

Joint ownership of Intellectual Property Rights and Biodiversity authority on Biological resources - An analysis

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Abstract

“Humankind should understand the importance of preserving biodiversity. The diversity of life forms on Earth is the culmination of millions of years of the productive genius of nature. It is nature’s insurance against extreme events that may disturb the delicate balance of life on this planet. We need to work together and act before a catastrophe is upon us. India stands committed to work with all parties to reach the happy compromise that will secure a future that provides ecological and economic space for each one of us and sustainable growth for all of us”²

Keywords: Biodiversity, Intellectual property, Biological resources, etc.

1. Introduction

Biodiversity enables bio-life forms in earth. Its presence achieves sustainable development. The important principles of protection of Biodiversity is to acknowledge the vast Genetic resources that are abundant on the planet Earth. The impacts of the International Legal Framework for the promotion of Intellectual Property Rights in India is facing tremendous changes. The intellectual property rights stimulates high monetary returns its market might provide otherwise³ The legal regime concerning the control over biological resources and inventions

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² Hyderabad Pledge of cop 11. <https://www.cbd.int/doc/speech/2012/sp-2012-10-16-cop11-hls-in-pm-en.pdf> last visited 9.3.2018

³ Kothari.A,Biodiversity and Intellectual Property Rights,'Can the two co-exist?.,Journal from Kalpakavrish action group,1999, p.3.

derived from biological resources is immense.⁴ The control of biological resources is done and derived through Property rights.

The term 'ownership' origin relates back to the Ancient Rome period meaning 'dominium' or absolute right over a thing rather than physical control over it. However, gives the right to use a thing thereby excluding the right of others from using it. The term 'joint ownership' means and includes where two authorities having a cumulative hold on property resources. The legal maxim 'per my but not per tout' can be interpreted here as that the Biological resources can also be held by two authorities and it's also regulated by the authorities jointly. The Intellectual property Rights is given to biological resources in the form of statutory Patent right for any kind of invention for a particular period by the regulatory authority. '*Expressio unius est exclusion alterius.*' that is to say, when one thing is included the other thing is excluded. When the right is conferred it means that others are excluded from making, using, selling, importing the patented product for the purpose without its content.

1.1. Concept of Biological Resources

Biological resources mean animals, plants, micro-organisms, or part thereof their genetic materials byproduct with neutral or potential use or value but does not include human genetic material.⁵ It enables bio-life forms in earth. Its presence achieves sustainable development. The important principles of protection of Biodiversity is to acknowledge the vast Genetic resources that are abundant on the planet Earth. The Biological resources are part of the Public domain and it belongs to Individual, group, or a State⁶. The utilization of the Biological resources is non-rival, in the sense the use of the resource person does not compete with another. Biodiversity is part of common heritage of mankind. India is one of the twelve mega diversity centers of the world. There are significant changes in the rule governing Biodiversity

2. International Convention on Biodiversity

The Convention on Biological Diversity 1992 is the International Framework on Biological resources. It came into force in 1993. The objective is to deal with the conservation and management of biodiversity. It not only conserves biological diversity, but also ensures the sustainable use of its components, and the fair and

⁴Philippe Cullet and Jawahar Raja, Intellectual Property Rights and Biodiversity Management: The Case of India http://assets.wwfindia.org/downloads/ipr_biodiversity_management_india_2.pdf last visited 10.3.2018.

⁵ Sec.2(c) of Biodiversity Act,2002(Act.No:93 of 2002).

⁶ Paul Gepts,'Who owns Bio-diversity and how the owners need to be compensated?'

equitable sharing of the benefits derived from the use of genetic resources.

The International Convention provides several general obligations for its member States. These include a commitment to develop National strategies, plans or programs for the conservation and sustainable use of biological diversity. Member States must also integrate the conservation and sustainable use of biological diversity into relevant sectoral or cross-sectoral plans, programs and policies. The convention gives access to biological resources and the sharing of benefits arising from their use. It attempts to provide a framework that respects donor countries' sovereign rights over their biological and genetic resources while facilitating access to those resources for users. It therefore requires member states to provide access on "mutually agreed terms" and is subject to the "Prior informed consent" of the country of origin of those resources.⁷ India exercises principles of State Sovereignty⁸ and its acknowledged by the convention, not to exploit their resources in accordance to environmental policies together with the responsibility to ensure that activities within their own jurisdiction or control do not cause damage of the environment of other states and ensure sue-generis system.

