

## GENE PATENTING IN PLANTS: INDIAN SCENARIO

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### Abstract

Today, demand for high production in agricultural sector is increasing rapidly due to increase in world population. Biotechnology through genetic engineering has paved the way for the production of super crops with desired qualities by manipulating the genome of plants. In order to give incentive to research in agricultural sector, some legal protection is required. Patent is one of such methods. Granting of patent like monopoly on plant genetic resources give rise to issue of bio-piracy. Biotech companies of developed countries have obtained many patents on genes of plants misappropriating the genetic resources of developing or underdeveloped countries which are rich in biodiversity. This free flow of genetic resources and information related therewith from South to North take place due to concept of “free access” and “common heritage of mankind.” Huge profit is generated from such resources without compensating the country of origin. This paper aims to analysis the law relating to gene patenting of plants in India and measures taken to address the issue of bio-piracy.

### I Introduction

### II Concept of gene patenting in plants

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### IV Gene Patenting in Plants: India Scenario

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### I Introduction

GENES ARE vital component of biotechnology and represents an increasingly significant area of research and development. Gene sequence offer a wealth of knowledge and information to genetic researcher. The ability to identify and utilize the gene has great potential for the medical and agricultural sector. Research in agriculture sector mainly focuses on evolving new plant varieties capable of catering the modern-day needs. Genetic researches are boon for the agricultural sector as improved varieties with high productivity fulfill the food security need of

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growing population. It involves huge investment and laborious efforts which deserve protection. Therefore, there is need to encourage research in agricultural sector by offering protection to the plant genetic inventions. Gene patents are essential incentive for biotech industry including in agricultural sector.

## **II Concept of gene patenting in plants**

Gene patent is broad term which refers to the patent of process of manipulation of DNA as well as chemical substance related therewith. Patent can be claimed not only on genes but also on gene sequence, fragment of gene for example an express sequence tag or even a sequence from a non-coding region of the genome. It may also cover vector or plasmid incorporating the sequence and organism (*e.g.*, a plant variety) that has been transformed by means of such vector. DNA products are not patentable in natural state. They become patent eligible when they have been “isolated, purified, modified or synthesized to produce a unique form not found in Nature.” Moreover, gene-based invention must have real world utility.

### **I. Comparative analysis of jurisdictional approaches of United States and European Union**

#### **a) United States (US)**

In US, doctrine of Product of Nature is prevalent. According to this doctrine any kind of structure made by man is patent-eligible, but the thing in its natural state, namely the product of nature are not patentable. However, “Purified and isolated doctrine” provides exception to “Product of Nature doctrine.” This doctrine holds that purified and isolated natural substance are patentable, if the act of isolation makes them more useful in comparison to their natural state.

Further, in the landmark case *Diamond v. Chakrabarty*<sup>1</sup> US Supreme Court by holding that “anything under the Sun that is made by man is patentable” paved the way for life patent. In this case court held the “non-naturally occurring man-made life such as genetically engineered micro-organism as patent eligible.” It established that the “relevant distinction between invention and product of nature was not between living and inanimate things, but between product of nature and man-made inventions. The nature and extent of human intervention and the degree of value added by such intervention is the criteria to decide whether a patent eligible invention has been

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<sup>1</sup>*Diamond v. Chakrabarty*, 447 US 303.

made or not.” This decision opened the floodgate for biotechnology patent. Although, it did not say anything about the eligibility of gene patent, but this decision formed the basis of DNA patent.

In the light of “Isolated and purified” exception to “Product of Nature doctrine” and decision of US Supreme Court in *Diamond v. Chakrabarty*,<sup>2</sup> US Patent and Trademark Office adopted the liberal approach of granting of gene patents on the ground that “gene sequences were compositions of matter isolated by man and markedly different from what is found in nature.” In 1991, Federal Circuit upheld the validity of patenting of purified and isolated DNA sequence in *Amgen, Inc. v. Chugai Pharmaceutical Co.*<sup>3</sup>

However, recently in *Association for Molecular Pathology v. Myriad Genetics, Inc.*<sup>4</sup> validity of patenting of BRCA1 and BRCA2 genes, mutations of which can dramatically increase the risk of breast and ovarian cancer, was in issue. US Supreme Court unanimously held that “a natural occurring DNA sequence is a product of nature and not patentable just because it has been isolated, but DNA is patentable because it is not natural occurring.” This decision is equally applicable on genes of plants.

