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Confederation of Indian Industry

CII RECOMMENDATIONS ON ISSUES ASSOCIATED WITH BIODIVERSITY LAW AND ITS COMPLIANCE

Submitted to
Department of Biotechnology
Government of India

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EXECUTIVE SUMMARY

India is a party to the United Nations Convention on Biological Diversity signed at Rio de Janeiro in 1992. To give effect to this Convention, on February 5, 2003, the Biological Diversity Act, 2002 ("The BD Act") was introduced. The legislative intent of the Act is to provide for the conservation of Indian biological diversity, sustainable use of the components and fair and equitable sharing of the benefits arising out of the use of biological resources and associated knowledge.

As per the Act, access to the biological diversity of India is to be regulated. The administering authority for this purpose is the National Biodiversity Authority (NBA). The Act bars any access to Indian biological resources by non-Indian citizens or non-resident Indians or entities which have any non-Indian participation in its share capital or management, without taking an approval from the NBA. Similarly, all such entities are required to take prior approval from NBA before transferring any research data to any such entity.

The BD Act further restricts any applicant from filing any Intellectual Property Right (IPR) within or outside India, before seeking prior approval from the NBA. This requirement is applicable to Indian as well as non-Indian applicants. In case of patents, such approval may be sought any time before the grant of a patent.

The NBA approval is in the form of a written agreement between the applicant and the NBA which requires fixed royalty sharing on commercial gains based on the use of the biological resources in question. Non-compliance of the requirements under the BD Act, can attract severe penalties which includes heavy fine or even imprisonment.

The Indian Patent Office (IPO) issued guidelines in 2012 and 2013 to its Examiners, instructing them to ask for requisite NBA approvals before granting patents in cases which involved Indian biological materials. This has led to widespread objections from the IPO, even though the patent applicant even in cases where Indian biological resources may not have been used.

This booklet aims to highlight some of the practical difficulties faced by stakeholders operating in the area of life sciences and biotechnology in view of the implementation and interpretation of the BD Act by the NBA. It also highlights the prevailing practice at the NBA as well as the IPO in implementing these regulations which appears to have a direct impact on the foreign collaborative research projects as well as the number of patent filings in this sector in India.

This White Paper also provides certain recommendations on each highlighted aspect to address these issues and improve ease of doing business in the biotech and life sciences sector in India. Suitable amendments in the law and practice have been suggested which will pave way for encouraging researchers and innovators to collaborate globally and make India, an attractive jurisdiction to invest and protect IPRs while ensuring that the spirit of this legislation is upheld.

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CONTENTS

A. LEGISLATIVE INTENT OF THE BIOLOGICAL DIVERSITY ACT (BDA) 2002

The Biological Diversity Act (BDA) was passed by the Parliament as a direct result of India having ratified the Convention on Biological Diversity (CBD) in 1994. The Convention was opened for signature on 5 June 1992 and came into force on December 29, 1993. The main objective of BDA is for conservation and sustainable use of Indian biological diversity by ensuring fair and equitable sharing of benefits arising out of the utilization of Indian biological resources. In light of this objective, the BDA has been crafted to regulate the access of the Indian biological resources and provide a mechanism for sharing of benefits arising therefrom..

As the BDA is currently being interpreted, the effect on agricultural research in India is adverse at best, and crippling at worst. If access to biological resources is blocked or the route is made so difficult to traverse, development of new and improved varieties will be affected. This, in turn, affects the availability of the latest tools and products to Indian farmers. The tone should that of facilitation rather than of hindrance, and a rational and reasoned reading of the BDA would go a long way to address the current problems in the implementation of this Act.

B. ISSUES IN IMPLEMENTATION AND COMPLIANCE – LACUNAE, IMPACT THEREOF AND RECOMMENDATIONS

1. Requirements of a patent specification under section 10 of the Patents Act and Form 1 under the Patents Rules, 2003

There is no direct provision in the Patents Act linking the BDA with the Patent process. The only link is found as a declaration by the Applicant in Application Form 1 (i.e. Application for Grant of Patent, paragraph 12(iii)), as to whether the invention as disclosed in the specification uses biological material from India and if so, necessary permission from the competent authority shall be sought before the grant of the patent.

Thus, it is clear that once the applicant declares in Application Form 1 that a biological material from India has been used, necessary permission from NBA under section 6 of the BDA will be required. On the other hand, if no Indian biological material was used, the declaration would be struck off and the question of NBA permission would not arise.

Recommendation: The term "use" must be more precisely defined. There are several situations where the invention may have 'used' an Indian biological resource but does not form a part of the claims (ownership). In such situations, BDA approval exemption is in order.

For example, if the "Biological resource" is widely and freely available and is used for testing or validating the claim, it must not warrant any approval from BDA.

Section 10(4)(ii)(D) of the Patents Act requires that the patent Applicant should disclose the source and geographical origin of the biological material in the description of the patent application, if such information is not readily available to the public. Non-disclosure or wrongful disclosure of source of biological material and any associated knowledge is a ground for opposition/ revocation of patent.

