Biodiversity Laws as a Means to Protect Traditional Knowledge: Issues, Challenges and Success Stories

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Abstract

India is a country rich in biodiversity. The associated traditional knowledge has been an important part of Indian culture and society. Being a diversity rich spot, India has been victim of bio-piracy several times, though it has learnt its lessons from haldi, neem and basmati incidents. While it is important for countries to conserve its biodiversity and associated indigenous knowledge, it is also important to protect rights of those who add value to it and make its use more extensive through the tools of intellectual property rights. This results in conflict between biodiversity conservation and intellectual property rights. Biodiversity conservation conventions and statutes seek to achieve a balance between the rights of both. In India, the Biodiversity Act, 2002 provides for requirement of prior informed consent of the indigenous communities before accessing and using the concerned bio-resource. It also provides legal framework to ensure benefit sharing in various forms in case any intellectual property is obtained on the bio-resource or the relevant traditional knowledge. However, effective implementation of the same remains a challenge. This ultimately deprives the actual holders of the concerned traditional knowledge who have either nurtured the bio-resources for years. This paper discusses the framework of biodiversity conservation laws as a means to protect rights of traditional knowledge holders in the international and Indian context. It highlights instances where legal framework has been successful in protecting rights of traditional knowledge holders. It also discusses various issues and challenges in protection of traditional knowledge in India.

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Keywords: *Traditional Knowledge, Prior Informed Consent, Documentation, Benefit Sharing, Technology Transfer, Implementation Challenges*

I. Conservation of Biodiversity: Background

The Convention on Biodiversity, 1992 is a landmark international agreement on protection of environment and sustainable development. It was adopted at the United Nations Conference on Environment and Development, 1992 (the Earth Summit) at Rio de Janeiro. CBD recognized that States shall have sovereign rights over the biological resources within their territories, and can establish laws to regulate access to those resources.[2]CBD has three fundamental objectives - conservation of biological diversity; sustainable use of its components and; fair and equitable sharing of benefits arising from the use of genetic resources.[3]The last objective is of much relevance to the developing countries. Many developing countries hold most of the world's biological diversity, but are deprived from getting a fair share of benefits derived from use of their resources. This reduces the incentive for the biologically richer but economically poorer countries to conserve and ensure sustainable use of their resources.[4]

In 2002, in pursuance of the CBD, Bonn Guidelines were framed to support member countries to frame Access and Benefit Sharing (ABS) schemes and in identifying the steps involved therein.[5]Bonn Guidelines serve as inputs when member states frame legislative, administrative or policy measures on ABS.[6] In 2010, a supplementary agreement to CBD was framed, known as the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity (also known as the Nagoya Protocol on Access and Benefit Sharing).

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[2]The Convention on Biodiversity, 1992,art. 3.
[3]The Convention on Biodiversity, 1992, art. 1.
[4]THEBONN GUIDELINES ON ACCESS TO GENETIC RESOURCES AND FAIR AND EQUITABLE SHARING OF THE BENEFITS ARISING OUT OF THEIR UTILIZATION, 2002, *available at:*https://www.cbd.int/doc/publications/cbd-bonn-gdls-en.pdf(last visited on October 8, 2019).
[5]*Id.*
[6]The Bonn Guidelines, 2002, arts. 8 (j), 15.

The Nagoya Protocol aims to ensure sustainable development through cooperation by building research and innovation capacities for adding value to genetic resources in developing countries. It also aims to ensure public awareness of the economic value of ecosystems and biodiversity, and fair and equitable sharing therein.[7]

II. Interface between CBDand TRIPS

Article 15 of the CBD recognises the sovereign rights of States over their natural resources. The national governments have the authority to determine access to genetic resources. Countries should create conditions for facilitating access to genetic resources for environmentally sound uses by other contracting parties. Access to genetic resources shall be on mutually agreed terms. Thus, CBD aims to conserve, sustainably use, and share the benefits of biological resources arising out of such use equitably.