The donor countries ensure that the microorganisms, plants, or animals are used with Benefit-sharing and also done in accordance with "Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization"⁹. It takes the form of monetary benefits or non-monetary benefits such as sharing the results of research and development; collaboration, cooperation and contribution in scientific research and development programs, participation in product development; and access to scientific information relevant to the conservation and sustainable use of biological diversity.¹⁰ New approaches are needed to biological resource management and potential economic uses of biological resources.

⁷ Art.15 of Convention on Biological Diversity 1992.

⁸ (Art.39(b) of the Indian Constitution,1950 states that the ownership and control of the material resources of the community are so distributed as best to sub serve the common good)

⁹ <https://www.cbd.int/doc/publications/cbd-bonn-gdls-en.pdf> website last visited 6.12.2019

¹⁰ Bonn Guidelines 2002.

The outbreak of the Second World War¹¹ led to General Agreement on Tariff and Trade (GATT)¹¹ set up for enhancing International Trade in 1948. Subsequently it was replaced by World Trade Organization (WTO)¹² in 1995 that included Intellectual Property Rights. Intellectual Property Rights (IPR), as the term suggests, are meant to be rights, ideas and information, which are used in new inventions or processes. These rights enable the holder to exclude imitators from marketing such inventions or processes for specified period of time; in exchange the holder is required to disclose the formula or idea behind the product/process. The effect of IPR is therefore monopoly over commercial exploitation of the idea /information, for a limited period.¹³ The very object of Intellectual Property Rights is to simulate innovation.

Trade Related Aspects of Intellectual Property Rights Agreement (TRIPS): The agreement shapes domestic policies for biodiversity management. It was concluded as part of the WTO and extends the standards of intellectual property rights protection to OECD countries and to other WTO member states. It covers different fields of intellectual property among which patent rights are the most important from the perspective of the management of biological resources. Patents confer statutory rights. It provides that the inventor of a product or process when it is new and includes an inventive element and that is capable of industrial application, has monopoly rights for twenty years.¹⁴ The TRIPS agreement establishes the principle that patents should be available in all fields of technology if it involves inventive steps in the industrial production¹⁵.

Some general exceptions to patentability are permitted to protect human health or the environment but all member States must, for instance, extend patentability to

¹¹ GATT. Available from: <http://www2.econ.iastate.edu/classes/econ355/choi/gatt.htm> last visited 22.2.2020.

¹² M. D. Nair, 'GATT, TRIPS, WTO and CBD: Relevance and Agriculture', J IPR VOL:16 March 2011 pg.176-182, available at <http://nopr.niscair.res.in/handle/123456789/11576> last visited 22.2.2020.

¹³ Kothari A, Biodiversity and Intellectual Property Rights: Can the two coexist, Journal from Kalpavriksh-Environment Action Group 2,1999,3.

¹⁴ . Article 27 (1), TRIPS Agreement 1994.

¹⁵ John Tabari, 'Viewpoints on TRIPS and Bio-Diversity' Cuts International,2005,<http://www.cuts-citee.org/pdf/VP0305.pdf> last visited 20.2.2020.

microorganisms. They must also offer legal protection for plant varieties either through patents or through an alternative property rights system (*sui generis*).¹⁶ The TRIPS agreement marks a radical shift from previous intellectual property rights treaties in requiring that member states provide legal protection to inventions based on biological resources. The patentability exclusion is one of the controversial subjects.¹⁷

While the TRIPS agreement has a direct impact on biological resource management, the objectives of the treaty contain no injunction that the introduction of patents in biodiversity related areas must contribute to sustainable development. The agreement lacks cognizance of sovereign rights and hence at present disclosure of Prior Informed consent, country of origin for patent applications are disregarded there seemed to be conflicting provisions among the TRIPS and the CBD. While looking into issues such as private rights and public rights or when it comes to the rights of the Indigenous communities or corporations or rights of the commercial breeders or right of the farmers.

Doha declaration demanded a deep examination between TRIPS and CBD. The developing countries have criticised the TRIPS as its imbalanced and undermines the progress towards the sustainable development.¹⁸ One of the main criticism is that it places private rights than public rights. It must explicitly recognize Public International Law and Principles of State Sovereignty over the natural resources. The declaration paved a way for relook in TRIPS and insisted on protecting the Traditional knowledge. The declaration called for interim suspension of granting patents for those which does not fulfill Art.15 of the CBD. It also gave a clarification

¹⁶ Article 27 (3), TRIPS Agreement 1994. (Members may exclude animals and plants from patentability though micro-organisms for product and micro-biological and non -biological processes for plant and animal must be subjected to patenting.) This formulation was chosen because negotiating states could not agree on a more precise formula. This gives member states some latitude in deciding the form of the protection regime they want to implement for plant varieties.

