



THE BATTLE OF BIOPIRACY AND THE TREASURE OF TRADITIONAL MEDICINAL KNOWLEDGE

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INTRODUCTION

“Dear Mr. Moore,
Sub.: BIOPIRACY AND WTO
India is a country which has centuries' old indigenous knowledge systems based on its rich biodiversity which the Indian people have conserved through their traditional lifestyles and local economies. Two-thirds of our population even today is directly dependent on the biological resources and the indigenous knowledge. These resources and knowledge are used in an ethic of sharing so that the livelihoods and needs of the poorest are met. This is in direct contradiction with the ethics (or the lack of it) perpetrated by the World Trade Organisation through the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). TRIPS has globalised and legalised a perverse and unethical intellectual property rights system which encourages the piracy of our indigenous knowledge and subverts our decentralised democratic system.¹”

This letter was written to WTO head by the citizens of India , It outlines a disputable discussion that has emerged between the supporters of a universal system of intellectual property rights and a network of masses who feel their knowledge has in effect unreasonably appropriated under such a system and this constitutes the general

backdrop that situates the current debate over the issue of misappropriation and exercise of proprietary rights by the developed nations over the biological material of the developing nations, within the framework of TRIPS. This is what has been labeled as "biopiracy," a term that describes the means by which corporations from the industrialized nations claim ownership of, free ride on, or otherwise take unfair advantage of, the genetic resources and traditional knowledge and technologies of developing countries.²

The paper will answer the following question as what do we mean by biopiracy. The mechanism of appropriation and commodification of traditional Indian medicine by multinational companies and what legislation and policies the Indian government has taken to stop biopiracy and evaluating the same .

CONCEPT OF BIOPIRACY

An overview of trips :

To understand biopiracy it is necessary to have an overview and background of TRIPS patent regime under TRIPS and traditional medicines .Trade-Related Aspects of Intellectual Property Rights) Agreement . TRIPS agreement led by USA was signed by many countries under the auspices of WTO. TRIPS was basically an instrument signed to provide a conducive environment for free trade it envisaged to provide for a basic framework for intellectual property rights. It established a very important link between intellectual Property and TRIPS.

¹ <https://ratical.org/co-globalize/BPandWTO.html>

² NECTARIA CALAN. GLOBALISING BIOPIRACY: INTELLECTUALPROPERTY

RIGHTS, THE TRIPS AGREEMENT, AND THE APPROPRIATION OF TRADITIONAL KNOWLEDGE (2006)



Another aspect is that is Amalgamated and unified the rudimentary features of IPR ,TRIPS also broadened their scope .

In addition to consolidating the basic features of IPRs, TRIPS also broadened their scope. It allows any invention, in any field of technology, to be patented, provided that it is (1) new, (2) involves an inventive step (non-obviousness) and (3) is capable of industrial application.¹³ Novelty and non-obviousness are judged against everything publicly known before the invention. This body of public knowledge is called 'prior art.' TRIPS does not define 'new' and 'prior art', which, in the absence of a global minimum standard of novelty, are left for states to decide.^{3,4}

TRIPS also introduces the principle of non-discrimination, which ensures that: (1) once a foreign patented product has entered a Member State's national market, the holder of the patent should be treated no differently from nationals (national treatment, Article 3); (2) if granting privileges, nations must treat all foreign nationals equally, with certain exceptions (most favoured nation treatment, Article 4).⁵

TRIPS obliges to treat pharmaceutical invention like any other invention thus giving it the power to Pharma Companies to exploit its patent . Such cannot be in the case of developing countries where Healthcare can become a pricey affair due to the same provisions

³ Carvalho NP de. The TRIPS Regime of Patent Rights. Kluwer Law International, 2010: 807. 15

⁴ For one legal definition of 'prior art' see Regulations(i) Under the Patent Cooperation Treaty, Rule 63. Available at: <http://www.wipo.int/pct/en/texts/rules/rtoc1.htm>.

⁵ Suchita Shah, plants, Patents and Biopiracy: The Globalization of Intellectual Property Rights and Traditional Medicine,2014

The next question that arises is what traditional medicinal knowledge is

THE CONCEPT OF TRADITIONAL MEDICINAL KNOWLEDGE

WHO Defines traditional medicinal knowledge as

“Traditional medicine refers to the knowledge, skills and practises based on the theories, beliefs and experiences indigenous to different cultures, used in the maintenance of health and in the prevention, diagnosis, improvement or treatment of physical and mental illness.”