However, the main objective of the Agreement on Trade Related aspects on Intellectual Property Rights, 1994(TRIPS) is to recognize and protect monopolistic and private intellectual property rights (IPRs).TRIPS, 1994 (agreement between all members of WTO) lays down the minimum standards which member states are required to follow in their intellectual property regimes. TRIPS agreement provides flexibility regarding protection of life-forms. Article 27.3 of the TRIPS provides that member countries may exclude plants and animals from patentability. It provides three ways in which member countries shall provide protection for plants - by patents, or by an effective *sui generis* system, or by combination of both.The basis of this protection is exclusivity and monopoly.Thus, member countries have been given a choice to opt for any of the above three alternatives for protection of plants. Thus, TRIPs looks at individual rights while CBDencourages recognition of collective rights of communities.This implies that States do not actually enjoy the sovereignty on intellectual property rights based on biological resources.

Though CBD takes the position that IPRs must not conflict with the conservation and sustainable use of biodiversity and States should cooperate to ensure that IPRs should be supportive of and do not run counter to the objectives

[7]The Nagoya Protocol, 2010, art. 1.

of CBD, conflicts are bound to arise.[8]The interface between CBD and IPRs is well recognized by the Second Conference of Parties (COP2) to the CBD. It was suggested that there is a need to develop a common appreciation of the relationship between the TRIPs agreement and CBD, in particular on technology transfer and on the three-fold objectives of the CBD, viz., conservation and sustainable use of biodiversity and the equitable sharing of benefits arising from such use. It was further stated that WTO through its Committee on Trade and Environment (CTE), should consider a better appreciation of the relationship between trade and agricultural biodiversity, and collaborate with CBD.[9]It was emphasized that there is a need for co-operationpertaining to the inter-linkages between Article 15 of on access to genetic resources in CBD and the TRIPs agreement.[10]

II.I Differences in Standard of Protection

Under the Indian Patent Act, 1970, plants and animals are not inventions for the purpose of the Act and thus, not patentable.[11] Also, inventions which cause serious prejudice to human, animal or plant life or health or to the environment are not an invention for the purpose of patentability.[12]Thus, India excludes plants and animals from patentability.

However, countries like U.S.A. have broader criteria of patentability. Patent may be obtained by anyone who invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof.[13] There has to be sufficient human intervention in making or improving of the thing for which the patent is sought. The Plant Patent Act of 1930 and the Plant Variety Protection act of 1970 specifically provide for ownership rights to new plant varieties. Court decisions in *Diamond v.*

[8]Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS), 1994, art. 16.5.
[9]AGRICULTURAL BIOLOGICAL DIVERSITY, UNEP/CBD/COP/3/L 12, *available at:* https://www.cbd.int/kb/record/meetingDocument/1097?FreeText=UNEP/CBD/WG-ABS/4/INF/12 (last visited on October 8, 2019).
[10]*Ibid.*
[11]The Patent Act, 1970, s. 3(j) (India).
[12]The Patent Act, 1970, s. 3(b)(India).
[13] 35 U.S.C. § 101

Chakraborty[14] and *Ex parte Hibberd*[15] afford the individuals additional option of seeking protection over a new plant variety. Under the Plant Patent Act, 1930, the distinctive characteristic of a plant variety and its value can be granted a patent, provided the same was not appreciated by anyone prior to the discovery by the inventor, or had no knowledge of the existence of the variety.[16]

III. Bio-Piracy: Sabotaging Biodiversity Based Traditional Knowledge

CBD aims at equitable distribution of benefits arising out of the research and commercialization of biological resources, including IPR, among the users and providers. It seeks to achieve a balance between the competing interests of stakeholders by creating an international mandate for access through prior informed consent and benefit sharing based on mutually agreed terms. This is required because plant and animal species are used to obtain raw material for manufacturing pharmaceuticals and other commercially valuable compounds. Thus, genetic resources and associated knowledge contribute to the creation of value-added products, which in turn have enormous economic potential. Intellectual Property Rights are used as legal tools to acquire monopoly rights over this extremely valuable information and thereby ensure commercial exploitation. However, creation of private property rights through the grant of patents can result in obstructions for future research. The holders of IPR obtain significant benefits, but these benefits are not shared with the actual conservers and holders of biological resources and knowledge associated therein. This results in bio-piracy.[17]