This requirement was included under the Patent (Amendment) Act, 2002 on June 25th, 2002 immediately after India ratified the Budapest Treaty on December 17th, 2001. Till this time, the BDA was not enacted. The BDA was enacted on February 5th, 2003 and became effective October 1st, 2003. Clearly, the legislative intent for section 10(4)(ii)(D) was that if the biological material used in the invention was not clearly defined or available to the public, the applicant should inter alia, disclose the mention the source and geographical origin of such material as part of the specification. The intention of this requirement is to simply make such biological material (not clearly defined or available to the public) accessible for working of the invention It is thus clear that the definition of biological material under section 10 of the Patents Act specifically relates to microorganisms or any replicating genome (covered under Budapest Treaty) alone, irrespective of whether the same is of Indian origin or not.

Clearly therefore, this requirement under section 10(4)(ii)(D) of the Patents Act is an independent provision and has no bearing on the requirement of Section 6 of the BDA.

Further, the words "source" and "geographical origin" are often mixed up, although they mean two different things. While "source" may refer to the person/entity from where the biological material was obtained, "geographical origin" encompasses history of the biological material, for example, when the biological material was originally isolated/found, and is a complex issue involving several considerations. This information is often obscure and rarely available. Therefore, if the source of biological material is disclosed this requirement should be considered to have been met.

The requirement under section 10 (4)(ii)(D) is independent and is to be complied with only if the biological material:

I. does not satisfy the clauses (a) and (b) of Section 10(4);

II. is not available to the public; and

III. is not deposited with an international depository authority under the Budapest Treaty.

Recommendation: The IPO should not raise such objections during examination if the applicant has struck off the declaration in Form 1 related to use of Indian biological material.

2. Abuse of Section 6 – IPO going beyond the mandate

Two Controller's Order refusing applications on ground of necessary permission from NBA (1079/KOL/2009) and (085/KOL/2010):

To sum up both these cases, the IPO rejecting the application, reasoned that importing the biological material, otherwise available in India on commercial scale, may make the product unaffordable for Indian public. It further observed that the supposed deficiency defeats the intent of Section 83(a) and 83(g) of Patents Act (working of patents) and that in light of said provisions, necessary permission from NBA ought to be taken.

In both these orders, even before granting a patent, the IPO assumed that the invention, if made from imported material, would not be reasonably priced for sale in India. Further, it was assumed that the patent "will" be commercialized.

If one were to interpret the order that the IPO expects Applicants, domestic and foreign alike, to use biological material sourced from India (if available commercially), and consequently seek NBA approval, this would put an undue burden on the Applicant anywhere in the world, and may in fact detract and demotivate from filing for intellectual property rights in India.

Recommendation: From the above, it is clearly established that the interpretation of Section 6 by the IPO is overstretched, incorrect and clearly goes beyond the scope and intent of both the BDA and the Patents Act.

3. Formality issues

- para 9(iii) of Form 1 (Patents) states that *"The invention as disclosed in the specification uses the biological material from India and the necessary permission from the competent authority shall be submitted by me/us before the grant of the patent to me/us".*

So, if biological material is not obtained from India, the applicants simply score out this entire para. And if biological material, is obtained from India, this is retained and necessary approval from NBA is sought before the grant of the patent. It is not clear what is the course of action to be taken if the biological material/resource is obtained from India, but for said resource an exemption/No Objection Certificate (NOC) under "Value Added Products" (VAP) is desired.

Recommendation:

- Clarity on how said para in Form 1 is to be treated should be given by the NBA/IPO or an option of re-wording said para should be provided
- Currently there is no provision for getting an NOC when the patent applicant believes that there is an exception possible – NTAC/VAP/Human material etc.
- Clear provisions for obtaining NOC's in such scenarios should be made available immediately. Further, the process of issuing the NOC's should be simple and speedy.

4. Grant of Foreign Patents contravening Section 6

Section 6 states that no IPR (including patent) shall be applied in or outside India without prior approval from NBA. Further, such approval may be obtained after filing of the patent, but before sealing of the same by the patent authority concerned. This provision has procedural flaws since patent Applicants have the right to file applications in multiple foreign jurisdictions (irrespective of the filing/non-filing of Indian Patent Application) wherein the grant of such foreign patents is not governed by the NBA approvals in India.

Further, section 6 clearly provides the Applicant an opportunity to obtain NBA approval any time before sealing of the patent (including foreign patents). Accordingly, there may be cases wherein even though an Indian and foreign application(s), or only foreign application(s) are filed,

such foreign applications may proceed to grant while the application under section 6 (Form III) is not filed or is still under processing by the NBA.

Recommendation: In such scenarios, the NBA must allow the Applicant a retrospective approval if necessary and proceed in a manner which is in line with the principles of natural justice rather than proceed with a negative approach.

5. More clarity needed – BD ACT

a) Value Added Product (VAP)

- There is no clarity on what is to be considered as a "Value Added Product" (VAP). Additionally, there is no clarity on what is considered 'physically inseparable'. NBA has not identified and provided an exhaustive list of Value Added Products over which exemption can be sought u/s 2(c) and 2(p) of the BDA.
- Interpretation of VAP by NBA should be harmonized with well-established definitions of VAP by recognized authorities.

  For e.g. A patent application mentioned use of additives including coconut oil. The application was filed by a Section 3(2) company. The NBA sent a show cause notice not only requiring Form III but also on not filing Form I for seeking prior approval for conducting research. Here, it is imperative to note that an authority such as The Coconut Development Board categorizes coconut oil as a VAP, but the NBA considers it as a bioresource thus requiring intimation/approval.