In India Traditional medicinal knowledge is categorized into 2 -Codified and Uncodified

- Codified: Codified refers to Documented and is present in the Ancient manuscripts and related to medicine and surgery. This includes systems like Siddha ,Unani, Ayurveda and the Tibetan system . Codified Traditional medicinal Knowledge is easily available in Public Domain.
- Uncodified : Uncodified refers to the traditional medicinal knowledge which passed from one generation to another orally . It is based on empirical experiences.⁷

⁶ Traditional medicinal knowledge definition , <https://www.afro.who.int/health-topics/traditional-medicine>

⁷ Darshan Shankar, Traditional Medicine And Biopiracy, Ancient Science of Life, Vol. No 17(1), July 1997 pages 67 - 71



UNDERSTANDING THE IPR AND TRADITIONAL MEDICINES NEXUS

An estimate of 7,500 species of Plants and Animals and also metals are utilized in Indian folk medicines⁸. Companies use this same Traditional Medicinal Knowledge to develop medicines on which patents can be granted via bioprospecting. Bioprospecting is a process of scrutinizing the biogenetic resources.⁹ The Patents granted to such bio prospected products is problematic if due credits are not given to the exact source of knowledge and the communities who possess such knowledge. The origin of biopiracy can be traced here. The biopiracy term has emerged as a powerful counter to the perception of new hegemonies imposed by IP rules with global reach, such as the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement). The principle of misappropriation is given out by the WIPO draft of protection of traditional knowledge and the principles goes by the following words

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Any acquisition or appropriation of traditional knowledge by unfair or illicit means constitutes an act of misappropriation. Misappropriation may also include deriving commercial benefit from the acquisition or appropriation of traditional knowledge when the person using that knowledge knows, or is grossly negligent in failing to know, that it was acquired or appropriated by unfair means; and other commercial activities contrary to honest practices that gain

inequitable benefit from traditional knowledge.¹¹

Taking this concept of misappropriation in the current paper the misappropriation done by leading pharmaceutical companies of the traditional medicinal knowledge derived from plant and other natural resources to derive patents. Biopiracy was present in the society from colonization period till the present day just the way this was done has changed over a period of time with the advent of globalization and the strengthening of IP Regime which has made Patents more of cash minting business especially in the pharmaceutical industry. Developing Countries like India have always been a hotbed of biopiracy thanks to its rich biodiversity and diverse Ancient traditional knowledge of which not all were documented thus giving an easy pass from the novelty requirement of patent regime. The rate of biopiracy has reduced to a considerable amount thanks to legislations and traditional knowledge digital library we shall be discussing at length about the same later in this paper.

This brings us to the cases where traditional medicine faced the brunt of biopiracy

BIO-PIRACY CASES THAT CHANGED THE COURSE OF HISTORY.

Turmeric is medicinal plant from the ginger family which grows extensively in the Indian sub-continent and south east Asia. Turmeric is used is known because of the bright yellow colour which is produced by the rhizome or root. As Turmeric is a very important part of the Indian Cuisine and has healing properties

⁸ *Ibid.*

⁹ Palpu Pushpangadan*, Varughese George, Thadiyan Parambil Ijinu and Manikantan Ambika Chithra Biodiversity, Bioprospecting, Traditional

Knowledge, Sustainable Development and Value Added Products, 2018

¹⁰ WIPO/GRTKF/IC/7/5, Annex II, page 3

¹¹ *Ibid*



turmeric finds a pivotal place for itself in the Indian households. USTPO had granted a patent on turmeric. In 1995 the USTPO granted patent Dr suman cohly and Dr. Hari har .P for wound healing .¹²In their abstract the scientist spoke about their about the ability to isolate the active ingredient of the turmeric and use it for healing of ulcers and wounds . And it could be administered both topically as well as orally ¹³.

The Council of Scientific and Industrial Research in India challenged the validity of this patent stating it to be devoid of any novelty and stated that the use of turmeric was cited in many of the ancient literatures ,and the healing properties of was a known fact. The USTPO cancelled the patents given out to turmeric.

