

COMBATING BIOPIRACY OF INDIAN TRADITIONAL KNOWLEDGE (TK) – A LEGAL PERSPECTIVE

Dr. P. Sree Sudha*

Introduction

In India, centuries of intimate human dependence on biodiversity have generated a rich traditional knowledge of the use and conservation of wild species, and have increased the genetic diversity of agriculturally important plants and animals.¹ The country is one of the world's eight major centers of crop diversity with an estimated 163 fruit tree and crop species having originated there. India is a country which has centuries' old traditional knowledge (hereinafter TK) systems based on its rich biodiversity which the Indian people have conserved through their traditional lifestyles and local economies. Two-thirds of Indian population even today is directly dependent on the biological resources and the indigenous knowledge. India is subjected to the problem of biopiracy—where the unique properties of biological material, from the forests and the seas is taken from them without the knowledge and consent of it and these are developed and patented into useful products and medicines which are often unaffordable to the people from where the resources and knowledge generates from. A study conducted in 1999 estimates the global market value of industries using biological and genetic material is between \$500-800 billion. TK has been developed in many fields and is still evolving. It is a technology or know-how capable of providing sustainable solutions to many modern day problems. This fact should be acknowledged and the commercial use of TK should be handled in the same way that other technologies are. The economic value of TK is to be seen in the herbal medicine and pharmaceutical sector which is estimated to touch roughly 5 trillion by the year 2020.² The share of benefits accruing to communities from the commercialization of TK should reflect this figure. Biopiracy and patenting of indigenous knowledge is a double theft because first it

* Assistant Professor, Faculty of Law, Dr. B.R. Ambedkar University, Srikakulam, Andhra Pradesh, India.

¹ India covers only 2.4% of the world's land area, but accounts for 7.3% of the global fauna. It is considered the origin of 30,000 to 50,000 varieties of crops and is home to 2 "hotspots"—the Western Ghats and eastern Himalayas. It has 5 world heritage sites, 12 biosphere reserves and 6 wetlands.

² Anup Shah, *Food Patents—Stealing Indigenous Knowledge?*, GENETICALLY ENGINEERED FOOD (2002), <http://www.globalissues.org/EnvIssues/GEFood/FoodPatents.asp> (last visited Jan. 5, 2014).

allows theft of creativity and innovation, and secondly, the exclusive rights established by patents on stolen knowledge steal economic options of everyday survival on the basis of indigenous biodiversity and knowledge. Over time, the patents can be used to create monopolies and make everyday products highly priced. National laws and policies relating to biodiversity therefore have immense implications for the livelihoods, food security and health of the majority of India's 1.1 billion people.³ But inconsistencies in two Indian laws⁴ enacted in the recent years encourage the unfair misappropriation of Indian genetic resources. The problem of biopiracy is a result of Western style IPR systems, not the absence of such IPR systems in India. This article aims to discuss how the loop holes in international and national laws are responsible for the growth of biopiracy of TK of India, and finally ends with a set of suggestions which will be helpful to India for the conservation of biodiversity.

Meaning of Biopiracy

'Biopiracy' is a negative term for the appropriation, generally by means of patents, of legal rights over indigenous biomedical knowledge without compensation to indigenous groups who originally developed such knowledge,⁵ Being covered by patents granted to multinational companies, bio-piracy promotes inequality between developing and less developed countries rich in biodiversity, and developed countries supplied by pharmaceutical industries exploiting the resources.

According to Vandana Shiva⁶ the term 'biopiracy' describes the appropriation of biological resources and traditional knowledge of farmers or local communities by patents without permission (prior informed consent) or payment (benefit sharing), carried out by multinational corporations with the aim to use the patent for their own investigation, production and marketing activities. However, biopiracy is an epidemic. It was seen in *neem*, *haldi*, pepper, *harar*, *bahera*, *amla*, mustard, *Basmati*, ginger, castor, *jaramla*, *amaltas* and now *karela* and *jamun* etc., 'biopiracy' refers to the ways that

³ Biplab Dasgupta, *Patent Lies and Latent Danger: A Study of the Political Economy of Patent in India*, 34 (16/17) ECONOMIC AND POLITICAL WEEKLY 980 (1999).

⁴ The Protection of Plant Varieties and Farmers' Rights Act of 2001 (PPVFR Act); the Biological Diversity Act of 2002 (BD Act).

⁵ *Biopiracy and Bioprospecting*, WIKIPEDIA, www.wikipedia.org/bio-ipr (last visited Oct. 5, 2014).

⁶ The term 'biopiracy' was first used by Indian scientist and activist Vandana Shiva (1997) in her book, *BIOPIRACY: THE PLUNDER OF NATURE AND KNOWLEDGE*.

corporations⁷ almost all from the developed world-claim ownership of, free ride on, or otherwise take unfair advantage of, the genetic resources, indigenous knowledge (hereinafter IK) and technologies of developing countries. Biopirates are those responsible for one or both of the following acts:

- the theft, misappropriation of, or unfair free-riding on, genetic resources and/or IK through the patent system; and
- unauthorized and uncompensated collection for commercial ends of genetic resources and/or IK.