Recommendation:

a) Issuance of a notification pertaining to the exemption provided to VAP as defined under Section 2(p) of the Act, to clarify the ambit and applicability of the said definition (such as clarity on what constitutes unrecognizable and physically inseparable form) for removal of ambiguity and effective implementation of the legislation.

b) An exemplary and non-limiting list of VAP be provided to give guidance to the Applicants.

c) Products such as oils/extracts derived from biological resources should be considered as VAP since the biological resource undergoes a chemical process to extract such oils/ extracts. Further, if the applicant has purchased such oil from a commercial manufacturer/ supplier, NBA requirement should be waived off.

d) Furthermore, as the stand on VAP is unclear, the NBA should allow affidavits from the Industry experts to showcase that the product/biological resource employed is a VAP and hence an exemption is to be provided. Such moves by the NBA would be welcome by the stakeholders and Applicants and could accordingly boost the IPR filings in India.

e) Vaccines should be listed in the VAP list since natural resources are/may be added to vaccine either as excipient or adjuvant for value addition to immunity generated against the antigen. Even though the same may be in 'unrecognizable and physically inseparable form' only at the time of vaccine formulation in a given scenario, where antigen and adjuvant are supplied separately and mixed only at the time of administration. There should be provisions to address such cases.

6. No provision yet for retrospective NBA approval or remedy for contravention of the BDA

As per current scenario there is no provision under which post facto i.e., retrospective approval to be granted by NBA u/s 3, 4, 6 or 7. Also there is no clarity on whether there have been any instances wherein retrospective approval was granted by NBA u/s 3, 4 or 7 based on bona fide of the applicant.

Also, for cases where the IPO had not raised objection pertaining to seeking approval under Section 6, there is no clarity on available remedy for such unintentional contravention by the Applicant.

Recommendation: NBA should consider the bona fide of the applicant and be open to issuing approvals retrospectively. It must be kept in mind that the intent of the legislation is not to hinder research and development or commercial advancement but to ensure sustainable conservation. Retrospective approvals can encourage even those applicants who may have unintentionally missed seeking the approval as against spreading fear among innovators.

7. Intention/Purpose of utilizing biological resources should be considered under Section 6

Since the objectives of BDA are clear and aim at preventing over-exploitation, thereby resulting in conservation and sustainable use of biological resources, the primary purpose/intention of utilizing the biological resource in an invention for IPR should be considered while passing any order regarding contravention.

As mentioned in part A of this document, "use" of biological resource in several situations such as testing/validation, may not require BDA approval and hence could be exempted.

Recommendation: Approval under Section 6 should not be required in scenarios where the actual objective of the Act is not contravened. Alternately, if this approval is applied for, NOC should be granted by NBA expeditiously and without any ABS agreement to avoid unnecessary hassles and delay in grant of IPR.

8. Certain material to qualify or not as biological resource

a) Exemption of 'Waste' under biological resource

NBA guidelines do not provide clarity whether waste resources such as waste water/ sewage waste/agriculture waste of India would be exempted from falling under the ambit of the definition of "the biological resource". It is important to note that the Ministry of new and renewable energy, Government of India, identifies the importance of developing new technologies for energy generation from waste biomass resources such as bagasse, cotton stalks, rice husk, straw, saw dust, etc.

Further, 'waste' should also include plant pathogens, disease causing organisms, weeds, etc, which are "biological resources" but which are unwanted/scrounges and do not in

any way hamper the sustainable biodiversity of India. As per the legislative intent of the BD Act, sustainable conservation of natural resources and benefit sharing thereof is the key rather than limiting use of lifeless "waste" arising out of such natural resources for the benefit of society.

Recommendation: To encourage researchers in this area and to boost alternate energy technologies, waste materials arising from biological resources should be kept out of the ambit of the BDA and appropriate clarification should be issued in this regard. In such scenarios, instead of making the Applicant undergo the ordeal of lengthy approval procedures/hearings, a clear-cut exemption of use of such biological resources should be provided, without having to intimate or seek approval from the NBA/SBB.

b) Exemption of other resources

In the matter of Western Coalfields Ltd., Coal India Ltd & Union of India vs. Biodiversity Management Committee, NGT, 2013, it was held that coal is not a biological resource in terms of section 2(c) of BDA. It was argued that unless a material has the capacity to grow, reproduce and evolve, the same does not qualify as a biological resource.

Recommendation:

- The NBA should clearly consider such arguments where similar case would be applicable and if the Applicant is able to establish that a material would not qualify for the aforementioned reasons, to be a biological resource, use of the same by the Applicant should be exempted from seeking any approval/ intimation.
- Similarly, exemption should be made for "use" of plant varieties and hybrids under cultivation; whether notified by central/state variety release committees or not. Such materials are not "endangered" and can be directly accessed from the market or other field without restriction by anyone.

9. NTAC exemption

Products that have been listed in NTAC (Normally Traded as Commodities) list are obviously abundant, and therefore Access and Benefit Sharing (ABS) should not be imposed on their use as is or in a processed form. For instance, coconut is on the NTAC list, and therefore accessing coconut or coconut oil should not come under the purview of ABS whether traded as a commodity or employed otherwise for research to arrive at an invention.

