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Biological Diversity Act: A Concern for Conservation of Genetic Resource and Associated Traditional Knowledge in India

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The Convention on Biological Diversity (CBD) is the first international agreement aiming at the conservation, sustainable development and fair and equitable benefit sharing out of use of biological resources. The Biological Diversity Act, 2002 (BDA) is India's attempt to operationalize CBD. Some parts of this Act are ambiguous and keep a gap which may lead to misappropriation of genetic resources (GR) and traditional knowledge (TK). Section 3(p) of Patent Amendment Act, 2005 makes the inventions using Indian traditional knowledge as non-patentable, but according to BDA the application for patent using Indian GR and/or TK is allowed (Section 6) while it is mandatory to get the permission from National Biodiversity Authority (NBA). Till 2010, 11 patents are granted based on approval of NBA. Another weak part is the exception of 'normally traded commodities' (NTC) from the provisions of BDA (Section 40), this provision leaves a potential chance for misappropriation of these GR and TK and no room is open for legal challenges. This article will try to do the analysis of BDA; it will consider how to clarify the ambiguity regarding patentability/non-patentability of inventions related to GR and associated TK and what is BDA's role in prevention of misappropriation of Indian GR/TK by using intellectual property rights; it will discuss the vulnerability of NTC provision.

Keywords: Convention on Biological Diversity, National Biological Authority, normally traded commodities, The Biological Diversity Act, 2002, biological resource, traditional Knowledge, genetic resources

The Convention on Biological Diversity (CBD) is the first international agreement aiming at the conservation, sustainable development and fair and equitable benefit sharing out of use of biological resources. The Biological Diversity Act, 2002 (BDA) is India's sole attempt to operationalize the provisions of CBD. To get proper conservation and sustainable development there is a need to analyse BDA in depth. This paper will enquire into the fact that whether some parts of this Act are ambiguous and keep a gap which may lead to misappropriation of Indian genetic resources (GR) and related traditional knowledge (TK).

This article will consider how to clarify the ambiguity regarding patentability/non-patentability of inventions related to GR and associated TK and what is BDA's role in prevention of misappropriation of Indian GR/TK by using intellectual property rights; it will discuss the vulnerability of 'normally traded commodities' (NTC) provision; it will also examine how far the BDA is transparent regarding benefit sharing with the traditional communities for their overall development and whether actual involvement of traditional communities in access and benefit sharing mechanism is ensured in BDA.

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India is rich in biological diversity and according to the CBD the State has the sovereign rights over their biological resources. Aim of BDA, as comparable to CBD, is conservation of Indian biological diversity, sustainable use of its components and fair and equitable benefit sharing. According to general understanding, sustainable use of the components of biological diversity is the mean to reach the goal of conservation of biodiversity. The third objective of fair and equitable benefit sharing is related with the commercialization of the biological diversity as a whole or part thereof. Indian biodiversity is used by Indian people since ages for their livelihood and usually ancient people used to use their resources (plant and animal) in such a way that objective of conservation was obtained. So, it can be said that, without knowing the terms 'conservation' and 'sustainable use' traditional people understood the need of it and used the components of biodiversity accordingly. It is the modern men with the initiation of industrialization started commodification and commercialization of everything, including components of biodiversity and started unlimited utilization of useful components. Situation become worse with the concept of intellectual property rights, which brings the private monopoly over the commodities.

Issue of patent protection of inventions using components of biological diversity (which is an important component of our ecosystem and environment at large) should be handled with great care as patent monopoly may initiate unrestrained utilization of components of biodiversity leading to loss of balance in ecological system, hence the objective of sustainable use and conservation would be jeopardized. Next section will elaborate the Indian stand regarding this.

Obtaining Patent on Genetic Resource or Associated Traditional Knowledge

Indian Patent Amendment Act, 2005 has quite a few thoughtful provisions regarding issue of obtaining patent on inventions using biological diversity, genetic resource and associated traditional knowledge.