Acts Constitute Biopiracy

1. Take-and-run approach

As recently as a decade ago, the legalities of obtaining samples of plants, microbes, and animals were straightforward. In many instances, a researcher could simply arrive at a field site, collect samples, and take them home. There was no applicable law. The researcher might obtain informal permission from a local community or landholder, as much for being on the land as for collecting.⁸ At most, the researcher might be required to obtain a permit to collect from national lands, like fishing or hunting license. 'Take-and-run' describes the old approach to collecting, lately termed as 'biopiracy'. The recorded history of international plant collecting missions goes back at least 3500 years when Egyptian rulers began bringing plants home after military expeditions.

Earlier scientists used to take specimens from anywhere in the world without repercussions. In the last century, the British Empire instituted regular plant collections. During the Voyage of the Beagle, Charles Darwin simply took what interested him, from the Galapagos and elsewhere, and brought it home.

The Royal Botanical Gardens took rubber trees from Brazil, and planted them in Southeast Asia. They took cinchona seeds from Bolivia, in violation of national law, and planted them in India. In the same way Commodore Perry's naval mission to Japan collected a wide variety of plants to bring back to the United States.

⁷ Uzma Jamil, *Biopiracy: The Patenting of Basmati by Rice Tec*, COMMISSION ON ENVIRONMENTAL, ECONOMIC AND SOCIAL POLICY-SOUTH ASIA AND SUSTAINABLE DEVELOPMENT POLICY INSTITUTE, 1998, available at <http://www.iucn.org/themes/ceesp/publications/art-ono/basmati.doc> (last visited Oct. 5, 2014).

⁸ S.S. CHAUHAN, BIODIVERSITY, BIOPIRACY AND BIOPOLITICS: THE GLOBAL PERSPECTIVES (Kalinga Publications, Delhi 2001).

The adventures of Richard Schultes during the mid-twentieth century have become a legend among ethno botanists. He was able to befriend local shamans, who allowed him to collect thousands of voucher specimens of medicinal plants, hundreds of which had never previously been identified taxonomically. After discussing popular acts on biopiracy following section will throw some light on biopiracy with reference to cattle biodiversity.⁹

2. Cattle Biopiracy

• **Brief Overview of Indian Cattle Biodiversity**

India is the most significant source of the cattle diversity in the world and India's cattle breeds are being used in Australia, South Africa, Latin America and USA for developing major livestock economies. While India's gift of its animal wealth to the world's economy has not undermined our own sovereignty to his wealth, the emergence of the animal patenting and cattle bio-piracy creates a major threat to the sovereignty of animal biodiversity. The FAO had estimated 61 breeds of cattle in India but there are 26-30 well defined breeds according to Indian literature. These diverse and rich breeds are being used world wide to enhance the genetic wealth of cattle. However, in India our cattle biodiversity is under severe threats through cross breeding programme which are replacing our unique breeds with crossbred Jersey and Holstein cows. On the one hand, this is displacing our indigenous diversity; on the other hand, it is leading to the severe erosion of draught cattle and the replacement of renewable animal energy with imported fossil fuel. The endangered Indian cattle breeds which need attention for their conservation are: Red Sindhi , Sahiwal, Tharparkar, Vachur, Punganur, Mewati, Kenkatha, Kheriagarh, Bargur, Panwar, Siri, and Krishna Valley.

• **Proximate causes affecting cattle biodiversity are:**

- Lack of awareness
- Economic benefits
- Overall policy of breed improvement
- Shrinkage of grazing land
- Over population of livestock-high density
- To improve yield and economic benefits
- Replacement of local non-descript breeds to productive cattle
- Over mechanization of agriculture and transport
- Inadequate attention on identification of germplasm and

⁹ wikipedia.ac.in (last visited May 20, 2014).

- performance recording
- Indiscriminate cross breeding with exotics for other purposes

• **Consequences of loss of cattle genetic biodiversity are**

- Stagnation and even deterioration of production performance of indigenous breeds
- Loss of indigenous genetic resources
- Disappearance of native varieties and breeds
- Threat to native draught breeds
- Loss of indigenous biodiversity
- Shrinkage and even disappearance of grass-lands lead to loss of biodiversity
- Grassland ecosystem is disturbed

• **Cattle Biopiracy**

The theft of plants and animals native to a particular region and their exploitation for commercial purposes is called biopiracy. This disturbing phenomenon has been prioritized as an important aspect of the many troubles that surround the conservation of biodiversity. The recent *case of the sale and export of the Ongole bull's semen* is just one among a number of issues that fail to make it to public attention. Following section exclusively concentrates on biopiracy of Indian cow.

➤ ***The Story of an Indian Cow***

Ongole breeds are very hard working animals. With long legs, loose skin, very strong and round hump over the shoulders and neck, the white coloured native animals are elegant. They have a good milk production capacity also. These animals known for their resistance to diseases like 'mad cow' disease and extreme hot climate due to their protective and reflective coat have been exported since four decades and have been bred in Brazil, especially for meat.¹⁰ At present population of these Ongole cattle is depleting and their semen have been exported from India and used for breeding in Brazil. But this is happening indiscriminately in violation of bio-piracy laws, as officials have found recently. Some officials of the National Biodiversity Authority of India were alarmed after reports surfaced that an Ongole bull was sold at an exorbitant Rs. 35 lakh to a middleman working for some Brazilian

¹⁰ Available at file:///C:/Users/acer/Desktop/ongolu-bull-piracy.htm (last visited May 20, 2014).

firm.¹¹ Following this development an investigation was launched to find out whether the sale was done illegally. It was also found that embryos of another indigenous cattle breed 'Gir' native of Gujarat were also being sold likewise. The other thing that was noticed in this case was that under Biological Diversity Act of 2002-India is also a signatory-prior permission is required for any export of Indian genetic material (which was not granted in this case).