Additionally, it is unclear which SBB is to be approached by Applicant that takes biological resource directly from traders/market and employ it in their invention, as the Applicant may not know the origin of the biological material to provide proper details in Form III of BDA.

Recommendation: The NBA must have stake-holder meetings involving cross section of people to get business perspective legal perspective. At present, the implementation of the law appears to be beyond what was envisaged by the drafters of the BDA or as mandated under the Convention of Biological Diversity.

10. Special Exemptions

Section 6 of the BDA requires the Applicant to enter into a benefit sharing Agreement regardless of the purpose or the type of invention. However, a special scenario has been carved out under Regulation 14(2) of the "Guidelines on Access to Biological Resources and Associated Knowledge and Benefits Sharing Regulation, 2014", for inventions that are developed for controlling epidemics/diseases, mitigating environmental pollution affecting human/animal/plant health, etc. for the purpose of benefit sharing. However, clarity and effective implementation of the same is needed.

Recommendation:

a) said 'special consideration' be specifically clarified to mean exemption in order to avoid any ambiguity at the time of receiving approval from NBA and the same be inserted as a part of the BD Rules for effective implementation;

and

a notification be issued for exempting the technologies/products developed for controlling epidemics/diseases, mitigating environmental pollution affecting human/animal/plant health, etc.;

or

b) based on the details relating to the biological material and the purpose of invention, authorities should provide a NOC stating that approval under the BDA is not required for the said invention.

11. Flaws with Form III of BDA

Form III for seeking approval for patent applications has flaws:

- Form III in word format and in electronic format on the Official website of NBA are different (u/s 19(2) & 19(3)).
- The electronic filing of Form III format is too detailed and asks for information/enclosures that are irrelevant at the stage of mere filing of patent. Filing of patent is no proof of commercialization and therefore there can be no royalty. Therefore, detailed information on Form III is daunting, and in several instances, the Applicant has preferred to allow the patent application to lapse in view of this complicated procedure..

Recommendation: The design of Form III needs to be simplified for ease of applicants and to facilitate quick issuance of approval from the NBA and grant of patent applications.

12. Qualification criteria for "certain persons" under Sections 3 & 4 of the BDA

Said provisions of the BDA deter foreign joint ventures as well as collaboration with foreign scientists because of strict prohibition on even minor equity holdings in a company.

It would be impractical for a company holding thousands of shares to follow this procedure when only a minor portion of shares are held by other persons or corporations not based in India.

Further, in case of a listed company, at any given time, a non-Indian may buy shares thereby making it a person under Section 3(2)(c)(ii) and hence required to take NBA permission.

Recommendation: There should be restrictions only when the non-Indian shareholders are in a position to influence the decisions and management of the company in question, not otherwise. In a world of open innovation and extensive research collaborations, such restrictions are draconian and contradictory to progress of science.

13. NBA Approval timelines

The timeline for obtaining approvals under sections 3, 4 and 6 are between 1 to 3 years from the date of filing the application. While, section 6 states that NBA has to dispose the applications for approval within 90 days from the date of application, there are considerable delays in the same.

Currently the BDA does not provide any remedy for failure of NBA to dispose the applications within 90 days.

Recommendation: Timelines should be strictly adhered to by the NBA to provide such approvals as any delays in this regard, can be prejudicial to the patent Applicant. Suitable remedy to the Applicant should be provided in case of such delay by the NBA.

14. Abuse of Section 7 by SBB

For Indians, approval under sections 3 and 4 is not required for filing an application under section 6. But lately, SBBs are objecting to such approvals by NBA under section 6 stating that intimation under section 7 has to be made before hand due to enlargement of scope of section 7 under Regional State Rules.

Further, under section 7, Indian Citizen or an Indian entity are only required to give prior intimation to the concerned SBB for undertaking commercial utilization or bio survey for commercial utilization. In other words, Indian Citizen or an Indian entity undertaking research activity does not fall under the ambit of section 7. However, in practice, various SBBs through its state rules have included research activities within the scope of section 7, which is prima facie ultra vires.

Recommendation: SBBs should stop issuing such notices and act as per the BDA which requires an applicant to merely intimate the SBB in case of obtaining biological resource for commercial utilization, or bio-survey or bio-utilization for commercial utilization.

15. Penal provisions - harsh and unnecessary

Though enacted in the year 2002, the link between BDA and patents was effectively implemented only in the year of 2012 when the Controller General of Patents (CG) issued Guidelines for Processing of Patent Applications relating to Traditional Knowledge and Biological Material. Under these circumstances, till the issuance of the said guidelines by the CG, most of the Applicants were unaware about such regulatory linkage under both these Acts.

Since Sections 55(1) and 55(2) of the BDA provide for contraventions under the BDA as cognizable and non-bailable offences, researchers and other entities engaged in businesses involving any Indian bio-resources are deterred from innovating in this area. The objectives of the BDA, i.e., conservation, sustainable use, fair & equitable sharing of benefits arising out of the utilization of biological resources is therefore, in conflict with innovative spirit and entrepreneurship in this area.

