is subject to prior informed consent of country of origin, unless otherwise determined."[22] It further requires the parties to ensure "prior informed consent or approval and involvement of indigenous and local communities in obtaining the access to the genetic resources."[23] For implementation of these provisions, member countries are required "to take the necessary legislative, administrative or policy measures." For more legal certainty, Article 6(3) lays down elaborate procedural requirement that should be followed by all member countries requiring prior informed consent at the domestic level.

Article 7 obliges each party "to take appropriate measures to ensure that the prior informed consent and mutually agreed terms" in relation to "access to traditional knowledge associated with genetic resources" have been established. Aim of this provision is to contribute in implementation of Article 8(j) of the CBD. Article 8 of Nagoya Protocol requires that special consideration should be given to the "importance of genetic resources for food and agriculture and their special role for food security."

For further implementation of access requirement, Articles 13 and 14 provide for the required institutional framework at the national and international level. Article 13 requires the "designation of a national focal point" which shall give "information as to procedure for obtaining prior informed consent or approval or involvement of indigenous communities and establishing mutually agreed terms, including benefit-sharing" to applicant seeking access to genetic resources and traditional knowledge associated therewith. It shall also give information on "competent national authorities, relevant indigenous and local communities and relevant stakeholders."[24] It further requires the member countries to designate "one or more competent national authorities on access and benefit-sharing" which shall be "responsible for granting access or issuing written evidence that access requirements have

[21] *Supra* note 18, art. 3.
[22] *Id*., art. 6.1.
[23] *Id*., art. 6.2.
[24] *Id*., art. 13.1.

been met and be responsible for advising on applicable procedures and requirements for obtaining prior informed consent and entering into mutually agreed terms."[25] Single entity may be designated "to fulfil the functions of both focal point and competent national authority."[26]

Article 14 also plays an important role by establishing an Access and Benefit-Sharing Clearing-House which serve as a means for sharing of information related to access and benefit-sharing made available by member country relevant for implementation of the Protocol. Such information shall include "legislative, administrative and policy measures taken on access and benefit-sharing; information on the national focal point and competent national authority; permits or their equivalent issued at as evidence of the decision to grant prior informed consent and of the establishment of mutually agreed terms." Aim of this provision is to improve the link between providers and users of genetic materials.

However critics are of view that additional requirement under the *Nagoya Protocol* for the "enactment of a law or regulation as a precondition for priorinformed consent", which is not required under the CBD, creates a condition that would be detrimental to the country of origin (developing countries) having no specificaccess and benefit sharinglaws and regulatory mechanism.[27] Further the requirement of "fair and non-arbitrary rules and procedures on accessing genetic resources" undermines the privilege of the provider country to determine conditions for access as it deems fit in the exercise of its sovereign right.[28]

(v) Benefit Sharing Mechanism

Fair and equitable benefit-sharing is key feature of the Nagoya Protocol. Article 5 reiterates the basic principle already incorporated in Articles 15(3) and 15(7) of the CBD. It provides that "benefits arising from the utilization of genetic resources as well as subsequent applications and commercialization shall be shared in a fair and equitable way with the Party providing such resources."[29] This also applies to the "utilization of genetic resources held by Indigenous and local communities", including their "traditional knowledge."[30] Such benefit sharing shall be on mutually agreed terms. For implementation of these provisions, again member country is required "to take appropriate legislative, administrative or policy measures."[31] Referring to annex, Article 5(4) provides that benefits may be monetary as well as non-monetary. Annex provides indicative and non-exhaustive list of potential monetary and non-monetary benefits to be shared.

Article 9 obliges the Parties "to encourage users and providers to direct benefits arising from utilization of genetic resources towards the conservation of biological diversity and sustainable use of its components." Article 10 requires the Parties "to consider the need for a global multilateral benefit-sharing mechanism to address the fair and equitable sharing of benefits derived from the utilization of genetic resources and traditional knowledge

[25]*Id*., art. 13.2.
[26]*Id*., art. 13.3.
[27]Abdul Haseeb Ansari and Lekha Laxman, "A Review of the International Framework for Access and Benefit Sharing of Genetic Resources with Special Reference to the Nagoya Protocol"16 *Asia Pacific Journal of Environmental Law* 105, 128 (2013).
[28]*Id*. at 130.
[29]*Supra* note 18, art. 5.1.
[30]*Id.*, art. 5.2, 5.5.
[31]*Id.*, art. 5.3.

associated with genetic resources that occur in transboundary situations or for which it is not possible to grant or obtain prior informed consent."

