

PROTECTING TRADITIONAL MEDICINAL KNOWLEDGE AND ASSOCIATED KNOWLEDGE HOLDERS THROUGH ACCESS & BENEFIT SHARING MODEL: AN INDIAN PERSPECTIVE

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ABSTRACT

India is a habitat to several biological resources, of which many such biological varieties are native only to this country and not found elsewhere. India proudly exhibits hugely rich traditional knowledge pertaining to these biological resources, in several forms starting from being incorporated in food habits, life habits, cultural expressions, medical use etc. But unfortunately, this traditional knowledge in India has not been adequately tapped in terms of generating revenue out of it or claiming ownership over the same because of lack of awareness among the holders of such knowledge regarding the means of protecting such knowledge against actual & potential threats. These threats come from the big pharmaceutical companies who take away the medicinal knowledge held by traditional medicinal knowledge holders (vaidas & hakims) over medicinal plant genetic materials and utilize such knowledge to create patented medicine only to sell them to the people of same provider country, who give them the traditional knowledge. This paper will highlight the threat to such traditional knowledge and would focus on the role of Intellectual property protection in extending protection to such traditional knowledge holders pertaining to medicinal plants in the light of Access and Benefit Sharing mechanism, trying to come up with several ways of ensuring fair and equitable sharing of benefits with the benefit claimers in order to protect and promote their interests in consideration of the role played by them in conserving and protecting the biological diversity.

Keywords: Intellectual Property protection, Traditional knowledge, Medicinal Knowledge Holders, Biological Resources, Medicinal Plants, Access and Benefit Sharing Mechanism.

INTRODUCTION

The importance of traditional medicine and medicinal knowledge has been deep rooted in our healthcare system since time immemorial. The reference of these traditional medicines and associated medicinal knowledge can be found in the most ancient texts referred for curing ailments. From Ayurveda to Siddha and Unani, all these traditional/indigenous medical practices and the role of such practitioners who have specific skills in this regard to cure diseases have not only been recognized in our society but also have been deeply regarded to the extent that they have been often referred by the modern day medical/ healthcare systems. And this not only creates a nexus between the modern medicine and traditional medicine and associated knowledge but also gives rise to a conflicting situation. And the conflict comes in the form of a threat to all these traditional/ indigenous medicinal knowledge holders making them vulnerable by exposing them to the external threats of patented medicines manufactured by the organized sector in this field i.e. the pharmaceutical sector. Patented medicines are those medicines which are manufactured by a specific pharmaceutical company which are to be used and managed by its manufacturer exclusively to the extent of excluding the rest of the world from doing anything with regard to such medicines. And this right of exclusivity is conferred upon such entity through an Intellectual Property Right in the form of Patent which in itself is an exclusive and a negative right. Conflict arises between these two groups (i.e. the traditional medicinal knowledge holders and pharmaceutical companies) when the later without any authorization and prior permission/consent of the former incorporates the former's knowledge pertaining to traditional medicine in its own manufactured medicine and seeks a patent over it and thereby restricting the later by virtue of the exclusive right granted under Patent to use his traditional medicines and practice his traditional medicinal knowledge. This of late has become a common practice in the medical sector which has raised serious concerns for these vulnerable groups (traditional medicinal knowledge holders) who are not even given due benefits for sharing their knowledge with these big pharmaceuticals. This paper will discuss this identified problem/ conflict and will look for mechanisms like that of Access and Benefit Sharing Mechanism to help these vulnerable groups in protecting groups as

they are not even aware of their rights under the Intellectual Property protection framework in the light of role of IPR policy in this context.

Resources for any nation are those, which it can exploit within its own territory or with which it can bargain with other powers and move towards development and generating revenue for the betterment of the entire nation. Resources are considered as assets because of the simple reason that they can be valued, in either monetary or non-monetary forms. The understanding of resources has a very broad scope here.¹ It can include anything which can be commercially exploited to generate certain quotient of value. Whenever there is an issue of revenue generation, the first concern that arises is that who is entitled to claim the generated value, irrespective of its form. This marks the justification behind creating the concept of property in any kind of resources. Property indicates ownership rights of the owner of his/ her property and that is how the issue of entitlement towards the generated revenue out of such resource is determined. The owner will be entitled to claim all the benefits (monetary or non-monetary) arising out of exploitation of all such resources which can in turn be regarded as his property. So, in most of the cases property and resources become synonymous.