Provisions of The Patents Act

Section 3 of The Patents Amendment Act, 2005 enlisted the non-patentable inventions and some of them can be used directly or indirectly for prohibition of obtaining patent on invention using biodiversity or genetic resource. Following are the provisions,

i) If the invention is causing serious prejudice to human, plant or animal health or to the environment [Section 3(b)] - genetically modified plant or animal may cause serious harm for human health and/or for the environment, without proper risk assessment it could be dangerous to use;

ii) The invention is actually discovery of any living thing occurring in nature [Section 3(c)] - any species of living plant or animal are thus non-patentable;

iii) The invention is about a new form of a known substance or mere discovery of any new property or new use of a known substance [Section 3(d)] - a new mannose binding insecticidal lectin isolated from seeds of Annona is recently granted patent in India which is a mere discovery of a known substance as Annona is known for its insecticidal property for long time and used by traditional farmers;

iv) The invention is obtained by a mere admixture resulting only in the aggregation of properties of the components of genetic resource [Section 3(e)] – herbal and medicinal plants of India are known and used for various therapeutic and cosmetic purposes, any new product or process of their making should not be patentable;

v) The invention is about mere arrangement or re-arrangement or duplication of known devices [Section 3(f)] - Vaids and Hakims are using many devices for extraction, purification and preparation of traditional Ayurvedic medicine, those should not be the part of patentable invention;

vi) The invention is a method of agriculture or horticulture [Section 3(h)] – any traditional methods of agriculture or horticulture should not be patentable as that will hamper the traditional agricultural activity and will give negative impact on our sustainable use and conservation of biodiversity;

vii) The invention is about a method of treatment of human or animals [Section 3(i)] – traditional methods of treatment are thus non-patentable which includes huge number of plant and animal genetic resources;

viii) The invention involves plants or animals (whole or their part) including seeds, varieties, species and essentially biologically processes for production or propagation of plant and animals [Section 3(j)];

ix) The invention involves a traditional knowledge or involves aggregation or duplication of traditionally known components of genetic resources [Section 3(p)] – wound healing property of turmeric or pesticidal extracts of neem components were not patentable, hence revoked abroad.

Components of genetic resources or their known characteristics are in public domain, hence difficult to pass the novelty requirement of patentability criteria [Section 2(1)(j)]. The Controller has got the power to refuse to proceed with the application or may ask for the amendment to the application or specification or other documents if the application is not in compliance with the requirement of the Patent Act [Section 15]. Pre-grant and post-grant opposition is allowed for any invention using traditional knowledge [Section 25(1)(k) and Section 25(2)(k)], or for any application whose complete specification is not disclosing or wrongfully disclosing the geographical origin of the used biological material [Section 25(1)(j) and Section 25(2)(j)]. Post-grant opposition on these grounds may cause revocation of such faulty patent [Section 64(1)(p) and Section 64(1)(q)]. These included provisions are making the Indian stand stronger for prevention of biopiracy and misappropriation of genetic resources and associated traditional knowledge.

Provisions of Biodiversity Act, 2002

Strict rules have been made in Biological Diversity Act, 2002 (BDA) regarding the application for any form of intellectual property right (IPR) for the inventions based on Indian biological resources. Section 6 deals with this provision and it prevents all Indian citizens as well as foreign nationals from applying for any form of IPR in India or abroad

unless the applicant get the prior approval from National Biodiversity Authority (NBA) [Section 6(1) & Rule 18]. Proviso for Section 6 said that instead of getting the permission before application of patent, the applicant can get the approval after acceptance of the patent but before sealing of patent by patent authority.

As per the requirement of the patent application in Form 1, the applicant has to give the declaration that he/she will submit the necessary permission from the NBA before grant of patent [Clause 9(iii) of Form 1 for Application for Grant of Patent]. Approval from NBA is a necessary requirement to stop the misappropriation of genetic resources of Indian origin. It is the duty of NBA to make proper enquiry regarding the application of any form of intellectual property right [Section 19(2)] and to consult with an 'expert committee' regarding the issue [Section 19(3) of Biological Diversity Act, 2002]. The application fee needs to be collected by NBA; they can collect necessary additional information to judge the merit of the application and has to give a decision within 3 month time period [Section 6(1), 2002 & Rule 18(3)].

