INTELLECTUAL PROPERTY & BIODIVERSITY- INTERPLAY

BIOLOGICAL DIVERSITY PROTECTION - GENESIS

Biodiversity is the degree of variation of life forms within a given species, ecosystem, biome, or an entire planet. It is a measure of the health of ecosystems which includes genetic diversity within and between species and of ecosystems. Thus, in essence, biodiversity represents all life. Since, humans are exploiting the ecosystem for their personal gains, which has led to extinction of some species, endangering and threatening some of the other species to the verge of extinction, the world community felt the necessity of a regulatory mechanism to conserve, regulate and ensure sustainable use of ecosystem.

To achieve this objective, the Convention on Biological Diversity was adopted at the UNCED Earth Summit at Rio de Janeiro in Brazil in June 1992. The Convention came into force on December 29, 1993. At present, there are 196 Parties to this Convention. India ratified this Convention and has been a party to it since 1994.

Before CBD came into existence, all genetic and biological resources fell into the category of "mankind's universal heritage' thereby requiring no access regulation or benefit sharing obligation in place. The most dispute circumstance in this regard has been that of the plant Rosy Periwinkle – originally native to Madagascar and used in treatment of Hodgkin's disease and juvenile leukaemia. Rosy Periwinkle was resultantly grown in almost all of Texas to aid manufacture of essential drugs, without any compensation to the local community or sharing of profits.[1] CBD on the other hand, identified the sovereign power a State would have over its own biological resources and the need to provide a mechanism for its equitable sharing. CBD is the main international instrument that provides a comprehensive and holistic approach to the conservation of biological diversity, the sustainable use of its components and the fair and equitable sharing of benefits deriving from the use of genetic resources.[2]

It is pertinent to note here that almost simultaneously, in 1994, many industrialized nations of the world concluded Uruguay Round of General Agreement on Tariffs and Trade (GATT). GATT established the World Trade Organization (WTO) and promulgated various trade-related agreements including Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement). It was only in the Uruguay Round of GATT, that Intellectual Property Rights (IPR) were introduced as a part of

[1]James A. R. Nafziger, Robert Kirkwood Paterson, Alison Dundes Renteln, *Cultural Law: International, Comparative, and Indigenous*, Cambridge University Press, 2010.

[2] Hamdallah Zedan, Executive Secretary, Convention on Biological Diversity, *The WIPO Seminar on Intellectual Property Development*, 2005.

international multilateral trading through a set of comprehensive disciplines. Resultantly, TRIPS Agreement came into existence in 1995 and is the most comprehensive multilateral agreement on Intellectual Property (IP). TRIPS Agreement lays down the minimum standards of protection that the member nations must adhere to in protecting IP in their respective jurisdictions. At present, there are 164 Parties to TRIPS Agreement. India has been a Contracting State to TRIPS Agreement since 1994.

It was noticed by stakeholders that there could be potential contradiction between provisions laid down under TRIPS Agreement *vis-à-vis* CBD in specific situations. It was also debated that provisions of CBD trump the objective of TRIPS Agreement or that the TRIPS Agreement would make implementation of CBD ineffective. For example – Article 16.5 of CBD reads as below:

> *"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 (CBD's) objectives."*

Further, Article 22 of CBD reads as below:

> *"The provisions of this Convention shall not affect the rights and obligations of any Contracting Party deriving from any existing international agreement, except where the exercise of those rights and obligations would cause a serious damage or threat to biological diversity."*

Although not inherently contradictory, on a combined reading of these two Articles of CBD with the objectives with which TRIPS Agreement was entered into, one has to admit that it is a daunting challenge of judgment to balance out the objectives of these two instruments. This seeming dichotomy is also reflected in India's domestic legislations i.e. the Biological Diversity Act, 2002 and The Patents Act, 1970 as seen below.