CREATING CONCEPT OF PROPERTY IN MEDICINAL PLANTS: RECOGNIZING SOVEREIGN OWNERSHIP

Various components of the biodiversity are considered as resources as they generate value and hence are also named as bio resources or biological resources. As per the above mentioned analysis, if biodiversity is considered as a resource then it can also be considered as property too. And in that situation the biggest question that arises is that *if biodiversity or biological resource becomes property, then who will own them? Who will be entitled to the benefits arising out of use and exploitation of such property?* The answer to this very question was put forth by Convention of Biological Diversity (CBD) formulations, according to which, each and every component of biodiversity collectively or individually which are found within the territory on a country, will fall under the regulation and control of that country. Such nation can exercise its sovereign rights over all biological resources available within its territorial limits. CBD formulations marked the

¹ Introduction to Access and Benefit Sharing, available at <https://www.cbd.int/abs/infokit/all-files-en.pdf> (last Accessed on 27/05.2018)

beginning of a new era in this context which discarded the idea of commons over bio resources and tried to bring them under the purview of individual Nation's regulation there by curtailing the right of exploitation of others over such bio resources, promoting sovereign monopoly in terms of the commercial exploitation of such bio resources. ²CBD by recognizing the idea of sovereign ownership over biological resources allowed countries to bring regulations within their domestic legal system in order to check the unauthorized access to various biological resources and the associated traditional knowledge pertaining to such biological resources and to protect the interests of the holders of such traditional knowledge who preserve the rich flora & fauna and the knowledge about their usage for betterment of human race.

TRADITIONAL MEDICINE AND ASSOCIATED KNOWLEDGE HOLDERS: ANALYSIS OF THE VULNERABILITY

Traditional medicine is the collective accumulation of knowledge, skills & beliefs, expressions indigenous to different cultures used in the maintenance of health as well as in the prevention, diagnosis, improvement or treatment of physical as well as mental illness.³

In a country like India, where a substantial part of the population still rely on the medical services form an indigenous practitioner having expertise on the usage of traditional medicine for curing several ailments, the importance of traditional medicines and such medical knowledge and practices can't be undermined. Traditional medicines, which is often referred to as Herbal medicine and associated medical practices have been adopted as an alternate medical system since time in memorial in India. And this becomes a major reason for the people in India to rely on traditional medicinal knowledge holders & practitioners and their armamentarium of medicinal plants in order to meet health care needs. In India, we have several forms of ancient medicines. Out of these forms three system of traditional medicine have been most effectively adopted and they are the Ayurvedic medicine, the Siddha medicine form South India and the Unani or Greco-Arabic medicine. The popularity of these systems of traditional medicine is because of the historic and cultural reasons. So traditional/ herbal medicine is not only a part of the health care system

² Ben Collen, et al. (eds.), "Biodiversity Monitoring and Conservation: Bridging the Gap between Global Commitment and Local Action", 1st Ed., 2013, p. 338.

³ Mercila Ouma "Keynote Address on Intellectual Property and Traditional Knowledge", (Geneva, November 25, 2016)

but it is also deep rooted in the history and culture of a community or may of an entire civilization. Most of the traditional or herbal medicines are derived from plants and are called as plants by-products. In this context it is to be noted that in developed countries such as United States, plants drugs comprise up to 25% of the total drugs, while in fast developing countries such as China and India, it comprise up to 80%. It is expected that there are 250,000 to 500,000 species of plants on Earth. Out of these small percentages (1 to 10%) are used as foods and medicine by both humans and animal. It is possible that rest of plant may be used for foods and medicinal purposes. Hence, it has turn out to be very important to review on herbal medicine which will play important role in research on plant to find their possible medicinal importance.⁴