¹⁷ Resource Book on Trips and Development, Capacity building project on IPR and Sustainable Development, Cambridge University Press, Nov.30,2004. p.253.

¹⁸ David Vivas Eugui, 'What agenda for review of TRIPS ? ;A Sustainable Development Perspective, Centre for International Environmental Law' https://www.ciel.org/Publications/AgendaTrips_Summer02.pdf website last visited 20.2.2020.

that no patent should be given for life. There are several areas of conflict of interest between them. For instance, Art.27 disregards that genetic material or traditional knowledge can be used as an inventive process. Art.27(3) (b) to be amended to require prior informed consent and the existence of fair and equitable benefit sharing agreements.

2.1 Patentability of biotechnological innovations, genetic resources, plant variety protections, traditional knowledge, and folklore

Tracing the background of the pre-TRIPS standing example of patenting living organism *per se* as decided in U.S.¹⁹ and also means and includes stem cells, cloning, genes, etc., Patents were not granted for inventions relating to (a) living entities of natural or artificial origin, (b) biological materials or other materials having replicating properties, (c) substances derived from such materials and (d) any processes for the production of living substances/entities including nucleic acids until 2002²⁰ but however, patents could be granted for processes of producing non-living substances by chemical processes, bioconversion and microbiological processes using micro-organisms or biological materials. For instance, claims for processes for the preparation of antibodies or proteins or vaccines consisting of non-living substances were allowable.²¹ Next paradigm shift occurred when the Patents Act got amended so as to include biochemical, biotechnological and microbiological processes were included within the scope of chemical processes for the grant of patent. Moreover, the definition of “invention” was also changed to “any new product or process involving an inventive step and capable of industrial application” thereby deleting the word “manner of manufacture” as mentioned in the earlier Act.

India also joined the Budapest Treaty on the International Recognition of the

¹⁹ *Diamond v Chakraborthy* 447 U.S .303(1980).

²⁰ *Dimminaco AG v Controller of Designs and Patents*. Cal. H.C 15 th Jan 2002. <http://www.pfc.org.in/info/microbio.htm> last visited 21.2.2020.

²¹ Report of the Controller of Patents, Designs and Trademarks, March 2013. http://www.ipindia.nic.in/writereaddata/Portal/IPOGuidelinesManuals/1_38_1_4-biotech-guidelines.pdf last visited 21.2.2020.

Deposit of Microorganisms for the Purposes of Patent Procedure on 17th December 2001. Consequently, Section 10 of the Act was amended in 2002 to provide for deposition of the biological material. The Patents (Amendment) Act, 2005 provides for the grant of product patents in any field of technology including biotechnology with certain exceptions. The International Depository Authorities (IDAs) under the Budapest Treaty where biological material can be stored.

Section 10 of the Patents Act, 1970 as amended in 2005, wherein the disclosure of the source and geographical origin of the biological material was made mandatory. Form 1 of the Patents Rules, 2003 gives the required permission from the competent authority. Therefore, the issues related to the BD Act and those related to mandatory disclosure of the source and geographical origin constitute an essential element of examination of biotechnology related aspects.

2.2. Biological Diversity Act, 2002:

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, India commenced on February 5, 2003, the Biological Diversity Act, 2002 (hereinafter referred to as the "The BD Act"). The object of the act is to conservation of biodiversity, 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) established in 2003. The NBA is a statutory, autonomous body performing facilitative, regulatory, and advisory functions for the Government of India on *"issues of conservation, sustainable use of biological resources and fair and equitable sharing of benefits arising out of the use of such biological resources"*.

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 basis first and on the use of the biological resources in question.

It provides access to the genetic resources and benefit sharing. Section 6 of the BD Act came into force on 1st July 2004 and prescribes that obtaining IPRs from the utilization of biological resources in India is subject to the approval of the National Biodiversity Authority. To facilitate this access and benefit sharing and to prevent any unauthorized use of the biological resources of India Sec.6 of the Biological Diversity Act ²² says that before going to the patent authority permission ought to be obtained from the NBA. The authorities are entitled to lay down guidelines under Sec.6²³. The procedure for the same shall be complied with in accordance to the Form 111. The said section forbids an application for any intellectual property right in or outside India, for any invention based on any research or information on biological resources obtained from India, without prior approval of National Biodiversity Authority (NBA). But it provides some relaxation in case such an application for IPR has already been made, by enacting: Provided that if a person applies for a patent, permission of the National Biodiversity Authority may be

²²(Any person who seeks to apply for any Intellectual Property Right, anywhere, within or outside India, for any invention based on any research or information on a biological resource obtained from India has to apply and obtain prior approval of National Biodiversity Authority, before applying for such IPR. In cases where the IPR sought is a patent, the approval from National Biodiversity Authority may be applied and obtained subsequent to acceptance of the application for patent but prior to sealing of the patent.