Moreover, in US asexually reproduced plant varieties are protected under Plant Patent Act, 1930 (hereinafter PPA, 1930). Plant Variety Protection Act, 1970 (hereinafter PPVA, 1970) protects the sexually reproduced plant varieties. In *J.E.M Ag Supply, Inc. v. Pioneer Hi-Bred International, Inc.*<sup>5</sup> US Supreme court upheld the validity of utility patent on plant variety. Decision of court makes it clear that neither the PPA, 1930 nor the PPVA, 1970 precludes utility patents from being issued for plant varieties, therefore, US PTO may grant utility patent to plant varieties.

## **b) European Union (EU)**

European Patent Convention was signed at Munich on October 5, 1973 to make strong the co-operation among the European countries for protection of inventions.<sup>6</sup> It provides a uniform patent procedure applicable to all member countries. As per article 52(1) of EPC, 1973 European

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<sup>2</sup>*Ibid.*

<sup>3</sup>*Amgen, Inc. v. Chugai Pharmaceutical Co*, 927 F.2d 1200 (Fed. Cir.1991).

<sup>4</sup>*Association for Molecular Pathology v. Myriad Genetics*, 133 S. Ct. at 2107 (2013).

<sup>5</sup>*J.E.M Ag. Supply, Inc. v. Pioneer Hi-Bred International, Inc*, 534 U.S. 124 (2001).

<sup>6</sup>European Patent Convention, 1973, Preamble.

patents can be granted for “any inventions, in all fields of technology, provided that they are new, involve an inventive step and are susceptible of industrial application.”

As per article 52(2) (a) “discoveries” are not patentable inventions. To find a substance which freely occur in nature is merely a discovery, hence not patent eligible. Beside a discovery a human technical intervention and ingenuity are also essential to make the invention patent eligible.

In order to harmonize the protection of “biotechnological inventions” amongst EU member countries Biotechnological Directive 1998 was adopted.<sup>7</sup> According to article 3(2) of this Directive “biological material which is isolated from its natural environment or produced by means of a technical process may be the subject of an invention even if it previously occurred in nature.” Since gene is “biological material”, therefore, patent can be granted on it, if it has been “isolated from its natural environment.”

Article 53(b) of EPC, 1973 provides that European Patents are not available for “plant or animal varieties or essentially biological processes for the production of plants or animals.” However, as per article 4(2) of Biotechnology Directive, 1998 “inventions concerning the plants or animals are patentable, if the technical feasibility of the invention is not confined to a particular plant or animal variety.”

### **III Gene patenting in plants: Indian scenario**

#### **a) Plant genetic resources as patentable subject matter in India**

Section 3(c) of the Patent Act, 1970 specifies that “discovery of any living thing or non-living substance occurring in nature” would not be patentable. Section 3(j) is also relevant which stipulates that “plants and animals, in whole or any part thereof, other than micro-organisms but including seeds, varieties and species and essentially biological processes for production or propagation of plants and animals cannot be patented.”

A gene occurs in nature; therefore, it cannot be patent eligible under section 3(c) of the Act. However, it is also accepted fact that considerable skill is required to identify its function,

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<sup>7</sup> Directive 98/44/EC of the European Parliament and the Council of the European Union on the Legal Protection of the Biotechnological Inventions, July 6, 1998, 1998 *OJL* 213.

location and isolation. Likewise, section 3(j) prohibits “patenting of plants and animals as a whole or part thereof.” Therefore issue arises would gene be regarded as a “part of plant or animal” and not patent eligible? What is required to make a gene patent eligible? Provisions of Act are not sufficient to answer the question. Therefore, it is desirable to examine the Indian Biotechnology Guidelines, 2013<sup>8</sup> and Manual of Patent Office Practice and Procedure issued by Indian Patent Office<sup>9</sup> and approach taken by them.