Hence the medicinal plants under flora are considered to be apt subject matter of commercial exploitation as the medicinal properties that these plants possess are of very great value in terms of contributing significantly to the entire health and medical sector of the nation. All those nations which are developed in terms of medical science and medical infrastructure always eye upon these medicinal plants, their properties and the associated traditional medicinal knowledge which are possessed by comparatively less developed countries in terms of medical science, medical technology and other medical infrastructure but fairly developed in terms of possessing rich biodiversity base of medicinal plants and the traditional medicinal knowledge pertaining to such plants possessed by the various knowledge holders individually or collectively as a community in the public domain as a matter of customary practice. These developed nations take advantage of the lack of awareness of these comparatively less developed countries in general and the people of such countries in particular who are not aware of their rights over their traditional knowledge and that they can claim such knowledge as their intellectual property, considering them a subject matter of commercial exploitation which will lead to subsequent revenue generation. This lack of awareness facilitates unregulated access over such resources in order to carry out experimentation over them in anticipation of desired research results which can be commercially exploited in terms of generating revenue and then solely enjoying such revenue generated without giving anything back to that access provider country by sharing the benefit in order to acknowledging the contribution of the later in the process revenue generation. This gives rise to a need for a proper framework which will ensure protection of the traditional medicinal knowledge and the rights of

⁴ Herbal Medicine: A Comprehensive Review, International Journal of Pharmaceutical Research. Available at: (last accessed 18/05/2018).

such knowledge holders against misappropriation of their knowledge and depriving them of the benefits arising out commercial use of such traditional medicinal use.

NEED FOR FRAMEWORK ENSURING PROTECTION TO TRADITIONAL MEDICINAL KNOWLEDGE HOLDERS AGAINST ACTUAL & POTENTIAL THREATS

There should be serious efforts by the nation in order to protect the medicinal plants, considering the fact that they are constantly exposed to the threats of bio-piracy. Bio-piracy is that phenomena by which one entity (an individual/ organization of a country/ nation) establishes an access over a component of the biodiversity which can individually be considered as a bio resource and which is owned by another entity (a country/ nation), without prior approval or permission of the later and exploits such resource to derive benefit in its own name. ⁵As per CBD formulations, each sovereign nation will exercise its sovereign rights over all the biological resources that are available within their territorial limits and hence should also be the sole authority in protecting these resources against external threats of bio-piracy by regulating the access over such resources. And hence any access established over any bio resource which is the subject matter of protection of a nation, without taking prior approval of the competent authority of such nation which leads to the commercial exploitation of such resources in turn leading to revenue generation in the name of such access establishing entity, will amount to bio-piracy and will be dealt with seriously under the given appropriate framework available in that country which owns such bio resource. ⁶

Unfortunately very few nations which are rich in biological resources realize the potential of such resources and hence have not been able to come up with such frameworks which not only will promote conservation and preservation of the biological resources but also will extend protection to such resources against unwarranted access over them, which will substantially reduce the risks of bio-piracy. This is the only reason why we see such rampant cases of bio-piracy which involves all such countries (mostly developing or under developed countries) which are potentially rich in biodiversity but poorly aware about the potential of that biodiversity in terms of commercial

⁵ *Supra Note 3.*

⁶ *Supra Note 2*

exploitation and revenue generation which can play significant role in the overall development of such countries.⁷ Hence developing such domestic frameworks and models which will take care of the above mentioned concerns is the pressing need of the hour for all those countries which lack such mechanisms despite having a strong biodiversity base as that would give them a better bargaining power while bargaining with other nations before approving their requests for having access over such resources which are owned by them. Apart from this such framework can also acknowledge the contribution of another very important stake holder i.e. the knowledge holders either individually (traditional vaidas and hakims) or collectively (a native community or a tribe) in upholding the traditional medicinal practices through their day to day customary practice and hence make appropriate measures to benefit them for sharing their traditional medicinal knowledge and providing the platform for further experimentation over such knowledge which can lead to revolutionary contribution in the medical history which can be highly beneficial to the mankind.⁸ Such measures can derive its force from the doctrine of public good, which emphasizes that any contribution which brings out public good should be rewarded and in this context such reward can come in the form of appropriate mechanism which will not only recognize the contribution of such knowledge holders but also will protect their interest by providing measures which will ensure them the benefit either in monetary or in non-monetary terms, which they deserve fairly and equitably for their contribution.