Where the IPR sought is relating to rights under any law for protection of plant varieties in India, such application for IPR is exempted. In such cases, the authority granting the right has to endorse a copy of the relevant document granting the right, to National Biodiversity Authority.)

²³ Sec 12 of the Biological Diversity Act,2002.

obtained after the acceptance of the patent but before the sealing of the patent by the patent authority concerned; and Provided further that the National Biodiversity Authority shall dispose of the application for permission made to it within a period of ninety days from the date of receipt thereof. Any Violation of Section 6 of BDA leads to imprisonment which may extend to 5 years, or fine up to Rs.10 lakhs or damages with fine.²⁴

The Act extends to citizens, non-citizens, non-resident Indians, body corporate, associations or organizations that are either not incorporated in India or incorporated in India with non-Indian participation in its share capital or management. These individuals or entities require the approval of the NBA when they use biological resources and associated knowledge occurring in India for commercial or research purposes or for the purposes of bio-survey or bio-utilization. The conflict between the BDA and the latest Patent legislation the National Biodiversity authority takes time to carry out research based on the information it receives on a biological resources and grants permission. Before the process of sealing of the patent is carried out biodiversity authority it grants the same within the stipulated time. Sometimes it has an impact on the applicant due to delay and latches his application in the Patent office would be pending until the Biodiversity authority grants patent.

In the draft amendment Rules, 2019²⁵ the central government has made the rule by exercising power under Sec.159 of the Patent Act.²⁶ The new rules amend certain provisions of Patent Rules 2003 under Rule6 sub-rule 1A wherein a patent agent can file his document by electronic submission duly authenticated within 15 days otherwise the document is deemed to have not been filed. The draft Patent amendment rules 2015 called for deposition of a Biological material shall be made within 3 months from the date of filing the application. And if the invention relates

²⁴ (Offences are Cognizable and non –bailable) available at <http://nbaindia.org/unep-gef/pub1/Guidance.pdf> last visited 22.2.2020.

²⁵ G.O. N0:540 Dated 17.9.2019

²⁶ Act No:39 The Indian Patents Act of 1970.

to any Biological material that is produced in India necessary permission from Biodiversity authority be obtained before applying for grant of patent.

An application made under Sec.21 of the Act, the draft patent amendment Rules, 2015 that amended the Patent rules, 2003. As per this the issues of conflict not resolved where in clause 3 when an applicant has not complied with Rules 24B and 24 C necessitating permission from the competent authority as per Sec.15 the controller was given wider power to pass appropriate order by giving a reasonable opportunity of being heard. The time stipulation granted is four months within which examination of the application extended for further two months where in the applicant must comply with the requirement of obtaining permission from the NBA as per 24B and 24C. In case if the process is delayed in NBA, then the controller of Patents has the Power to sue motto decide and issue appropriate order wherever fit and deemed necessary.

The Controller of Patents and the National Biodiversity Authority have mutual co-existence and both are distinct from one another. This creates a real problem in case of conflict situations supposing exercising discretionary power if the Patents office grants necessary requirement to the applicant before any assent from NBA, but subsequently the authority denies permission then the Patent granted by the Patent authority may be obviously terminated and if at all any benefits that are accrued must go to the stake holders. The term 'Biological Material' is not defined in Biodiversity Act²⁷ or in the Patents Act or its amendments. Proviso of Sec.10(4)(ii) merely mentions the term biological material. But does not include human genetic material though United States of America recognizes it. In India human genetic material is not recognized under the Biological Diversity Act. Therefore, there is a need to clarify the definition of the term human genetic material and expand the term Biological material so as to include these and as explained under the Patents Act. There is a greater urgency to combine these authorities to confer joint

²⁷ The Biological Diversity Act, 2002 Act No.93 of 2002 (Ministry of Environment and Forests, New Delhi, 2002).

ownership on the Biological material by properly carrying out research and analysis on the subject matter to be patented.