Manual of Patent Practice and Procedure, 2005 had an annexure specially dealing with biotechnological and pharmaceutical inventions. According to this annexure the “living entities of natural origin such as animals, plants in whole or any parts thereof, plant varieties, seeds, species, genes and micro-organism are not patentable.” Likewise, any “living entity of artificial origin such as transgenic animals and plants, any part thereof” are not patentable. However, biological material such as “recombinant DNA, plasmids and processes of manufacturing thereof are patentable provided they are produced by substantive human intervention.”<sup>10</sup>

Subsequent Manual of Patent Practice and Procedure, 2008 does not contain any such annexure. However, while describing the “unity of an invention”, the manual provides that “when a genetically modified gene sequence/amino acid sequence is novel, involves an inventive step and has industrial application gene sequence/amino acid sequence; a method of expressing above sequence; an antibody against that protein/sequence; a kit made from the antibody/sequence can be claimed.”<sup>11</sup>

According to Indian Biotechnology Guidelines, 2013, products such as “micro-organisms, nucleic acid sequences, proteins, enzymes, compounds *etc.* which are directly isolated from nature will be treated as a discovery and are not patentable subject-matter.” Therefore, genes of plants “directly isolated from nature” would not be patentable.

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<sup>8</sup> Guidelines for Examination of Biotechnology Applications for Patent, 2013. These guidelines were issued by the Indian Office of the Controller General of Patents, Designs and Trade Marks.

<sup>9</sup> Manual may be considered as a practical guide for effective prosecution of patent applications in India. However, it does not constitute rule making and hence, does not have the force and effect of law.

<sup>10</sup> Annexure I, Manual of Patent Practice and Procedure, 2005, *available at*: [www.ipindia.nic.in; https://www.itagbs.com/Links/Acts/manual-2052005.pdf](http://www.ipindia.nic.in; https://www.itagbs.com/Links/Acts/manual-2052005.pdf) (last visited on Nov. 2, 2019).

<sup>11</sup> See Manual of Patent Practice and Procedure, 2008. Para 5.3.10, *available at*: [http://www.ipindia.nic.in/writereaddata/Portal/IPOGuidelinesManuals/1\\_59\\_1\\_15-wo-ga-34-china.pdf](http://www.ipindia.nic.in/writereaddata/Portal/IPOGuidelinesManuals/1_59_1_15-wo-ga-34-china.pdf) (last visited on Nov. 10, 2019).

Therefore, it can be said that a gene is patent eligible only if it is, “recombinant and having inventive step and industrial application.” The condition of “substantial human intervention” does not find any place in the latest manual.

In *Monsanto Technology LLC v. Nuziveedu Seeds Ltd.*<sup>12</sup> Division Bench of the High Court of Delhi held that “genetically modified plants, genetically modified seeds and gene sequences that provide genetic traits to plants are not patentable subject matter in India.” Bench invalidated Monsanto’s patent on the basis of two key conclusions: Firstly, that genetically modified having Bt. Trait, produced by hybridization which is an “essential biological process” are excluded from purview of patenting under section 3(j), and that Monsanto cannot claim patent right on a gene which is integrated into the generations of plant; and secondly, that a genetically modified trait (gene sequence) was nothing but a part of a seed. Court observed that the “trait by itself had no intrinsic worth. It is meant to be implanted or introgressed and later hybridized into a variety to be further hybridized through back-crossing and cross-breeding with other existing varieties to produce seeds that are ultimately used. Without introgression, they are inert and inanimate. Their function is to be part of seeds.”

Hearing the arguments of both parties, Supreme Court observed, “suit involved complicated mixed questions of law and facts with regard to patentability and exclusion of patent which could be examined in the suit on basis of evidence.” Accordingly, court set aside the order of the Division Bench and remanded the suit to learned single judge for disposal in accordance with law. No concluding remarks have been made regarding the patenting of isolated DNA and cDNA. This question has been left open. Yet it has not been settled.

For protection of plant varieties, India has developed the *sui generis* system of protection by introducing the Protection of Plant Varieties and Farmer’s Rights Act, 2001.