ACCESS AND FAIR & EQUITABLE BENEFIT SHARING MODEL: TOOL FOR PROTECTING INTERESTS OF THE TRADITIONAL MEDICINAL KNOWLEDGE HOLDERS

The idea behind promoting “Access and Benefit Sharing” models/ mechanisms is to help the developing or under developed countries negotiate better and wiser with the developed countries aiming at the maximum generation of benefit, more specifically on economic terms for the former, where both mutually agree to facilitate their infrastructure for an experiment to be conducted on

⁷ Kanchi Kohli, (ed.) “Understanding the Biological Diversity Act: A Dossier”, 1st ed., 2006, p. 159

⁸ *Id.*

a component of the Biodiversity, which not only aims at promoting innovation in this area but also generating value for exploitation of such biological resource.⁹

The concept of “benefit sharing’ is an outcome of the basic formulations achieved at the Convention on Biological diversity and was also adopted as one of the three basic objectives with which CBD entered in to force and hence these three objectives are also called as the three pillars on which CBD rests. This mechanism can also be understood as a basic bargain forwarded by the access providing countries with the access receiving countries as a means of providing some recognition of the role and contribution of the indigenous people in developing biogenetic resources and taking care of the biodiversity. Benefit sharing can be understood to be a process of distribution of any benefits/ funds/ profit obtained as a matter of allowing such access. In this regard strong enforcement of intellectual property rights can be discussed as a possible mode of securing “benefit sharing” as the joint ownership of IPRs over the final product obtained as a result of such facilitating access can be considered as both as a monetary and non-monetary benefit which can be adequately shared by both the parties in order to secure benefit sharing efforts.¹⁰

It is to be noted here that the benefits which will be obtained from the commercial use of traditional use of medicinal plants need to be shared fairly and equitable i.e. firstly the sharing has to be on reasonable grounds which means that the terms and conditions of the benefit sharing agreement which will be entered in to by the parties to such sharing have to be fair and reasonable without any ambiguity and secondly the sharing has to be equitably and not equally which means that if there are two parties to the benefit sharing agreement, the benefit need not be shared equally i.e. in two equal halves rather should be shared depending upon the contribution by each party toward the generation of such benefit and hence such agreement can be entered in to in 60-40 model or 70-30 model or any other model depending upon the fact of contribution of each party in each individual case.¹¹

⁹SrividhyaRagavan, “New Paradigms for Protection of Biodiversity, Journal of Intellectual Property Rights”, Vol. 13, (2008), pp. 18-20.

¹⁰ *Supra Note 6*

¹¹ *Supra Note 8.*

ACCESS AND BENEFIT SHARING NORMS: ANALYSIS OF INTERNATIONAL SCENARIO

The concept of Access and Benefit Sharing norms and their role in protecting the interests of the traditional communities, to the extent of their contribution in protecting and preserving the various components of biological diversity, was first discussed in Convention on Biological Diversity (CBD). But of late this concept has gained importance and has attracted the attention of policy makers of various countries mostly the provider countries and has successfully been addressed by several other international legal frameworks in the form of treaty negotiations, protocol, guidelines, and Model law at an international level. Many provider countries, i.e. the countries which allow access over their biological resources to other countries have legislated their model provisions on Access and Benefit sharing taking force from the most comprehensible & accepted international framework in this context i.e. CBD and other such frameworks to this effect. To name few countries in this context are African Countries like Ethiopia, Kenya, South Africa, Uganda etc., Asian countries like India, China, Japan Malaysia etc., Middle Eastern Countries like Egypt, Jordan, U.A.E etc., Pacific Countries like Australia, New Zealand, Latin American & Caribbean countries like Brazil, Colombia, Costa Rica, Mexico etc.

Limiting the scope of discussions on the International stand towards ABS norms, this research paper will not look in to the individual legal framework of these countries exhaustively rather would focus on the **major international framework i.e. Convention on Biological Diversity (CBD) and its Protocols like Nagoya Protocol and Bonn Guideline**, from which these above mentioned countries have taken the force to legislate such norms within their domestic legal regime

1. Access and benefit sharing under CBD

The three pillars on which the Convention on Biological diversity rests which are also known as the three basic objectives of CBD are:

- Conservation of biological diversity
- Sustainable use of the components of biological diversity
- Fair and equitable sharing of benefits arising from the use of genetic resources.