(vi) Traditional Knowledge Associated with Genetic Resources

In Nagoya Protocol, Parties are under obligation "to take into consideration indigenous and local communities' customary laws, community protocols and procedures, with respect to traditional knowledge associated with genetic resources."[32] Members are also encouraged "to support Indigenous and local communities in developing community protocols for access to traditional knowledge, minimum requirements for mutually agreed terms and modern contractual clause for benefit sharing arising from utilization of traditional knowledge associated with genetic resources."[33]Purpose of these provisions is to ensure the prior informed consent and involvement of concerned indigenous and local communities in granting access as well as to ensure the benefit sharing with them.

Here, Nagoya Protocolcan be considered as CBD-plus, as it deals with the right of indigenous and local communities in relation to both genetic resources and traditional knowledge associated with it, in comparison to CBD, which only deals with traditional knowledge of indigenous and local communities.[34] However, it lacks strong provision on the protection of Indigenous and local communities regarding the utilization of their traditional knowledge associated with genetic resources. Parties are only obliged to "take into consideration" and "endeavor to support."[35] Further, issue of "publicly available traditional knowledge"[36]is not covered under Protocol. This created huge controversy during negotiation as it has led to "misappropriation of traditional knowledge associated with genetic resources." Further, effective implementation of provision will mainly depend on domestic legislation as well as interpretation of the ambiguous language by Parties to Protocol.[37]

(vii) Compliance

In Nagoya Protocol member countries are under obligation to take "appropriate, effective and proportionate legislative, administrative or policy measures in ensuring that genetic resources utilized within its jurisdiction have been accessed in accordance with prior informed consent and that mutually agreed terms have been established, as required by the domestic access and benefit-sharing legislation or regulatory requirements of the other Party."[38] Further, they have to take "appropriate, effective and proportionate measures to address the situation of non-compliance with measures adopted under Article15(1)."[39] They are obliged to "cooperate in cases of alleged violation of domestic access and benefit-sharing legislation or regulatory requirements."[40]Article 16 extends these obligations to "access and benefit-sharing for traditional knowledge associated with genetic resources."

---

[32]*Id.*, art. 12.1.
[33]*Id.*, art. 12.3.
[34]*Supra* note27 at 135.
[35] Achmad Gusman Siswandi, "The Nagoya Protocol: unfinished business remains unfinished"inMatthew Rimmer (ed.) *Indigenous Intellectual Property* 355 (Edward Elgar Publishing, Cheltenham, UK, 2015).
[36] Situations where 'the knowledge was not obtained directly from indigenous and local communities' or alternatively where there was 'no identifiable owner of the resource as the traditional knowledge was passed down from generations ago.' See *supra* note27 at 136.
[37]*Supra* note35 at 355, 356.
[38]*Supra* note 18, art. 15.1.
[39]*Id*., art. 15.2.
[40]*Id*., art. 15.3.

In order to ensure compliance with mutually agreed terms, "parties are obliged to encourage providers and users of genetic resources as well as traditional knowledge associated with genetic resources to include dispute resolution provisions in mutually agreed terms."[41] For that purpose, member countries are under obligation to ensure that "opportunity to seek recourse is available under their legal systems in cases of disputes arising from mutually agreed terms."[42]

These compliance provisions can serve as practical means to address infringement of access and benefit sharing scheme. However, their effectiveness remains questionable as no guidelines have been laid down as to measures which are considered 'appropriate, effective and proportionate.'[43]

(viii) Monitoring

To support compliance, Protocol obliges member countries "to take measures, to monitor and to enhance transparency about the utilization of genetic resources." Such measures include designation of one or more checkpoints; encourage the parties to genetic resources to include mutually agreed terms clause that require information sharing and reporting on the implementation of such terms; and use of cost-effective communication tools and systems.[44]

According to Article 17(2) of Nagoya Protocol "permit issued under Article 6(3)(e) and made available to the Access and Benefit-sharing Clearing-House, shall constitute an internationally recognized certificate of compliance." It also states:

> "An internationally recognized certificate of compliance shall serve as evidence that the genetic resource which it covers has been accessed in accordance with prior informed consent and on mutually agreed terms as required by the domestic access and benefit-sharing legislation or regulatory requirements of the Party providing prior informed consent."[45]

(ix) Transfer of Technology

Article 23 of Nagoya Protocol focuses on two non-monetary benefits -*firstly*, collaboration and co-operation in technical and scientific research and development programmes, including biotechnological research activities; and*secondly*, access and transfer of technology.[46] It provides:

> "In accordance with Articles 15, 16, 18 and 19 of the Convention, the Parties *shall collaborate and cooperate in technical and scientific research and development programmes, including biotechnological research activities*, as a means to achieve the objective of this Protocol. The *Parties undertake to promote and encourage access to technology by, and transfer of technology to,*

[41]*Id*., art. 18.1.
[42]*Id*., art. 18.2.
[43]*Supra* note 35 at 357.
[44]*Supra* note 18, art. 17(1).
[45]*Id*., art. 17.3.
[46]*Supra* note 20 at 29.

