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PROTECTION OF HERBAL MEDICINES AND BIODIVERSITY IN INDIA UNDER PATENT REGIME: THE MYTH AND THE REAL PICTURE

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ABSTRACT

Since ancient days, Herbs and plants are always useful as medicinal property. Entire Traditional Medicine Therapies across the globe are based on curative properties of these substances. There is hardly a plant which does not have any medicinal property. So, the quantity of medicinal plants varies between expert people. As per one estimate there are over 15,000 medicinal plants in India of which 10 percent of them find specific mention in the Indian Systems of Medicine such as Ayurveda among which almost 4 percent of total plants are used in the preparation of the drugs. The medicinal properties documented in the texts of these systems as well as the traditional knowledge associated with the plants have been a valuable source for research and development (R&D) of new medicines in the allopathic system of medicine. The recent system is heavily dependent on patent protection for commercial production of the drugs. Consequently, most of the new drugs or new qualities of an existing drug in this system have been patented. The current allopathic medicinal system got momentum after the chemical industry thrived due to use of chemicals in two world wars. Subsequently, the world forgot the use of herbal medicines and concentrated on allopathy helped by invention of new chemical entities and patent system. The traditional system of herbal medicines got slowly forgotten as Pharmaceutical world focused on allopathy. After the emergence of Trade Related Intellectual Property Rights in the era of World Trade Organization, the patent system thrived and developed countries started exploiting biological diversity of country like India. The patents of turmeric and neem are examples of the

dichotomy these big nations apply in implementing patent laws. However, after the Earth Summit and Convention on Bio Diversity in 1992, India enacted law related to Biological Diversity but the implementation of the law has been on weak. There is only one organic way to implement biological diversity law and balance it with the current patent system. Promote invention and Protect Biological diversity at the same time is not easy but it is the only way for sustainable development.

Key words: *Herbs, Traditional System, Biological diversity, Sustainable development*

INTRODUCTION

We live in the medicinal system where knowledge has to be made protected instead of sharing. This is the world of patent laws where invention is new, unique and is capable of industrial application. On the other hand, we have traditional system of Herbal medicines advocated by Ayurveda, Unani and Homeopathy kind of medicinal systems. After the emergence of World Trade Organization and Trade Related Intellectual Property Rights, Big multinational pharmaceutical companies have started manipulating their patent laws in their own nation to take patents of India's herbal products. The patents taken for neem and turmeric are potent examples of this. India needs to strengthen and implement its own Biological Diversity act, 2002. The ministry of environment and forests (MoEF)[1] also enacted the Biological Diversity Rules, 2004 under the act. The Biological Diversity Act, 2002 has the unique system of governing access and benefit sharing through the National Biological Authority, State Biological Boards and Biological Management Committees at different level**s.**

Provisions under Patent Law of India

As per the Office of Controller General of Patents, Designs and Trademarks under Indian Law, the patent act has enough parameters to safeguard Traditional Knowledge as well as Biological Resources. Traditional knowledge, by its own name, is in the public domain and so, any application for patent relating to Traditional Knowledge cannot pass as an invention under section 2 (1) (j) of the Patents Act, 1970, that says that "invention means a new product or process involving an inventive step and capable of industrial application". [2]

In addition, as per the section 3(e) of the Patents Act "a substance obtained by a mere admixture resulting only in the aggregation of the properties of the components thereof or process for producing such substances" is not an invention and hence, not patentable. The

[1] The Ministry of Environment and Forests
[2] Office of Controller General of Patents, Design and Trademarks," Guidelines for Processing of Patent Applications Relating to Traditional Knowledge and Biological Material"

Indian Patents Act also has a unique provision under Section 3 (p), wherein "an invention which, in effect, is traditional knowledge or which is an aggregation or duplication of known properties of traditionally known component or components" is not an invention and hence, not patentable, within the meaning of the Patents Act. Further, sections 3 (b), (c), (d), (f), (h),(i) and (j) are of relevance with respect to the patent applications related to Traditional Knowledge and/or biological material.[3]

Provisions under Biological Diversity Act, 2002

The provisions under section 6 (1) of the Biological Diversity Act, 2002 says very clearly that "no person shall apply for any intellectual property right, by whatever name called, 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 National Biodiversity Authority before making such application; provided that, if a person applies for a patent, permission of the National Biodiversity Authority may be obtained after the acceptance of the patent but before the sealing of the patent1 by the patent authority concerned; provided further that the National Biodiversity Authority shall dispose of the application for permission made to it within a period of ninety days from the date of receipt thereof. The Indian Patent Law complements this provision of the Biological Diversity Act, 2002 by making it mandatory for the applicant of a patent to submit a declaration under Form-1 (Application for Grant of Patent) of the Patent Rules 2003 to the effect that "the invention as disclosed in the specification uses the biological material from India and the necessary permission from the Competent Authority shall be submitted by me/us before the grant of patent to me/us." [4]
The Biological Diversity Act, 2002 has a penal provision for this offence under section 55 (1) which provides that "whoever contravenes or attempts to contravene or abets the contravention of the provisions of the section 3 or section 4 or section 6 shall be punishable with imprisonment for a term which may extend to five years, or with fine which may extend to ten lakh rupees and where the damage caused exceeds ten lakh rupees such fine may commensurate with the damage caused, or with both."[5]