Recommendation:

- Since one of the key objectives of the legislation is 'benefit-sharing', NBA should emphasize and work on the philosophy of essentially benefit-sharing, and not 'penalization for contravention', especially when a party is willing to enter into benefit-sharing-arrangement.
- This is particularly relevant because most of the bio-resource industry appears to have contravened certain provisions of BDA at some point in time, primarily due to lack of clarity or awareness. Hence, providing a blanket retrospective approval (with a fixed one-time royalty) for all such Applications is recommended in case of bona-fide conduct of applicant.

16. Multiple Approvals & benefit sharing agreements – tedious process

A foreign national, or entity or an Indian Body corporate having foreign national or a non-resident Indian has to undergo multiple approval processes and benefit sharing agreements right from access / commercial utilization of biological resource (section 3), followed by applying for IPR (section 6).

Similarly, even Indian citizen/entity has to provide intimations if it involves commercial utilization (section 7) or transfers research results to a non-Indian (section 4) or seek approval applying for IPR (section 6) leading to multiple approvals/benefit sharing agreements.

In essence, an Applicant on applying for IPR and subsequently for commercialization of the invention 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 and Rules & Regulations thereunder render as a tool for double taxation against such an Applicant for accessing and using the same biological material. Need for seeking multiple approvals at every stage and overtly stringent laws levied, is a sure deterrent for Applicant, especially for start-ups having some form of foreign investment and outside nationals to file patent applications in India.

Recommendation:

- A single and simplified form/approval process be developed to cover all intimations/approvals so that the Applicant is not required to enter into separate agreement/s or continue making payments under any existing arrangement/s with the respective SBBs.
- Further, if 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.

17. Issues with the ABS agreement:

1. **Arbitration** – Presently, under the Agreement, in case of dispute, it is to be settled by sole arbitrator appointed by Chairman, NBA.

> **Recommendation:** Disputes should preferably be settled through Courts of Law. If disputes are to be settled through Arbitration, then, each party viz. the Company and NBA should have equal rights to appoint one Arbitrator each and these two Arbitrators will mutually appoint a third Arbitrator.

2. **Employment of people** – Presently, Agreement says that Company should employ people in consultation with NBA.

> **Recommendation:** Company should have full freedom to employ people as it deems fit based upon its specific requirement.

3. **Utilisation of Biological Resources** – Agreement says that Company should utilize India as its first source of supply. In case Company wants to cultivate the biological resources, then, such cultivation should also be done in India. Further, if the Company wants to license or sub license the IPR then, these clauses should appear in such agreements.

> **Recommendation:** This clause may be done away with. Especially if the Company proposes to license or sub license the IPR to a foreign entity then, such restrictions may not be acceptable by the foreign entity.

4. **Payment of Royalty –**

   Royalty clauses in the agreement - There should be some provisions/clear guidelines for addressal of following scenarios:

   Scenario 1: If the biological resource is used as an excipient in vaccine, the royalty should be calculated on the basis of cost of biological resource alone. This is proposed because antigen costs in vaccine formulation are relatively very high.

   Scenario 2: Company has to pay royalty based on the Net Sales of the product / vaccine manufactured using the biological resource. However, it seems unfair to pay royalty on the entire sale price of the product. It should rather be based on the value of the biological resource which is used for making of the product / vaccine.

5. Liabilities & Indemnification - Presently under the Agreement, Company needs to pay a sum as determined by NBA for any material breach of the Agreement in addition to the compensation commensurate with any damage incurred by benefit claimers or Republic of India.

> **Recommendation:** Clause is not clear and one sided. This should be reviewed and reconsidered.

6. Status Reports:

- Presently, the agreement requires the applicant to submit a status report for each reporting year not later than two months of the end pf each reporting year. This is unclear.
- Status reports in connection with corresponding foreign IPRs need to be provided no later than 2 months of the end of the reporting year. This is unnecessary and undue burden on the applicant. Further, it is beyond the mandate of the BDA.
- A copy of Form 27 (working statement) to be provided to NBA within one month of submission at the IPO. This is undue and unnecessary burden and beyond the mandate of the BDA.

Recommendation:

- All the above clauses are unnecessary, one-sided and cause undue burden on the applicant/patentee. These clauses must be done away with.
- The NBA is not responsive to applicant requests on mutual negotiation of any of these obligatory clauses and is pressurized to enter into such one-sided agreements. This should be looked into and appropriate corrections to the procedure made.

18. Role of local communities

An analysis of the provisions reveals that local concerned communities do not have any real power in the decision-making process. Regulation of access is done by NBA and SBB and not the local communities. The communities have no say in deciding whether or not the access should be allowed in the first place. They are not well informed as to their rights and have very less knowledge of the system of IPRs or commercial use of the traditional knowledge, and this highly centralized approach is not of any great benefit.

Recommendation: Active participation of local communities to facilitate benefit sharing is recommended. The local communities should be educated about the intent and objective of NBA. The NBA may consult the communities to work out benefit sharing mechanisms after the decision to allow access is made.

A more transparent module intimating the Applicant on utilization of the funds collected by NBA is required.

C. IMPLEMENTATION OF BDA PROVISIONS - COUNTERPRODUCTIVE TO INDIAN START-UPS AND INNOVATION

Start-Ups, with limited resources and manpower can sustain only through continuous growth and development oriented innovations. For this, it is equally crucial that they protect their IPRs. To protect and promote IPR of Start-Ups thereby encouraging innovation and creativity among them, Government of India (GoI) is continuously working hard to bring out several initiatives and schemes [including Start-Ups Intellectual Property Protection (SIPP) scheme, Make-in-India initiative and so on].