With increased cross-breeding in the domestic animals, India is fast losing its native pure breeds which are resistant to many diseases. A popular naturalist in Tamil Nadu Nammazhvar said: "Ongole is a dual purpose animal. It is used for both milking and drought purposes. Our animal husbandry planners have not taken the right decision by allowing Brazil to breed Ongole." "Instead of using our native animals in crossbreeding and increasing the milk production in India, they have brought animals from foreign countries. Those animals which can give a lot of milk are from cold climate regions, and they cannot survive for long in India. We do not respect our traditional wisdom. But outsiders use this for commercial purposes, like Brazil has done. As discussed earlier India faced the same problem with Neem when someone from US tried to get it patented." Brazil has continued importing live cattle, embryos and semen samples from India.¹² Unless the government takes a stand on this, interpretations would continue to be in a flux.

A majestic cow belonging to Gir breed of Gujarat, at present named as Shera clocked 62.033 litres of milk in a 3-day milk competition at the 40th Expaja in Brazil, beating her own record of 59.947 litres. While Indian cattle breeds are doing exceptionally fine abroad, the fascination of our own policy makers for exotic breeds seems to be never ending. Meanwhile, Brazil has emerged as the biggest exporter of Indian breeds of cows.¹³ Recently newspapers in Punjab reported that "an American company-World Wide Sires Ltd.-is planning to provide high quality semen to dairy farmers. Some days back, I had heard that the Kerala Minister for

¹¹ C. Alexander Reddy, Secretary of National Biodiversity Authority of India (NBA), said: "There is no ban on the animals being sold to other countries. The only thing is that they have to register with NBA for this process so that we know what is happening. Besides, we can also work on the conservation of that particular breed for other purposes. We have started an investigation in the sale of these animals."

¹² See <http://174.142.148.204/en/story/brazil-eyes-indian-bulls/27/16158/> (last visited May 20, 2014).

¹³ See *Holy Cows-acclaimed abroad, despised at home*, <http://devinder-sharma.blogspot.in/2010/09/holy-cows-acclaimed-abroad-despised-at.html> (last visited May 20, 2014).

Animal Husbandry was thinking of importing some improved cattle breeds from Denmark for cross breeding with local cows.”¹⁴

Not only in Brazil Indian cattle breeds also been improved in the United States and Australia. In the US, the breed is called *Brahman*. Recently, after a study visit to Malaysia, Sagari Ramdas, the co-director of Anthra in Andhra Pradesh, wrote in the *Down to Earth* magazine: “On our visit to Malaysia, we were intrigued when we came across a cattle breed, which the farmers kept referring to as ‘the Brahman’. This was a complete mystery to us. Which Brahman came to Malaysia and named these cattle the Brahman? On our visit to the government’s Department of Veterinary Services in the state of Selangor we saw photographs of the Grey Brahman, the Red Brahman and the Nellore—all part of a poster on cattle breeds of Malaysia. Not to mention that the Jamunapari goat also featured in the poster as a goat breed of the country. This intrigued us even further, but none of the veterinary officers could explain how the Nellore from Andhra Pradesh and the Jamunapari from Uttar Pradesh happened to figure in a poster on the breeds of Malaysia.”

According to her research Brahman breed is a product of biopiracy of several Indian breeds, which occurred over 100 years ago, when India was a colony of the British Empire, when ‘pirates’ of today’s ‘Empire’—and modern day ‘Brahman’, the US—spirited out a nucleus of approximately 266 bulls and 22 females of several *Bos indicus* (Indian cattle), imported them to the US between 1854 and 1926, and developed the breed.

The Brahman¹⁵ has become the most popular beef cattle breed in the southern parts of the US and in South America, Asia, and Australia because of its excellent adaptability to sub-tropical climates and its production abilities.

Brahman-type cattle were, in fact, imported to Australia from the US, and today the Australian Brahman is the mainstay of the northern beef industry of Australia. The Brahman in Malaysia has primarily been imported from Australia, which has a virtual monopoly in exporting the breed to several south-east Asian

¹⁴ See *Punjab to have advanced institute of dairy farming*, <http://post.jagran.com/punjab-to-have-advanced-institute-of-dairy-farming-1341507876> (last visited May 20, 2014).

¹⁵ According to the literature, the Brahman is the progeny of 4 Indian cattle breeds: ‘Kankrej’ and ‘Gir’ from Gujarat, ‘Ongole’ (earlier known as ‘Nellore’) from Andhra Pradesh with the fourth breed being the ‘Gujarat’. But no such breed exists in the list of Indian cattle breeds.

countries. So much so that Malaysia's beef cattle industry is completely dependent on continued import of the Brahman from Australia.¹⁶

What is also little known is the fact that Indian cows and buffaloes produce a more nutritious milk than the exotic breeds like 'Jersey' and 'Holstein-Friesian'. A recent study¹⁷ by Karnal-based National Bureau of Animal Genetic Resources (NBAGR) showed Indian cows have a rich A2 allele gene which helps them produce healthier milk. The frequency of this A2 allele in Indian breeds is 100% whereas in exotic cattle breeds it is less than 60%. Imported breeds possess A1 allele, which is considered to be associated with diabetes, obesity and cardiovascular diseases.