NBA can reject the application if the applicant failed to furnish necessary information to judge the merit, in that case the reasons has to be recorded and the applicant has to be provided with a chance to defend himself in a hearing in front of the Authority before rejection [Section 19(3) Act, 2002 & Rule 18(6)]. It is also duty of NBA to supervise the intellectual property applications abroad regarding misappropriation of Indian biological resources and associated traditional knowledge which is obtained from India in an illegal manner and to take necessary measures to oppose those applications [Rule 12(xix)].

Any person applying for the protection of plant variety shall not take any permission from NBA, which means that breeders applying for the protection of new plant variety will not come under the provisions of Section 6 of BDA [Section 6(3)].

Ambiguous Law and More Ambiguous Implementation

According to Section 6 approval has to be taken from NBA before applying for the intellectual property in India or outside by the applicant, but the Act or the Rule never specifies the criteria according to which NBA will provide the necessary approval or reject the application for approval. In the website the latest Annual Report of NBA which is available is of the year 2009 – 2010, as per that Report NBA received 97 applications for approval for patent, among which 10 is cleared and rest 87 was in process. No detailed information is available in the Report or elsewhere in the website regarding those applications or based on what the applications were accepted or judged. Same Annual Report tells us that until 31 March 2010 eleven patents were granted based on approval of NBA, Report provides the Application number, Applicant name and one line description of the invention. It is difficult to presume on what basis those approvals had been given.

All these inventions supposedly involve commonly used biological material of Indian origin like fenugreek seed, annona, pineapple leaf etc. In spite of above mentioned provisions in Patents Act and Biological Diversity Act if so many patents are granted in India for inventions primarily using Indian biological resources, then the important question of proper implementation come into mind. In the next section one interesting case study will further elaborate the implementation failure on the part of NBA.

Implementation Failure: Case Study

NBA is under the statutory duty of supervising the intellectual property applications worldwide and to search out whether any biological material / genetic resource are utilised in any application in India or abroad. If any such circumstances appear, NBA has the power to take proper initiatives to oppose the grant of such intellectual property right in such country. Proper implementation of this power and discharge of the duty requires planning, motivation, and manpower.

A query comes in the way about the role of NBA regarding discharge of its duty while discussing the interesting case of opposition of Monsanto's European Patent (EP 1962578) on Clostero virus-resistant melon plant. A Dutch seed company, DeRuiter, used the variety of Indian melon to develop Cucurbit yellow stunting disorder virus (CYSDV) – resistant melon variety in 2008 to help farmers of North America, Europe and North Africa to prevent spreading of this virus in the melon plantation.[1] Cucurbit yellow stunting disorder virus (CYSDV) was endemically disseminated in North hemisphere of the world, and this CYSDV-resistant melon variety aided a lot to the melon farming communities. Later on Monsanto took over DeRuiter and they applied patent for the 'invention' of this virus-resistant variety of melon, the EPO granted the patent to Monsanto in May 2011. On 3 February 2012 Indian scientist and activist Dr. Vandana Shiva with the help of one

European NGO 'No Patents on Seeds' filed an opposition against this patent in European Patent Office.[1] Dr. Shiva has mentioned that as DeRuiter or Monsanto has not taken the prior approval from NBA before applying for the patent for an invention using an Indian melon variety, which is mandatory as per Section 6 of BDA, they can be prosecuted for biopiracy.[2] The shocking fact is that NBA, who is having statutory authority and duty to take proper action against anybody applying for any intellectual property rights for inventions involving Indian biological resources, are silent about this matter.

Neither they have discharged their duty by proper supervision and initiate necessary action, nor have they tried to help Dr. Shiva and the NGO who were taking personal initiative for the larger societal interest. The question here is NBA being the government body and duty bound by the statute for protection of biological resource of Indian origin, the stand taken by them in this case is not only frustrating but also very alarming. India is an agricultural based country, innumerable farmers' livelihood is related with the biological resources, and moreover the new trend of commodification and monopolisation of biological resources usually targets the country rich in biodiversity like India. Legal system is made by the lawmakers and implementation is given in the hand of a national authority, but if the authority is failed to discharge the duties properly they should face the rigid consequences as a result of what they should change the attitude.

Access to Genetic Resource and Transfer of Knowledge

NBA is the nodal authority (designated 'competent national authority' as required by CBD) in India to look after the protection of Indian biological resources.