2.3. Drawbacks in the authorities constituted both under the Biodiversity Act and the Controller of Patents Authority

There are many setbacks in exercising power by the respective authorities. No authority wants to be the boss of another. Similar power is conferred to both the authorities where the process only delays the proceedings. Verification of the Biological material is done twice, and applicants due request is unnecessarily dragged. For Instance, for any Patent application under Sec.10 of the Patent Act, must satisfy the required form under the Patent Rules as amended to comply with Form 1. The irony is that there is no provision that connects both the Patent act and the Biodiversity Act. The patent process given is not similar in these acts. The only link as found is the direct 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, 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.

Another ambiguity is that National Biodiversity Authority shall have power provided if the applicants biological material is from India. If it is not, then securing permission from it for Patent right does not arise. Another notable point is that if the term use of the Biological Resource is not equivalent to owning it and its merely used then again obtaining permission from National Biodiversity Authority shall not arise. In cases where a use of a Biological resources is abundant, and it commonly used for testing then Biodiversity authority has no say in it.

India is not a party to the Budapest Treaty but made a comprehensive analysis and

consideration and ratified it on 17 Feb 2001²⁸. The convention deals about cross border data. While disclosing a data if its biological resource is from elsewhere the origin of the Biological Resource or any associated information²⁹ 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.³⁰ If the biological material source is not specified then that would be a ground for rejection of the Patent application.

Before the Biological Diversity Act could come into existence the Patent (Amendment) Act, 2002 came into force and therefore the definition clause of the term biological material not defined and it is not clear and explicit as to what, when, how, why etc., Biological material is constituted. Therefore, under these circumstances reading through provision Section 10(4)(ii)(D) of the Patent Act³¹ 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. As reiterated the biological material is either not defined or not made available in the public domain. This does not have any the nexus to the term geographical origin specified in the Sec. 6 of the BD Act and convey different meaning of the term source relates to biological material the term geographical origin relates to the history of the biological material. If the source of the biological material is disclosed, then it must be considered equivalent. Sec.10(4)(ii)(D) shall be complied only on the presence of Biological material if it does not satisfy the other clauses of the section say not available to the public or is not deposited in IDA(International Deposit Authority

²⁸ Convention on Cybercrime. Council of Europe European Treaty Series No. 185, Budapest, 23 November 2011, http://www.europarl.europa.eu/meetdocs/2014_2019/documents/libe/dv/7_conv_budapest_/7_conv_budapest_en.pdf last visited 22.2.2020.

²⁹ Sec.10 (4)(ii)(D) of the Patents Act 1970 discloses the source and geographical origin of the biological material in the specification, when used in an invention) http://www.ipindia.nic.in/writereaddata/Portal/IPOAct/1_31_1_patent-act-1970-11march2015.pdf last visited 22.2.2020.

³⁰ Recommendations of the Confederation of Indian Industry on issues associated with the Biodiversity Law and its compliance,” Submitted to the Government of India by Confederation of Indian Industry, K. S. Partners and Associates.

³¹ Ibid.,

that has been constituted as per the Budapest Treaty.³² The ultimate expectation is that the patent office should not raise objections during examination of the applicant non- use of the term biological material in filled in Form1. At times the patent office goes beyond its power where applications are refused on the ground of non-compliance of Sec.6 . Thereby it has rejected the applications ³³³⁴reasoned that importing a biological material, otherwise unavailable in India is made available on commercial scale and thereby product is unaffordable to the users.

Thus, the nexus between Patents Act and Biological Diversity Act, during prosecution of Applications which discloses the use of the biological material, the patent office practice has been made abundantly clear that inventions which discloses the use of any Biological material not only limited to claims if obtained from India but would be subjected to Sec.6 (1). The application will not be granted until compliance is sought and received by the Applicant. There is no provision in the Patent Act, conferring power upon the patent authority to defer or want of BDA compliance this is one of the few instances of effective collaboration of two authorities in denying a Patent Right.³⁵ In the said applications the Patent authority denied with reference to Sec.83 (a) wherein the case the applicants had used the biological material which were sourced from outside India. The reason that was substantiated is that the said material is available for commercial scale if the same is imported from outside India it's unclear as to whether the product is available to

³² (The proposal for International treaty on deposits of microorganisms was first put forward by United Kingdom. The treaty was adopted in 1977 at Budapest and came into existence in 1980. At that time 18 countries ratified this treaty such as France, USA, UK, Italy etc. The main objective of this treaty is to deposit live microorganisms for their patent purpose. To deposit live microorganisms in one place, member country has to develop IDA where depositors can safely deposit live microorganisms)

India has thirteen more culture collection centers known as designated repositories, storing different kinds of biological resources and are recognized by National Biodiversity Authority (NBA) India has 30 culture collection centers that store approximately 194174 cultures as per WDCM record <https://www.wipo.int/treaties/en/registration/budapest> last visited 22.2.2020.