#### **b) Effect of gene patenting on agricultural sector in India**

Countries with strong gene patenting laws for plants have an efficient genetic engineering in plants which enriches the existing pool of new varieties. It is beneficial for agricultural as well as food industry of the Nation. It also attracts the FDI as foreign breeders will be encouraged to invest in Nations having gene patenting laws. Biotechnology in agricultural sector is developing

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<sup>12</sup> Civil Appeal Nos.4616-4617 of 201 (decided on Jan. 8, 2019).

rapidly. Lack of strong legal protection for genetic engineering in plants hinders agro-biotech inventions. However, it has its own drawbacks for developing countries like India.

India is basically an agricultural economy and vast majority of its people are farmers. Plant genetic resources have been slowly developed over thousands of years with the domestication of plants. Peasants and local community by their traditional practices have significantly contributed to the creation, conservation, exchange & utilization of genetic diversity.<sup>13</sup> Since gene patenting in plants is permitted in many nations especially in developed nations as biotech industry is dominated by them, therefore, taking the advantage of this legal regime, agro-biotech companies have obtained several patents on genetic inventions relating to plants. They generate huge profits by misappropriating the genetic resources of developing or under-developed countries, which are rich in bio-diversity. This free flow of biological resources and associated knowledge from South to North take place due to concept of “free access” and “common heritage of mankind.” Therefore, while accessing the genetic resources consent of country of origin is not obtained. Further, genetic material is taken without compensating and acknowledging the contribution of indigenous communities of provider country. This gives rise to issue of ‘bio piracy’ and ‘cultural piracy’. Moreover, granting of patent like monopoly on genes of plants may require the farmers to pay royalties to obtain protected seeds along with related restrictions on saving, replanting and selling saved seeds.

### **c) Access to genetic resources and benefit sharing regime**

In order to address the issue of bio-piracy, measures have been taken under Patent Act, 1970 and The Protection of Plant Variety and Farmers Right Act, 2001 and Biological Diversity Act, 2002.

#### ***i. Disclosure requirement under Patent Act, 1970***

The Patent Act, 1970 addresses the issue of bio-piracy by requiring the applicant “to disclose the source and geographical origin of the genetic material in the specification if it is used in an invention.”<sup>14</sup> Further, “non-disclosure” or “wrongful disclosure” of “source or geographical

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<sup>13</sup>Sanjit Kumar Chakraborty, “Intellectual Property Rights Over Plant Genetic Resources: Enviro-Legal Issues and Perspective in India” 2(1) *KJLS* 83 (2012).

<sup>14</sup> Patent Act, 1970 (Act 39 of 1970), s. 10(4)(ii)(D).

origin of biological material used for the invention” is ground for opposition and for revocation of patent, if granted.<sup>15</sup>

TRIPS Agreement leaves a considerable room for patenting of biotech inventions. Convention on Biological Diversity, 1992 provide for the requirement of “prior informed consent, mutually agreed terms and benefit sharing” in case of use of genetic resources. Having ratified both the agreement, India provides that in case of biotechnological inventions, patent application is complete only when it discloses the source of biological material.

**ii. Protection of Plant Varieties and Farmer’s Rights Act, 2001**

Purpose of Act is “to establish an effective system for protection of plant varieties, the rights of farmers and the breeders and to encourage the development of new varieties of plants in consonance with the TRIPS.”<sup>16</sup>

- **Disclosure requirement-** A new variety is registerable under the Act subject to satisfying the criteria of “novelty, distinctiveness, uniformity and stability.”<sup>17</sup> For registration along with other details applicant must provide “complete passport data of the parental lines from which the variety has been derived along with the geographical location in India from where the genetic material has been taken including the contribution made by any farmer, village community, institution or organization in breeding in evolving or developing the variety.” He must also declare that “genetic material acquired for breeding, evolving or developing the variety has been lawfully acquired.”<sup>18</sup>
- **Benefit Sharing-** Once certificate is issued it shall be published by authority. The purpose is to invite claims of benefit sharing if any with respect to respective registered plant variety. Citizen of India or group thereof; Indian firm, governmental or non-governmental organization may submit a claim of benefit sharing. If such a claim is made, a copy of the same shall be served on the breeder of the respective plant variety to invite his oppositions to benefit sharing. Thereafter, an opportunity of being heard shall be given by authority to both the parties before making any decision. While determining the sum of benefit sharing, the authority shall consider the factors such as “extent and nature of the use of genetic material

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<sup>15</sup>*Id.*, ss. 25(j), 64(p).