➤ **Monsanto Case**¹⁸

Indian National Biodiversity Authority (NBA) filed legal action against Monsanto (and their collaborators) for accessing and using local eggplant varieties (known as 'brinjal') to develop their Bt genetically engineered version without prior approval of the competent authorities, which is considered an act of biopiracy.

The 'alleged violation' referred to by the NBA was the ESG's complaint: "...[S]pecifically charging these agencies for criminally accessing at least 10 varieties of brinjal in Karnataka and Tamil Nadu without in any manner seeking prior and informed consent from the National Biodiversity Authority, State Biodiversity Boards and applicable Local Biodiversity Management Committees as required. Such a rigorous process of appraisal is mandatory to protect loss of biodiversity due to misuse or overuse, theft of biodiversity and to secure biodiversity from contamination when transgenics are involved. In addition, the law mandates that when biodiversity is to be accessed in any manner for commercial, research and other uses, local communities who have protected local varieties and cultivars for generations must be consulted and if they consent benefits must accrue to them per the internationally applicable Access and Benefit Sharing Protocol." Ultimately the initiation of criminal action against Monsanto/Mahyco and their collaborators may result in an

¹⁶ See *The loss of our breeds*, DOWN TO EARTH, <http://www.downtoearth.org.in/content/loss-our-breeds> (last visited May 20, 2014).

¹⁷ See *Indian cow, buffalo breeds give healthier milk*, <http://news.outlookindia.com/items.aspx?artid=725938> (last visited May 20, 2014).

¹⁸ <http://www.greenmedinfo.com/blog/breaking-news-monsanto-face-biopiracy-charges-india>, (last visited May 20, 2014).

immediate suspension of all applications by any of the agencies involved in bio-piracy seeking access to any biological resource of India. According to ESG “this would imply that NBA must stop processing Monsanto’s application for accessing two varieties of Indian onions.”

India has a strong tradition of thwarting¹⁹ the commercialization of indigenous knowledge associated with bioprospecting, which includes biopiracy and the search for previously unknown compounds in organisms that have never been used in traditional medicine, with the aim of obtaining lead and/or novel compounds for pharmaceutical patents.

Relevant International and National Legal Regimes on Biopiracy

1. International

- **Rio Declaration**

Rio Declaration speaks about the protection of indigenous knowledge: “Indigenous people and their communities and other local communities have a vital role in environmental management and development because of their knowledge and traditional practices. States should recognize and duly support their identity, culture and interests and enable their effective participation in the achievement of sustainable development”.²⁰

- **TRIPS**

The patenting of life forms, for example, has increased tremendously since the establishment of the Trade Related Intellectual Property Rights (TRIPS) Agreement of the World Trade Organization (WTO) in 1995. TRIPS makes it mandatory for WTO member states to allow patenting of at least some life forms (i.e., microorganisms) and some living processes (i.e., microbiological

¹⁹ For instance, in 1995, two expatriate Indians at the University of Mississippi Medical Centre were granted a US patent (no. 5, 401, 504) on use of turmeric in wound healing. After the Indian Council of Scientific and Industrial Research (CSIR) filed a re-examination case with the US Patent and Trading Office challenging the patent on the grounds of its existing prior use in traditional *Ayurvedic* medicinal practice, the patent was canceled. Another example occurred when the Indian government took legal action against a pharmaceutical firm who received a patent for a technique to extract an anti-fungal agent from the *neem* tree, with the patent eventually being overturned in 2005.

²⁰ Article 22 of the Rio Declaration, 1992.

processes).²¹ It also requires the protection of plant varieties, either through patents, or through an ‘effective *sui generis* system’ a reference to an independently created system developed by a government. This part of TRIPS has been a major mistake.

It has opened the floodgates to the patenting of biological resources, and of IK about the use of these resources.²² In broad terms, biopiracy removes the rights of communities (mostly in developing countries) and instead supports the rights of private institutions (mostly in developed countries) that are granted patents. These IPR holders are able to make monopoly profits by commercializing the patented products and the IK associated with them. In contrast, the local communities that developed or made use of the knowledge in the first place and should therefore be considered as the rightful owners usually get no benefit. And an ironic situation arises if the patented process or product leads to the sale of products at high prices in those very developing countries from which they originated. Indeed, this form of biopiracy creates a form of ‘reverse technology transfer’, as it is the poor developing countries that transfer knowledge and technology to the rich developed world.²³ But the developing countries involved get scant reward for their contributions; and indeed may eventually have to pay institutions in the rich countries a high price (itself sustained by monopolistic IPRs) for the use of the product or process, potentially creating a large drain on developing countries’ foreign exchange, and adding to their foreign debt. Another problem is the way in which the patenting of biological resources restricts or prevents other producers from using processes and products related to traditional knowledge. For example, a corporation that has successfully applied for a patent on the use of a plant for certain functions could try to prevent others from using it in the same way.²⁴ As a result, those who have been using traditional knowledge for many generations could face restrictions on doing so in the future.

²¹ Catherine Tinker, *Responsibility for Biological Diversity Conservation under International Law*, 28 (4) VANDERBILT JOURNAL OF TRANSNATIONAL LAW 777-822 (Oct. 1995).