However, the entire purpose of such initiatives/schemes for spurring, adopting and motivating IPRs amongst start-ups in the area of life sciences, is defeated due to the approach/lack of application of mind by IPO towards BDA provisions, lengthy and rigorous NBA approval processes and additional issues as discussed above as well as in the forthcoming paragraphs.

In particular, most of the Start-Ups are hesitant to apply for IPR due to these regulatory approval requirements and lengthy procedures involved. It is also pertinent to note here that the recently implemented Patent (Amendment) Rules effective from May 2016 provides a provision of 'expedited examination' for the Start-Ups to boost innovations and provide speedy IPR protection. However, the tedious and lengthy NBA related procedures defeat said purpose.

More importantly, start-ups having foreign equity are the most impacted wherein access of Indian biological material is governed by regulatory approvals (section 3), let alone the approvals required by NBA under section 6. Most of the start-ups have foreign investors, hence in one way, Start-UP India and other initiatives are looking to promote their growth; whereas Section 3 of BDA potentially restricts their work/growth as they would be able to 'touch' a biological resource only after an approval.

Recommendation: We propose that:

- The patent applications using Indian biological material be granted without awaiting NBA approvals (provided the patentability requirements under the Indian Patents Act are met);
- A special provision be carved out for start-ups expediting the approval processes;
- Additionally, to promote Make-in-India initiative of GoI by attracting foreign investments and working of inventions in India, the regulatory intimation/approval processes for foreign entities under Sections 3, 4 and 6 should be simplified based on the below recommendations.
- The above may even need legislative amendments but this may be the way forward to improve the innovative/startup environment in India in this sector.

D. SUMMARY AND CONCLUSION

- The BDA lacks effective provisions towards conservation; rather it lays more emphasis on profit-sharing from the commercial use of the biological resources.
- The legislative intent must be kept in context while deciding any approval/contravention.
- Clarifications/guidelines must be provided on various items as highlighted above to smoothen the process and remove redundancies.
- Regular meetings with stakeholders should be conducted to bridge the gaps and ensure conservation of biodiversity, sustainable use of the components of biodiversity and fair and equitable sharing of benefits arising out of the utilization of biological resources of India, in its true sense.
- Regulations to specify the quantum of non-Indian participation in Sec. 3(2)(c)(ii) that would trigger the approval requirement under Section 3(1), e.g. >50% of total shares held by a non-Indian.
- Specify a list of biological resources as laid down in Article 7 of the CBD, which would be

covered by the BDA. These should be confined to rare species, endangered species, landraces, wild species.

- Industry context is important. Specifically, for the agricultural sector, "wild relatives of domesticated or cultivated species; of medicinal, agricultural or other economic value" have been mentioned with the intention to exempt cultivated crop species from the provisions of the BDA.
- The list of exempted crops (NTAC) notified under Section 40 and exempted by their parts, to be exempted in its entirety. Include all 64 crop species of the multi-lateral system under International Treaty on Plant Genetic Resources (ITPGR) for Food and Agriculture. Further, no requirement for approval under sections 3 to 6 for these NTAC resources.
- Adopt the scope of 'conventional breeding' and 'traditional practices in agriculture'. A list of activities coming under these terms can be developed by the NBA in conjunction with the ICAR and Seed Industry, which would facilitate quick processing of application forms.
- Specify that routine activities such as those mandated by regulatory authorities, product testing protocols, comparative field trials, etc., are not controlled by, or come under the ambit of, the BDA. Access and use of insects, microbes, pathogens and weeds that are agricultural pests from different locations throughout India for use as testing tools in the development of new plant varieties and evaluation of crop protection molecules (for insecticides, fungicides and herbicides) should be exempted from the purview of the BDA as the insects, pests, pathogens and weeds will not themselves be used as commercial products.
- Meetings of the NBA be held more frequently and coordinated with the meetings of the Expert Committee. Timelines under the BDA to be strictly adhered to and provisions for 'deemed approval' if the timeline is not met to be included.
- Scrutiny of forms submitted to the NBA to be done on firm guidelines. NBA should develop a checklist for scrutiny of forms, just as they have published for filing of forms. These must be in line with the published ABS guidelines.
- For the purposes of ABS Guidelines, honour and respect agreements made between the provider of resources and an accessor with mutual consent. Currently, the agreements are one-sided and very harsh on the accessor.
- The above recommendations may be considered for further action for better harmonization between patent laws and biodiversity laws as well as for ease of doing business in India as envisaged under the "Make in India" and "Start-Up" initiatives by Government of India.

ANNEXURE – I

SPECIFIC ASPECTS OF THE BD ACT WHICH NEED ATTENTION AND REVISIONS

1. Preamble: The Preamble of the BDA starts with the words, *"An Act to provide for conservation of Biological Diversity, sustainable use of its components and fair and equitable sharing of the benefits arising out of the use of biological resources, knowledge and for matters connected therewith or incidental thereto..."*

   The emphasis of the implementation of BDA so far has been on earning royalty benefits by NBA rather than a real emphasis on conservation or sustainable use. The implementation of the provisions of the BDA should be to harmonize innovation, research and sustainable conservation of natural resources as well as benefit sharing rather than as a tool to police the researchers and industry and 'tax' it for its activities.