<sup>16</sup> Protection of Plant Varieties and Farmers’ Right Act, 2001 (Act 53 of 2001), Preamble.

<sup>17</sup> *Id.*, s. 15(1).

<sup>18</sup>*Id.*, s. 18.



of the claimant in the development of the variety, commercial utility and demand in the market of the variety.” The breeder of variety shall deposit the amount of benefit sharing so determined in the National Gene Fund.<sup>19</sup>

- **Critical Analysis-** The object of benefit-sharing provisions is to compensate the peasants and indigenous community for their contribution in the development of new plant varieties. However, the proper implementation of this scheme is not so easy as inviting of claims for benefit sharing pre-suppose that the indigenous people will have proper awareness in this regard. In a country like India, due to the socio-economic and educational conditions, local people and peasants are often ignorant of such provisions. In order to overcome these practical difficulties, it is important for the state to make the traditional societies aware of their rights.

### *iii. Biological Diversity Act, 2002*

Generally, the purpose of Act is to provide for the “conservation of biological diversity, sustainable use of its components and for the equitable sharing of benefits arising out of the use of biological resources,” mirroring in the CBD.<sup>20</sup> For this purpose, it institutes a National Biodiversity Authority and State Biodiversity Authorities as nodal bodies to supervise the conservation, use and sharing of benefits from the utilization of “biological resources.”<sup>21</sup>

- **Access to biological resources-** Act provides for strict criteria for access to genetic resources and related knowledge for all foreigners. They are required to take prior permission of the National Biodiversity Authority “for obtaining any biological resource occurring in India or associated knowledge for research or for commercial utilization or for bio-survey and bio-utilization.”<sup>22</sup> The Act forbids the transfer of results of any such research for consideration without previous authorization of the NBA.<sup>23</sup> Indian citizens, body corporate, association or

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<sup>19</sup>*Id.*, s. 26.

<sup>20</sup>Biological Diversity Act, 2002, (18 of 2003), Preamble.

<sup>21</sup>*Id.*, s. 2(c)- Biological resources mean “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.”

<sup>22</sup>Biological Diversity Act, 2002, s. 3- Person who must seek previous approval of National Biodiversity Authority includes “any person who is not a citizen of India; a citizen of India, who is a non-resident; a body corporate, association or organization not incorporated or registered in India, or 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.”

<sup>23</sup>Biological Diversity Act, 2002 (Act 18 of 2003), s. 4.

organization registered in India are under obligation to give prior intimation of intention to obtain biological resources to the state board concerned.<sup>24</sup> In relation to intellectual property protection over biological resources, section 6 is key provision. It provides that “without obtaining the prior approval of the National Biodiversity Authority, no person can apply for any intellectual property right in or outside India for any invention based on a biological resource obtained from India.” However, if application has been submitted for patent, approval of the National Biodiversity Authority (NBA) may be obtained after the acceptance of the patent but before the sealing of the patent by the patent authority concerned. While granting the approval, the authority may impose “benefit sharing fee or royalty or both or impose conditions including the sharing of financial benefits arising out of the commercial utilization of such rights.” Section 18 also imposes a duty on NBA to issue guidelines for access to genetic resources and for fair and equitable benefit sharing. Application for registration of plant varieties regulated under The Protection of Plant Variety and Farmers Right Act, 2001 (PPVFR Act) are exempted from above-mentioned rule.<sup>25</sup> This exclusion of plant variety laws from the scope of this Act creates apprehension that plant varieties may be developed from biological resources without approval of NBA. This doubt has been clarified by section 18 of PPVFR Act, 2001, which requires the applicant “to provide complete passport data of the parental lines from which the variety has been derived along with the geographical location in India from where the genetic material has been taken including the contribution made by any farmer, village community, institution or organization in breeding in evolving or developing the variety.” He must also declare that “genetic material or parental material acquired for breeding, evolving or developing the variety has been lawfully acquired.”