²² Jessica Long, *WTO Kills Farmers: India Free Market Reforms Trigger Farmers’ Suicides*, CENTRE FOR RESEARCH ON GLOBALIZATION (2007), <http://www.globalresearch.ca/index.php?context=va&aid=6522>, (last visited May 20, 2014).

²³ Eija Pehu & Catherine Ragasa (2007), *Agricultural Biotechnology Transgenics in Agriculture and Their Implications for Developing Countries* (2007) 7 (Background Paper for the World Development Report 2008).

²⁴ M.B. RAO & MANJULA GURU, *UNDERSTANDING TRIPS: MANAGING KNOWLEDGE IN DEVELOPING COUNTRIES* 134 (Response Books, New Delhi; Thousand Oaks CA; Sage Publications 2003).

Typical examples include a US patent on the use of turmeric for healing wounds (although this was successfully challenged by the Indian government), a Japanese patent on the anti-diabetic properties of banana (traditionally used as herbal medicine in the Philippines), and the US patenting of a protein from a native strain of Thai bitter melon (after Thai scientists found its compounds could be used against HIV infection).²⁵ Such practices are rapidly eroding the world's store of traditional knowledge and, in doing so, are undermining the conservation and sustainable use of biodiversity.

The patent system should not be used to reward research into biological resources and processes, as living organisms are qualitatively different from non-living materials, and knowledge relating to biological processes and materials cannot therefore qualify as an 'invention', as required in patent legislation.

• **Convention on Biodiversity (CBD)**

Convention on Bio-diversity(CBD)²⁶ provides that: "Each contracting Party shall, as far as possible and as appropriate, subject to its national legislation, respect and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biodiversity and promote the wider application with the approval and involvement of the holders of such knowledge, innovations and practices and encourage the equitable sharing of benefits arising from the utilization of such knowledge, innovations and practices." The CBD deals with the protection of biological diversity, sustainable use of its components and the fair and equitable sharing of the benefits arising out of the utilization of genetic resources, and TRIPS deals with the protection of intellectual property but in some areas the two interrelate.

It further says: "The contracting Parties, recognizing that patents and other IPRs may have an influence on the implementation of this Convention, shall cooperate in this regard subject to national legislation and international law in order to ensure that such rights are supportive of and do not run counter to its objectives".²⁷

²⁵ *Supra* note 7.

²⁶ See Article 8 (j) of the Convention on Biodiversity (CBD).

²⁷ Article 16.5 of the Convention on Biodiversity (CBD).

- **The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits, 2010**

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 Diversity²⁸ is an international agreement which aims at sharing the benefits arising from the utilization of genetic resources in a fair and equitable way, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies, taking into account all rights over those resources and to technologies, and by appropriate funding, thereby contributing to the conservation of biological diversity and the sustainable use of its components. It was adopted by the Conference of the Parties to the Convention on Biological Diversity at its 10th meeting on 29 October 2010 in Nagoya, Japan. The fair and equitable sharing of the benefits arising out of the utilization of genetic resources is one of the three objectives of the Convention on Biological Diversity.

Article 18 of the Convention speaks about capacity building and explicitly says: “The Parties shall cooperate in the capacity-building, capacity development and strengthening of human resources and institutional capacities to effectively implement this Protocol in developing country Parties, in particular the least developed countries and small islands developing States among them, and Parties with economies in transition, including through existing global, regional, sub-regional and national institutions and organizations. In this context, Parties should facilitate the involvement of indigenous and local communities and relevant stakeholders, including non-governmental organizations and the private sector.”

2. National

- **The Biodiversity Act, 2002**

In India, enabling provisions have been made for protecting the traditional knowledge is the Biological Diversity Act, 2002 (herein after referred as BD). Relevant provisions of this Act are discussed below.

BD Act provides²⁹ for protection of knowledge of local people relating to biodiversity through measures such as registration of

²⁸ <http://www.cbd.int/abs/> (last visited May 20, 2014).

²⁹ See § 36 (iv) of the Biological Diversity Act, 2002.

such knowledge, and development of a *sui generis* system. For ensuring equitable sharing of benefits arising from the use of biological resources and associated knowledge Sections 19 and 21 stipulates prior approval of the National Biodiversity Authority (NBA) before their access.³⁰ While granting approval, NBA will impose terms and conditions, which secure equitable sharing of benefits. Section 6 provides that anybody seeking any kind of intellectual property rights on a research based upon biological resource or knowledge obtained from India; need to obtain prior approval of the NBA. The NBA will impose benefit-sharing conditions. Further it stipulates³¹ that one of the functions of NBA is to take measures 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.

• **The Patents (Amendment) Act, 2005**

In the Patent (Second Amendment) Act, 1999, the grounds for rejection of the patent application as well as revocation of the patent include non-disclosure or wrongful disclosure of the source of origin of biological resource or knowledge in the patent application, and anticipation of knowledge, oral or otherwise. It has also been made incumbent upon patent applications to disclose the source of origin of the biological material used in the invention in their patent applications. Further provisions have been incorporated to include anticipation of invention by available local knowledge, including oral knowledge, as one of the grounds for opposition as also for revocation of patents, if granted. Now the present law The Patents (Amendment) Act of 2005, has also introduced some important provisions in this regard. In this Act clear provisions included in the context of pre-grant and post-grant opposition in the revised Section 25 of the Principal (1970) Act under the heading 'Opposition Proceedings to Grant of Patent'. The revised Section³² which deals with pre-grant opposition, provides that: "Where an application for a patent has been published but a patent has not been granted, any person may, in writing, represent by way of opposition to the Controller against the grant of patent within the prescribed period on the grounds of (a) patentability including novelty, inventive step and industrial applicability, or (b) non-disclosure or wrongful mentioning in complete specification, source and geographical origin of biological material used in the invention and anticipation of invention by the knowledge, oral or otherwise available within any local or

³⁰ §§ 19 and 21 of the Biological Diversity Act, 2002.