Duties of NBA

It is also statutory duty of NBA to regulate the access of biological resources of Indian origin for any kind of research activity and also to regulate the transfer of result of such research activity with third parties. Legislation is clear enough to mention that *'a person who is not a citizen of India; or a citizen of India who is a non-resident; or a body corporate, association or organization not incorporated or registered in India; or a body corporate, association or organization incorporated or registered in India which has any non-Indian participation in its share capital or management'* has to take permission from NBA before obtaining any biological resource of Indian origin for any kind of research or for commercial utilization or bio-survey or bio-utilisation (Section 3 of Biological Diversity Act, 2002). It is also mentioned that nobody is permitted to transfer the result of any research on biological resources of Indian origin to these above mentioned persons or body corporates or associations or organizations (Section 4). 'Transfer' is explained in the statute in terms of certain exclusions, which are publication of research paper (according to the guideline issued by Central Government) or knowledge sharing in any seminar or workshop [Section 4 (Explanation)]. For Indian citizens or Indian body corporate/ association/organization the prior approval clause is similarly applied before any commercial utilization, or bio-survey, or bio-utilization of Indian biological resources but that approval has to be taken from respective State Biodiversity Board (Section 7). Research activity in not included in the list of activities for which prior approval has to be taken, nor there is any restriction of transfer of research result to the other Indian citizens or body corporate/ association/organization of Indian origin.

But in practical situation non-incorporation of research activity for Indian scientists or funded by body corporate/association/organization of Indian origin should not be a problem from misappropriation of biological resources as everybody has to get the prior approval before any commercialization or commodification of the research results or before transfer of such research result to any non-Indian citizen or to any body-corporate/association/ organization of non-Indian origin. This will be helpful if all the scientists, engaged in research activities related with Indian biological resources, strictly abide by the norms and rules made thereof.

This is a grim fact that norms and rules are usually not been followed properly. The next section of this paper will elaborate the case of development of Bt brinjal using local indigenous brinjal varieties without any prior approval and bizarre response of NBA in the whole process.

Failure to Discharge the Duty by NBA: Case Study

It is an immense duty to NBA to supervise all illegal activity throughout India and take necessary measures. They have been given full authority, but with that authority usually come immense responsibility, now the questions will arise how much sincerely that responsibility is discharged. This issue will be discussed here with reference of the first ever

case on biopiracy in India by NBA, i.e. Mahyco-Monsanto *Bt* Brinjal case. Monsanto, world's biggest agro-biotechnology company with its Indian subsidiary Mahyco along with different public funded agricultural institute of India (University of Agricultural Sciences, Dharwar, Karnataka; Tamilnadu Agricultural University, Coimbatore, Tamilnadu; and Indian Institute of Vegetable Research, Uttar Pradesh) accessed about 10-16 local brinjal varieties from Karnataka & Tamilnadu to produce genetically modified *Bt* brinjal variety,[3] the whole research process was facilitated by Sathguru Foundation, Hyderabad, who was coordinating on behalf of United States Agency for International Development and Cornell University, New York.[3] This project was the direct outcome of the India-US bilateral Agreement called Knowledge Initiative on Agriculture (KIA), signed by US President Mr. George Bush and Indian Prime Minister Mr. Manmohan Singh on 18 July 2005.[4]

Environment Support Group (ESG) had taken the first initiative to identify that Mahyco-Monsanto alliance is using indigenous brinjal varieties to produce genetically modified brinjal for the obvious commercial purposes but that had been done with non-compliance to BDA as they have not taken any prior approval before access the indigenous brinjal varieties.[5] ESG activists worked tirelessly informing several authorities including Karnataka Biodiversity Board (KBB), Karnataka Chief Minister, NBA, Indian Prime Minister, and media to raise the voice against this biopiracy but they received bizarre response from KBB and NBA. NBA had to face harsh criticism from the government (from Lok Sabha's Public Account Committee and Parliamentary Standing Committee on Agriculture).[6] Finally NBA lodged criminal case against all stakeholders and the case is in Karnataka High Court before the bench. Table 1 will show the gist of the efforts of ESG and the response with dates mentioned therewith.

Following relevant questions will arise after careful investigation of all the facts of this case and NBA should take the responsibility to answer all these questions.