CBD is considered as the first international treaty which links the access to genetic resources to equitable sharing of benefits related to those resources and hence trying to secure economic exploitation of the biological resources in turn creating avenues for revenue generation for such countries which are rich in biological resources.

The emergence on the concept of “access and benefit sharing” is basically a result of the lobby of the developing countries unhappy with the “open access” system in place with respect to the use of the various components of biodiversity and hence strongly advocating for treating biological resources and the traditional knowledge over such resources as the property of the sovereign state as they hold the lion’s share of the global biological resources.

As a result of which CBD recognizes “sovereign rights of states over their natural resources and the authority to determine access to genetic resources rests with the national governments and is subject to national legislation.¹² It also obliges each contracting parties to create conditions to facilitate access to genetic resources for environmentally sound uses where granting of such access shall be *mutually agreed terms*”¹³ and shall be subject to *prior informed consent* of the contracting party providing such resources.¹⁴ CBD further provides obligation on contracting Parties to take proper steps to ensure fair and equitable sharing of the research results and the benefits received out of commercial exploitation of the genetic resources with the party providing access over such resources.¹⁵

2. Access and benefit sharing under Bonn Guidelines

“Bonn Guidelines on ‘Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising out of Their Utilization”, was adopted in the intergovernmental meeting at Bonn in 2001 by the parties of the “Convention on Biological diversity” as a tool for the countries to negotiate for an international regime on the “Access and Benefit Sharing” mechanism for the utilization of genetic resources within the broader framework of “Convention on Biological diversity” aiming towards fulfilling the execution of the various measures of “Convention on Biological Diversity” and in turn safeguarding not only the natural

¹²The Convention on Biological diversity, Art. 15.1

¹³The Convention on Biological diversity, Art. 15.4

¹⁴The Convention on Biological diversity, Art. 15.5

¹⁵The Convention on Biological diversity, Art. 15.7

wealth of the globe but also to secure the rights and the interests of the community holding knowledge over those resources traditionally.

The Guidelines prescribe for providing assistance to Parties, Governments and other stakeholders in designing the overall strategies for securing access and benefit sharing to this effect and lending clarification on the various procedural requirements required to avail such access. These guidelines strives to provide a better insight to the mechanism of access and benefit sharing in order to equip countries to design legislative, administrative or policy measures on “access and benefit-sharing”. “The Guidelines identify the steps in the access and benefit-sharing process, with an emphasis on the obligation for users to seek the prior informed consent of providers. They also identify the basic requirements for mutually agreed terms and define the main roles and responsibilities of users and providers and stress the importance of the involvement of all stakeholders”.¹⁶ “Although they are not legally binding, the fact that the Guidelines were adopted unanimously by some 180 countries gives them a clear and indisputable authority and provides welcome evidence of an international will to tackle difficult issues that require a balance and compromise on all sides for the common good”.¹⁷

a. Access and benefit sharing under Nagoya Protocol

As an attempt to provide clarity on the issue of both the provider country and user country’s responsibilities with respect to facilitating access requirements and securing benefit sharing provisions respectively, the parties to the Convention on Biological diversity at its 10th meeting in the year 2010 in Nagoya, Japan, adopted the Nagoya Protocol on Access to genetic resources and the fair and equitable sharing of benefits arising from their utilization which stands as a international agreement aiming at the sharing of the benefits at fair and equitable terms arising out of access over such genetic resources which may include the appropriate transfer of the related technologies keeping in view all rights over such resources and technologies and by appropriate funding and hence attempting in contributing towards conservation of biodiversity and sustainable use of its components.

The protocol prescribes for extensive provisions on access stating “the access on the genetic materials is to be provided based on the PIC (Prior Informed Consent) of the provider of genetic