BIOLOGICAL DIVERSITY PROTECTION IN INDIA

All Contracting States to CBD were required to enact national legislations to carry out the objectives as agreed upon under CBD. For their guidance, guidelines on access and benefit sharing were released in April 2002 known as 'Bonn Guidelines' based on which national frameworks could be drafted. The Guidelines bridged the gap between policy development and implementation by providing the elements of a transparent and predictable framework for both users and providers of genetic resources.[3]

[3] *Ibid*

India having ratified the CBD in 1992, recognized its sovereign rights to use its own biological resources, and enacted the Biological Diversity Act, 2002 (BDA Act) facilitating a regulatory mechanism to genetic resources by other Parties subject to national legislation. The main objectives of the BDA Act are:

- Conservation of biological diversity
- Sustainable use of the components of biodiversity
- Fair and equitable sharing of benefits arising out of the utilization of biological resources

Thus, the BDA Act was passed by the Parliament and ensured to be implemented at national, state and local levels, through a decentralized three tier system. At the National level, the National Biodiversity Authority (NBA)[4] was established by Government of India. NBA is an autonomous and statutory body performing enabling / facilitative, regulatory and advisory role to relevant agencies and Ministries of Government of India on issues of conservation of biodiversity, its sustainable use and ensuring fair and equitable sharing of benefits arising out of such use. NBA operates through consultative process involving expert committees and stakeholders. At State level, State Biodiversity Boards (SBBs) are established by the State Governments,[5] while at local level the Biodiversity Management Committees (BMCs) are constituted by the Local Bodies.[6]

In order to understand the basic structure of BDA Act and its interplay with Patents Act, it is essential to discuss a few basic terms[7] referred in BDA Act. Amongst the definitions provided under the enactment, following are of prime importance:

- "***Benefit claimers***" are those persons who are the conservers of biological resources, their by-products, creators and holders of knowledge and information relating to the use of such biological resources, innovations and practices associated with such use and application.
- "***Biological resources***" are defined as plants, animals and micro-organisms or parts thereof, their genetic material and by-products (excluding value added products) with actual or potential use or value, but does not include human genetic material.
- "***Bio-survey***" and "***Bio-utilization***" mean survey or collection of species, subspecies, genes, components and extracts of biological resource for any purpose and includes characterization, inventorisation and bioassay.
- "***Commercial utilization***" is when end use of biological resources is for commercial utilization such as drugs, industrial enzymes, food flavors, fragrance, cosmetics, emulsifiers, oleoresins, colors, extracts and genes used for improving crops and livestock through genetic intervention, but does not include

[4] Section 8 – Establishment of National Biodiversity Authority
[5] Section 22 – Establishment of State Biodiversity Board
[6] Section 41 – Constitution of Biodiversity Management Committee
[7] Section 2 – Definitions

conventional breeding or traditional practices in use in any agriculture, horticulture, poultry, dairy farming, animal husbandry or bee keeping.

- "***Research***" is defined as study or systematic investigation of any biological resource or technological application, that uses biological systems, living organisms or derivatives thereof to make or modify products or processes for any use.

BDA Act implements its objectives by regulating access to the biological resources. This regulation is achieved through providing approvals for using the biological resources. The approval is for accessing the biological resources and for procuring IPR over the inventions on or by using biological resources. The approval for accessing the biological resources is broadly categorized into two buckets. Firstly, the purpose for access and secondly, persons who are accessing the biological resources.

Purpose of access is further sub-categorized into four categories namely, research, commercial utilization, bio-survey and bio-utilization, and for transferring research results.

Persons who are accessing the biological resources are sub-categorized into two categories namely Indians and non-Indian. As per the settled law of jurisprudence, a person includes natural person and legal person. Likewise, the BDA Act categorizes the aforementioned access by citizens of India, corporate entities registered and incorporated in India; non-citizens of India, Non-Indian Resident, Foreign Companies and an Indian entity having foreign participation in its share capital or management. This foreign participation may be either by way of participation through individual foreigner or through a foreign entity duly incorporated under the laws its respective country.