Table — 1 Time line of events for Mahyco-Monsanto *Bt* Brinjal case[5]

S No.	Event	Date
1	GEAC approval of *Bt* brinjal	14 October 2009
2	Moratorium imposed by Ministry against *Bt* brinjal	9 February 2010
3	ESG filed complaint to KBB (copying to NBA)	15 February 2010
4	KBB 13th Board Meeting to enquire into the matter with University of Agriculture regarding whether it was a Govt. of India approved research project or the permission of NBA had been taken	26 February 2010
5	KBB forwarding the complaint of ESG to NBA	10March 2010
1	KBB's repeated request to NBA to initiate the proceedings	29 March 2010
2	KBB's repeated request to NBA to initiate the proceedings	12 April 2010
3	KBB's Report to NBA mentioning that 6 local brinjal varieties has been used without prior permission for the said project	28 May 2011
4	NBA decided to initiate the prosecution (more than one year and four months after the initial information by ESG	20 June 2011
5	KBB's 18th Board Meeting: Decision to wait for further intimation or guidance from NBA regarding legal action; it was also decided that in future R&D and bio-safety trials on *Bt* crops in Karnataka would require KBB's permission and communicated to Central Government	14 September 2011
6	NBA decided not to take any legal action (sudden change in their stand!)	22 November 2011
7	KBB 19th Board Meeting: Clarified that the subject matter coming under purview of NBA, so NBA had to take necessary action	20 January 2012
8	NBA decision to initiate criminal prosecution against all relevant stakeholders (taken two years to finally start the proceedings)	28 February 2012
9	ESG filed RTI query to NBA	26 April 2012
10	15th Lok Sabha's Public Account Committee Report criticized NBA	27 April 2012
11	NBA refused to give documents of the case to ESG	21 May 2012
12	ESG representation of the issue to Karnataka CM	23 June 2012
13	Parliamentary Standing Committee on Agriculture in their 37th Report criticised NBA for their stand	9 August 2012
14	NBA Chairman released all the relevant documents to ESG	13 August 2012
15	Writ Petition by ESG at Karnataka High Court against some issues in BDA	October 2012
16	Stay order by Karnataka HC in favour of accused regarding criminal proceedings	3 January 2013
17	Karnataka vacated stay order and ordered NBA to continue criminal proceedings	11 October 2013

- How much safe is Indian biological diversity in the hand of NBA who is the nominated caretaker of protection of that?
- How fair is NBA in discharging their duties towards Indian biological resources?
- Why the responsible NGOs like Navdanya or ESG can't expect NBA to support them even after locating the misappropriation and initiating protest against it?
- Why there is internal contradiction in KBB's decision in the timeline regarding their responsibility and authority towards a serious misdeed?
- Why NBA wasted valuable two years (from ESG's first complaint to KBB with copy to NBA on 15 February 2010 to NBA's final decision of criminal prosecution on 28 Febrary 2012) in this case?
- Why NGO has to push KBB and NBA (the national and state authorities who are duty bound) to discharge their duty and responsibility properly and to initiate necessary action against wrongdoers?
- Why there is no communication and cooperation between different authorities (like GEAC and NBA for example) handing same or similar inter-related and very sensitive issues like approval of GM crop development and use of indigenous crops for that purpose?

Hopefully in future cases of biopiracy NBA will show the responsible behaviour and the answer of these questions will come forward.

Exemptions in BDA and its Impact

BDA provides certain exemptions to the rule of prior approval for access, or research or transfer of result. Certain group of people is mentioned in the statute for the exemptions that is depicted in Table 2.

Rationale of Exemption to Collaborative Research Project

Section 7 of BDA is carefully exempted the local and traditional community people whose livelihood is mainly based on biological resources surrounding them; traditional farmers who are helping the maintenance of diversity in biological resources by natural selection; and local Vaids & Hakims practising the indigenous medicine for years. But rationale of the exemption of scientists involved in collaborative research projects is not clarified in the statute. Section 5(1) says that the prior approval from NBA before access for research on biological resources or commercial utilization or transfer of research results will not be applicable for the *"collaborative research projects involving transfer or exchange of biological resources or information relating thereto between institutions"* if those collaborative projects are in compliance with the policy guidance issued by Central Government or approved by the Central Government. The institutes which may be involved in those projects can be Government Sponsored Institutions of India or of other countries. So the foreign institution engaged in the collaborative research project approved by Central Government can also claim the suggested exemption. Who will give the guarantee that the scientists of Government Sponsored Institutions of India or their foreign partners will not lead the mishandling of Indian biological resources and will not cause misappropriation for their own economic profit.