¹⁶ *Supra* Note 6 at 142

¹⁷Graham Dutfield, “Intellectual Property Rights, Trade and Biodiversity”, 39-40 (Earthscan Publications Ltd., London, 2000)

resources, and ‘as appropriate’ and ‘in accordance with domestic law’ on the PIC of indigenous / local communities where they have established right to grant access”.¹⁸ Similarly the Protocol also provides for fair and equitable benefit sharing between the parties where one is the country of origin of the genetic resources and the other is the country acquiring such genetic resources in “accordance with the Convention, where such sharing will be done on the basis of mutually agreed terms. Each Party shall take legislative, administrative or policy measures, as appropriate, with the aim of ensuring that benefits arising from the utilization of genetic resources held by indigenous and local communities, in accordance with domestic legislation over these genetic resources, are shared in a fair and equitable way with the communities concerned, based on mutually agreed terms”.¹⁹ Nagoya Protocol also is known for prescribing specific provision for ‘access to traditional knowledge associated with genetic resources’ which is independent of the provision which facilitates access on genetic resources as mentioned in Article 6 of the Protocol. “In accordance with domestic law, each Party shall take measures, as appropriate, with the aim of ensuring that traditional knowledge associated with genetic resources that are held by indigenous and local communities is accessed with the prior and informed consent or approval and involvement of these indigenous and local communities, and that mutually agreed terms have been established”.²⁰

INDIAN PERSPECTIVE ON ACCESS & BENEFIT SHARING: ANALYSING PROVISIONS OF BIOLOGICAL DIVERSITY ACT 2002

India being a signatory to the Convention on Biological Diversity (CBD) is obliged to give effect to the basic objectives of the convention within the contours of domestic legal framework including the objective “to ensure Fair and Equitable Sharing of Benefits arising out of commercial exploitation of biological resources”. This objective of CBD makes its stand very clear with regard to bringing regulations within the territorial limits of the member countries to prevent bio-piracy. Depending upon the past experience that India has had being a victim of the cases of bio-piracy in mid 90s era be it in the case of filing of patent by other countries over

¹⁸Nagoya Protocol on Access to Genetic Resources and the fair and equitable sharing of benefits arising from their utilization” to the Convention on Biological diversity 2010, Art. 6.

¹⁹ 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 2010, Art. 5.

²⁰Nagoya Protocol on Access to Genetic Resources and fair and equitable sharing of benefits arising from their utilization to the Convention on Biological diversity 2010, Art. 7.

medicinal properties of Turmeric or Neem, which has been a part of the rich traditional medicinal knowledge system in India or that of Basmati rice case, India too has been one of the countries to have complied with the Access and Benefit sharing norms as laid down by CBD by incorporating it with in the Intellectual Property Law regime under the Biological Diversity Act.

b. Access

Access under Biological Diversity Act, 2002 means making the biological resources available within the territorial limits of the country available for research and experimentation provided the conditions stipulated under the Act to be fulfilled before the grant of the Access are duly complied with. The Act provided for a three tier system of regulatory bodies facilitating Access and Benefit Sharing, considered as the statutory bodies established in the Act. The regulatory body at the apex in the National Biodiversity Authority (NBA)²¹ has the power to regulate the access over the biological resources available in India, in case of foreign nationals, companies etc.²² No transfer of research results involving research conducted under biological resources available in India can be transferred from Indian to any other country without prior approval of NBA.²³ Similarly upon any research obtained from the experimentation conducted over biological resources of India, no Intellectual Property application can be filed before any Patent or similar IP offices across the countries in the world including India, without taking prior approval from NBA for the same.²⁴ These provisions creates a very effective mechanism of regulating access over Indian bio-resources by the foreign entities and hence contribute a lot in fighting against the cases of bio-piracy. NBA also takes the responsibility of determination of Benefit Sharing which stands as one of the most prominent features of the Act and which effectively tries to protect and promote the interests of the local people who contribute in conservation, preservation of bio resources and possessing traditional knowledge over them by sharing with them what deserve. The State level regulatory body in this regard is called as the State Biodiversity board (SBB)²⁵ which is answerable to the NBA and has the power to regulate Bio-diversity Management Committee (BMC) which directly reports to the SBB

²¹ The Biological Diversity Act, 2002, (Act 18 of 2003) s. 8.

²² The Biological Diversity Act, 2002, (Act 18 of 2003) s. 3.

²³ The Biological Diversity Act, 2002, (Act 18 of 2003) s. 4.

²⁴ The Biological Diversity Act, 2002, (Act 18 of 2003) s. 6.