³³ Patent Application No (085/KOL/2010) ,Official Journal of the Patent office,2014http://www.ipindia.nic.in/writereaddata/Portal/IPOJournal/1_139_1/official-journal-30-05-2014-part1.pdf last visited 22.2.2020.

³⁴ Patent Application No(1079/KOL/2009),Office journal of the Patent,2012http://ipindia.nic.in/ipr/patent/journal_archieve/journal_2012/pat_arch_042012/official_journal_06_042012_part_i.pdf last visited 22.2.2020.

³⁵ Id., to 33.

the public at a negotiable price. Therefore, there is supposed deficiency which defeats the purpose of Section 83(a) and 83(g) of Patents Act³⁶ (working of patents) and that considering said provisions, necessary permission from NBA ought to be taken.³⁷

In another order ³⁸ the controller reasoned out the fact that how the product would be made available to public at a reasonable Price. Sec 83 (G) is applied Critics argue ³⁹ that there is no basis as to how the Patent authority came to this conclusion. The basis of principles of reasonableness is not explained. What yardstick was followed in determining the scope is also not clear. 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. Therefore, it is suggested that interpretation made by the Patent Authority is ambiguous and unclear and goes beyond the legislative intent of Sec.6.

Looking into the Procedural formality as per Para 9(iii) of Form I clearly affirms that only invention as disclosed in the specification uses the biological material from India and therefore permission ought to be obtained from the competent authority. It does not explain as to for a biological material outside India at all which means no permission from the NBA required. I the light of the above Form I also requires amendments.

In obtaining No objection certificates must be made simple and speedy. In case of

³⁶ General Principles relating to working of Patented Applications.

³⁷ IPR Amicus Issue No.49 , dt 8.8.2015

³⁸ Id., to32,

³⁹ <https://www.lakshmisri.com/insights/articles/controller-overreach-or-common-sense-a-tale-of-section-83-of-the-patents-act/> last visited 22.2.2020

foreign Patents, it comes exclusively under multiple foreign jurisdictions any applicant has the option of filing it in India or elsewhere. As the grant of foreign patent does not come within the preview of the National Bio-diversity Authority. However, can obtain NBA approval before sealing a Patent. Critics argue that any application made under Sec.6) Form III ⁴⁰. shall be given a retrospective application and shall comply with the Principles of Natural Justice.

Moreover, the authorities are not clear as to what is considered as the Value-added product^{41,42}. The Act covers certain elements of Biological diversity and for the purpose of regulation it is termed as biological resources.

Since Value added product is excluded, there is ambiguity regarding what to be considered as a value-added product. The legislation has not prescribed any words or phrases relating to what are all value-added product. That can seek exemption under the said provisions.

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 biological resource thus requiring approval⁴³. It is suggested that the Issuance of a notification pertaining to the exemption provided to VAP as defined under Section 2(p) of the Act, needs clarity and the ambit and applicability of the said definition (such as clarity on what constitutes unrecognizable and

⁴⁰ (Application for seeking prior approval of NBA for applying for IPR (Section 6 and 19(2)) <http://nbaindia.org/unep-gef/pub1/Guidance.pdf> last visited 22.2.2020.

⁴¹ (As per Section 2 (c) of the Biological Diversity Act, 2002, biological resources means plants, animals and micro-organisms or parts thereof, their genetic material and by-products which have an actual or potential use or value. This definition excludes 'value added products' from the term biological resources. Further, human genetic material is also not included under the ter). <http://nbaindia.org/unep-gef/pub1/Guidance.pdf> last visited 22.2.2020.

⁴² (Value added products are defined under Section 2 (p) of the Act, as being products that may contain portions or extracts of plants and animals in unrecognizable and physically inseparable form.). <http://nbaindia.org/unep-gef/pub1/Guidance.pdf> last visited 22.2.2020.

⁴³ Id., to 30.

physically inseparable form) for removal of ambiguity and effective implementation of the legislation must be specific. What is Value added products must be given a guidance. The oil extracts derived from chemical process and it purchased from a commercial manufacturer then NBA shall not take the issue with its preview. This would improve IPR filings in India.