When knowledge from indigenous communities is accessed by outsiders who exploit it for profits and claim to be owners of that knowledge, it amounts to bio-piracy. Generally, living resources or traditional knowledge and practices

[14]447U.S. 303 (1980).
[15]*227* USPQ 443 (PTO Bd. Pat. App. & Int. 1985).
[16]NEW DEVELOPMENTS IN BIOTECHNOLOGY: PATENTING LIFE, *available at*: https://www.princeton.edu/~ota/disk1/1989/8924/892407.PDF(last visited on October 10, 2019).
[17]URMIKA VINAY TRIPATHI, "BIOPIRACY: MYTH OR REALITY?" *available at*: http://docs.manupatra.in/newsline/articles/Upload/1246C8AA-74EF-4D0E-A1F9-04E9554B99EE.Biopiracy%20Myth%20Or%20Reality_Urmika%20Vinay%20Tripathi_p21-32.pdf (last visited on October 10, 2019).

are patented and thereby restrictions are put to their use, based on intellectual property laws. Bio-piracy poses challenges not just related to cultural heritage and traditional knowledge but also threatens rights of the indigenous communities to have commercial benefits over resources which might have been nurtured and conserved by them.[18]

The R&D in biotechnology is mainly limited to developed countries particularly in private hands. They rely on the genetic resources provided by the biodiversity rich developing countries. The products or plant varieties developed from these genetic resources are then not accessible to developing countries. These products are exported to them at high value adding without acknowledging the source or repaying cultivation and protection of this "raw material."

Changes in patent laws of some countries (for instance, U.S.) widened the ambit of patentability, including new variety of plants, micro-organisms etc. These changes increased the scope of living organisms to be classified as patentable. This in turn increased the number of cases of biopiracy. Generally developing countries which are rich in biodiversity are the sufferers as before they could develop technologies to commercially exploit the bio-resources, these resources are accessed and put to commercial use by the developed nations. Their use by the actual and local owners is restricted by applying IPR laws.

India is one of the 17 mega biodiversity countries of the world. With only 2.5% of land area, India's biodiversity accounts for about 7.8% of the recorded species of the world.[19] Being a bio-diversity rich country, India has been a victim of bio-piracy a number of times. For instance, Basmati Rice was patented by US as aromatic rice, which was challenged by India.Qualities of turmeric, neem, pepper,aswagandha, amla, hessian ginger etc were patented by US, and time and again have been challenged by India.[20]

IV. Legal Framework in India

[18]*Ibid.*
[19]National Biodiversity Authority, *available at:*http://nbaindia.org/undp/(last visited on October 11, 2019).
[20]M.B.RAO AND MANJULA GURU, "Understanding Trips: Managing Knowledge In Developing Countries" (Response Books, New Delhi, 2003).

Being a member of WTO, India is bound by the minimum intellectual property standards laid down in TRIPS. The India Patent Act, 1970 has kept plants and animals out of the purview of patentability.[21]

In 2001, the Protection of Plant Varieties and Farmers Rights Act was passed with the objective to establish an effective system for protection of plant varieties, rights of farmers and plant breeders and to encourage the development of new varieties of plants. This gives effect to Article 27 Paragraph 3 (b) of TRIPS.

Learning from its experiences as well as after ratifying the CBD, India enacted the Biodiversity Act, 2002. In order to deal with bio-piracy, the Act specifically lays down restrictions on applying for any intellectual property rights based on the biological resources obtained from India. It prohibits application by any person for IPR in or outside India for any invention based on any research or information on a biological resource obtained from India without obtaining the previous approval of the National Biodiversity Authority (NBA).[22] While granting such approval, the NBA may impose benefit sharing fee or (and) royalty. It may also impose conditions for sharing of financial benefits arising out of the commercial utilization of such rights.[23] Citizens of India and body corporate, associations or organizations registered in India are required to give prior intimation to the State Biodiversity Board for obtaining biological resources for bio-survey and bio-utilization for commercial use.[24] However, certain people are not required to give prior intimation, for instance, local people and communities of the area and growers and cultivators of biodiversity as well as *vaids* and *hakims* who have been practicing indigenous medicine.[25]

On behalf of the Central government, NBA has been empowered to take suitable measures required to oppose the grant of IPRs in any country outside India on any biological resource obtained from India or knowledge associated with such biological resource derived from India.[26]