In addition, applications for patents which are based on Traditional Knowledge and/or biological material opposing the provisions of law can be rejected under section 15 or in pre-grant opposition under clauses Section 25 (1) (d), Section 25(1) (f) and Section 25(1)(k) and

[3] Office of Controller General of Patents, Design and Trademarks," Guidelines for Processing of Patent Applications Relating to Traditional Knowledge and Biological Material"

[4] Ibid
[5] Ibid

patents which are already granted can also be revoked in post-grant opposition under clauses Section 25 (2) (d), Section 25(2) (f) and Section 25(2) (k) of the Patents Act, 1970. [6]

Not disclosing the source or wrong mention of the source or geographical origin of biological material used for an invention in the complete specification as well as also attracts ground for pre- and post- grant opposition under clause (j) of Sections 25 (1) and 25 (2) respectively of the Patents Act, 1970.[7]

Traditional Knowledge Digital Library and Provisions of Patent Law

The Traditional Knowledge Digital Library (TKDL)[8]consists of more than 3.5 lakh traditional medical combinations in Ayurveda, Unani, Siddha and Yoga as of January 2021.[9] When patents are given which are based on biological resources, it is termed as "Biopiracy". It is done without due authorization by a country's consent which has been traditionally using these biological resources. To prevent such wrong patents from getting granted, Indian Patents Act, 1970 has safeguards. As per Section 3, the following are not patentable:

"Plants and animals in whole or any part thereof other than microorganisms but including seeds, varieties and species and essentially biological processes for production or propagation of plants and animals." "An invention which in effect is traditional knowledge or which is an aggregation or duplication of known properties of traditionally known component or components." [10]

These provisions make sure that India does not grant patents on extant medicinal plants as well as traditional knowledge associated with them.[11] The above grounds are also base for the on pre grant as well as post grant opposition for the patent application. In fact, in the grounds of opposition, it is very clearly mentioned that, "knowledge, oral or otherwise, available within any local or indigenous community in India or elsewhere" (emphasis added) is ground enough for opposing the patent. The grounds for opposition also have specific provision as to disclosure of the source or geographical origin of biological material used for the invention. Any non-disclosure or wrongful disclosure of such source is enough to reject the patent application or for revocation of the granted patent.

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[6] Ibid
[7] Ibid
[8] Traditional Knowledge Digital Library
[9] "CSIR celebrates 20 years of India's Traditional Knowledge Digital Library, the first of its kind globally" available at https://pib.gov.in/PressReleasePage.aspx?PRID=1693143
[10] Section 3(j) Patents Act, 1970
[11] Section 3(p) Patents Act, 1970

Patent Law and Biological Diversity Law of India

The Indian Patent Office, though, granted a patent for a composition consisting of jamun and lavangpatti for "synergistic Ayurvedic/functional food bioactive composition" in 2007. The claimed use for patent was for the treatment of diabetes. It was revoked in 2012 by Section 66 of the Patents Act, 1970 which empowers the Central Government to revoke any patent on the ground that the patent is "generally prejudicial to the public". The patent in question was for an invention which was essentially traditional knowledge associated with medicinal plants. To complement these statutory provisions, the form for application for grant of patent requires a declaration by the applicant that where the invention uses biological material from India, the necessary permission from National Biodiversity Authority has to be sought by him before the sealing of the patent. [12] The Authority may while granting the approval impose benefit sharing fee or royalty or both or impose conditions including sharing of financial benefits arising out of the commercial utilization of such rights.[13]

National Biodiversity Authority enacted under the Biological Diversity Act (BDA), 2002 is the the competent authority for the grant of such permission to use traditional knowledge with existed medicinal plants. This Act was enacted by India to fulfill its obligations under the United Nations Convention on Biological Diversity (CBD), 1992, for conservation of biological diversity, sustainable use of its components and fair and equitable sharing of the benefits arising out of the use of biological resources, knowledge. 'Biological Resources', as per the Act, means "plants, animals and microorganisms or parts thereof, their genetic material and by-products (excluding value added products) with actual or potential use or value, but does not include human genetic material".

The Biological Diversity Act,2002 also empowers the National Biodiversity Authority to "impose benefit sharing fee or royalty or both or impose conditions including the sharing of financial benefits arising out of the commercial exploitation of such rights." Exploitation of medicinal plants including attached traditional knowledge such as in traditional medicines for purposes of obtaining patent is, thus, regulated and requires benefit sharing in the form of payment of royalty or fee or both to the conservers of those plants, usually a community.[14]

Patentability of Herbal Medicines across the world

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[12] Section 6(1) Biological Diversity Act, 2002
[13] Section 6(2) Biological Diversity Act, 2002
[14] Ibid.