BDA states[8] that *non-citizens of India, Non-Indian Resident, Foreign Companies and an Indian entity having foreign participation* in its share capital or management, cannot

[8] **Section 3 – Certain persons not to undertake Biodiversity related activities without approval of National Biodiversity Authority**
(1) No person referred to in sub-section (2) shall, without previous approval of the National Biodiversity Authority, obtain any biological resource occurring in India or knowledge associated thereto for research or for commercial utilisation or for bio-survey and bio-utilisation.
(2) The persons who shall be required to take the approval of the National Biodiversity Authority under sub-section (1) are the following, namely:-
(a) a person who is not a citizen of India;
(b) a citizen of India, who is a non-resident as defined in clause (30) of Section 2 of the Income-tax Act, 1961 (43 of 1961);
(c) a body corporate, association or organisation—
(i) not incorporated or registered in India; or

access biological resources or knowledge of biological resources without approval from NBA for the purposes of research, bio-survey, bio-utilization or commercial utilization. In other words, any of the aforementioned persons who are interested in obtaining access to the biological resources should obtain a prior approval from the NBA for such access by filing necessary application and entering into an equitable benefit sharing agreement with NBA. On ground, it is seen that for obtaining access for the purpose of research NBA is not insisting upon execution of an agreement for benefit sharing, however, for the purposes of commercial utilization of biological resources NBA insists upon execution of an agreement for equitable benefit sharing with such persons.

It is further provided[9] under BDA that the access of biological resources by *Indian Citizens and Indian entities incorporated under the provisions of Indian Law* for the purpose of commercial utilization or for bio-survey and bio-utilization for commercial utilization should intimate SBB for its access.

With respect to transfer of research results, BDA Act states[10] that no person shall *transfer the results of any research relating to biological resources* occurring in or obtained from Indian for any consideration either in monetary or otherwise *to any person who is a non – citizen, non-resident, or to any foreign body corporate or an Indian body corporate where a foreigner is involved in the share capital or management* without approval from NBA. On ground, it is seen that for the purposes of transfer of research results NBA is insisting for execution of an agreement with the applicant.

(ii) incorporated or registered in India under any law for the time being in force which has any non-Indian participation in its share capital or management.

[9] **Section 7 – Prior intimation to State Biodiversity Board for obtaining biological resource for certain purposes**

No person, who is a citizen of India or a body corporate, association or organisation which is registered in India, shall obtain any biological resource for commercial utilisation, or bio-survey and bio-utilisation for commercial utilisation except after giving prior intimation to the State Biodiversity Board concerned:

Provided that the provisions of this Section shall not apply to the local people and communities of the area, including growers and cultivators of biodiversity, and *vaids* and *hakims*, who have been practising indigenous medicine.

[10] **Section 4 – Results of research not to be transferred to certain persons without approval of National Biodiversity Authority**

No person shall, without the previous approval of the National Biodiversity Authority, transfer the results of any research relating to any biological resources occurring in, or obtained from, India for monetary consideration or otherwise to any person who is not a citizen of India or citizen of India who is non-resident as defined in clause (30) of Section 2 of the Income-tax Act, 1961(43 of 1961) or a body corporate or organisation which is not registered or incorporated in India or which has any non-Indian participation in its share capital or management.

Explanation.- For the purposes of this Section, "transfer" does not include publication of research papers or dissemination of knowledge in any seminar or workshop, if such publication is as per the guidelines issued by the Central Government.

Further, following introduction of Nagoya Protocol[11] on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization (Nagoya Protocol) as a supplementary agreement to CBD, India issued **Guidelines on Access to Biological Resources and Associated Knowledge and Benefits Sharing Regulations** (ABS Regulations) in 2014. It provides a transparent legal framework for the effective implementation of one of the three objectives of BDA Act: the fair and equitable sharing of benefits arising out of the utilization of biological resources.