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[21]The Indian Patent Act, 1970, s. 3.
[22]The Biodiversity Act, 2002, s. 6(India).
[23]*Ibid.*
[24]The Biodiversity Act, 2002, s. 7.(India)
[25]*Ibid.*
[26]The Biodiversity Act, 2002, s. 18(4)(India)

While giving the required permissions for accessing of and transfer of biological resource or knowledge, the NBA is required to ensure equitable sharing of benefits arising out of the use of accessed biological resources, their by-products, innovations and practices associated with their use and applications and knowledge relating thereto as per mutually agreed terms and conditions between the applicant, concerned local bodies and benefit claimers. The NBA may determine benefit sharing, inter alia, by grant of joint ownership of intellectual property rights to the NBA, or to the benefit claimers in those cases in which they can be identified.[27]

In 2002, Biodiversity Rules were framed which specifically provide for equitable benefit sharing.[28] NBA is empowered under the rules to frame guidelines for benefit sharing. Benefits can be monetary as well as non-monetary such as- royalty, joint ventures, technology transfer, product development, education and awareness raising activities, institutional capacity building and venture capital fund. Exact formula for benefit sharing is determined on case-by-case basis. The NBA while granting approval to any person for access or for transfer of results of research or applying for patent and IPR or for third party transfer of the accessed biological resource and associated knowledge may impose conditions to ensure equitable sharing of the benefits arising out of the use of accessed biological material and associated knowledge.[29] The quantum of benefits shall be mutually agreed upon between the persons applying for such approval and the Authority in consultation with the local bodies and benefit claimers and may be decided in due regard to the defined parameters of access, the extent of use, the sustainability aspect, impact and expected outcome levels, including measures ensuring conservation and sustainable use of biological diversity. Depending upon each case, the Authority shall stipulate the time frame for assessment of benefit sharing. The benefits shall ensure conservation and sustainable use of biological diversity. Where biological resources or knowledge is accessed from a specific individual or a group of individuals or organizations, the Authority may take steps to ensure that the agreed amount is paid directly to them through the district

[27]The Biodiversity Act, 2002, s. 21.(India)
[28]The Biodiversity Rules, 2004, s.20.(India)
[29]*Ibid.*

administration. Where such individuals or group of individuals or organizations cannot be identified, the monetary benefits are to be deposited in the National Biodiversity Fund. The Authority shall monitor the flow of benefits in a manner determined by it.[30]

The Biological Diversity Act, 2002 empowers the NBA to frame guidelines for application of provisions of the Act.[31] In exercise of this power as well as in pursuance of the Nagoya Protocol, the National Biodiversity Authority framed the Guidelines on Access to Biological Resources and Associated Knowledge and Benefit Sharing Regulations in 2014. The Guidelines lay down the procedure to be followed to access the biological resources and associated knowledge as well as the mode of benefit sharing for commercial utilization, bio-survey and bio-utilization. Specific guidelines for obtaining intellectual property rights and mode of benefit sharing therein are also mentioned.

IV.I NBA in Action

The NBA Annual Report 2016-17 reveals that it has initiated action in ten cases in various patent offices around the world.[32] Most of these patent applications related to various nutraceutical, pharmaceutical and cosmetic compositions. These compositions use various biological resources from India including medicinally-valued substances like turmeric, Indian Gooseberry, neem, ginger, ashwagandha, centella, Indian Bay leaf, Aloe vera, Sphaeranthus indicus etc. [33]

CBD specifically upholds the sovereign rights of State to determine access to its genetic resources and insists that access to genetic resources shall be subject to national laws of member states providing such resources.[34] Pursuant to the international obligations under CBD and in accordance with the provisions under the respective foreign patents laws, observations have been filed in Canadian Intellectual Property Office, European Patent Office, State Intellectual Property Office (China) and the World Intellectual Property Office. These observations have led to a few applicants approaching the NBS to obtain