³¹ § 18 (iv) the Biological Diversity Act, 2002.

³² See 25 (l) of the Patents (Amendment) Act, 2005.

indigenous community in India or elsewhere, and the Controller shall if requested by such person for being heard, hear him and dispose of the representation in such manner and within such period as may be prescribed.”

Regarding post-grant opposition the Act further stipulates that³³ at any time after the grant of patent but before the expiry of a period of one year from the date of publication of grant of a patent, any person interested may give notice of opposition to the Controller in the prescribed manner on certain specified grounds. The eleven grounds stipulated for such post-grant opposition include the following two grounds:

- That the complete specification does not disclose or wrongfully mentions the source and geographical origin of biological material used for the invention;
- That the invention so far as claimed in any claim of the complete specification was anticipated having regard to the knowledge, oral or otherwise, available within any local or indigenous community in India or elsewhere. The 2002 Amendment Act has furthermore introduced another provision³⁴ which allows revocation of a patent on grounds of:
 - Non-disclosure or wrongful mentioning in the patent application of the source or the geographical origin of biological material used for the invention concerned,
 - Knowledge, oral or otherwise, available within any local or indigenous community in any country as anticipation of the invention concerned.

Notably, the aforesaid provision on revocation has been introduced by the lawmakers of the country by making use of another leeway available under the TRIPS Agreement. This is because TRIPS does not have any stipulation regarding the grounds for revocation of patents. The only obligation imposed by TRIPS on the Member countries’ pertaining to revocation or forfeiture of patents is that “an opportunity for judicial review of any decision to revoke or forfeit a patent shall be available.”³⁵

• Rationale behind the Indian provisions

In order to comprehend the rationale behind the inclusion of the abovementioned TK-related provision as a ground for revocation of a patent one has to be aware of the basic criteria of a patentable

³³ § 25 (3) of the Patents (Amendment) Act, 2005.

³⁴ § 64 (1) of the Principal (1970) Act, dealing with revocation of patents.

³⁵ Article 32 of TRIPS.

‘invention’. According to TRIPS,³⁶ in order to qualify as patentable an invention has to satisfy three criteria:

- Novelty
- Inventive step
- Industrial applicability

It is in line with this stipulation of TRIPS that the Indian Patents Act has defined³⁷ the term ‘invention’ to mean “a new product or process involving an inventive step and capable of industrial application”.

The question that arises here is if an invention is anticipated on the basis of a TK of any country then can it at all be regarded as ‘novel’? The answer will definitely depend on how the term ‘novelty’ or newness is defined and interpreted. Since the TRIPS Agreement does not specify the definition of ‘novelty’, the members are free to define and interpret the term in their own ways. As far as India is concerned, the inclusion of the aforesaid second ground for revocation of a patent in the Indian law clearly reveals that if some TK, oral or otherwise, is used for anticipating an ‘invention’ then the patented subject matter does not satisfy the criterion of ‘novelty’ according to the Indian interpretation of the term ‘new’. Thus, the Indian Patent Act recognizes even the existence of oral or non-written TK as part of what is called ‘prior art’ in the terminology of the patent laws, and refuses to allow patenting of any ‘invention’ based on such ‘prior art’.

• **‘Novelty’ requirement-a bone of contention**

However, in the backdrop of the silence of TRIPS regarding the definition of ‘novelty’, significant differences are observed to exist in the national patent laws of different countries with regard to the concept of ‘novelty’. For instance, the US Patent Law does not consider that the ‘novelty’ requirement has been lost when an invention has been divulged outside the United States by ‘non-written’ means such as public use and sale. US law defines³⁸ ‘prior art’, reads as follows:

Conditions of patentability: Novelty and loss of right to patent. A person shall be entitled to a patent unless:

³⁶ Article 27.1 of TRIPS.

³⁷ § 2 (j) of the Indian Patents Act (as per the Amendment of 2002).

³⁸ § 102 of the US Patent Law.

- A.** The invention was known or used by others in this country or patented or described in a publication in this or a foreign country before the invention thereof by the applicant for patent.
- B.** The invention was patented or described in a trade publication in this or a foreign country or in public use or on sale in this country more than one year prior to the date of the application for patent in the United States.

Thus public use or sale in a foreign country does not constitute 'prior art' according to the US patent law. Only existence of a patent or a published description of the invention is considered to be part of 'prior art' in case of a foreign country. This is in sharp contrast with the definition of a 'new invention', which has been inserted in the Indian Patents Act by means of an amendment introduced in the 2005 Amendment Act. According to this latest addition, Section 2 (l) of the Principal Act now reads as below:

“New invention means any invention or technology which has not been anticipated by publication in any document or used in the country or elsewhere in the world before the date of filing of patent application with complete specification, i.e., the subject matter has not fallen in public domain or that it does not form part of the state of the art.”