BRIDGING INTELLECTUAL PROPERTY & BIOLOGICAL DIVERSITY

It is pertinent to note here that, although India had a legislation (Patents Act) for governing Patent Law since 1970, the same went through major modifications post TRIPS Agreement. Being a developing nation, India had a grace period till 2005 to ensure that its national legislation adhere to its international obligations.

With this background, the aspect that bridges BDA Act with Patents Act is laid down under Section 6 of BDA Act which reads as under:

> ***"Section 6 - Application for intellectual property rights not to be made without approval of National Biodiversity Authority***
> *(1) No person shall apply for any intellectual property right, by whatever name called, in or outside India for any invention based on any research or information on a biological resource obtained from India without obtaining the previous approval of the National Biodiversity Authority before making such application:*
> > *Provided that if a person applies for a patent, permission of the National Biodiversity Authority may be obtained after the acceptance of the patent but before the sealing of the patent by the patent authority concerned:*
> > *Provided further that the National Biodiversity Authority shall dispose of the application for permission made to it within a period of ninety days from the date of receipt thereof.*
> *(2) The National Biodiversity Authority may, while granting the approval under this Section, impose benefit sharing fee or royalty or both or impose conditions including the sharing of financial benefits arising out of the commercial utilisation of such rights.*
> *(3) The provisions of this Section shall not apply to any person making an application for any right under any law relating to protection of plant varieties enacted by Parliament.*
> *(4) Where any right is granted under law referred to in sub-section (3), the concerned authority granting such right shall endorse a copy of such document granting the right to the National Biodiversity Authority. "*

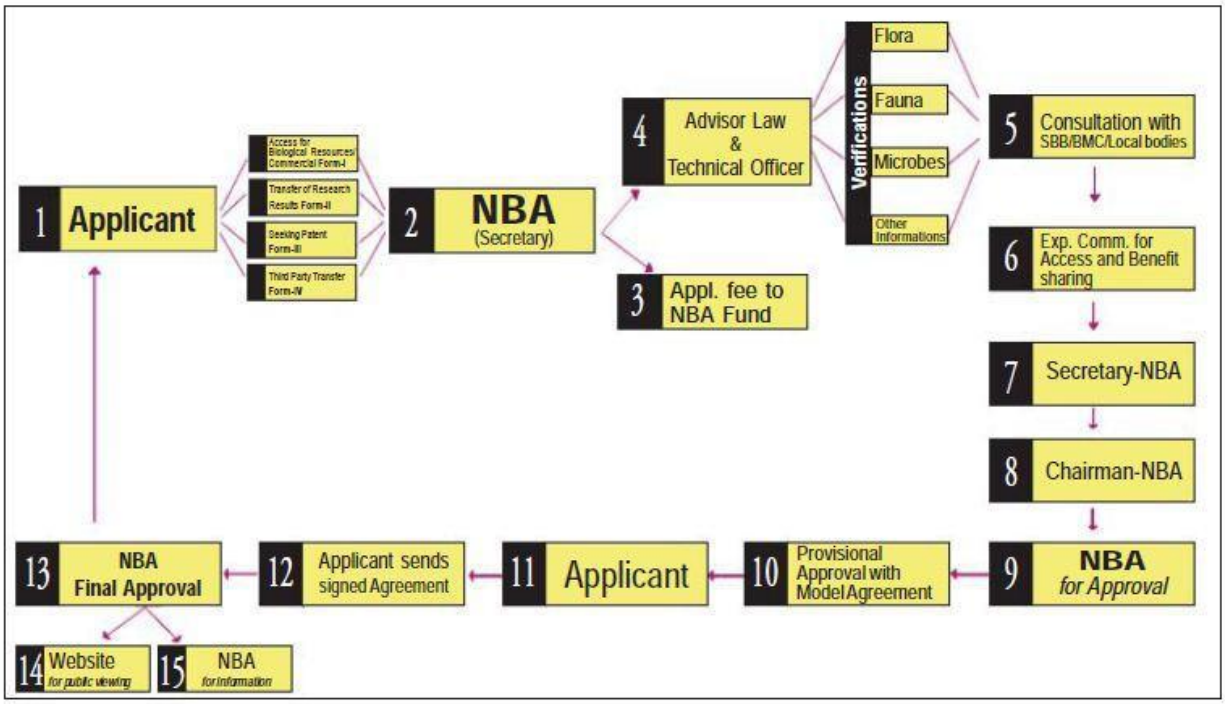
A direct effect of this provision is that, a patent application involving biological resource[12] accessed from India, cannot be made in India, without prior approval of NBA.