This was India's first victory towards medical biopiracy also after this episode, the concept of misappropriation of traditional knowledge was taken as a serious concern. Activist like Vandana Shiva who have played a pivotal role in protection of traditional knowledge opined that India should resist all the international IP agreements and the there is need of cross-cultural scrutiny of Prior art to avoid such acts of biopiracy ¹⁴. Another case of biopiracy is the neem case. Neem a tree native to the Indian subcontinent. A controversial patent was filled by a pharmaceutical giant W.R grace , the patent was "for storage of stable insecticidal composition comprising neem seed extract" which permits "increasing the shelf-life stability of azadirachtin solution." The Indian government wanted to cancel the

patent citing it to be devoid of the requirement of novelty . European patent office cancelled the patent license for the above patent. ¹⁵The Indian government's reaction to the traditional knowledge issue when all is said in done, and to the neem case specifically, additionally represents the vital employments of intellectual property rights. In 1999, the Indian law making body considered changes to the Patent Act that would explicitly give patent rights to indigenous people .The proposed revisions would give assurance to plant assortments to any individual or gathering of people or any administrative or non-legislative associations following up for the benefit of a town or nearby network. India has come a long way from these days to the present day where the government proactively is making new policies a digital library to counter the issue of bio piracy. In the following part of the paper we shall be evaluating these legislation and policies.

LEGISLATIONS MADE TO PROTECT TMK FROM BIOPIRACY

These legislations may not be providing for protection directly to traditional medicinal knowledge but they are competent to enough to include plant and other natural resources based ingredients that are highly under the threat of misappropriation under the hands of corporation these acts provide a safe haven for the communities who posses such knowledge and give them the due credit for the same .

¹² U.S. Patent No. 5,401,504.

¹³ See Abstract , U.S. Patent No. 5,401,504.

¹⁴ VANDANA SHIVA, PROTECTING OUR BIOLOGICAL AND INTELLECTUAL HERITAGE IN THE AGE OF BIOPIRACY 12-17 (1996);

¹⁵ 1 U.S. Patent No. 5,124,349



THE BIOLOGICAL DIVERSITY ACT

The Act was ordered to meet the obligations under Convention on Biological Diversity (CBD), to which India is a gathering in 2002. A outsider, non-inhabitant Indian as characterized in provision of section 2 of The Income tax Act, 1961 or a remote organization or body corporate need to take permission from the NBA before getting any biological assets or related information from India for investigate, study, business utilisation. Indian residents or body corporates need to take permission from the concerned state biodiversity board ¹⁶.

After effect of research utilizing biological assets from India can't be moved to a non-resident or an outside organization without the permission of NBA. Be that as it may, no such permission is required for publication of the exploration in a diary or course, or in the event of a shared research made by institutions affirmed by Central Government.

No person ought to apply for patent or other type of licensed innovation protection dependent on the exploration emerging out of biological assets without the permission of the NBA. The NBA while allowing such permission may make a request for advantage sharing or royalties on utilization of such protection.

THE PROTECTION OF PLANT VARIETIES AND FARMERS RIGHT ACT.

The act was enacted to provide Protection to plant varieties through a sui generis system.

this was an attempt made to grant IPR s to the farmers and the local breeders and to encourage them to innovate new varieties of plants

THE KERALA INTELLECTUAL PROPERTY RIGHTS POLICY

The Kerala intellectual Property Rights policy was a step forward initiative taken by the kerala government in the year 2008. It was implemented to protect its traditional knowledge especially that of Ayurveda. The rights are given out to the people who own and practice that particular traditional knowledge since generations any other person who wants to practise the same has to obtain a commons licence. The kerala traditional knowledge authority looks after the affairs. This policy runs parallel to the National Biodiversity Act. The authorities of the act decide on factors such as benefit sharing and see to it that the owners of the knowledge get their dues.

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Another pro-active step that the government had taken was in the establishment of Traditional knowledge digital library.

Traditional Knowledge Digital Library.