   The present benefit sharing mechanism proposed is so fuzzy that implementation has practical difficulty. For e.g., it may be difficult to establish the claimants.

2. Section 2, Definitions: (c) *"biological resources" means 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*

   - The term currently covers every living resource except human. It should be narrowed down to endangered/potentially endangered organisms like land varieties or wild relatives - cultivars and commonly available material should be explicitly kept exempt to make it practicable and in-line with the CBD.
   - Specify a list of biological resources as laid down in Article 7 of the CBD. Art. 7, "Identification and Monitoring", inter alia states that each Contracting Party shall, as far as possible and as appropriate, in particular for the purposes of Art. 8 (In-situ conservation), Art.9 (Ex-situ conservation) and Art. 10 (Sustainable use of components of Biological Diversity), identify the components of biological diversity important for its conservation and sustainable use having regard to the indicative list of categories set down in Annex 1 of the CBD, i.e.-
     - Ecosystems and habitats: containing high diversity, large numbers of endemic or threatened species, or wilderness; required by migratory species; of social, economic, cultural or scientific importance: or, which are representative, unique or associated with key evolutionary or other biological processes
     - Species and communities which are: threatened; wild relatives of domesticated or cultivated species; of medicinal, agricultural or other economic value; or social, scientific or cultural importance; or importance for research into the conservation and sustainable use of biological diversity, such as indicator species: and
     - Described genomes and genes of social, scientific or economic importance.

3. Section 2(f) Definition of "commercial utilization" means end user of biological resources for commercial utilization such as drugs, industrial enzymes, food flavours, fragrance, cosmetics, emulsifiers, oleoresins, colours, extracts and genes used for improving crops and livestock through genetic intervention, but does not include conventional breeding or traditional practices in use in any agriculture, horticulture, poultry, dairy farming, animal husbandry or bee keeping.

   The intent of the legislators seems to have been to exclude conventional breeding activities from the purview of the BDA. This can further be seen from a reading of S. 2(f) with S. 6(3) which excludes PVP applications from the requirements of S. 6 and with S.7 which requires that State Biodiversity Boards (SBBs) be prior intimated only in respect of obtaining biological resources for commercial utilisation or for bio-survey or bio-utilisation for commercial utilisation.

   In addition, the Nagoya Protocol at Art. 8 states: "In the development and implementation of its access and benefit-sharing legislation or regulatory requirements, each Party shall.... (c) Consider the importance of genetic resources for food and agriculture and their special role for food security".

4. Section 2(d) "bio-survey or bio-utilisation" means survey or collection of species, sub-species, genes, components and extracts of biological resource for any purpose and includes characterisation, inventorisation and bioassay.

   This definition is so broad that routine activities would be affected. E.g. obtaining a variety or hybrid to use as a check / reference variety for the purpose of preparing a application for plant variety protection; or collection of insect pests for conducting bio-assays for generation of baseline data.

   The Authority has indicated that the exception contained in "commercial utilisation" is not included here and therefore traditional practices and conventional breeding activities coming under this definition are not exempted.

5. Section 2(m) "research" means study or systematic investigation of any biological resource or technological application, that uses biological systems, living organism or derivatives thereof to make or modify products or processes for any use

   This is also very broadly worded. This definition covers the daily activity of any seed company, research based seed or other biotechnology company using biological resources.

   The Authority has indicated that the exception contained in "commercial utilisation" is also not included here and therefore traditional practices and conventional breeding activities coming under this definition are not exempted.

6. Section 3 states (emphasis supplied): 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 utilization or for bio-survey and bio-utilization.

   (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 243 of 1961of the Income-tax Act, 1961;

(c) a body corporate, association or organization –

(i) not incorporated or registered in India; or

(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."

7. Section 3(2): any company registered in India under Indian laws, but having any non-Indian participation in share capital or management, is treated as a non-Indian or foreign entity. This means that having even one share held by a non-Indian or an NRI Indian, or having a Director who is non-Indian or an Indian NRI, means that such company must take permission for access to bioresources covered under the Act and is treated differently from other Indian companies. The definition of a foreign company under the Companies Act, 1956 and 2013 is any company that is not registered in India – therefore the BDA is at variance with Indian Companies law. Different treatment is given to Indian companies based on their shareholding pattern and composition of Board of Directors.

Further, the requirement is to take prior approval for obtaining any biological resource for research or for bio-survey or bio-utilisation or for commercial utilisation and these terms cover the daily activities of the agro industry. Complying with the requirement of this section has the potential to at best delay access and at worst prevent the access to breeding material, that will in turn have a long-term impact on making the best of science, technology and performing products available to the Indian farmer and affect food security.

The experience of S. 3(2) companies in complying with the Act and this section is that either, approval is not received, or takes a long time in coming, and time periods prescribed in the Act expire. Compliance concerns would be somewhat mitigated if the process of approval is timely. Although in compliance with the Act, applications for approval have been made to the designated Authority, the delay in the approval process makes fate of research commitments uncertain.

The definition of a Sec. 3(2)(c)(ii) entity could be relaxed to cover only those entities that have non-Indian participation in capital of above 50%.

It is not clear as what 'occurring in India' means.