²⁵ The Biological Diversity Act, 2002, (Act 18 of 2003) s. 22.

in matters pertaining to the protection, preservation and management of biological resources including the documenting activities that are needed to be complied with as per the provisions of the Act. In case of allowing access to biological resources of India, NBA only has the power to either allow or deny access to foreign citizens, companies etc. and this power of NBA is provided in the Act, which enables NBA not only to grant access to foreign citizens etc. but also gives the power to reject any such application which is duly filed before it seeking for such approval, upon satisfaction of the fact that the conditions required to fulfilled in order to grant such access is not duly complied with. But it is also to be noted that while rejecting any such application, NBA can't act unreasonably or arbitrarily and will always have to record he reasons of such denying in written and communicated back to the applicant stating the reasons for denial. However the SBB doesn't have any such power to reject applications seeking access as this statutory body works on the mode of intimation and that too only in case of Indian citizens, companies etc.²⁶ Any Indian Individual or company wants to have an access on biological resources available in India then they will have to intimate the concerned SBB about the same. Concerned SBB in this case will that SBB within whose territorial limits the resources are available. SBB doesn't have any power to reject any such application. However definitely is granted with the power under the Act to monitor the access by such Indian individual or company to see if the access is properly executed as per the disclosed purpose and mode of conduct etc. in the intimation application filed before it before executing the access on such biological resources. Last but not the least, Biodiversity Management Committee (BMC)²⁷ though falls under the last category in the hierarchy of the statutory regulatory authorities established under the Biological Diversity Act, 2002, performs the most important task of documenting the biological resources available under the territorial limits of its jurisdiction including the task of identifying the various traditional knowledge associated with these and taking proper steps to protect and promote the same. While SBB becomes the connecting link between NBA and BMC, BMC become the authority for undertaking the ground work interacting with traditional knowledge holders and documenting them and hand it over to NBA through concerned SBB in order to keep a check on the cases of bio-

²⁶ The Biological Diversity Act, 2002, (Act 18 of 2003) s. 7.

²⁷ The Biological Diversity Act, 2002, (Act 18 of 2003) s. 41.

piracy involving the biological resources of India resulting in their unauthorised appropriation.

- c. **Benefit Sharing**, as discussed above is one of the most prominent provisions of the Biological Diversity Act²⁸ and is determined by the NBA in a fair and equitable manner in case to case basis, taking in to account the facts and conditions of nature of access, contribution of both the parties (access seeking party and access providing party) in generating the benefit out of commercial exploitation of biological resources available in India. Till date India hasn't come up with any uniform model of benefit sharing and in absence of such model/framework each of such cases are studied and considered individually and the determination of benefit sharing is done. The determination of benefit sharing can be a complex process as at times the valuation of the benefits generated or still generating is very difficult hence such determination is not always done upon monetary terms. Hence different modes of benefit sharing has been adopted in case to case basis and after studying few cases of benefit sharing agreements entered in to by both the parties i.e. the individual entity using biological resources of India and NBA on behalf of those communities or knowledge holders who are also called as benefit claimers²⁹ under the Biological Diversity Act and who preserve such resources or have knowledge associated with such resources facilitated by the NBA the following few modes can be considered as ways of fair and equitable sharing of benefits³⁰:

Ways of sharing monetary benefits:

- i) Granting joint ownership over IPRs to NBA, otherwise to individual benefit claimers where the determination of individual benefit claimers is possible³¹
- ii) Providing the money value as a matter of compensation
- iii) Claim of royalties
- iv) Claim of one time up-front payment

²⁸ The Biological Diversity Act, 2002, (Act 18 of 2003) s. 21.

²⁹ The Biological Diversity Act, 2002, (Act 18 of 2003) s. 2 (a)

³⁰ The Biological Diversity Act, 2002, (Act 18 of 2003) s. 2 (g)

³¹ Ashish Kothari, "Conserving life: Implication of the Biodiversity Convention for India", (Kalpavriksha, New Delhi, 1994)

- v) Claim of continuous sharing of benefit till the other party is making benefit out of it.³²
- vi) Access Fee or Fee per sample collected or acquired
- vii) Joint Ventures
- viii) Milestone Payments
- ix) Upfront Payments
- x) Licensing Fees in case of commercialization
- xi) Research Funding
- xii) Salaries of people (from the local/ traditional communities, knowledge holders) engaged in the carrying out of the research
- xiii) Special fees submitted to the trust funds supporting conservation sustainable use of biodiversity
- xiv) Royalties sharing
- xv) Funding the Funds established to add to the cause of such benefit claimers