As per the Indian Patent Act, 1970 the patent can be given if it is

- A new invention [15]
- It should be new and non- obvious with respect to prior art
- It must useful and
- Not previously in use in India Invention,

As per the act, the patent for pharmacy can be granted if

- The invention contains New chemical entities, after 2005
- New formulation processes
- New composition of matter

Invention which isn't patentable in India as per Section 3 of Patent Act, 1970 includes

- Discoveries
- Methods of detection, diagnosis or treatment of diseases
- Analytical methods
- Methods of agriculture/cultivation
- The products made by Chemical synthesis
- Animal, plant, and biological methods for growing and rearing them

Patent for new use of the herbal plant is permissible. Patent from isolation of herb is also maintainable in India. The new use of the herbal plants is Patentable in India – only through novel dosage forms/formulations or synergistic combinations.[16] But herbs are Patentable in Europe – Even through known dosage forms, if efficacy in new indication is demonstrated. Herbal plants are Patentable in United State of America preferably as a Method of Treatment.

The Curious case of Kani Tribe

This case is one of oldest recorded benefit sharing examples in intellectual property rights based on traditional medicinal knowledge of plants. The Tropical Botanical Garden and Research Institute (TBGRI),[17] Thiruvananthapuram gained information about the medicinal properties of the plant locally known as "Arogyapacha" (Trichopus zeylanicus) from the Kani tribe way before the Biological Diversity Act, 2002 and the Patents (Amendment) Act, 2005

[15] Section (2)(1)(l) Patents Act, 1970
[16] Section [3(c)] of the Patent Act, 1970.
[17] Tropical Botanical Garden and Research Sharing Institute

that made specific provisions about traditional knowledge and biological resources. The Kanis are a tiny tribal community of about 25,000 people on the Agastiar hills in South Kerala. The Institute developed the medicine "Jeevani" (a poly herbal product) based on that knowledge and obtained a process patent for the same since the Product Patents were not available in India for pharmaceutical products at that time. The Institute commercialized the product through the Arya Vaidya Pharmacy, Coimbatore. Half of the share goes with Kani tribe from the royalty received by the Institute. This became compulsory of course by enactment of the Biological Diversity Act, 2002 and Biological Diversity Rules, 2004 much later. [18]

The Real Picture

Biological Diversity Act, 2002 is among the most unused piece of law among all the environment laws. After 19 years of its enactment, the implementation of this particular law has remained on the weaker side. For the proper implementation of law, there is three-fold structure of National Biodiversity Authority at national level in terms of National Biodiversity Authority, state level in form of State Biodiversity Authority and at local levels in form of Biodiversity Management Committees. The basic responsibility of the BMCs is to keep record of the local biodiversity and associated information in the form of People's Biodiversity Registers.[19]

Even after 19 years of implementation, most of the local bodies of the states of India have not created People's Biodiversity Registers that are considered to be the basic records of a region's biological resources such as plants, wild life and the traditional knowledge of the local people. In the oblivion of PBRs when the act is not properly effective, the environment clearances are given for various projects without registering the real state of Biodiversity make the environment impact assessment report arbitral and make the whole exercise deprived of logic and validity.[20]

Judicial Approach

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[18] Chaturvedi S,"Kani Case. A Report for GenBenefit (2007)", available at: http://www.ris.org.in/images/RIS_images/pdf/Kani_Case.pdf

[19] James T.C., IPR issues related to medicinal and aromatic plants available on the website: http://jamesthanickan.tripod.com.

[20] Ibid

The Pune residing activist Chandra Bhal Singh had filed a petition in July, 2016 before the National Green Tribunal for effective implementation of the Biological Diversity Act, 2002. When he filed the petition, among 2,70,573 local bodies across the nation, only 9,700 local bodies had a Biodiversity Management Committees at local body levels. Uttarakhand in the famous landmark judgement also held biological diversity is not only the property of the nation but also of the indigenous and local communities who have conserve ed it through centuries. The judgement also emphasized that "Indigenous and local communities, who either grow 'biological resources' or have traditional knowledge of these resources are also the beneficiaries under the Biological Diversity Act, 2002."

CONCLUSION

There is only one way to maintain the quality of Herbal Medicinal plants which is to produce them organically. The Biological Diversity Act, 2002 and The Protection of Plant Varieties and Farmer's Rights Act, 2001 along with Traditional Knowledge Digital Library are welcome progress in the right direction. Yet, things need to be worked upon. Constitution of Biodiversity Management Committees at Local Level is not made at panchayats, municipalities and corporations in many states and thus causing delay in the preparation of People's Biodiversity Register which can protect them from being patented by other countries. The Biodiversity is needed for the proper functioning of ecosystems that give us various products like food, oxygen, fresh water and fertile soils which are necessary for the sustaining quality herbal plants. India has some very important biological hotspots with wide variety of biological diversity. Measures to protect the rich biodiversity of India have not been enough. Despite many laws in place on wildlife protection, forest conservation and Biological diversity, there is lack of effective enforcement of the laws to protect biodiversity. The ineffective implementation of the Biodiversity Law has made the act like toothless tiger which is fooling its own image. Much of India's forestland has been taken by Industrial and Infrastructural activities. Implementation of all environment related laws especially Biodiversity Law will ensure that the developed countries don't benefit from India's Biological Diversity at the same time by harming us in multiple ways in the name of encouragement of inventors and their patent laws.

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