Thus unlike the US law, the Indian law does not discriminate between the home country and foreign country while determining the 'novelty' of an 'invention'. The aforesaid provision of the US law implies that a patent conferred by the US Patent Office, which involves, say, an act of biopiracy of an Indian TK, can be challenged by India only if some written proof of that knowledge can be produced, for want of which such bio-piracy would continue. Although patents are supposed to be granted for new inventions, this denial or non recognition of non-written 'prior art' elsewhere (in the US law) allows patents to be granted for existing knowledge and use in other countries. It is this glaring loophole of the US law, which opens the door for biopiracy of the non-written TK of India and other countries of the South by the MNCs.

The earlier discussed provisions included in the Indian Patents Act in conjunction with the PIC and benefit sharing requirements incorporated in the Biological Diversity Act, 2002 create sufficient room for combating the biopiracy threats at the national level in India. Nevertheless, the problem remains that existence of a similar protective shield for Indian bioresources and TK cannot be guaranteed under the national patent laws of other countries.

Because, notwithstanding the leeway's available under TRIPS for such provisions (as have been introduced in Indian Patents Act), the Agreement does not make it obligatory for the member countries to include in their respective patent laws provisions aimed at protecting the bio-resources and TK of the country of origin against bio-piracy. However, the protection of these precious assets cannot be guaranteed until and unless certain compulsory provisions are included in TRIPS in this regard, which all the Member countries would be obliged to comply with.

After discussing the gaps in Indian Patent Act, following section discusses the loopholes in the Protection of Plant varieties and Farmers Act is also facilitating biopiracy.

- **The Protection of Plant Varieties and Farmers' Rights Act of 2001 (PPVFR Act)**

Besides allowing for variety protection, the Protection of Plant Varieties and Farmers Rights Act, 2001 (PPVFT Act) also provides protection to farmers and farm communities to evolve, preserve and refine crop varieties. The Indian government has initiated the registration of plant varieties with the Protection of Plant Variety and Farmers' Rights Authority (PPV & FRA) to provide them internationally-recognized protection against piracy. At present 12 varieties of crop were registered under the *sui generis* system (specifically evolved own system) of plant variety protection mooted in the Plant Variety and Farmers' Rights Act, 2001. The PPV and FRA will, to begin with, undertake the documentation and registration of varieties of rice, wheat (bread wheat types), maize, sorghum (*jowar*), pearl millet (*bajra*), chickpea (*chana*), pigeon pea (*arhar*), green gram (*moong*), black gram (*urad*), lentil (*masur*), field pea (*matar*) and kidney bean (*rajmah*). The Plant Variety and Farmers' Rights Authority was set up in November 2005 under the Act, for the registration of plant varieties. It has evolved detailed rules and regulations and crop-specific guidelines for seeking patent protection.

Besides allowing for variety protection, Indian law also ensures the rights of farmers and farm communities to evolve preserve and refine crop varieties. Germplasm from seeds cultivated indigenously by farmers for generations is often used by researchers to develop newer varieties. Now that the varieties are registered, farmers will get the benefit when a trait is used from this germplasm to develop new varieties. A new programme of giving recognition to these communities is also being launched simultaneously which is called as Plant Genome Saviour

Community Recognition, this programme will be financed from a proposed gene fund to be set up under this Act. Farmers and communities will have to provide documentary evidence to prove that they conserved, improved and made available or shared material with active plant-breeding programmes for the development of a new plant variety. Details of the new variety and its contribution to the advancement of agriculture will also have to be provided to claim recognition and rewards. The law also upholds the traditional rights of farmers to use or exchange seeds they have grown, between themselves.³⁹

The PPVFR Act does not differentiate the nationalities of people or organizations accessing Indian genetic resources, including varieties protected by plant breeders' rights, for breeding new varieties. The only exception is the need for prior informed consent for repeated use of such a protected variety as a parental line for the commercial production of a new variety. These mean that non-Indian entities can freely access plant genetic resources and associated knowledge for use in breeding or for biosurveys within India. Secondly, having freely accessed the genetic resources of choice to develop breeding lines or new varieties or nothing, seeds of this material can be taken out in different pretexts as 'exports'. The lack of a legal system regulating seed exports and of an informed customs system with the capacity to verify what is exported leaves a wide open door for the unchecked outflow of the planting material of virtually any genetic resource including farmers' varieties, land races and pre-bred material. Once these resources are taken out through the trade route and used in conventional or non-conventional breeding, there is virtually no way to ensure that benefits are shared equitably to the communities that generated and conserved these resources.

The irony is that laws established to protect these resources and promote their conservation are in fact legitimizing their piracy and misappropriation from the holder community.

Developing Countries Stand on Biopiracy

India and some other like-minded developing countries (e.g., Venezuela, Bolivia, Colombia, Ecuador, Nicaragua, Peru, Thailand, Cuba, Brazil, and Pakistan etc.) have been fighting against biopiracy at the WTO for quite some time now. In various communications to the TRIPS Council of the WTO during the last few years, it has time and again been emphasized by this group of countries that the rights

³⁹ See www.centad.org (last visited May 20, 2014).

of the holders of TK to share benefits arising out of innovation based on their knowledge and the associated bioresources should be recognized in the TRIPS Agreement.⁴⁰ This, according to them, calls for harmonization of the provisions of TRIPS with those of CBD. It is apprehended by India and others that in the absence of clear provisions in TRIPS providing for a mutually supportive relationship of that Agreement with the Members' obligations under CBD, implementation of the TRIPS Agreement may allow for acts of biopiracy and thus result in systemic conflicts with the Convention.⁴¹ With a view to avoiding such conflicts an amendment of the TRIPS Agreement to accommodate some essential elements of CBD is considered necessary by India and allies.