Another Value-added Product is vaccines. It may be treated as a natural resource though it's not recognizable and physically inseparable from where antigen and adjuvant are supplied separately and used together at the time of administration. What to be done for contravention of the Biological diversity Act or retrospective application of provisions of NBA Approval while adhering to Sec.3,4,6 and 7 is not clear. Sometimes its conferred based on bona fide of the applicant. In cases where the patent authority has not raised any objection under Sec.6 no remedy exists for unintentional contravention by the applicant. Therefore, it is suggested that for retrospective approvals hitherto to be made bona fide of the applicant must be considered towards sustainability. Utilizing biological resources shall not result in over exploitation when ever contravention occurs. Hence it is suggested that Sec.6 should not be required in scenarios where the actual objective of the Act is not contravened. Access Benefit sharing agreement should not be asked by NBA without which No objection Certificate must be granted.

Another aspect is the exemption of waste from agricultural lands where in no clarity as to whether it would fall within the ambit of the Biological resource. Only certain elements are considered as the biological resource. The amended Patents Act,2005 gives a new perspective for Microorganisms and therefore there is a great need to bring new technologies for energy generation from waste biomass Therefore it is suggested to encourage researchers in this area and to boost alternate energy technologies, waste materials arising from biological resources. It 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.

What could be deemed to be a biological resource the Biodiversity Act definition is limited in scope and it's not clear therefore biological resource elements are periodically tested in courts⁴⁴. In this case it was observed coal is not a biological resource. Where the Plant varieties are used under cultivation exemption from use of Biological resource must be given and it should be freely accessible without any restriction. Traded commodities that are abundant must be free from access benefit sharing formality in the use or in process form. eg., Coconut.

The National Biodiversity authority must call for a public hearing wherever it deemed fit and necessary when the law is silent in certain matters and when a situation arises where the implementation of the law is beyond the scope of the legislation. ABS agreement is entered regardless of the type of innovation made by the Applicants⁴⁵. Guidelines assists in entering into agreements.⁴⁶ The guidelines assist in guiding inventions that are developed for controlling epidemics/diseases, mitigating environmental pollution affecting human/animal/plant health, etc. for the purpose of benefit sharing. The regulations are unclear and ambiguous. Implementation of the same is needed. It is suggested to provide exemption from NBA and a notification be issued for exempting the technologies/products developed for controlling epidemics/diseases, mitigating environmental pollution affecting human/animal/plant health, etc from the preview of NBA and 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. Secondly, the Flaws with Form III of BDA for

⁴⁴ Western Coalfields Ltd., Coal India Ltd & Union of India vs. Biodiversity Management Committee, NGT, 2013 <https://www.casemine.com/judgement/in/574989a8e56109100ce98676> last visited 22.2.2020.

⁴⁵ Id.,

⁴⁶ Cl.14(2) of the "Guidelines on Access to Biological Resources and Associated Knowledge and Benefits Sharing Regulation, 2014, http://nbaindia.org/uploaded/pdf/Gazette_Notification_of_ABS_Guidlines.pdf last visited 22.2.2020.

seeking approval for patent applications need to be addressed Form III in word format and in electronic format on the Official website of NBA are different (u/s 19(2) & 19(3))⁴⁷. Any application filed before the NBA has to be disposed of within 90 days timeline must be strictly adhered.

State Biodiversity Authority⁴⁸ shall not question the approval given by the National Biodiversity Authority under the state regional rules. 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. A person belonging to other states does not fall within Sec.7 but however State boards seemed to bring their subject within the preview of the State which clearly violates the Act.

3. Liability Provisions

The Patent guidelines enacted only in 2012⁴⁹ have minimized the imposition of liability provisions. However, the penalty could be increased for non-compliance. The offences are cognizable and non-bailable.⁵⁰ The objective of the legislation must be benefit sharing not to penalize the contravention. Multiple benefit sharing agreements becomes a tedious process for accessing the Biological material if an

⁴⁷(Sec.19 (2) Any person who intends to apply for a patent or any other form of intellectual property protection whether in India or outside India referred to in sub-section (1) of section 6, may make an application in such form and in such manner as may be prescribed to the National Biodiversity Authority.

(3) On receipt of an application under sub-section (1) or sub-section (2), the National Biodiversity Authority may, after making such enquiries as it may deem fit and if necessary after consulting an expert committee constituted for this purpose, by order, grant approval subject to any regulations made in this behalf and subject to such terms and conditions as it may deem fit, including the imposition of charges by way of royalty or for reasons to be recorded in writing, reject the application: Provided that no such order for rejection shall be made without giving an opportunity of being heard to the person affected).
<http://nbaindia.org/uploaded/Biodiversityindia/Legal/31.%20Biological%20Diversity%20%20Act,%202002.pd>
last visited 22.2.2020.