Because of this exemption, NBA will have no control on unlimited access of any kind of biological resource or any commercial utilization of the end

Table — 2 Exemptions Provided in BDA

S No.	Exempted bodies	Relevant Section of BDA	Exempted from	Not exempted from
1.	Local people & communities	Section 7	Prior approval before access	Prior approval before transfer of knowledge or application for IPRs
2.	Growers & cultivars of biodiversity	Section 7	Prior approval before access	Prior approval before transfer of knowledge or application for IPRs
3.	Vaids & Hakims	Section 7	Prior approval before access	Prior approval before transfer of knowledge or application for IPRs
4.	Collaborative research project	Section 7	Prior approval before access, Commercial utilization & transfer of result	Prior approval before application for IPRs
5.	Normally traded commodities	Section 40	Prior approval before access for trading activities	Prior approval before research or commercial activity or application for IPRs

products of the research using those resources. If a project is planned in compliance with the policy guideline of Central Government or approved by the Central Government, what is the assurance that those projects will not lead to biopiracy; and if something happens of that sort NBA being the whole sole authority will not have the right to intervene because of statutory exemption.

In the above discussed *Bt* brinjal case of biopiracy, some intellectuals argued that scientists involved in that project should get the Section 5 immunity as the project resulted from a bilateral India-US Agreement on KIA, so it has to be taken as a government approved project.[7] So the non-compliance with the prior approval before access of indigenous brinjal varieties is justified and the involved scientists should not face the criminal consequences. Matter is under Karnataka High Court now, though in January 2013 High Court had given a stay order in favour of the Registrar, and former and present Vice-Chancellor of University of Agricultural Sciences, Dharwad, but after challenge by NBA and KBB Court had vacated the stay in October 2013 and stated NBA and KBB to continue the criminal proceedings against all the accused.[8] It is not yet the situation that court has considered about the Section 5 immunity about the accused, but if that is considered then no criminal charges will be applied to them. Moreover, this may create a big loophole with the help of this statutory provision and may lead to more misappropriation or biopiracy regarding Indian biological resources.

Rationale of Exemption for Normally Traded Commodities

According to Section 40 of BDA Central Government has been given a special authority to provide complete immunity to some notified biological resources as 'normally traded commodities' (NTC) (by notification in the Official Gazette) from all the provisions of BDA. Ministry of Environment and Forests (MoE&F) had given the said notification on 26 October 2009 which declared a list of 190 biological resources which will get the exemption from all provisions of BDA.[9] The list is prepared based on the list of 190 names of biological resources identified by the 'expert committee,' which was set up by NBA in November 2005, after consultation with different government bodies and research organizations.[10] MoE&F also provided a clarification (16 February 2010) regarding this notification,[10] which gives different comprehension about the statutory provisions. It is clearly mentioned in Section 40 of BDA that *"the provisions of this Act shall not apply to any items, including biological resources normally traded as commodities."* This gives an impression that Section 40 is providing all the 190 notified biological resources the complete immunity from all the prior approval requirements, i.e. for access, for research, for commercial exploitation, for transfer of research result, and for application of intellectual property rights. But according to the clarification, it is understood that all the 190 items will get immunity for export only (so, for export of these items no prior approval is required from NBA), but the prior approval has to be obtained for using the biological resources in any research or industrial activity as per the requirement of BDA. By simple understanding, it will be difficult for Indian authorities to supervise the forbidden activities (such as research and industrial utilization) by foreign entities once unregulated access is provided for all these 190 notified items. ESG had shown their concern about this issue in their Writ Petition to Karnataka High Court. ESG mentioned that they have reviewed the list carefully and found 15 plants of that list is already included in the officially declared list of threatened and/or critically endangered species by International Union for Conservation of Nature (IUCN) and the Convention on International Trade in Endangered Species of Wild Fauna and Flora, 1973 (CITES Convention). Table 3 provides some important examples in this regard.