Ways of sharing non-monetary benefits:

- i) Transfer of technology to the provider country to be used over the such plant genetic resources to generate value
- ii) Promoting capacity building for such native indigenous people;
- iii) Establishing production, research and development units in that local territory which can generate some employment options for the local people and help them to have a better standard of living.³³
- iv) Collaborative activities and research
- v) Ensuring education for the stake holders or the children of the stakeholder (the benefit claimers)
- vi) Institutional and professional capacity building and relationship
- vii) Participation in product development³⁴

³² *Id.*

³³ Neeti Wilson, "Guidelines for Access and Benefit Sharing for Utilization of biological Resources based on Nagoya Protocol effective", *Journal of Intellectual Property Rights*, Vol. 20, (2015), p. 67-70.

³⁴ *Id.*

- viii) Research directed towards Priority Needs for example food, shelter, hygiene, education etc.
- ix) Research exchange and Research partnerships
- x) Social Recognition
- xi) Training imparted to local people related to genetic resources in order to make them self-sufficient to commercially utilize such genetic resources available with them and generate value out of that³⁵
- xii) Access to information relevant to conservation and/or sustainable utilisation of the biological diversity
- xiii) Admittance to Ex-Situ Facilities of genetic resources and to databases
- xiv) Any other non-monetary ways of contribution to the local economy
- xv) Material resources for capacity building and/or enforcement of access regulations

Setting up of Biodiversity Funds at national, state & local level is provided under the Biological Diversity Act 2002³⁶ where the benefits received in the monetary terms as a result of the implementation of the various access agreements will be deposited to be used for preservation of the biological resources and the overall development of the people and the area from where such biological resources have been taken. The mode, manner and the amount of the benefit which is to be shared will be decided on case to case basis on the mutually agreed terms incorporated in the access agreement mutually by the applicant and the authority/ local people or bodies including the indigenous community.

CONCLUSION

In recent times biological/ natural resources have emerged as one of the biggest assets for any nation owning them in terms of commercially exploiting them and adding significantly to the economic development and in turn all round development of such nation. In achieving economic sufficiency, research and development sector of any nation plays the most important role and the two most essential aspects for a stable and ongoing research and development

³⁵ Stephan Jungcirt, :Access and Benfit Shainng under the CBD and Access to materials for Research”, available at, <https://www.ncbi.nlm.nih.gov/books/NBK92715/> (last accessed on 1/6/2018)

³⁶ The Biological Diversity Act, 2002, (Act 18 of 2003) s. 43.

sector are raw materials (subject matter of experimentation) and skill based workforce including technology and infrastructure (medium generating research results). True realization of all round development i.e. social, economic, cultural etc. for any society at large is not possible without focusing on the aspects of public health and ensuring a healthy standard of living for the members of such society. This is the reason special emphasis is being laid down by countries at large on improving the medical care facilities and ensuring the affordability of medicines. This is where, the potential of traditional medical practices by various native and indigenous knowledge holder communities across the countries and the medicinal properties of various biological resources more specifically that of medicinal plants found within the territory of various nations have been identified as major tools for boosting the research and development efforts in medicines sector at a global level. As per the international consensus achieved in Convention on Biological Diversity (CBD) formulations there will be territorial sovereignty over all biological resources available within the territorial limits of a nation and individual nations can regulate the access over such resources. But unfortunately few nations rich in bio resources realize the importance of this concept of sovereignty over their resources, resulting in cases of bio piracy, which are the direct consequence of unregulated access over these resources. In this context, it is important to understand a *Need based Model* where one nation will extend infrastructure for experimentation while the other will provide the access to biological resources towards a collaborative development in the field of medicine and health care. Additionally benefit sharing mechanism must be considered as a tool of Intellectual property right for generating value for the knowledge holder communities pertaining to traditional medical practices and medicinal knowledge over plants of various access provider countries by properly studying the link between Access & Benefit Sharing (ABS) Model and IPR regime and promoting ABS mechanism as suitable option for protecting knowledge holders pertaining to their traditional medicinal knowledge over medicinal plants.