⁴⁸ (Sec.7 Prior intimation to State Biodiversity Board for obtaining biological resource for certain purposes 7. No person, who is a citizen of India or a body corporate, association or organization which is registered in India, shall obtain any biological resource for commercial utilization, or bio-survey and bio-utilization for commercial utilization except after giving prior intimation to the State Biodiversity Board concerned: Provided that the provisions of this section shall not apply to the local people and communities of the area, including growers and cultivators of biodiversity, and vaid and hakims, who have been practicing indigenous medicine)
<http://nbaindia.org/uploaded/Biodiversityindia/Legal/31.%20Biological%20Diversity%20%20Act,%202002.pd>
last visited 22.2.2020.

⁴⁹ http://www.ipindia.nic.in/writereaddata/Portal/IPOGuidelinesManuals/1_39_1_5-tk-guidelines.pdf last visited 22.2.2020.

⁵⁰ Sec.55 of the BD Act.2002.

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.

In dealing with the Arbitration issues of the ABS agreement Chairman of the NBA appoints the Arbitrator. Preference must be also given to a company to appoint arbitrator. This is not being done. Then in such situation seeking remedy through courts of law is wiser. In the utilization of the Biological resources, cultivation must be done in India this clause shall be relaxed so that companies must be allowed to be license or sub-license with whomever it wanted to be with maybe even a foreign entity. The Royalty clauses is added based on the cost of the Biological resource. Based on the Net sales royalty would be given but royalty should not be collected based on the value of the resource in making the product. Whenever there is a material breach the company has to indemnify the loss as determined by the NBA. Critics argue that the clause is one sided and must be subjected to review.

The applicants are supposed to submit the Status report. There is an ambiguity as to by when status report ought to be filed. Critics argue that asking for the Status report is beyond the mandate of the Biodiversity Act. When the application is filed before the Patent authority within one month of the submission a working statement⁵¹ to file it before the National Biodiversity which is beyond the mandate of the Act.

The local communities under the BD Act do not have decision making process. The same is regulated by the National and the State Biodiversity Authority. The communities have no say whether the access to benefit sharing should be allowed in the first place as they lack knowledge on IPRs use and the use of Traditional Knowledge. Therefore, it is suggested that active participation of the local communities though encouraged but should not be totally conferred with the decision-making process.

⁵¹ Form 27 of the Biodiversity Rules 2004.

The Government of India has brought schemes such as Start-Ups Intellectual Property ⁵²Protection (SIPP) scheme, Make-in-India initiative and so on. This has been launched to encourage innovation and treaty. It provides 80 percent rebate in patent filing. 1029 facilitators empaneled by start-ups India to assist the startups in filing the Patent. The government initiative is defeated as there is a lack of approach to patent filing by the NBA and the Indian Patent Office. Regulatory requirements have become stringent that makes it difficult for implementation. Patent⁵³ rules provides for 'expedited examination' for the Start-Ups to boost innovations and provide speedy IPR protection. Though the rules exist startups do have foreign investors BDA restricts the expedite examination. Thus, the Patent application on biological material must be granted without awaiting NBA approval. The start-ups must be reviewed to undo NBA approval.

4. Conclusions

Any actions done must be in accordance with the legislative intent of the Act. The BDA lays emphasis on profit sharing but lack provisions towards sustainable conservation. Frequent meeting between the stake holders would fulfill omissions to 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. What are the elements of Biological resources must be specified like what has been given in the Convention so as to include rare species, endangered species, wild species, etc., 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? While the existing national regime is

⁵² <http://www.makeinindia.com/startup-ecosystem-in-india> last visited 22.02.2020.

⁵³ Patent (Amendment) Rules, 2016. http://www.ipindia.nic.in/writereaddata/Portal/News/230_1_Patent_Amendment_Rules_2016_16May2016.pdf last visited 22.02.2020.

insufficiently concerned with the overall coherence of the system put in place, it can be hoped that these shortcomings will be addressed at the level of implementation. Many Patent issues occur periodically and unresolved. The need of the hour is to establish joint- ownership of Intellectual Property Rights and National Biodiversity Authority which would improve the functioning of the board in the matters of Biological resources and constitute these two authorities as a single authority in conferring patent rights over Biological Resources.