- **Benefit sharing-** Keeping in view the international trends, the “access regime” is complemented by a “benefit sharing system.” Therefore, while granting access Authority has to ensure that the “conditions under which access is provided secure equitable sharing of the benefits arising out of the use of accessed biological resources and their by-products, innovations and practices associated with their use and applications and knowledge relating

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<sup>24</sup>*Id.*, s.7.

<sup>25</sup>*Id.*, s. 6(3).

thereto in accordance with mutually agreed terms and conditions between the person applying for such approval, local bodies concerned and the benefit claimers.”<sup>26</sup>

The Act provides a broad indicative list of benefits which includes monetary benefits as well as a number of other benefits. These include “technology transfer, the location of production, research and development in the area from where the benefit claimers come from and the association of Indian scientists, benefit claimers and local people with research and development in biological resources and bio-survey and bio-utilization.”<sup>27</sup>

From the conceptual point of view, the most significant contribution of the Biological Diversity Act, 2002 is to also provide that benefit sharing can imply the sharing of IPR. Where the benefit claimers can be specifically identified, the NBA is empowered to provide for joint ownership of IPR. It is also entitled to allocate itself joint ownership rights if benefit claimers are not identifiable.<sup>28</sup> In other words, this provides a situation where a biodiversity related authority will have the power to directly influence the grant of patent even though it has no role in implementation of the Patent Act, 1970. However, under the Biological Diversity Rule, 2004, there is no provision that provides for the implementation of this scheme which needs further elaboration as it is directly linked to the implementation of Biological Diversity Act 2002 as well as the Patents Act, 1970.<sup>29</sup> Section 21(4) mandates the NBA to frame the guidelines regarding benefit sharing by regulations, in consultation with Central Government.

While the Biological Diversity Act, 2002 introduces various benefits for the purpose of sharing there is still emphasis on monetary benefits. In case of monetary compensation, the authority has the discretion to require the deposit of amount in the National Biodiversity Fund or paid to particular person or group of persons if the origin of the genetic resources is traceable.<sup>30</sup> The significant powers of the Authority in determining what the benefits shared

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<sup>26</sup>*Id.*, s. 21(1).

<sup>27</sup>*Id.*, ss. 21(2) (b) (c) & (d).

<sup>28</sup>*Id.*, s. 21(2) (a).

<sup>29</sup> Philippe Cullet, *Intellectual Property Protection and Sustainable Development* 179 (Lexis Nexis Butterworths, New Delhi, 2005).

<sup>30</sup>Biological Diversity Act, 2002 (Act 18 of 2003), ss. 21(3), 27.

should be and to whom, are made even more important by the fact that in case of monetary benefits, the Authority has power to determine the specific percentage according to need of individual case.<sup>31</sup>

- **Role of biodiversity management committee-** Sharing of benefits requires identification of those individuals or communities who played major role in conservation of genetic resources and Traditional knowledge (TK) related therewith. Act does not contain any provision for identification of those individuals; however, it provides for documentation of biological diversity. Act provides for establishment of Biodiversity Management Committee (BMC) at local level for “promoting the conservation, sustainable use and documentation of biological diversity including preservation of habitats, conservation of land races, folk varieties and cultivars, domesticated stocks and breeds of animals and microorganisms and chronicling of knowledge relating to biological diversity.”<sup>32</sup>

The mandate of Biological Diversity Committee (BMC) has been clearly highlighted in the Biological Diversity Rule, 2004. The main function of the BMC is “to prepare People’s Biodiversity Register in consultation with local people.” The Register shall contain comprehensive information on “availability and knowledge of local biological resources, their medicinal or any other use or any other traditional knowledge associated with them.”<sup>33</sup> The other functions of the BMC are “to advise on any matter referred to it by the State Biodiversity Board or Authority for granting approval, to maintain data about the local *vaids* and practitioners using the biological resources.”

- **Critical analysis-** Access to biological resources and benefit sharing regime under Biodiversity Act, 2002 is subject to many criticisms. *Firstly*, Act imposes a requirement that “all inventors should obtain the consent of the NBA before applying for intellectual property right where the invention is based on any genetic resource obtained from India.” Due to territorial nature of intellectual property right this provision can only be given effect in India and it is unlikely that the authority will be able to do much regarding foreign applications.