[11] <https://www.cbd.int/abs/about/> Last Accessed 18/01/2017, 22:24.
[12] Indian Patent Office (IPO) has also issued ***Guidelines for Processing of Patent Applications Relating to Traditional Knowledge and Biological Material*** on 18th December 2012.

However, in practical scenario it is seen that even if NBA's approval is not taken before filing of such application, such approval has to be sought for the patent to be granted. In other words, for a patent application made in India, involving biological resource accessed from India, will not be granted in absence of approval from NBA. Further, the Section casts an obligation on an applicant to seek NBA's approval before filing such patent application outside India too. It is possible in certain cases, that a patent application may have been filed outside India for an invention involving biological resource accessed from India, without NBA's approval. In such cases, it has been witnessed that, when and if a corresponding application is filed in India, such prior application in absence of NBA's approval are treated as a ground of objection.

The latter part of the Section mentions that while granting the required approval under Section 6 of BDA Act, NBA may impose benefit sharing fee or royalty or both or impose conditions including the sharing of financial benefits arising out of the commercial utilization of such rights. The State Biological Boards also proactively monitor projects and commercial utilization of biological resources and inspecting whether prior intimation has been given thereto.

The entire process of obtaining approval from NBA is pictorially[13] depicted below in Fig 1:



Note: The timeline for granting approvals under Sections 3, 4 and 6 would be between 1 to 3 years from the date of filing the request. However, Section 6 states that the NBA has to dispose the requests filed for approval thereunder

[13] <http://nbaindia.org/content/684/62/1/applicationprocess.html> Last Accessed 05/01/2017, 19:24.

should be disposed within a period of 90 days from the date of such request. However, on ground, it is seen that NBA is not disposing theses requests within the prescribed period. Further, BDA Act does not provide any remedy for failure of NBA to dispose the applications under Section within 90 days.

Although the Biological Diversity Rules, 2004 (hereinafter referred to as "BDA Rules") were enacted in the year 2004, actual implementation of the BDA Rules as pertains to applications seeking approval for filing of IPR[14] started only in the year 2006-2007 as reflected from the Annual Reports of NBA tabulated below in Table 1.

Year wise status of applications	**Form III Filed under Section 6 for Approval for obtaining IPR**
2006-2007	0
2007-2008	11
2008-2009	21
2009-2010	9
2010-2011	4
2011-2012	6
2012-2013	8
2013-2014	14
2014-2015	22
2015-2016	51
2016-2017	78
Total	**225**

Any person failing to comply with any of the provisions stated above can be prosecuted and penalized. The offences under the BDA Act are cognizable and non bailable offences.

- Under **Section 55 (1)**,[15] failing to comply with Sections 3, 4 and 6 shall be punishable with imprisonment which may extended upto 5 years and/or fine which may extend upto Rs 10,00,000/- (Rupees Ten Lakhs ~USD 20,000/-) or in

[14] <http://nbaindia.org/content/683/61/1/approvals.html> Last Accessed 05/01/2017, 20:00.