8. Section 4 *"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 the Income-tax Act, 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."

One of the important outcomes of any research oriented organization, public or private, is publishing of research results in peer reviewed scientific journals and publications. As per the explanation to Section 4 of BDA, publication of research papers or dissemination of knowledge in any seminar or workshop are not considered as 'transfer', if such publication is as per the guidelines issued by the Central Government. The said guidelines are not yet framed.

Further, the explanation to the section only refers to publication in a seminar or workshop and does not refer to journals or any other form of publication. This has the potential to affect every Indian scientific paper, research article, thesis, abstract, poster, etc., whether in the public or private sector, and including submission of data pursuant to regulatory and statutory requirements as well as submission of progress reports owing to contractual requirements. It may be noted that all peer reviewed publications and most regulatory authorities have on-line publication and posting of data – available and accessible equally to Indians and non-Indians. Thus, publication of science papers, most of which are time-sensitive, would be delayed by an approval process.

Commercial and proprietary hybrids and parent lines are considered 'results of research'. Any transfer of commercial hybrids to any S. 3(2) entity or person, in the absence of any clear directions to the contrary from the Authority, would require the prior approval of the Authority. This is a patently absurd situation where approval is required to transfer material that is freely available in the market. Similarly, in the absence of clarity, permission will be required to transfer any proprietary material, even if developed using resources accessed before the coming into force of the Act.

Contract activities with a S. 3(2) entity such as service, job work, which may involve providing of bio resources, but where there is no transfer / access in the true sense of the word as the activity is purely for service and not research, e.g. cloning, protein generation and transformation. Biotech vendors sell plasmid, promoters, protein. It is impractical to go through the approval process for these activities.

9. Section 18(1) *Functions and powers of National Biodiversity Authority – (1) It shall be the duty of the national Biodiversity Authority to regulate activities referred to in section 3, 4 and 6 and by regulations issue guidelines for access to biological resources and for fair and equitable benefit sharing.*

   (2) the National Biodiversity Authority may grant approval for undertaking any activity referred to in section 3, 4 and 6."

   NBA has notified Access and Benefit Sharing guidelines on 21stNov. 2014.. The guidelines mention about benefit sharing arrangement under different categories of applications, and also provide a provision (Proviso 1 of Reg. 15: Sharing of benefits) to honour any agreement executed between biological material provider institution/organisation. However, NBA does not honour the private contracts while approving applications. Thus, a proper implementation of provisions of ABS guidelines can solve many problems.

10. As per Section 21(2)(a) of the BDA, The National Biodiversity Authority shall, subject to any regulations made in this behalf, determine the benefit sharing which shall be given effect in all or any of the following manner, namely:

    (a) grant of joint ownership of intellectual property rights to the National Biodiversity Authority, or where benefit claimers are identified, to such benefit claimers; …

    This provision is very harsh and unfair as it undervalues the importance of the invaluable elements of innovation, research and funds in developing any scientific innovation/technology. Mere use of an Indian biological resource in the development of an innovation does not call for benefit sharing in terms of granting joint ownership in IP rights. This provision must be removed.

11. As per Section 40 Power of the Central Government to exempt certain resources – Notwithstanding anything contained in this Act, the Central Government may, in consultation with National Biodiversity Authority, by notification in the Official Gazette, declare that the provisions of this Act shall not apply to any items, including biological resources normally traded as commodities

    The exemption list notified by the Central Government under this provision provides exemptions as per plant parts – rather than the crop as a whole. The reasoning seems to be that the exempted parts are the 'commodity'. However, the contention of the seed industry is that as per the Schedule to the Essential Commodities Act, 1955, seed is a commodity, and therefore should be covered in the exemption list of Sec. 40.

    Further, the Authority has repeatedly indicated that exemption is dependent on what the intended use of the accessed item is for, contrary to the language of the gazette notification and S. 40, and this is of concern.

    It is also important to include all the 64 plant species of the multi-lateral system under International Treaty on Plant Genetic Resources (ITPGR) for Food and Agriculture, in the exemption from Ss. 3 & 4, and honour the Gazette Notification of the MoEF of Dec 2015 coupled with the office memo from the MoA of Feb 2016.

12. Commencement date of the Act; Act to be prospective: There is no clarity on the commencement date of the Act from the Authority. The operative provisions of the Act came into force on 1 July 2004. There is indication that the Authority considers the Act to be retrospective, which is contrary to settled law on the subject of legislation being prospective and not retrospective, save provisions that are purely procedural in nature without any impact on rights. As a result, applications are being made 'without prejudice' for abundant caution.

13. Section 55 (Penalties) and Section 58 (offences to be cognizable and non-bailable): the penalties are out of proportion to the offences under the Act. Imprisonment for terms of 3-5 years and their cognizable and non-bailable nature, are extreme consequences, out of proportion with the nature of the offence.

14. In addition, the above said issues in relation to BDA, many companies have often received notices from State Biodiversity Boards (SBBs) about seeking benefit sharing and requiring application in Form I. One of the reasons for these notices is contradictions between BDA and the State Rules. The BDA under section 7 requires intimation to the SBBs in the case of access of biological resources for commercial utilisation and bio-survey and bio-utilisation for commercial utilisation. On the contrary, State Rules require prior approval as against intimation and include research as well.

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