Hence, this group of countries has proposed in the WTO that the TRIPS Agreement should be amended in order to provide that Members shall require that an applicant for a patent relating to biological materials or to TK shall provide, as a condition to acquiring patent rights:

- disclosure of the source and country of origin of the biological resources and of the traditional knowledge used in the invention;
- evidence of prior informed consent through approval of authorities under the relevant national regimes; and
- evidence of fair and equitable benefit sharing under the national regime of the country of origin.

In a significant attempt towards expediting the process of resolution of this contentious issue, India along with other like-minded developing countries has submitted a 'Checklist of Issues'⁴² on the relationship between TRIPS and CBD. The basic purpose of the 'Checklist' is to facilitate more focused, structured and result-oriented discussions on the subject.⁴³

Several developing countries are also proposing that a measure be introduced into the WTO requiring the prior approval of countries of origin before patent applications involving a biological resource, or traditional knowledge about its use, are granted.⁴⁴ This would enable countries of origin either to prevent such patent applications, or to

⁴⁰ <http://www.globalresearch.ca/biopiracy-gm-seeds-and-rural-india/13820> (last visited May 20, 2014).

⁴¹ <http://commerce.nic.in/dec05/main.htm> (last visited May 20, 2014).

⁴² Communication dated Mar. 2, 2004 (IP/C/W/420).

⁴³ See <http://www.twinside.org.sg/title2/twninfo374.htm> (last visited May 20, 2014).

⁴⁴ Edgar J. Asebey & Jill D. Kempenaar, *Biodiversity Prospecting: Fulfilling the Mandate of the Biodiversity Convention*, 28 (4) VANDERBILT JOURNAL OF TRANSNATIONAL LAW 703-754 (Oct. 1995).

require benefit-sharing arrangements with the applicants. Developed countries should support not block this proposal.

As part of the implementation of the Convention on Biological Diversity, developing countries should also establish national arrangements for collecting and using biological resources and the knowledge associated with them, as well as for sharing the benefits from any commercial transactions with those communities which have developed this knowledge.

Unfortunately current efforts by individual countries to review their national laws on intellectual property, in order to bring them in line with their obligations under the TRIPS agreement, is likely to accelerate the biopiracy phenomenon. For this process now requires countries that previously forbade the patenting of life to allow patents on certain types of organisms and living processes.

With careful and intelligent legal and policy choices, developing countries can avoid some of the worst dangers that can arise from the implementation of their obligations under TRIPS.⁴⁵ In the long run, however, a fundamental revision of multilateral trade rules is essential if the injustice inflicted by biopiracy on local communities and their indigenous knowledge is to be corrected.

Conclusion

After climate change, biopiracy is becoming the new battleground between rich and poor nations, because rich countries are opposing a legal framework for use of biological resources.⁴⁶ India and other developing countries are pushing for a protocol on Access and Benefit Sharing (ABS) “that will provide an opportunity to biodiversity-rich countries such as India to realize benefits for its people from the use of the biodiversity”. At this scenario this article suggests that on the question of whether or not to allow IPRs over biological resources should be drawn from two perspectives; one, the international level, taking into account the developments relating to the TRIPS Agreement at the WTO; and two, the national level, taking into account the domestic situation and needs.⁴⁷ A two-prong strategy has been suggested. International cooperation and initiatives will be required to strengthen the monitoring of biopiracy and to establish international mechanisms to ensure equitable sharing of benefits

⁴⁵ <http://www.jnu.ac.in/SIS/CITD/DiscussionPapers/WTO.pdf> (last visited May 20, 2014).

⁴⁶ http://articles.economictimes.indiatimes.com/2009-08-10/news/28479711_1_bio-piracy-trips-ag... (last visited May 20, 2014).

⁴⁷ <http://www.cuts-citee.org/pdf/BP09-WTO-01.pdf> (last visited May 20, 2014).

from the use of biological and genetic resources. Challenging biopiracy-based patent claims will also be an important component of international level measures. However, these measures must be complemented by measures at the national level to ensure the recognition and protection of traditional or indigenous knowledge. “An important next step is to set up a Peoples Register of Biodiversity, so that traditional knowledge passed down through the oral tradition can also be documented and protected.” Finally it is hoped that surely we can bring back our *desi* cow breeds to our country.

Suggestions

Government of India should consider following suggestions while granting permission to research on biodiversity:

- **Protect** farmers’, indigenous peoples’ and local communities’ rights over plant genetic resources and associated knowledge, including farmers’ rights to conserve, exchange and reproduce seeds.
- **Reject** international agreements that force governments to grant patents or other forms of IPRs on life forms, including plant varieties and micro-organisms.
- **Protect** traditional and indigenous knowledge against biopiracy.
- **Ensure** public access to medicines and genetic resources, including plant genetic resources.
- **Maintain** the right to regulate in pursuit of national health and safety and environmental protection.
- **Maintain** indigenous peoples’ and local communities’ legal and customary rights to make decisions concerning their local, traditional resources, even where no legal rights have previously been allocated.
- **Ensure** equitable access to land, seeds, water, credit and other productive resources, for small farmers, and especially women.