[15] **Section 55(1)** – Whoever contravenes or to or abets the contravention of the provisions of Section 3 or Section 4 or Section 6 shall be punishable with imprisonment for a term which may extend to five years, or with fine which may extend to ten lakh rupees and where the damage caused exceeds tend lakh rupees such fine may commensurate with the damage caused, or with both.

cases where the damages exceed Rupees Ten Lakhs such amount which may deem necessary.

- Under **Section 55(2)**,[16] for non-compliance under Section 7 shall be punishable with imprisonment which may extend upto 3 years and/or fine which may extend upto Rs. 5,00,000/- (Rupees Five lakhs app. ~USD 10,000/-).

RECENT DEVELOPMENTS

NBA has been actively screening all the activities pertaining to access, transfer and obtaining of IPR over the biological resources. One such example is where NBA denied access of *Jatropha curacas* (ratanjyot) germplasm in India to D1 Oils India. As D1 Oils India applied to NBA in February 2006 with the intention of converting vegetable oil into bio-diesel to the standards stipulated by European Union (EU). The company had proposed to collect 500gms to 1kg of *jatropha* seeds throughout India at every 10 degree latitude. However, its application was not approved by NBA keeping in mind that a controversy around the misappropriation of *jatropha* germplasm from Indira Gandhi Agriculture University, Raipur was yet to be resolved. This decision of NBA set an example of combating exploitation and proper regulation of bio-resources.

NBA prosecuted Company Mahyco for failing to intimate and failing to obtain approval for accessing the eggplants (*BT Brinjal* issue) in India. However, Mahyco is taking a stand under Section 5, seeking for an exception, stating that the research was carried out in collaboration with an Indian Government funded institution. Karnataka State Bio Diversity Board lodged a criminal complaint under Section 55[17] of the BDA against Mahyco, University of Agricultural Sciences, Dharwad and two others before the Chief Judicial Magistrate, Dharwad. The notices have been issued under these complaints by the Magistrate.

Environmental Support Group filed a Public Interest Litigation against Central Government challenging the constitutional validity of the list under Section 40 of BDA and alleging bio piracy by Mahyco in BT Brinjal issue before the Karnataka High Court. The Court directed the matter to be heard by National Green Tribunal. The matter is pending before the National Green Tribunal. However, an SLP is being filed by the Environmental Support Group challenging the constitutional validity of National Green Tribunal in hearing petitions of PIL nature, Section 40 and bio piracy. The matter is yet to be listed before the Supreme Court.

[16] **Section 55(2)** – Whoever contravenes or attempts to contravene or abets the contravention of the provisions of Section 7 or any order made under sub-section (2) of Section 24 shall be punishable with imprisonment for a term which may extend to three years, or with fine which may extend to five lakh rupees, or with both.

[17] *Supra* 15, 16

Further, it has been observed that for certain materials procured from nature, it is not clear if the same would qualify as 'biological resource' and invite corresponding obligations under BDA Act. in October 2015, the Central Zonal Bench of National Green Tribunal (NGT) gave a very balanced interpretation of the term 'biological resource'. Issue in this matter was to determine if access of coal would fall under the preview of BDA Act as it was disputed if coal could be termed as biological resource for the purpose of BDA Act. The Bench laid down that:

> *"The living biological resources have two important properties, the combination of which distinguishes them from non-living resources. They are renewable, if conserved, and they are destructible, if not. The biological resources have capacity to grow, reproduce and evolve. They are amenable to conservation – 'in-situ' and 'ex-situ'. Coal has no capacity to grow, evolve and reproduce. It is not amenable to in-situ and ex-situ conservation. It is a fixed and finite resource, the extent of which is pre-determined in time and space. There is no way in which human or technical intervention can help to increase the extent of coal present in a particular geographical area over time."*

It was held that the mere fact that coal is of plant origin does not imply that coal can be termed a biological resource. It was stated that giving an interpretation to qualify coal as biological resource would go beyond the legislative intent, objective and purpose of the Act. Coal was hence not deemed to be a biological resource as defined under Section 2(c) of the BDA Act.