India's TKDL is a collaboration work between the Council of Scientific and Industrial Research (CSIR) which is India's largest state-owned research body, and the Department of AYUSH.¹⁸ One of the eligibility criteria for getting a patent granted is Novelty. Many of the patents have been granted outside India thanks to the unavailability of prior art as most of the

¹⁶ Section 7 of Biological Diversity Act, 2002

¹⁷ <https://www.wipo.int/edocs/lexdocs/laws/en/in/in048en.pdf>

¹⁸ In 2003, the Department of Indian Systems of Medicine and Homeopathy (ISM&H) which had been

created in March 1995, was renamed the Department of Ayurveda, Yoga & Naturopathy, Unani, Siddha and Homeopathy (AYUSH) with a view to focusing attention on the development of education and research of these systems



traditional medicinal knowledge was not recorded in the database.

“Today, thanks to its TKDL, India is capable of protecting some 0.226 million medicinal formulations and at zero direct cost. Access to the database helps patent examiners root out at an early stage those applications that clearly do not satisfy the novelty requirement. Absent a database such as the TKDL, the process of revoking a patent can be a costly and time-consuming affair. It takes, on average, five to seven years and costs between 0.2-0.6 million US dollars to oppose a patent granted by a patent office. Multiply this by India’s 0.226 million medicinal formulations and it is clear that the cost of protection, without a TKDL, would be prohibitive.¹⁹ The TKDL is a unique, proprietary database that integrates diverse knowledge systems – Ayurveda, Unani, Siddha, modern science and modern medicine – and languages – Sanskrit, Arabic, Urdu, Persian, Tamil, English, Japanese, Spanish, French and German. It is based on 148 books of prior art relating to Indian Systems of Medicine, available at a cost of around US\$1,000. The TKDL connects patent examiners around the world with these books of knowledge. Thanks to the TKDL, Sanskrit slokas can be read electronically in English, French, German, Japanese and Spanish by an examiner at the EPO or any other patent office.”²⁰

CONCLUSION

There is a conflict of interest between those who are rooting for a strong IP regime to

protect their scientific innovations and those who claim biopiracy of their traditional knowledge as these legislation are not strong enough to protect the interest of the one who originally holds out this knowledge. The innovation process which includes the system of isolating modification of the compounds present in the natural resources in a way offends the communities.²¹ Another view point is as SUBHA GHOSH in her paper²² argues that blocking of patents which are derived from traditional medicinal knowledge and claiming biopiracy just because the content was available in public domain would vitiate the growth of new ideas and inventions and that broad interpretation of prior art and public domain are harmful for new innovations. The problem of bio-piracy has to be addressed with not always with the solution of cancellation of patents by the authority but also by giving more emphasis on the concept of benefit sharing. Corporations should be made responsible for the social and economic development of communities of which they source the knowledge from. Another point is As given out in the judgement of *Bishwanath Prasad Radhey Vs Hindustan Metals*²³ as the supreme court judgement gave out:

“In order to be patentable, an improvement on something known before or a combination of different matters already known, should be something more than a mere workshop improvement, and must independently satisfy the test of invention or an inventive step. It must produce a new

¹⁹ Dr. V.K Gupta, Protecting Indian Traditional Knowledge from Biopiracy

²⁰ ibid

²¹ Suchita shah, Plants, Patents and Biopiracy: The Globalization of Intellectual Property Rights and Traditional Medicine, 2014

²² Subha ghosh, GLOBALIZATION, PATENTS, AND TRADITIONAL KNOWLEDGE, 2003

²³ *Bishwanath Prasad Radhey Vs Hindustan Metals*, AIR 1982 SC 1444



result, or a new article or a better or cheaper article than before. The new subject matter must involve "invention" over what is old. Mere collocation of more than one, integers or things, not involving the exercise of any inventive faculty does not qualify for the grant of a patent"

If this judgement is applied in present context the principle can be used as a suggestion that when it comes to patenting of traditional medicinal knowledge now that the Indian pharmaceutical markets are also big players worldwide .Patents when applied to traditional medicinal should be given out to the medicines which are cheaper and a better alternative of the present traditional medicine which does the same function keeping in mind the concept of benefit sharing and due accreditation. This step would in course of time improve the Quality of traditional medicines as it would come in contact with proper research and development thus increasing its efficacy ,such a step can also improve the health care scenario of the nation and prosperity and development would usher in the communities rich in traditional knowledge . The battle of biopiracy is long drawn international organizations like WIPO and countries rich in Traditional medicinal knowledge should come together and frame a policy akin to the Nagoya Protocol which strikes a balance for multinational corporations as well as owners of traditional medicinal Knowledge.