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<sup>31</sup> Biological Diversity Rule 2004, Rule 20(3).

<sup>32</sup> Biological Diversity Act, 2002, s. 41(1).

<sup>33</sup> Biological Diversity Rule 2004, rule 22(6).

*Secondly*, Act strongly reasserts India's sovereign rights over its genetic resources but does little towards giving local knowledge holders strong control over their genetic resources and TK. In fact, it is noteworthy that Biological Diversity Act, 2002 does not implement the concept of "prior informed consent." It requires the previous authorization of the NBA which is a weak form of "prior informed consent." Without prior and informed consent of TK holder makes the Act much weaker in comparison to general framework proposed by the CBD. Further, they do not have capacity to defend their rights in the same way that it is available to government. *Thirdly*, it is clear from above analysis that two parallel benefit sharing schemes have been developed in the Biological Diversity Act, 2002 and PPVFR Act, 2001. However, little effort has been made to coordinate the two systems into a coherent manner. There is overlapping between the two-benefit sharing regimes. Biological Diversity Act, 2002 provides a comprehensive definition of benefit sharing encompassing the various options from monetary benefit to transfer of technology and the grant of joint ownership of intellectual property right. In contrast, in the PPVFR Act, 2001 only monetary compensation is recognized as means of benefit sharing. However, the procedure for determination of benefit sharing claim is more detailed in the PPVFR Act, 2001.

Procedural differences are not significant in themselves. What is more important is the fact that there is no need to have different benefit sharing mechanisms as the subject matter in the two Acts are largely similar despite the differences in scope. Therefore, benefit sharing regime and institutional structure implementing it should be one and the same for all relevant transactions.

Further, in the context of Patent Act, 1970 need of single benefit sharing regime and single institutional body administering it become more relevant as there is direct link between a patent application and benefit sharing. Benefit sharing is the result of the absence of property rights for traditional knowledge holders. However, Patent Act, 1970 is silent on the relationship between a patent application and benefit sharing. To a certain extent, the link is indirectly made in Biological Diversity Act, 2002 insofar as applications for intellectual property rights must be investigated by National Biodiversity Authority. Making this link direct and making the disclosure of the resources and knowledge used in the invention a

condition precedent for patent would make the overall benefit sharing regime more effective. In other words, the benefit sharing regime would be much strengthened and streamlined if it was applied as an integral part of overall intellectual property rights strategy.

#### IV Conclusion

Laws of developed countries are liberal in granting patent on genes of plants as biotechnology industry is dominated by them. However, at one hand, in order to fulfill its food security need, India is in need to promote the plant biotechnology, on the other hand it is an agricultural economy, therefore, it is under obligation to protect the interest of its farmers. Further, it is rich in biodiversity, therefore, it has its own concerns regarding the issue of bio-piracy. Therefore, there is need to make the balance. For that purpose, some measures may be suggested. *Firstly*, gene patenting practices in India are still governed by the Indian Biotechnology Guidelines, 2013 and Manual of Patent Office Practice and Procedure issued by Indian Patent Office. These guidelines are not rule and are also subject to interpretations by a court of law, statutory amendments and valuable inputs from stakeholders. In case of conflict between these guidelines and provisions of Patent Act, 1970 and Patent Rules, 2003, provisions of said Act and Rules will prevail. Therefore, in order to regulate the issue of gene patenting of plants, clear cut guidelines should be laid down in the Patent Act, 1970 itself. *Secondly*, these guidelines should ensure the farmer's right "to save, re-use, exchange and sell the farm-saved seeds in case of patenting of plant genetic materials." *Thirdly*, Issue of bio-piracy has been addressed in Patent Act 1970, PPVFR Act, 2001 and Biological Diversity Act, 2002. Two parallel benefit sharing schemes have been developed in the Biological Diversity Act, 2002 and PPVFRA, 2001. There is overlapping between the two-benefit sharing regimes. However, little effort has been made to coordinate the two systems into a coherent manner. Therefore, there is need of one and single comprehensive regime which should be applied as an integral part of overall intellectual property rights strategy. *Fourthly*, moreover, benefit claimers have no voice in determination of benefit sharing. Therefore, they should be given effective bargaining power in determination of benefit sharing.