The process of patent prosecution has also been adapted to satisfy the objectives of BDA Act. Where the applicant states that the disclosed biological resource has not been procured from India, inspite of its easy availability in India, IPO directs the applicant to seek a No Objection Certificate (NOC) from NBA. In such situations, it is seen that NBA requires the applicant to produce an affidavit to this effect and submit invoices of such purchase from outside India. NBA has, as a matter of regular practice, on application made under Section 6 (Form III of BDA), requested to file details regarding corresponding foreign patent applications declared/disclosed before the Patent Office.

NBA has been proactive in processing the requests for approvals especially in processing the applications filed under Section 6 of the BDA within a period of minimum 90 days. Thereafter the Applicant needs to execute an agreement for benefit sharing with NBA. The entire process is being completed within a period of 4 to 6 months from the date of filing of an application for approval under Section 6 of the BDA.

The State Biodiversity Boards have joined hands in enforcing the BDA in their respective regions. Few updates are as follows:

- Maharashtra State Biodiversity Board (MSBB):
  A petition in nature of a Public Interest Litigation was filed before the National Green Tribunal in 2015 on the grounds that MSBB has failed to implement the provisions of BDA and exercise its powers vested

thereunder. Thereafter MSBB has issued close to around 200 notices to various manufacturer, research and development boards and so on calling upon them to comply with the requirements under Section 7 and Section 24[18] of the BDA. Consequently, associations like Ayush and CIDMA have challenged this move by MSBB vide a writ before the Nagpur Bench of Bombay High Court. The matters are yet to be heard.

- Madhya Pradesh State Biodiversity Board (MPSBB):
  After having issued various notices to distilleries and other stake holders a bunch of petitions were filed before the National Green Tribunal challenging the validity of such notices by MPSBB. National Green Tribunal has quashed these notices and has directed MPSBB to look into all the matters afresh.
- Gujarat State Biodiversity Board (GSBB):
  GSBB has joined its hands in enforcing the BDA and its powers vested thereunder. At the moment, there is no information reported regarding issuance of any notices under the BDA by GSBB. However, GSBB is in a mode of investigation and collating data. We anticipate few notices to be issued by GSBB in coming months.

FUTURE PERSPECTIVE /SUGGESTION

It is indeed commendable as to how both NBA and IPO have acknowledged this seeming dichotomy and are actively working in a unified manner for a seamless implementation. However, for a smoother coordination which doesn't hamper incentive to either the innovator or benefit sharing to the local community, a few glitches have to be overcome.

As discussed before, as per the implementation of the Act currently, for any person (as defined under Section 3(2) of the Act) desirous of accessing a biological resource be it for the purpose of research, or for commercial utilization of for bio-survey and bio-utilization has to apply for an approval to NBA under Section 3 via Form 1 of the Act. Benefit sharing for such access is governed by Regulation 2 of Guidelines on Access to

[18] **Section 24 – Power of State Biodiversity Board to restrict certain activities violating the objectives of conservation etc.**

(1) Any citizen of India or a body corporate, organization or association registered in India intending to undertake any activity referred to in Section 7 shall give prior intimation in such form as may be prescribed by the State Government to the State Biodiversity Board.

(2) On receipt of an intimation under sub-section (1), the State Biodiversity Board may, in consultation with the local bodies concerned and after making such enquires as it conservation, may deem fit, by order, prohibit or restrict any such activity if it is of opinion that such activity is detrimental or contrary to the objectives of conservation and sustainable use of biodiversity or equitable sharing of benefits arising out of such activity:
Provided that no such order shall be made without giving an opportunity of being heard to the person affected.

(3) Any information given in the form referred to in sub-section (1) for prior intimation shall be kept confidential and shall not be disclosed, either intentionally or unintentionally, to any person not concerned thereto.

Biological Resources and Associated Knowledge and Benefit Sharing Regulations 2014 (ABS Regulations) and Rule 14[19] of the BDA Rules. An applicant is accordingly required to enter into a benefit sharing agreement based on recurring monetary arrangement with NBA for such access.