[30]The Biodiversity Rules, 2004, s. 20.
[31]The Biodiversity Act, 2002, ss. 64 r/w 18(1), 21(4).
[32]*NATIONAL BIODIVERSITY AUTHORITY INDIA ANNUAL REPORT* 2016-17, *available at:* http://nbaindia.org/uploaded/pdf/Annual_Report_2016-17__Eng.pdf(last visited on October 11, 2019).
[33]*Ibid*
[34]The Convention on Biodiversity, 1992, art. 15.

prior approval, not only for the patent application in question but also for several other applications where inventions make use of a biological resource obtained from India.[35]

a. Success Stories

Pursuant to enactment of the Biodiversity Act, 2002, NBA has played an active role in implementation of ABS principles in relation to biodiversity of the country. Following are some of the many experiences of NBA's application of ABS:

- The Kani tribe of Kerala was discovered to be consuming the fruit of *Arogyapacha*plant. The fruit bears medicinal qualities improving fatigue and provides energy. Research was conducted on the plant and a drug called *Jeevani* was developed. Patent was awarded to the Regional Research Laboratory, Jammu. The technology for making the drug was transferred to a pharmacy. Access and benefit sharing principles were applied and benefits were shared at a ratio of 1:1 with the Kani community. A trust for the Kanis was formed to ensure flow of money to the Kanis from the ABS agreement.[36]

- The Pepsico Seaweed case is another instance of the successful application of the benefit sharing principles. Under the ABS agreement, the Pepsico India Ltd. had to make payment to NBA for contract farming and exporting seaweed in Tamil Nadu.[37]

- Monsanto a US based company had sought a patent on a traditional variety of Indian wheat called Nap-Hal. The same was challenged on the ground of no prior informed consent being obtained. Ultimately the patent was revoked.[38] Earlier Monsanto India Ltd. was accused of

[35]*Supra* note 31.
[36]http://www.ip4growth.eu/sites/default/files/06_IP4GROWTH_Cote%20Divoire%20Case%20Studies%20on%20Biodiversity%2C%20Consent%20and%20Benefit%20Sharing%20Feb%202015_Suthersanen.pdf(last visited on October 13, 2019).
[37]https://www.cbd.int/doc/meetings/abs/emabschm-01/other/emabschm-01-india-en.pdf(last visited on October 13, 2019).
[38]SHAN KOHLI, "BIOPIRACY IN THE CONTEXT OF PLUNDER OF WHEAT IN INDIA" *available at*: https://spicyip.com/2016/03/spicy-ip-fellowship-2016-17-

accessing six local India varieties of brinjal and genetically engineering sixteen varieties of brinjal. The same was challenged and Monsanto was held liable for violating the provisions of the Biodiversity Act, 2002.[39]

V. Interpretational Issues in the Biodiversity Act, 2002: Revisiting*Divya Pharmacy V. Union OfIndia 2018*[40]

The Uttarakhand Biodiversity Board raised issue against Divya Pharmacy, a business undertaking of DivyaYog Mandir. Divya Pharmacy manufactures ayurvedic medicines and nutraceutical products. Biological resources constitute the chiefcomponentas raw material for manufacturing such products. The Uttakrakhand Biodiversity Board raised the issue that Divya Pharmacy was not abiding by the fair and equitable benefit sharing principles under the Biological Diversity Act, 2002 and the 2014 Regulations. Divya Pharmacy mainly argued that Uttarakhand Biodiversity Board cannot raise any such demand as the Board does not have power nor the jurisdiction. Its main contention was that only persons or entities which have some kind of foreign element are mandatorily required to obtain prior approval of NBA for undertaking biodiversity related activities. Consequently, Fair and Equitable Benefit Sharing (FEBS) principles are required to be followed only by the foreign entities. Since Divya Pharmacy is purely an Indian company, it is not obliged to follow the FEBS rules.

Divya Pharmacy also argued that State Biodiversity Boards (and consequently the Uttarakhand Biodiversity Board) have no power to impose FEBS in respect of Indian entities. Even NBA does not have powers under the Act for delegating these powers to SBB, as NBA itself is not authorized to impose Fair and Equitable Benefit Sharing on an "Indian entity." Thus, the Act does not require contribution in the form of fee or monetary compensation, or a contribution in any manner to be given by an Indian entity.