> *developing country Parties, in particular the least developed countries and small island developing States* among them, and Parties with economies in transition, in order to enable the development and strengthening of a sound and viable technological and scientific base for the attainment of the objectives of the Convention and this Protocol."

This provision can be considered as CBD-minus as it has reduced the obligation of developed countries to merely "promote and encourage" access and transfer of technology to developing and least developed countries.[47]While there is a definite obligation regarding collaboration and co-operation in research programmes, with regard to access to and transfer of technology to developing countries, there is only a general commitment, not an obligation.[48]

(x) Critical Analysis

Although Nagoya Protocol has provided a comprehensive framework for access and benefit sharing issues, its success is doubtful as it consists of only weak and ambiguous provisions. It does not contain stronger compliance and enforcement mechanisms.[49] Without appropriate standards and guidelines for procedural requirements,the Protocol will not be able to attain its objective. For example, there are no criteria or mechanism in Nagoya Protocol to objectively determine whether national legislation on access fulfils the requirements of legal certainty and clarity or not.Further, there is no authority to determine on whether domestic law on access and benefit sharing fulfils the criteria of legal certainty and clarity.[50]

Many of the access and benefit sharing provisions in protocol have merely reiterated the principles laid down in the *Convention on Biological Diversity 1992* and *Bonn Guidelines 2002*. Though, it has laid down a number of new important features for implementation of access and benefit sharing mechanism such as special consideration to certain factors; a global multilateral benefit sharing system; and monitoring the utilization of genetic resources, these are also impaired by discretionary and ambiguous language.[51]

Nagoya Protocolis mainly referred to as a "masterpiece in creative ambiguity" due to the compromise and avoidance of issues about which there was no consensus among member countries. It does not regulate disclosure requirements in detail. There is no provision in Nagoya Protocol to define 'bio piracy' or acts constituting bio piracy and measures to address the concerns of developing countries in this regard.There is currently no agreed concept of 'bio piracy.'[52] Further, it does not address the issue of "publicly available traditional knowledge."

Most of the provisions of Protocol require each party "to take appropriate legislative, administrative, or policy measures" for exercise of their rights and obligations under the protocol. Therefore, effective implementation of the Protocol would depend on national legislation enacted for utilization of genetic resources. Since, not all the parties to CBD have

[47]*Supra* note27 at 136, 137.
[48]*Supra* note46.
[49]*Supra* note35at 364.
[50]*Supra* note27 at 129.
[51]*Supra* note35 at 360-361.
[52]*Supra* note27 at 137, 138.

ratified the Nagoya Protocol, it is difficult to ensure that user countries which are not parties to Nagoya Protocol would act in accordance with its provisions.[53]

V. CONCLUSION

Present access and benefit sharing regime does not fulfil the expectations of developing countries, as it lacks the stronger compliance and enforcement mechanism. Though Nagoya Protocol 2010 added a new chapter to access and benefit sharing regime, nevertheless it has not moved significantly from the access and benefit sharing principles and standards already incorporated in *Convention on Biological Diversity 1992* and the *Bonne Guidelines 2002*.

For, effective implementation of the Nagoya Protocol through national legislation, some issues still need to be resolved. Firstly, there is need to clarify ambiguous provisions. Secondly, there should be mechanism for objective assessment of national legislation whether it fulfils the procedural requirement laid down in Nagoya Protocol or not. Thirdly, there should be obligation of full disclosure in patent application. Fourthly, there should be consultation mechanism to reconcile the competing interests of various stakeholders in genetic resources utilization. Fifthly, there should be specific provision to define bio piracy and measures to address such concerns.

Lastly, the issue of"fair and equitable sharing of benefits" centers around the question of value. In order to ascertain the appropriate value, benefits sharing should be linked to the outcome of the ultimate utilization of genetic resources, as opposed to their access. This would greatly reduce the uncertainty in the calculation of benefits. Thus there is an urgent need to develop an internationally accepted mechanism for valuation of genetic resources.[54]

[53] *Supra* note35 at 361.
[54] *Supra* note27 at 135.