Section 7 of the Act requires any person who is an Indian citizen or a body corporate, association or organization registered in India, desirous of obtaining biological resource for the purpose of commercial utilization or bio-survey and bio-utilization for commercial utilization, to intimate the relevant State Biodiversity Board (SBB) before obtaining such biological resource. Benefit sharing for such access is governed by Regulation 2 of ABS Regulations and the respective State Biodiversity Rules. An applicant is accordingly required to enter into a benefit sharing agreement based on recurring monetary arrangement with the relevant SBB for such access.

Post access of biological resource, whether under Section 3 or under Section 7, if such person wishes to apply for any IPR (in or outside India) for an invention developed using the accessed biological resource, he is required to request for an approval from NBA under Section 6 by way of filing Form 3 under the Act. An additional obligation is cast upon such applicant under Regulation 8[20] of ABS Regulations and Rule 18 of the Rules. By this, in addition to the pre-existing benefit sharing agreement consisting of recurring monetary arrangement (be it under Section 3 or Section 7), the applicant is required to enter into an additional benefit sharing agreement consisting of recurring monetary arrangement.

In essence, such an applicant on applying for IPR ends up making recurring monetary deposits (possibly simultaneously) owing to multiple benefit sharing agreements entered into under Section 3 and Section 6; or Section 7 and Section 6, as the case maybe. Such kind of an implementation of the BDA Act, BDA Rules and Regulations thereunder render as a tool analogous to double taxation against such an applicant for accessing and using the same biological material.

[19] Rule 14 – Procedure for access to biological resources and associated traditional knowledge.

[20] Regulation 8 – **Procedure for obtaining Intellectual Property Rights (IPR)**

(1) Any person who intends to obtain any intellectual property right by whatever name called, in or outside India, for any invention based on any research or information on any biological resources obtained from India, shall make an application to the NBA in Form III of the Biological Diversity Rules, 2004:
Provided that if the applicant is a person referred to under sub-section (2) of Section 3 of the Act, he shall provide evidence of approval of NBA for access to the biological resources and/or associated knowledge used in the research leading to the invention:
Provided further that any person applying for any right under the Protection of Plant Varieties and Farmers' Rights Act, 2001 (53 of 2001) shall be exempted from this sub-regulation.

(2) The NBA shall, on being satisfied with the application under sub-regulation (1), enter into a benefit sharing agreement with the applicant which shall be deemed as grant of approval for obtaining IPR.

It can hence be suggested that the moment an applicant enters into a benefit sharing agreement under Section 6, such agreement should supersede and replace all and any other previous benefit sharing agreements with the concerned authorities. It is accordingly suggested to have one agreement governing the benefit sharing mechanism and payments thereunder between the applicant and NBA alone whereby the applicant (if Indian) is not required to enter into separate agreement/s or continue making payments under any existing arrangement/s with the respective SBBs.

CONCLUSION/EXECUTIVE SUMMARY

"To improve is to change; to be perfect is to change often." Quoted Winston Churchill and hence the law evolves as per the need and time of society. Introduction of any new law brings with itself the challenges of its implementation. But, far more daunting is the task to ensure seamless co-existence of the new law with that of pre-existing statutes.

Operation of the two legislations that sparked a debate of 'IPR v Biodiversity', have come a long way and matured respecting their respective objectives. It has been recognized that the essence of law is in its spirit and not in its letter. When there is an apparent conflict between two or more statues or two or more parts of a statute then the rule of harmonious construction is adopted. This rule is founded on the simple principle that every statute has a purpose and intention of the legislature must be identified. Every statute has to be read as a whole. The most comprehensive and all-compassing interpretation is then adopted.

The only way forward can be this progressive approach of having a harmonious construction of the two statutes so that objectives under both these statutes can be met with in tandem.