Divya Pharmacy's arguments highlighted an important interpretational issue regarding the Biological Diversity Act, 2002. The State Biodiversity Board argued that as far as FEBS is concerned, there is no distinction between an

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biopiracy-in-the-context-of-plunder-of-wheat-in-india.html(last visited on October 14, 2019).

[39]*ibid.*

[40] 2018 SCC OnLineUtt 1035.

Indian entity and a foreign entity. Making a difference between these two would defeat the very purpose of the Act. Whereas a foreign entity is required to obtain "prior approval" of NBA before venturing into this area, an Indian entity has to give "prior intimation" to SBB before venturing into this area. The regulation and control is given to SBB under the Act. Therefore,SBB is the regulatory authority in case of an Indian entity, such as the petitioner. It can impose FEBS as one of its regulatory functions.

The main issue in the case was whether the SBB has power to impose FEBS on persons who don't have any foreign element attached to them, such as the Divya Pharmacy and whether NBA can delegate to State Boardthe power to impose FEBS to persons who are not citizens of India.[41]Regulating an activity in form of demand of a fee is an accepted practice recognized in law.

The court held thatFEBS is meant to take care of the interests of local and indigenous communities. It is actually a kind of a fee or a benefit given to the indigenous or local communities by the Act which has to be examined in

the light of international treaties dealing with the importance of FEBS. "Biological resources" are definitely the collective property of a nation where they are geographically located, but these are also the property of the indigenous and local communities who have conserved it through centuries.Therefore, the SBB as a regulator has power to demand a fee in the form of FEBS from the petitioner when the petitioner is admittedly using the biological resources for commercial purposes. Moreover, NBA has powers to determine the benefit sharing, subject to any regulation.[42]

What is Fair and Equitable Benefit Sharing cannot be looked through the narrow confines of the definition clause alone. The concept of FEBS has to be appreciated from the broad parameters of the scheme of the Act and the long history of the movement for conservation, together with our international commitments in the form of international treaties to which India is a signatory. NBA has powers to frame regulations to give payment of monetary compensation and other non- monetary benefits to the benefit claimers as the

[41]The Biodiversity Act, 2002, s. 7.
[42]The Biodiversity Act, 2002, ss. 21(2) (f), 21(4).

National Biodiversity Authority may deem fit, in form of Regulations and the State Biodiversity Board in turn has powers and duties to collect FEBS under its regulatory power.[43]

Thus, the Court held that State Biodiversity Boardhas powers to demand Fair and Equitable Benefit Sharing from Divya Pharmacy.

VI. Further Challenges

India had ratified CBD in 1992 and finally came up with ABS guidelines very late in 2014. Attempts to strike a balance between conservation of biodiversity and intellectual property rights still suffer from several challenges. In many cases, finding written proofs of traditional or indigenous knowledge is a major hurdle in challenging patents based on them. Even though Biodiversity Act, Rules as well as Guidelines propose "joint ownership of IP" as one of the modes of ABS, it is difficult to say MNCs would always be interested in the concept of joint ownership. Determination of time period for ABS is another challenge (whether it should be equal to or more than the patent term). It is easy to apply ABS in those cases where holder of the biodiversity component or associated knowledge (i.e., the benefit-claimers) is an ascertained community or tribe (Eg. the Kani tribe). It is very difficult to determine benefit claimers in cases of unascertained communities or same traditional knowledge spread over various communities (eg. Neem, Tumeric etc.). Ensuring participation of local communities in the process of determining benefit sharing arrangements is another challenge. Implementing benefit sharing principles while harnessing marine bio-resources is difficult as determination of benefit claimers in such resources is not easy. Whether state should be considered as owner of marine bio-resources in high seas is not very clear.

VII. Conclusion

Access and Benefit Sharing is considered as an essential tool to arrive at a balance between conservation of biodiversity and granting of IPRs. International conventions and consequently legal framework in India aim to seek to achieve

[43]The Biodiversity Act, 2002, s. 7 r/w23 (b).

this balance. The fact that ABS Guidelines in India were framed in 2014 reflects lack of awareness on this issue. ABS still suffers interpretational and implementation issues. Though NBA and SBBs are gradually making progress, India has a long way to go to conserve its natural bounty, while protecting rights of those who add value to it.