Vulnerable/threatened/endangered species of Indian biological diversity should be a huge concern for the MoE&F, concern is reflected in Rule 16 of Biological Diversity Rules, 2004 which has mentioned about special restrictions regarding the following requests:

(i) the request for access is for any endangered taxa;
(ii) the request for access is for any endemic and rare species;
(iii) the request for access may likely to result in adverse effect on the livelihoods of the local people;
(iv) the request to access may result in adverse environmental impact which may be difficult to control and mitigate;
(v) the request for access may cause genetic erosion or affecting the ecosystem function;
(vi) the request for use of resources for purposes contrary to national interest and other related international agreements entered into by India.

Table — 3 Endangered/threatened Species in the List of NTC[5]

S No.	Name of species	Item no. in NTC list	Notifying Authority
1.	*Acorus species*	2	Ministry of Commerce (List of species for protection by barring them from export)
2.	*Aloe species*	4	Ministry of Commerce (List of species for protection by barring them from export)
3.	*Gloriosa superba*	16	Ministry of Commerce (List of species for protection by barring them from export); Karnataka Medicinal Plant Authority (as vulnerable)
4.	*Artemisia species*	186	Ministry of Commerce (List of species for protection by barring them from export)
5.	*Rouwolfina serpentine*	175	Ministry of Commerce (List of species for protection by barring them from export); Karnataka Medicinal Plant Authority (as endangered)
6.	*Piper nigrum*	50	Karnataka Medicinal Plant Authority (as near threatened)
7.	*Aegle marmelos*	83	Karnataka Medicinal Plant Authority (as vulnerable)

Same concern is conformed in the clarification given by Mr. Jairam Ramesh (the then Minister of Environment & Forests) on 16 February 2010 as it specifically mentioned about special restrictions regarding the same issues as per provisions of Rule 16. Even stronger motivation was reflected in that clarification as it said about the preparation of State-wise list of endangered/vulnerable species along with the guideline for their rehabilitation. Such species had been already notified for the states of Himachal Pradesh (19 March 2009), Uttarakhand (23 April 2009), Uttar Pradesh (23 April 2009), Kerala (23 April 2009), Odissa (05 October 2009), Mizoram (05 October 2009), and Meghalaya (05 October 2009). Till date there is no further amended notification from MoE&F regarding revised list of NTCs. If such thoughtful steps have been taken by MoE&F since last four years, the usual question comes in mind that why there is no revision of the list of NTC till now and with unregulated trade of these items will take how long to increase the number of species in the list of endangered/vulnerable species in each and every state of India.

Conclusion

Historically all mega-biodiverse countries are exploiting there biological diversity since time immemorial, but never that exploitation went beyond a certain limit. Commodification started later on along the time line, but unless very recent years, not until the concept of intellectual property rights take a steep ride, the commercialization and commodification of biological resources have gone up to a level of beyond limit. Specifically after mandatory implementation of TRIPS Agreement the aggressiveness of getting monopoly over inventions based on biological resources have increased by huge extent. Research aimed for the purpose of commercial utilization augmented in such a way, specially by the multinational IPR oriented biotechnological research and development companies, that rules and regulation has become urgently necessary to get control over every such activity. Not many people are actually concerned about the fact that in spite of international and national legal rules and regulations there is lot of unregulated and unethical practices going on regarding access and commercial exploitation of the biological resources and associated traditional knowledge. Awareness and capacity building at every level, even up to the grass root level is one of the ways to prevent or at least restrict unlimited access for the variety of purposes.

Certain volume of biodiversity loss had already happened; the goal now should be to prevent the further loss, so that the future generation can be saved. It needs to be remembered that the impact of loss of biological diversity is vast; which may cause disturbance of balance in ecosystem, loss of food and cash crops, problem in agriculture as such and industry based on agriculture as well. The effect of that may endanger the very existence of human civilisation, our ignorance and carelessness will aggravate and accelerate the danger very soon. This is the right time to be careful about the situation and NBA being the designated authority, should take the lead role in the regulated access of Indian biological diversity by using the statutory model of BDA and amending the less clarified and ambiguous part of it with involvement of law making authorities.

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